Multiple Sclerosis and Related Disorders 35 (2019) 26–33

Contents lists available at ScienceDirect

Multiple Sclerosis and Related Disorders

journal homepage: www.elsevier.com/locate/msard

Three-week inpatient energy management education (IEME) for persons with multiple sclerosis-related fatigue: Feasibility of a randomized clinical trial

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ARTICLE INFO

Keywords:
Fatigue management education
Occupational therapy
Rehabilitation
Self-management
Occupational balance

ABSTRACT

Background: Multiple sclerosis (MS)-related fatigue limits participation in everyday activities and has a considerable impact on quality of life (QoL), thereby affecting productivity and employment. Outpatient education interventions involving energy conservation strategies and cognitive behavioral therapy techniques are helpful. However, no inpatient program is currently available. The inpatient energy management education (IEME) program is a novel group-based intervention that lasts for 6.5 h and is conducted by a trained occupational therapist (OT) during a 3-week period of inpatient rehabilitation. Persons with MS (pwMS) and OTs previously evaluated the IEME positively in a pilot study test run. The aim of this study was to evaluate the feasibility of a research protocol and collect preliminary data on the IEME effect size.

Methods: To assess the feasibility of conducting a randomized clinical trial, pwMS-related fatigue were recruited during a 3-week inpatient rehabilitation. Six IEME (experimental) group sessions or progressive muscle relaxation (PMR, control) group sessions comprised part of a personalized rehabilitation program. The recruitment and assessment procedures, dropout and follow-up assessment rates and the treatment fidelity were evaluated, and six telephone interviews were conducted with IEME participants after they returned home. Outcomes were fatigue impact, occupational performance, self-efficacy regarding energy conservation strategies, and QoL at baseline, discharge, and 4 months. Paired-sample and independent-samples *t*-tests were used to assess within- and between-group effects. Effect sizes were estimated using Cohen's *d*.

Results: Between August and November 2017, 47 pwMS were included and randomized. The dropout rate (4.2%) was low and the sample was balanced. The PMR was a well-accepted control intervention. The OTs reported no problems in conducting the IEME, and treatment fidelity was high. IEME participants confirmed the adequacy of the IEME. Within-group differences in fatigue impact and some QoL dimensions at discharge were significant ($p < 0.05$) in both groups. The IEME alone resulted in significant improvements in self-efficacy regarding energy conservation strategies, with a large effect size (Cohen's *d*: 1.32; 95% CI: 0.54–2.1), and in the QoL physical functioning dimension at T2 (Cohen's *d*: 1.32; 95% CI: 2.11–0.53). IEME participants spent significantly less time in individual OT sessions. A sample size of 192 participants in a randomized controlled trial would be sufficient to detect clinically relevant between-group differences.

Conclusion: This feasibility study has provided promising preliminary data about the effect of the IEME. The research protocol was confirmed to be feasible and a future study is justified. This study was registered in the German Clinical Trials Register (no. DRKS00011634).

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https://doi.org/10.1016/j.msard.2019.06.034
Received 20 November 2018; Received in revised form 3 June 2019; Accepted 28 June 2019

1. Introduction

Fatigue is one of the most common symptoms in persons with multiple sclerosis (pwMS) (Compston and Coles, 2008). Among such individuals, 65% consider it one of their three most troubling symptoms (Weiland et al., 2015). MS-related fatigue limits participation in everyday activities (Krupp, 2006) and has a considerable impact on quality of life (QoL), thereby affecting productivity and employment (Flensner et al., 2008). The National Institute for Health and Care Excellence guidelines (NICE, 2014) recommend a multidisciplinary approach for the management of fatigue, involving concurrent exercise therapy, self-management, and education, along with medication. The use of energy conservation strategies and cognitive behavioral therapy (CBT) techniques as part of a manualized outpatient group-based intervention has been shown to be moderately helpful (Asano and Finlayson, 2014; Blikman et al., 2013).

In many European countries, multidisciplinary rehabilitation for pwMS is delivered in specialized rehabilitation centers, where pwMS benefit from short intensive inpatient rehabilitation. The evidence-based outpatient education protocols (Thomas et al., 2013; Mathiowetz et al., 2005) are not compatible with the inpatient context as, in this context, it is usually impossible to create stable education groups over several weeks. Currently, it is still difficult to provide standardized group-based fatigue management education during short intensive inpatient rehabilitation courses. For this reason, we developed an inpatient energy management education (IEME) program (Hersche et al., 2019), integrating the principles of patient education (Lorig and Holman, 2003) and empowerment (Castro et al., 2016), the transtheoretical model of change (Norcross et al., 2011), the social cognitive theory (Bandura, 1977), and energy conservation strategies and cognitive behavioral techniques (Michie et al., 2013). The IEME is 6.5 h in duration and was conducted by a trained occupational therapist (OT) over a 3-week period.

An IEME pilot in 2017 included 12 pwMS-related fatigue (Hersche et al., 2019). The experiences of the IEME participants and OTs were recorded during focus groups to refine the program materials and to verify the program's feasibility in an inpatient setting. During the 3-week rehabilitation period, IEME participants showed behavioral change. Nevertheless, we could not draw conclusions regarding the strength of the intervention effects with respect to variables such as self-efficacy, fatigue impact, or QoL at discharge or the long-term effects of the program. To evaluate the effects of the IEME, a randomized controlled trial (RCT), in which the IEME is compared to another group-based intervention, is necessary. Conducting a feasibility study provides important preliminary data (i.e., effect size and sample size estimation) needed to increase the likelihood of success in a larger RCT and minimizes any waste of financial resources (Thabane et al., 2010).

The specific aims of the present study were to assess: (1) the recruitment and follow-up rates and reasons for exclusions; (2) protocol compliance of OTs; (3) patient satisfaction with treatment; (4) time requirementsr; (5) changes in outcomes of interest within and between groups; and (6) treatment effect size of the IEME.

2. Materials and methods

We performed a single-blinded randomized controlled feasibility study (Thabane et al., 2010). Ethical approval was obtained from the Local Research Ethics Committee (BASEC 2016-02142), and the study was prospectively registered in the German Clinical Trials Register (DRKS00011634).

2.1. Setting

The Rehabilitation Centre Valens (RCV) in Switzerland provides personalized and goal-oriented multidisciplinary inpatient rehabilitation. The number and types of therapeutic interventions are defined at admission based on the goals and preferences of each person. The RCV treats approximately 400 pwMS every year over 2–4-week periods.

2.2. Participants

The pwMS who were on the waiting list for a 3-week rehabilitation period at the RCV from August to November 2017, and who fulfilled the following inclusion criteria: >18 years of age; confirmed diagnosis of MS according to the McDonald criteria (Polman et al., 2011); Fatigue Severity Scale score > 4 (Valko et al., 2008); and Expanded Disability Status Scale (EDSS) score ≤6.5 (Kurtzke, 1983), were informed by post about the study. A few days before admission, they were contacted by phone by a researcher (AW) who verified their literacy in German and agreement to attend the IEME or control (progressive muscle relaxation [PMR] intervention, in addition to a 3-week rehabilitation as usual (RAU) program. The exclusion criteria comprised the following: telephone-based Mini Mental State Examination score < 21 (Newkirk et al., 2004) and Beck Depression Inventory-fast screening score > 4 (Neitzer et al., 2012). Prior to their involvement in any study procedures, each participant provided informed consent to participate.

2.3. Intervention procedures

All participants took part in the RAU program. This individualized program included physiotherapy (endurance and reinforcement training), occupational therapy (ability and adaptation training), speech therapy, neuropsychological training, and counseling (involving a physician and/or social worker), if relevant. The difficulties due to fatigue were discussed in individual OT sessions but no systematic fatigue management education was provided as part of RAU. In addition to RAU, the participants received the experimental or control intervention. That means that IEME participants received fatigue management group-based education during the experimental intervention and that they attended individual OT sessions only for other issues. The control group worked on fatigue management and other OT relevant issues during individual OT sessions as part of RAU. Neither participants nor OTs could be blinded to the interventions.

Experimental intervention: The goal of the IEME is to ensure that participants learn how to manage available energy in order to achieve a satisfying and meaningful daily routine. Participants acquired knowledge and understanding about factors that influence energy and the consequences of fatigue on their habits and lifestyle. Subsequently, they identified and implemented tailored behavior modification. The IEME involved face-to-face education sessions of 6.5 h in duration over a 3-week period, which was conducted by a trained OT. The IEME started with a 1-h individual session, followed by five 1-h self-contained IEME group sessions (min. 2, max. 7 pwMS) delivered twice a week, and it concluded with a 0.5-h individual session. Between the IEME sessions, the participants received training regarding the use of energy conservation strategies and planned the implementation of behavioral changes in their daily routine using self-training tasks. Six weeks after returning home, the participants received reinforcement in the form of a letter (Table 1). The treatment manual describes every session in detail, integrating the behavioral change techniques that can be used (Michie et al., 2013). The participant workbook contains detailed information on all topics, worksheets, and self-training tasks.

Control intervention: PMR was developed in 1938 by Edmond Jacobson (Conrad and Roth 2007). The aim of PMR is to achieve enhanced mental relaxation by reducing muscle tension (Dayapoğlu and Tan, 2012). PMR involves a standardized series of relaxation exercises (involving 11 large muscle groups) combined with deep breathing. During the PMR sessions, the participants lay on the floor in a quiet room and were instructed by a trained physical therapist for 1 h. The control participants attended six 1-h face-to-face group sessions of PMR (max. 12 participants), which were held twice a week over a 3-week period. They were also encouraged to continue to perform the PMR

Table 1
Description of the experimental intervention: inpatient energy management education (IEME).

Delivery modality	Lesson topic		Applied behavior change techniques	IEME - Materials
Individual face-to-face, 1 h	Energy account	Self - training	Shaping knowledge	Workbook for participants
Group (2–7 pwMS) face-to-face, 1 h	Break Management		Experience exchange & social support	Manual for OT
	Occupational balance		Feedback & monitoring	
	Use of body & environment		Compared behavior & outcomes	
	Simplifying activities			
	Effective communication			
Individual, face-to-face, 0.5 h	My goals		Goals & action planning	
Letter	Reinforce input		Antecedents	
			Self-belief	

exercises after discharge from the clinic. Research has shown that PMR has a moderate to large effect on QoL in pwMS (Ghafari et al., 2009). At 6 weeks after discharge, a reinforcement letter was sent to all control participants, to foster continuation of the PMR exercises.

2.4. Assessments and outcomes

Process quality: Two researchers (AW, RH) were involved in the recruitment, screening and follow-up data collection. Reasons for exclusion and data on the refusal, dropout, and follow-up assessment rates were gathered. At the end of the study, difficulties identified during the recruitment and data collection processes and possible improvements to the study protocol were recorded.

Treatment fidelity: The OTs used an IEME checklist that included all the steps and tasks described in the treatment manual for treatment fidelity monitoring. The number of steps and tasks varied from 14 to 17 per IEME group session.

Participant satisfaction: At week 10 after baseline, six IEME participants were contacted based on their personal characteristics (sex, age, MS type and onset, EDSS score, education level, employment status, and housing), for a semi-structured, audio-recorded, telephone interview. The aim was to maximize the sample diversity and to record participants' experiences after returning home from the RCV. The interview guidelines focused on four main topics: study procedures, the group-based nature of the IEME, the feasibility of applying the energy management strategies in the participants' daily routine, and the challenge of implementing behavioral changes. The interviews were arranged for a date and time that was convenient for each participant.

Time requirements Two types of time requirements were recorded. (1) Study management time: time spent by AW and RH on recruitment and data collection (based on daily records). (2) Intervention time: time spent by participants in OT sessions (individual and group) during their 3-week rehabilitation course (based on daily records held by the RCV central planning office).

Estimate of treatment effect size: We used five self-assessment scales at baseline, at week 3 (end of interventions and discharge, T1), and 4 months after baseline (T2) to assess the outcomes. The Modified Fatigue Impact Scale (MFIS) (Kos et al., 2007) evaluated the impact of fatigue on daily life. The Occupational Self-Assessment (OSA) (Kielhofner et al., 2010) measured self-reported changes in competence regarding 21 daily activities and is a useful tool for collaborative treatment planning. Health-related QoL (HRQoL) was assessed using the Medical Outcome Study 36-item Short Form Health Survey (SF-36)(Ware and Sherbourne 1992) . Self-efficacy was assessed using the University of Washington Self-Efficacy Scale (UW-SES, MS Version) (Amtmann et al., 2012) and the Self-Efficacy for Performing Energy Conservation Strategies Assessment (SEPECSA) (Liepold and Mathiowetz, 2005). All instruments were self-reported questionnaires, relatively brief (total duration, 45 min) and easy to administer, with robust psychometric properties. A blinded assessor, who was not involved in treatment, delivered the instructions to complete the questionnaires and conducted the scoring.

2.5. Randomization

The aim was to include around 50 participants over 4 months. Block randomization (four persons per block) was based on computerized random number generation. A blinded statistician (SD) prepared consecutively numbered opaque envelopes. After patients provided informed consent, AW opened an envelope and allocated participants to IEME (experimental intervention) or PMR (control intervention).

2.6. Statistical methods

Data were analyzed using Stata 15 software (Stata Corp., College Station, TX, USA). Key baseline sociodemographic and health variables were compared between the IEME and PMR groups using independent-samples *t*-tests for continuous data, and chi square tests for categorical data. Paired *t*-tests were used to assess within-group change over time. Independent-samples *t*-tests were used on the changes in the scores (post- vs. pre-intervention) to assess between-group effects. All tests were two sided and considered significant at the $p < 0.05$ level. As a standardized measure of effect size, we estimated the treatment effects using Cohen's *d*. We also calculated the sample size (based on a power of 0.8) needed for a future effectiveness study.

3. Results

3.1. Recruitment (process quality)

Between July and November 2017, 83 pwMS on the RCV waiting list were informed about the study. Sixty-three pwMS met the inclusion and exclusion criteria, of which 47 (76%) agreed to participate (Table 2), while 16 declined to participate. Twenty-four pwMS were allocated to IEME and 23 to PMR. Most participants attended at least five out of six sessions of the interventions to which they were allocated (IEME: $n = 22$, 91%; PMR: $n = 15$, 78%). In both groups, the main reasons for discontinuation were premature discharge from the RCV, missed sessions due to absent therapists, other conflicting appointments and noncompliance. Two participants (dropout rate, 4.2%) in the PMR group wished to stop treatment after one session. During the study, 10 participants had incomplete assessments (loss rate, 21.2%). At T2, the results from 35 pwMS (18 IEME/17 PMR participants) were included in the final analysis (response rate, 74.4%; Fig. 1).

3.2. IEME protocol treatment fidelity of OTs

During the study period, the OTs performed 46 individual and 21 group sessions. On average, they carried out 89% (range, 78.8–94.6%) of the tasks described in the IEME manual.

3.3. Participant satisfaction

Six telephone interviews with IEME participants (Table 3) were conducted (duration: 17–25 min). The transcripts were analyzed using

Table 2
Socio-demographic characteristics of participants.

Variables	Intervention groups		
	IEME (n = 24)	PMR (n = 23)	p-value
Age (years): mean (SD), range	51.2 (1.7), 35–68	51.8 (2.2), 31–70	0.836[a]
Sex (female): n (%)	16 (66.7)	15 (65.2)	0.917[b]
Self-reported disease type: n (%)			
Relapsing-remitting	7 (29.2)	8 (34.8)	0.844[b]
Secondary progressive	7 (29.2)	8 (34.8)	
Primary progressive	6 (25.0)	5 (21.7)	
Progressive relapsing	3 (12.5)	2 (8.7)	
Not stated	1 (4.1)	–	
Years since diagnosis			
Mean (SD), range	13.5 (10.2), 1–39	14.3 (9.8), 0–37	0.774[a]
MS-related fatigue and disability			
Fatigue Severity Scale: mean (SD)	9.8 (22.4)	10.1 (22.8)	0.966[a]
EDSS: mean (SD), range:	5.3 (1.14), 3–6.5	4.8 (1.47), 2.5–6.5	
OSA: five most important goals, n (%)			
Physically doing what I need to do	9 (10)	14 (17)	0.47[b]
Getting where I need to go	6 (7)	10 (12)	
Taking care of the place where I live	6 (7)	8 (9)	
Accomplishing what I set out to do	9 (11)	5 (6)	
Working towards my goals	7 (8)	5 (6)	
Level of education (years of schooling): n (%)			
Lower-secondary education (<12)	3 (12.5)	3 (13.0)	0.204[b]
Upper-secondary education (12–16)	14 (58.3)	11 (47.9)	
Tertiary level education (>16)	6 (25)	9 (39.1)	
Not stated	1 (4.1)	–	
Employment status: n (%)			
Full-time (>30 h per week)	4 (16.7)	2 (8.7)	
Part-time (≤30 h per week)	6 (25)	6 (26)	
Self-employed	3 (12.5)	2 (8.7)	
Non-employed (housework, in education, retired)	9 (37.5)	13 (56.5)	
Not stated	2 (8.3)	–	
Housing: n (%)			
Single	5 (20.8)	5 (21.7)	1.000[b]
Married or cohabiting	18 (75)	18 (78.3)	
Unknown	1 (4.2)	–	
Housing with children (≤18 years)	5 (27.8)	7 (38.9)	0.480[b]
Number of cohabiting persons: mean/range	2.4/2–3	2.7/2–4	0.153[a]

IEME: Inpatient energy management education; PMR: Progressive muscle relaxation; MS, multiple sclerosis; OSA: Occupational Self-Assessment; EDSS: Expanded Disease Severity Scale, n: number; SD: standard deviation;.
[a] *t*-test;.
[b] chi-square test.

thematic analysis (Braun and Clarke, 2006) by RH. According to the respondents, the experiences were generally positive. The study information was clear and the procedures needed no changes. Completing the self-assessments required a minimum of 30 min of full attention and deep thinking. The participants reported difficulties with the UW-SES due to questions involving double negatives and difficulties with the SF-36 because it required information about daily activities performed during the 'last 4 weeks', while the participants spent only 3 weeks at the RCV, and they had no daily routine while there. All the interviewed participants judged the IEME approach as very interesting and enriching. They had positive memories of exchanges between group members, the discussions on the different topics and the non-judgmental, supportive atmosphere. Although most participants stated that the education provided little new knowledge, they appreciated the time spent on in-depth reflection and on the practical application of fatigue management strategies. All participants achieved some behavioral change; however, this takes time and is not finished yet. Workload reduction and ergonomic behavior were easier to implement, whereas the redesign of daily structure, roles and responsibilities appeared to be more challenging because it was easy to fall back into old patterns. The participants thought that the behavioral changes were their own responsibility, but that a local group or OT could help to improve their self-confidence during the implementation of the changes.

3.4. Required time

Study management time: The screening procedure required 20 min per patient. The study administration and organization required 50 min per patient.

Intervention time: IEME participants spent a mean of 285 min in group sessions and 102 min (95% CI: 65–140 min) in individual OT sessions as part of RAU. PMR participants spent the same time (mean, 297 min) in group sessions but had significantly more individual OT time as part of RAU (mean, 172 min; 95% CI: 216–128 min; $p = 0.024$)

3.5. Outcomes and treatment effect sizes

Changes in outcome measures were compared within and between groups at baseline, T1 and T2 (Table 4). Regarding fatigue impact (MFIS), both groups improved significantly, with no significant difference between groups. Regarding perceived competence during daily activities (OSA), the change was larger at T1 compared to T2. IEME participants showed significant improvements in the OSA subscale 'managing and relationships' (OSA-MR), whereas PMR participants remained at the pre-intervention level. However, there were no significant differences between groups in the OSA-MR scores. No changes were observed in self-efficacy regarding managing MS symptoms (UW-SES, MS Version). In contrast, the SEPECSA score improved in the IEME group, which resulted in a significant difference between the two groups at T2.

Regarding HRQoL (SF-36), IEME participants had improved 'physical functioning' subscale scores at T1 and maintained this change at T2. These changes were significantly different from the scores in the PMR group. Regarding the 'role limitations due to physical health' subscale, the IEME group showed an increase at T1 whereas the control group showed no significant change. However, there was no significant difference between groups. Regarding the 'vitality/fatigue' and 'emotional well-being' subscales, both groups increased significantly, with no significant difference between the groups. Regarding the 'role limitations due to emotional problems' and 'pain and general health' subscales, no significant changes over time were observed in the IEME or PMR groups.

The within-group effect size (Cohen's *d*) (Cohen, 1992) on fatigue impact (MFIS) was large in both groups at T1 (IEME: 1.1; PMR: 0.86) and declined to a medium effect at T2 (IEME: 0.68; PMR: 0.64). There were also large between-group effect sizes for SEPECSA and SF-36-PF (physical functioning) (at T2); medium effect sizes for OSA-MR (at T1) and OSA-SEA (satisfaction, enjoyment, actualization) (at T2); and very small to no effects for the other SF-36 dimensions and MFIS (Fig. 2). A sample size of 192 participants (power, 0.8) would facilitate the detection of clinically relevant differences at T2 in the OSA-SEA too.

4. Discussion

The objective of this study was to evaluate the feasibility of a research protocol for comparing a novel IEME group-based intervention for pwMS-related fatigue (during a multidisciplinary RAU program) to PMR. Due to the RAU provided to both groups, we did not expect significant between-group effects on fatigue impact. However, we predicted significantly higher self-efficacy in the IEME group due to the format and content of the experimental intervention. Between-group differences in outcomes showed comparatively large effect sizes regarding SEPECSA and one HRQoL dimension (SF-36-physical functioning). As expected, because of the relatively small sample size in this study, the between-group differences in the other outcomes were not significant.

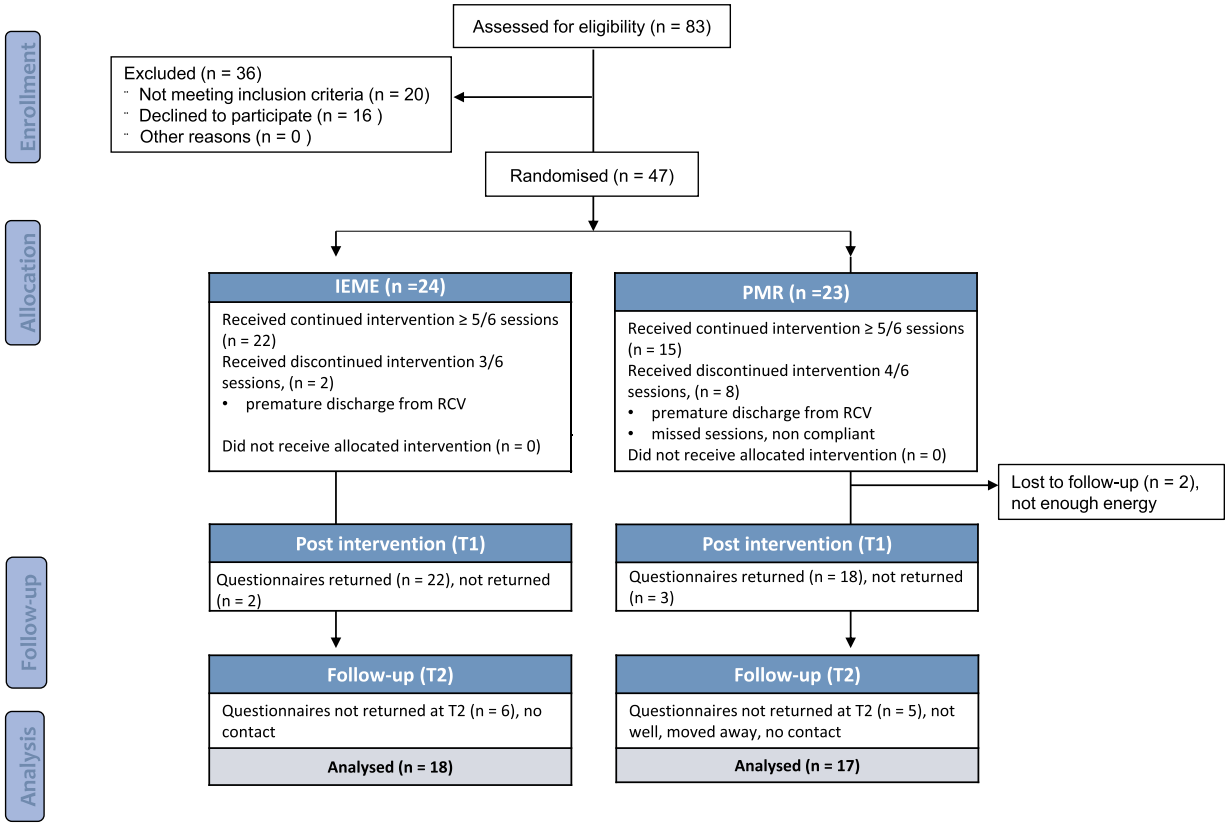

Fig. 1. Study flow diagram. RCV, Rehabilitation Centre Valens; T1, 3 weeks after baseline; T2, 4 months after baseline.

Table 3
Characteristics of interviewed IEME participants.

Gender: n (female/male)	3/3
Age: years (range)	39–57
EDSS: (median/range)	5/3–6.5
Years from onset: (range)	2–27
Education: years of schooling (<12 / 12–16 / >16)	2/3/1
Employment status: n (full-time /part-time/ family work)	2/1/3
Housing: n (single / cohabitation)	1/5

EDSS: expanded disability status scale.

Process quality: The inclusion and exclusion criteria were suitable for the characteristics of the pwMS at the RCV and permitted a high recruitment rate (56%). The sample was well balanced and the dropout rate was low. In general, PMR was a well-accepted control intervention. The study procedures and information were considered clear, but the use of the UW-SES and SF-36 (at T1) have to be reconsidered. The IEME participants expressed positive opinions about program, and the OTs had no problems in conducting the IEME, which confirms the conclusions of our previous study (Hersche et al., 2019).

Outcomes of interest and effect size: Both interventions, together with RAU, improved fatigue impact (MFIS), self-perceived performance of basic tasks of living (OSA-BT), satisfaction, enjoyment and actualization (OSA-SEA), and the HRQoL dimensions of fatigue/vitality and emotional well-being (SF-36) at T1. The improvements were maintained until T2 in the case of MFIS and SF-36-fatigue. In contrast to PMR + RAU, IEME + RAU yielded improvements in self-efficacy (SEPECSA), performance regarding managing and relationships (OSA-MR), and two HRQoL dimensions (SF-36 PF and RL due to physical health).

The Fatigue Impact Scale (FIS), and the corresponding short form, MFIS, are the most commonly used primary outcome tools in energy conservation management (ECM) studies (Asano and Finlayson, 2014). Asano and Finlayson (2014) reported a medium pooled effect size for educational interventions, while Miller and Soundy (2017) identified improvements in 45% (10/22) of CBT intervention studies and 100% (26/26) of ECM intervention studies. These studies compared fatigue management education to waiting list controls or bland control interventions while, in our study, pwMS participated in IEME or PMR, in addition to intensive multidisciplinary rehabilitation, which explains the relatively large within-group effect sizes observed at T1, and the medium effect sizes at T2. To interpret the cumulative effect of the 3-week rehabilitation period on fatigue impact in this study, it is useful to know that Asano and Finlayson (2014) reported a medium pooled effect size for physical exercise.

Regarding the change in self-efficacy (SEPECSA) in the IEME group, our results (1.2 at T1 and 1.4 at T2) are promising because they are higher than 0.92, which is considered by Liepold and Mathiowetz (2005) to be a clinically relevant change and in line with the results of Van Heest et al. (2017) after a six-session one-to-one fatigue management course and the results of Mathiowetz et al. (2005) after an group-based outpatient course.

Regarding occupational performance (OSA), IEME improved performance in meaningful daily activities, a finding which is supported by previous studies on MS-related fatigue (Kos et al., 2015, 2016; Lexell et al., 2014).

Regarding HRQoL, the SF-36 score is a widely used secondary outcome in education intervention studies involving pwMS. Blikman et al. (2013) reported in their meta-analysis that ECM treatment yielded short-term improvements in three SF-36 dimensions (role limitation, social function and mental health). These findings are only partially consistent with our data, as we detected the largest effect size in the SF-36 dimension of physical functioning.

These data indicate that IEME + RAU does not affect the perceived impact of fatigue significantly more than PMR + RAU, but it improves competence in daily activities (OSA) and reduce perceived participation restriction (SF-36-PF). In our study, all participants benefited from a

Table 4
Outcome data for fatigue impact, occupational performance, self-efficacy and quality of life.

Group n: (T1/T2)	BL	T1	T2
Modified Fatigue Impact Scale (MFIS) total			
IEME (18/14)[a]	47.3 ± 14.3	31.7 ± 13.9	34.5 ± 16.6
PMR (15/15)[a]	44.5 ± 12.8	32.1 ± 15.8	34.5 ± 10.9
Within-group difference from baseline[b]			
IEME Δ		−15.6 [−23.3; −7.8][d]	−10.6 [−18.6; −2.7][d]
PMR Δ		−12.4 (−20.0; −4.8][d]	−7.4 [−14.0; −0.8][d]
Between-group difference from baseline[c]		−3.2 [−13.7; 7.4]	−3.2 [−13.0; 6.5]
OSA-BT (basic tasks of living)			
IEME (22/16)[a]	15.9 ± 1.45	16.9 ± 1.82	16.37 ± 2.22
PMR (17/17)[a]	15.4 ± 1.66	16.3 ± 1.76	15.82 ± 2.19
Within-group difference from baseline[b]			
IEME Δ		0.96 [0.4; 1.5][d]	0.33 [−0.6; 1.2]
PMR Δ		0.88 [−0.01; 1.8][d]	0.41 [−0.8; 1.6]
Between-group difference from baseline[c]		0.08 [−0.9; 1.1]	−0.08 [−1.5; 1.4]
OSA-MR (managing and relationships)			
IEME (21/15)[a]	26.7 ± 2.99	29.2 ± 2.74	28.3 ± 2.47
PMR (17/16)[a]	27.5 ± 2.32	28.6 ± 2.89	27.6 ± 3.32
Within-group difference from baseline[b]			
IEME Δ		2.5 [1.3; 3.6][d]	1.0 [−0.2; 2.2][d]
PMR Δ		1.1 [−0.5; 2.7]	0.45 [−0.7; 1.5]
Between-group difference from baseline[c]		1.4 [−0.5; 3.2]	0.1 [−1.7; 1.9]
OSA-SEA (satisfaction, enjoyment, actualization)			
IEME (21/15)[a]	19.9 ± 3.35	22.1 ± 2.43	21.7 ± 1.99
PMR (16/17)[a]	20.6 ± 2.10	22.0 ± 2.06	20.3 ± 2.21
Within-group difference from baseline[b]			
IEME Δ		2.26 [0.8; 3.7][d]	1.43 [−0.2; 3.0]
PMR Δ		1.4 [0.4; 2.5][d]	0.42 [−0.6; 1.4]
Between-group difference from baseline[c]		0.82 [−1.0; 2.6]	1.0 [−0.8; 2.8]
The University of Washington Self-Efficacy Scale for Multiple Sclerosis (UW-SES)			
IEME (13/13)[a]	42.3 ± 5.7	41.4 ± 8.0	41.7 ± 5.6
PMR (15/14)[a]	42.9 ± 4.1	40.5 ± 8.0	39.4 ± 4.2
Within-group difference from baseline[b]			
IEME Δ		−0.9 [−4.1; 2.3]	−1.6 [−3.9; 0.7]
PMR Δ		−2.4 [−6.9; 2.1]	−4.0 [−7.1; −0.8][d]
Between-group difference from baseline[c]		1.5 [−4.0; 6.9]	2.4 [−1.4; 6.1]
Self-efficacy of performing energy conservation strategies assessments (SEPECSA)			
IEME(20/14)[a]	6.6 ± 1.7	7.8 ± 1.7	8.0 ± 1.2
PMR(16/17)[a]	7.5 ± 1.1	8.5 ± 2.2	7.3 ± 1.0
Within-group difference from baseline[b]			
IEME Δ		1.2 [0.6; 1.7][d]	1.4 [0.6; 2.1][d]
PMR Δ		0.9 [−0.3; 2.2]	−0.2 [−0.8; 0.4]
Between-group difference from baseline[c]		0.21 [−1.0; 1.4]	1.5 [0.7; 2.4][d]
SF-36-PF (physical functioning)			
IEME (22/17)[a]	35.0 ± 20.8	46.8 ± 21.8	44.8 ± 24.7
PMR (17/16)[a]	32.5 ± 17.2	36.9 ± 20.9	30.0 ± 16.5
Within-group difference from baseline[b]			
IEME Δ		11.8 [7.0; 16.6][d]	11.0 [1.5; 20.5][d]
PMR Δ		4.4 [−1.0; 9.9]	−4.2 [−10.9; 2.5]
Between-group difference from baseline[c]		7.3 [0.3; 14.4][d]	15.2 [3.9; 26.5][d]
SF-36-RL (role limitations due to physical health)			
IEME (21/17)[a]	30.4 ± 38.8	64.3 ± 38.4	44.8 ± 24.7
PMR (15/14)[a]	36.7 ± 42.1	41.7 ± 34.9	30.0 ± 16.5
Within-group difference from baseline[b]			
IEME Δ		33.9 [16.2; 51.7][d]	16.9 [−0.53; 34.3]
PMR Δ		5.0 [−23.3; 33.3]	14.3 [−17.1; 45.7]
Between-group difference from baseline[c]		28.9 [−1.5; 59.4]	2.6 [−30.0; 35.3]
SF-36-FV (fatigue/vitality)			
IEME (22/18)[a]	33.0 ± 15.9	52.9 ± 16.5	46.5 ± 16.6
PMR (17/17)[a]	35.9 ± 11.6	51.8 ± 19.7	43.5 ± 18.3
Within-group difference from baseline [b]			
IEME Δ		19.9 [11.8; 28.1][d]	11.7 [5.6; 17.8][d]
PMR Δ		15.9 [8.7; 23.0][d]	8.2 [0.7; 15.7][d]
Between-group difference from baseline[c]		4.0 [−6.8; 14.9]	3.5 [−5.8; 12.7]
SF-36-EWB (emotional well-being)			
IEME (22/18)[a]	70.2 ± 18.9	81.1 ± 11.6	76.9 ± 15.1
PMR (18/17)[a]	63.6 ± 16.5	73.9 ± 12.7	69.2 ± 13.4
Within-group difference from baseline[b]			
IEME Δ		10.9 [3.8; 18.1][d]	2.0 [−2.6; 6.6]
PMR Δ		10.3 [3.3; 17.3][d]	6.4 [−2.0; 14.7]
Between-group difference from baseline[c]		0.6 [−9.1; 10.4]	−4.3 [−13.3; 4.6]

Abbreviations: IEME, inpatient energy management education; PMR, progressive muscle relaxation; MFIS, Modified Fatigue Impact Scale; OSA, Occupational Self-Assessment; SF-36, health-related quality of life short form survey.

[a] Values represent mean ± SD.

[b] Δ = T1/2-BL [95% CI]. BL = Baseline; T1 = Time-point 1 (at discharge, 3 weeks from BL); T2 = Time-point 2 (4 months from BL).

[c] Between groups Δ = IEME Δ – PMR Δ [95% CI].

[d] Statistically significant differences (p-value ≤ 0.05).

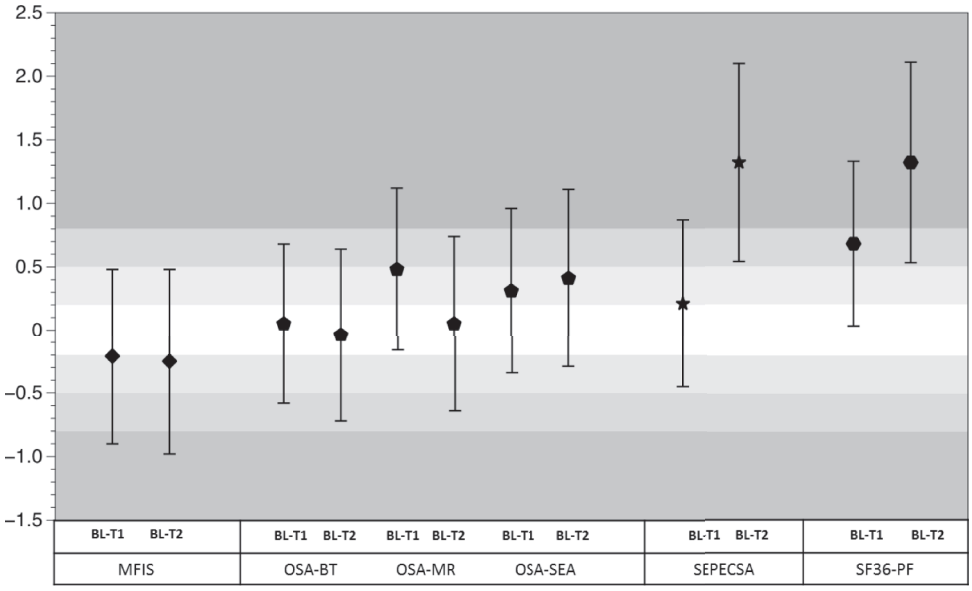

Fig. 2: Between-group effect sizes (Cohen's *d*) regarding fatigue impact, occupational performance, self-efficacy and quality of life. > 0.2, > 0.5 and > 0.8 indicate small, medium and large effect sizes, respectively.
Abbreviations:
MFIS, Modified Fatigue Impact Scale; OSA, Occupational Self-Assessment; BT, OSA subscale basic tasks of living; MR, OSA subscale managing and relationships; SEA, OSA subscale satisfaction, enjoyment, actualization, SEPECSA, Self-Efficacy for Performing Energy Conservation Strategies Assessments; SF-36-PF, Short Form 36 subscale physical functioning; BL = baseline; T1 = timepoint 1 (at discharge, 3 weeks after BL); T2 = timepoint 2 (4 months after BL).

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higher level of endurance and force due RAU, but only the IEME group, with its focus on behavioral change, improved self-efficacy, and perceived physical functioning (SF-36-PF) after the participants' return home. These outcomes are relevant, as they are linked to the goals declared by the participants at baseline, and they may indicate more effective management of fatigue in daily life. We hypothesize that, owing to their increased self-efficacy after the IEME, the participants increasingly applied useful strategies in everyday life, their range of action increased and they felt less restricted.

4.1. Strengths and limitations

This study provides sufficient and promising data for the development of a future large-scale RCT. The outcomes of IEME showed promising effect sizes. An important limitation of the study protocol is the lack of a control arm with IEME only, due to the restrictions in inpatient rehabilitation settings. According to the stages of change model (Norcross et al., 2011), long-term follow-up could provide further important information about the maintenance of behavioral change over time. Bias between groups was reduced by ensuring comparable treatment durations.

5. Conclusion

This feasibility study has successfully provided information about all the original research questions. The SEPECSA and OSA should be used to measure primary outcomes at T1, T2 and long-term follow-up, whereas the SF36 should be used at baseline, T2 and long-term follow-up. It may be useful to include the MFIS, which captures the effects of the multidisciplinary rehabilitation of all patients, as a secondary outcome. The IEME was effective in the short term (T1), and even more in the long term (T2), in improving self-efficacy in performing ergonomic behavioral change and fatigue management strategies. At the same time, IEME reduced individual OT time during inpatient rehabilitation and it positively affected the perceived influence of MS-related fatigue on physical functioning and vitality.

Declarations of Competing Interest

None.

Funding

This research was supported by grants from the Swiss MS Society Trust, the Foundation for Occupational Therapy Zürichand the Swiss Association of Occupational Therapists(ErgotherapeuteInnen Verband Schweiz EVS), as well as the University of Applied Sciences and Arts of Southern Switzerland and the Kliniken Valens. We would like to thank all participants involved in this study.

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