European Journal of Physical and Rehabilitation Medicine
EDIZIONI MINERVA MEDICA

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European Journal of Physical and Rehabilitation Medicine 2020 Mar 30
DOI: 10.23736/S1973-9087.20.06191-2

Article type: Original Article

Supplementary material available online at http://www.minervamedica.it
Article first published online: March 30, 2020
Manuscript accepted: March 30, 2020
Manuscript revised: March 24, 2020
Manuscript received: January 24, 2020

Standardized, comprehensive, hospital-based circuit training in people with multiple sclerosis (MS-FIT): Results on feasibility, adherence and satisfaction of the training intervention.

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Abstract

Background: We developed a standardized, comprehensive, ambulatory, hospital-based neurorehabilitation program ("MS-Fit") to improve disability, activities of daily living and quality of life in people with multiple sclerosis (PwMS).

Aim: To assess feasibility, adherence and satisfaction of the training intervention.

Design: Prospective multi-center cohort study analysis.

Population: PwMS, aged 18 to 75 years, complaining about multiple sclerosis-related disability affecting activities of daily living and/or quality of life.

Methods: A standardized, ambulatory, hospital-based circuit training consisting of six workstations (aerobic exercise training, strength upper limbs, balance, manual dexterity, reactivity, strength and flexibility lower limbs) was performed two hours, twice weekly, for two months in groups of two to six participants supervised by experienced physiotherapists. Physiotherapists adapted the type and intensity of training according to the participants' individual performance using a training booklet. Program satisfaction and adherence were evaluated using a questionnaire and the attendance rate (clinicaltrials.gov Identifier: NCT02440516).

Results: 55 participants started (mean age 52.82 years +/- 10.68 standard deviation, range 29-74; 69% female; median Expanded Disability Status Scale 3.5, range 1.0-7.0) and 49 (89%) finished the training program. Main reasons to drop out during the training were lack of time, travel problems, social issues or uthoff's phenomenon during the summer. All participants finalizing the training achieved >80% (mean 92.26%, ±7.59) attendance rate and sent back the questionnaire. Overall participant's satisfaction was high with a median of 9 points (range 4-10) on a Likert scale from 0-10. Program quality was rated "good" with an overall median score of 39/50 points (range 26-50) and 95% of the participants would recommend the program to others.

Conclusion: MS-Fit is a feasible training program with high patient satisfaction and adherence. It enables high intensity ambulatory training and can be easily reproduced due to its standardized nature.

Clinical Rehabilitation Impact: MS-FIT enables a standardized ambulatory high intensity training that is easily reproducible. Participants benefit from group training and from individual adaption of the training through professional supervision.

Keywords: multiple sclerosis, rehabilitation, neurorehabilitation, circuit training, comprehensive, ambulatory hospital based

Introduction

Multiple sclerosis (MS) is a chronic inflammatory disease of the central nervous system and the most common cause of non-traumatic disability in young adults in western countries.[1]

Despite increasing therapeutic options to ameliorate the disease course, most patients suffer from persistent neurological deficits over time. Neurologic symptoms can be manifold and are highly variable amongst patients and may, alone or in combination, lead to disability in people with MS (PwMS). Disability in MS impaires activities of daily living (ADL) and quality of life (QoL), and may lead to loss of work and the need of care. This results in considerable socioeconomic burden.[2-4]

Disease-modifying treatments prevent future disability progression. However, drugs to ameliorate persistent disability in MS are sparse.[5] Therefore, exercise training as well as physical and occupational therapies are important therapeutic approaches in MS. Various clinical trials show beneficial effects of exercise training on various symptoms and outcome parameters while being safe.[6, 7-9]

Despite this growing evidence and a high interest of PwMS in exercise training and guidelines, PwMS engage substantially less in physical activity than healthy individuals, which has not changed in the past 25 years.[10-11]

From patient's perspective, fatigue, lack of social support, problems with accessibility and travelling and no time due to the private or professional life situation are reasons for reduced exercise participation. Health care professionals might not initiate exercise therapies due to lack of specific therapeutic options and the absence of conceptual framework and toolkit for translating the evidence into practice.[8] Therefore, physical and occupational therapy is still usually performed close to patient's homes by therapists with different professional backgrounds in a non-standardized way and low frequency and intensity.

Ideally, the majority of PwMS should have access to standardized exercise training programs proven to be effective, which implies the need for different rehabilitation strategies adapted to the varying individual situations.

Circuit-training contains several workstations in which participant can exercise particular tasks adapted to their individual needs ("Task-oriented-circuit training") and previous studies showed a positive effect of circuit training on different outcome measures in MS.[12, 13] Supervised group exercise training has shown to improve functional status and quality of life in MS.[14-16] In addition, patients profit from group dynamics and peer social interactions.[13, 17]

We therefore developed a standardized, comprehensive two-month ambulatory hospital-based supervised circuit training ("MS-FIT") that can be easily reproduced to improve disability, ADL and QoL in PwMS. Herewith, we present the results on feasibility, adherence and satisfaction of the training intervention and describe the training program for best possible reproducibility.

Materials and Methods

Participants

Patients were recruited during routine visits in the MS consulting hours of the participating hospitals (Department of Neurology, University Hospital Bern, Switzerland; Neurocenter, Luzerner Kantonsspital, Lucerne, Switzerland). PwMS with relapsing-remitting MS (RRMS), secondary-progressive MS (SPMS) or primary progressive MS (PPMS) according to the revised McDonald's criteria, aged between 18 and 75 years, having an Expanded Disability Status Scale (EDSS) from 0-7 and complaining about MS related disability affecting ADL and/or QoL, were eligible.[18] Main exclusion criteria were rapid disease progression, a relapse within 60 days prior to screening, the presence of any other diseases/conditions that cause neurological deficits or disability besides MS, and a history of drug abuse in the 12 months prior to screening. Written informed consent was obtained from all participants prior to study entry. The study was performed in accordance with the 1964 Helsinki declaration and its later amendments, and approved by the responsible ethics committees for Bern and Lucerne (Ethics committees: Kantonale Ethikkommission Bern (KEK) and Ethikkommission Nordwest- und Zentralschweiz (EKNZ); Protocol number: 106/15; Date of approval: 11.01.2016 (KEK) and 20.01.2016 (EKNZ), Chairperson: Prof. Seiler). The clinicaltrials.gov Identifier is NCT02440516.

Study design

The training intervention was performed within a prospective double-center cross-over trial in which participants started the intervention immediately after Baseline visit (Therapy group) or after a waiting period of 3-10 weeks and a second baseline testing (Waiting list group). At baseline, demographic data (age, gender), handedness, MS type, date of MS diagnosis, disease duration, current medication, and current physical and occupational therapy were collected and the Expanded Disability Status Scale (EDSS) was performed by a certified EDSS rater (neurostatus.net).[19] Adherence,

program quality and satisfaction with the training intervention was evaluated after finishing the training intervention in an pooled analysis of both groups as described below. Outcome measurements evaluating the effect of the training program on disability, ADL and QoL were performed at baseline visits as well as directly and 2 month after the training intervention. These outcome parameters will be published separately.

Evaluation of adherence, program quality and satisfaction with the training intervention:

In order to evaluate the MS-fit training adherence rate, attendance to the training sessions was recorded with a maximum of 16 sessions. The adherence rate was the number of attended training session as a percentage of the overall session number.

Program quality was evaluated using a specific questionnaire. The 10-Items questionnaire covered different program aspects such as overall organization, exercise intensity or perceived change of fitness and strength and its implications on QoL. Every item was rated using a Likert scale from 1-5 (poor (1), moderate (2), good (3), very good (4), excellent (5)). For example, participants were asked to rate the “exercise choices” or the “program duration”. We calculated the sum of all items as an indicator of the program quality.

The overall participant’s satisfaction was evaluated using a Likert scale, ranging from 0 (low) to 10 (high). Finally, the participants were asked if they would recommend the program to others (yes or no).

Study interventions:

The MS-Fit circuit training contained six workstations (Figure I). Groups of 2-6 participants performed [illegible] weekly

(Monday and Thursday) for two hours over two months. Patients entered the training individually at different time points. During the first session, the participants were introduced to the circuit training and a booklet was handed out illustrating all workstations with 5-9 exercises options for each workstation ranging from easy to difficult enabling individual adoptions of the training (Supplementary Digital Material 1: Supplementary Text File 1: Training Booklet).

Together with the supervisor, exercise type and intensity was defined according to exercise guidelines in MS.[29] Throughout the training sessions, participant rated the exercise intensity using 20-point Borg's scale (RPE).[30] The Borg rating of perceived exertion scale helped to assess the intensity of training. The scale ranges from 6 "no exertion at all" to 20 "maximal exertion".

This information was used to guide and adapt the intensity from session to session in order to optimize exercise effect and participants received feedback by the physiotherapist during the progressive circuit training. Exercise intensity was ideally adapted and increased over the weeks. Resting time was used to discuss difficulties and possible further exercise adaptations.

Circuit Training:

The details of the workstations are illustrated in the training booklet and TIDieR Checklist (Supplementary Digital Material 1+2: Supplementary Text File 1+2: Training Booklet and Table I). 15 minutes of training were planned for each workstation with five minutes pauses between workstations.

Workstation 1: Aerobic exercise training (Booklet page 3/15)

Moderate aerobic exercise training was performed at 75-80% of the peak heart rate based on the fam exertion

scale (RPE) Level 13-14 (light to somewhat hard). Different options were offered such as treadmill walking, bicycling ergometer, repeated step training, and arm or leg ergometry. Exercise intensity progression was aimed.

Workstation 2: Strength upper limbs (Booklet page 4-5/15)

Strengthening exercise of the upper limbs were performed in a standing or sitting position using body weight, elastic band, weight or pulling machines. 2-3 exercises could be chosen from a set of 9 exercises and adapted to individual goals preferences and impairment with emphasis on shoulder girdle and spine. Recommendations were 1-4 series with 10-15 repetitions and 1-2 minutes rest between the series. Exercise intensity progression was systematically performed if possible.

Workstation 3: Balance (Booklet page 6-10/15)

Exercise static, dynamic or reactive balance training was performed using an Airex or Balance pad. Task progression or adaptation were done using modification of the base of support (for example, parallel feet, tandem stand) and/or in cumulating visual demand.

Option of exercising center of gravity shift, stepping tasks forwards, backwards, and sideward were also possible. Recommendations were 1-4 series with 10-15 repetitions and 1-2 minutes rest between the series.

Workstation 4: Manual dexterity (Booklet page 11/15)

Six different dexterity exercises, each lasting 60 seconds, were performed in sitting position (Finger tapping; Crossing circles; Turning discs, Nuts on Bolts, Modelling clay 1; Modelling clay 2). This training program ameliorated manual dexterity in MS patients in a home-based setting as previously published.[7]

Workstation 5: Reactivity (Booklet page 12/15)

Exercises challenging balance reactivity in sitting/standing position or walking were performed. Tasks involving position change under challenging conditions (sit to stand on a balance pad for example) or weight shifting were performed as well. Recommendations were 1-4 series with 10-15 repetitions and 1-2 minutes rest between the series.

Workstation 6: Strength and flexibility lower limb (Booklet page 13/15)

Strengthening exercise in lying, sitting or standing position, using body weight were performed. 2-3 exercises could be chosen from a set of 9 exercises and adapted to individual preferences and impairments. Recommendations for each exercise were 1-4 series with 10-15 repetitions, with 1-2 minutes of rest between the series. Exercise intensity progression was favoured. Flexibility exercises of the hip adductors, the hamstrings and foot plantar flexors were instructed as follow: "Please hold the stretch for 20-60 seconds in a comfortable range of motion".

Statistical analysis

Both groups (Therapy Group and Waiting List Group) were pooled for analysis. Descriptive statistics were used to present demographic characteristics and to calculate feasibility, satisfaction rates. One-way ANOVA (continuous data) or chi-square statistic (nominal data) were used to investigate whether baseline variables differed between the dropout rates (patients completing the training vs. patients dropping out). For missing data, the last value observed was carried forward. . For all analyses the level of significance was set at $p < 0.05$ (two-tailed). Statistical analyses were performed using PASW for Windows (version 24.0).

Results

From March 2016 to March 2019, 55 participants (Therapy group: n=36; Waiting List Group (n=19) started the training program. The characteristics of the population are shown in Table I. Of these 55 patients, 6 (11%) dropped out during the training. Main reasons for discontinuing the training were travel (n=2) and time issues (n=2). In addition, during the first year of the study, uhthoff's phenomenon in summertime was also a reason for dropouts (n=1). Therefore, the study was paused in the following years in the summer month (July and August). Only three patients stated the training program itself as reason for dropping out (intensity and/or nature of training) (Figure II). Furthermore, being male was associates with a higher drop-out rate whereas age, gender, disease duration, EDSS and MS type was not (Table I).

All 49 participants (89%) who completed the circuit training program achieved >80% (mean 92.26%, ±7.59 SD) attendance rate. There were no adverse events. All participants that finalized the training sent back the questionnaire. The overall participant's satisfaction was high with a median of 9 on the Likert scale from 0-10 (range 4-10). The rating of the program quality by the participants was good with an overall median score of 39/50 points (range 26-50). 95% would recommend the program to other PwMS.

The participants were very satisfied with the physiotherapeutic supervision during the intervention. All other items were predominantly rated as good except for the training booklet that was mostly rated as "fair" and can therefore be improved (Table II).

When looking at the general comments, participant mentioned impact on social participation, peer learning opportunities and increase in exercise management competences as positive results from the training program. Furthermore, participants valued the support of an experienced therapist giving professional advice based on actual EBP training recommendations. Expectation concerning further program availability was high.

Discussion

Our results show that the standardized comprehensive two-month ambulatory neurorehabilitation program was feasible and highly satisfying for the participating PwMS, resulting in a high attendance rate.

Circuit training enabled to perform a group training of patients with different bodily symptoms and different severity grades with regard to disability. Training could be adapted within each workstation to the individual patient with regard to intensity, individual capabilities and preferences. This is important because PwMS with different bodily symptoms need different kind of exercises modalities and equipment.[31, 32] In addition, patients could profit of social interaction and peer support between participants which are known advantages of group therapies.[17]

These advantages were main reasons for feasibility and high acceptance of the training program which could be shown by the high overall participant's satisfaction (median 39/50) and adherence with 89% of patients completing the training program with a mean attendance rate of 92.26%.[33]

In contrast, traditional group-based physical rehabilitation programs have several potential disadvantages such as the lack of flexibility in tailoring interventions according to the varied functional levels of individual MS patients as well as difficulties to match the patient's cognitive and psychological function in group therapy compared with individual therapy treatment goals.[34]

Another strength of the present study was to implement published intervention guidelines.[33] In a disease, which is characterized by changing wellbeing for example due to fatigue, the chosen exercises enabled an adaptation to the daily situation of participant and simultaneously to optimize exercise intensity.

The structure of the training program was well accepted with regard to duration (two month), training intensity (two hours twice weekly) and the performed training sessions (=workstations) as

shown by the results of the questionnaire (Table II). The vast majority of patients (95%) would recommend this training program to other patients.

Participants valued the supervision and support of an experienced physiotherapist having knowledge about the current exercise recommendation in PwMS. This is in accordance to findings published recently, in which PwMS want knowledge concerning planning, structuring and prescriptions of exercise.[11] This direct training support is an advantage compared to trainings delivered by non-specialized therapists and home-based self-training programs in which frequent professional adaptions over time are not possible.

The distribution of a training booklet to each patient was important for realization of the training program. We encouraged the participants to be actively engaged in using the booklet as individual feedback and training control. In addition, it was an important tool for training adaptations performed by the supervising therapists. The 20-point Borg's scale (RPE) was efficient in adapting the intensity of the program for each patient. Using the booklet increased learning opportunities, peer support, self-management and was in our opinion key to a high patient satisfaction as well.

Travel and time issues as well as Uthoff's phenomenon during summer month were main reasons for dropouts during the intervention period. We therefore recommend pausing the program during the summer, which we did in the last two years of the project. We can't explain why male patients tend to discontinue the study more often than females. During the recruitment process, we experience that people found it difficult to understand and manage several appointments with regard to their time schedule. It was however reassuring that only 11% of patients dropped out during training and only three of them complained about the training itself. In addition, age, disease duration, disability (EDSS) and MS type seemed to be no reason for dropping out. These finding suggest that the training program is feasible for different disability grades and MS types which is of major importance.

Current research in rehabilitation often can't be translated into clinical practice because the applied training programs are not reported adequately and therefore cannot be reproduced. We therefore developed a, within this paper, clearly described and reproducible training program with regard to the design of the program and the individual workstations. The training program and the individual adaption within the progressive therapy are illustrated in the booklet further enhancing reproducibility (Supplementary Digital Material 1: Supplementary Text File 1: Training Booklet). This enables therapist to offer an effective training program to PwMS in different ambulatory settings.

With regard to the possible training approaches for MS patients, this standardized comprehensive two-month ambulatory neurorehabilitation program is an opportunity for patients to take part at a high intensity ambulatory training program. It fills the gap between high intensity trainings within inpatient neurorehabilitations and low frequency/intensity community-based trainings and has the advantage of being supervised by health care professional compared to purely home-based self-training programs.

Conclusions

The standardized, comprehensive two month ambulatory hospital-based circuit training for PwMS (MS-FIT) is feasible and highly satisfying for PwMS resulting in a high adherence rate. It enables high intensity training in an ambulatory setting and participants benefit from group training advantages as well as from individual adaption of the training through professional supervision. In addition, MS-Fit can be easily reproduced due to its standardized nature.

Conflict of Interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

Author Contributions

All authors made substantial contributions to the concept and design, or analysis and interpretation of data, and to the drafting of the manuscript or revising it critically for important intellectual content. In addition, all authors provided final approval of the manuscript.

Funding

The study was supported by the Swiss MS Society (SMSG) by a restricted grant.

Acknowledgments

We thank Nicole Siegrist Klossner for managing the MS-fit circuit training group and Veronika Helfenstein for data managment.

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Figure Legends

Figure I: MS-FIT circuit training workstations

15 minutes of training were planned for each workstation with five minutes pauses in-between. For each workstation, 5-9 exercises options were available ranging from easy to difficult enabling individual adoptions of the training.

Figure II: Study Flowchart

n, number

Tables

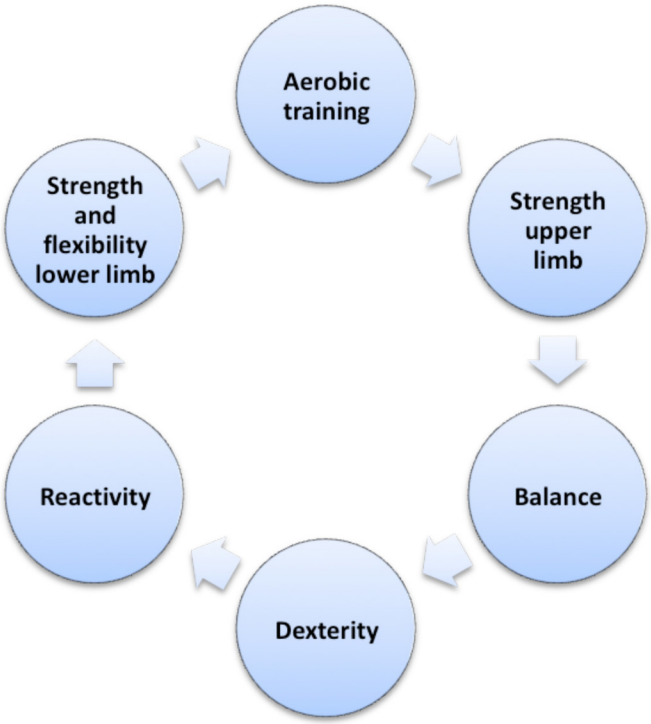
Table I. Patients' characteristics

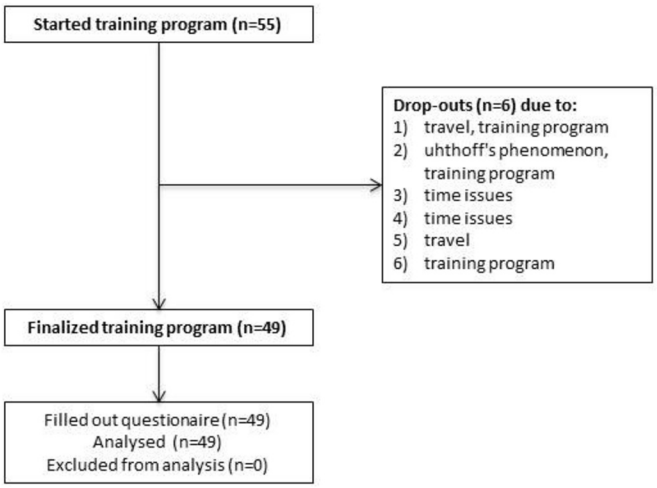
Characteristics	**Started training (n=55)**	**Completed training (n=49)**	**Drop-out (n=6)**	**Significance level (Training vs. Drop out population)**
Age (y), mean +/- SD (range)	52.82 +/- 10.68 (29-74)	53.37 +/- 10.22 (33-74)	48.33 +/- 14.24 (29-68)	p = 0.28
Sex (female), n (%)	38 (69%)	36 (73.5%)	2 (33%)	p = 0.05
Disease duration (y), mean +/- SD (range)	14.59 +/-11.88 (0-52)	14.76 +/-11.46 (0-52)	13.17 +/-16.17 (2-44)	p = 0.76
EDSS, median (range)	3.5 (1.0- 7.0)	3.5 (1.0- 7.0)	4.0 (3.0- 4.0)	p = 0.86
MS type, n (%)				p =0.19
RRMS	37 (67%)	31 (63%)	6 (100%)	
SPMS	8 (15%)	8 (16%)	0	
PPMS	10 (18%)	10 (21%)	0	
Unknown	0 (0%)	0 (0%)	0	

n, number; y, years; SD, standard deviation; EDSS, Expanded Disability Status Scale; RRMS, relapsing-remitting multiple sclerosis; SPMS, secondary progressive multiple sclerosis, PPMS, primary progressive multiple sclerosis

Table II: Questionnaires on patient satisfaction with the training intervention, items results (n=49, median, %)

	Excellent	Good	Fair	Poor	Very poor
First contact	13 (27%)	25 (51%)	10 (20%)	1 (2%)	0
Program instruction	12 (25%)	25 (51%)	9 (18%)	2 (4%)	1 (2%)
Program duration	8 (16%)	21 (43%)	18 (37%)	2 (4%)	0
Exercise intensity	8 (16%)	25 (51%)	13 (27%)	3 (6%)	0
Pauses	8 (16%)	21 (43%)	17 (35%)	1 (2%)	2 (4%)
Exercises options	15 (31%)	18 (36%)	15 (3%)	0	1 (2%)
Information	15 (31%)	19 (39%)	11 (22%)	4 (8%)	0
Booklet	7 (14%)	13 (27%)	18 (37%)	11 (22%)	0
Organisation	14 (29%)	23 (47%)	11 (22%)	1 (2%)	0
Supervision	24 (49%)	22 (45%)	3 (6%)	0	0





Supplementary Digital Material

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