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Effect of robot-assisted versus conventional body-weight-supported treadmill training on quality of life for people with multiple sclerosis

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Abstract—This study describes the effect of body-weight-supported treadmill training (BWSTT) on quality of life (QoL) for multiple sclerosis (MS) patients. Thirteen individuals with MS and gait impairment randomly received two blocks of six biweekly training sessions: (1) robot-assisted BWSTT then BWSTT alone (R-T) or (2) BWSTT alone then robot-assisted BWSTT (T-R). No statistically significant differences were found between robot-assisted BWSTT and unassisted BWSTT for improving QoL outcome measures. The change in Physical Component Summary scores from baseline to the end of the 12 training sessions improved significantly more in the R-T than the T-R group. Within-participant longitudinal changes in QoL for all participants from both groups combined showed significant improvements in 5 of the 13 QoL measures. The results of this pilot study suggest that both types of BWSTT may improve QoL for people with gait dysfunction secondary to MS.

Clinical Trial Registration: ClinicalTrials.Gov, NCT00156676, "Restoration of Walking in Multiple Sclerosis Using Treadmill Training"; http://www.clinicaltrials.gov/.

Key words: clinical study, disability, exercise, fatigue, gait, MS, quality of life, randomized, rehabilitation, treadmill.

INTRODUCTION

Multiple sclerosis (MS) can significantly impact quality of life (QoL) by virtue of its early onset, the range of impairments it can cause, its unpredictable course, its progressive nature, and the fact that currently no cure or completely effective treatment exists [1]. Studies indicate impaired QoL in persons with MS [2–3], and in recent years, research on MS has increasingly focused on QoL, particularly health-related QoL (HRQoL), which describes an individual's perception of how a disease affects his or

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Abbreviations: BWSTT = body-weight-supported treadmill training, EDSS = Expanded Disability Status Scale, FSS = Fatigue Severity Scale, HRQoL = health-related quality of life, IVIS = Impact of Visual Impairment Scale, LS = Life Satisfaction, MFIS = Modified Fatigue Impact Scale, MHI = Mental Health Inventory, MOS = Medical Outcomes Study, MS = multiple sclerosis, MSQLI = MS Quality of Life Inventory, MSSS = Modified Social Support Survey, PCS = Physical Component Summary, PDQ = Perceived Deficits Questionnaire, PES = Pain Effects Scale, PP = primary progressive, QoL = quality of life, R = robot-assisted BWSTT, RR&D = Rehabilitation Research and Development, RRSP = relapsing-remitting secondary progressive, SF-36 = 36-Item Short Form Health Survey, T = unassisted BWSTT, T1 = baseline, T2 = first phase, T3 = washout period, T4 = end of second phase/end of study, VA = Department of Veterans Affairs.

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her life in a broad sense—physically, psychologically, and interpersonally [4].

Quality of Life and Exercise Rehabilitation in Multiple Sclerosis

Changes in QoL commonly serve as outcome measures in clinical trials because such changes can provide information on the benefits or harms of an intervention, which may be more meaningful to patients [1] than structural (e.g., brain magnetic resonance imaging changes) or physiological (e.g., lower-limb strength) outcomes. Some studies have included indices of QoL among outcome measures [5–9], and other studies of rehabilitation for people with MS have focused exclusively on QoL [10–14].

Several studies over the past 2 decades have demonstrated improved QoL with exercise training in patients with MS [10–11,14]. Motl and Gosney's recent meta-analysis of 13 studies found that exercise training is associated with a small improvement in QoL among persons with MS [15]. Although the majority of studies have reported improved QoL outcomes as a result of exercise training, other studies have found no benefit for QoL. For example, a 2005 randomized controlled trial found no significant differences between the control and exercise groups at 6 months on the Multiple Sclerosis Functional Composite, the Expanded Disability Status Scale (EDSS), the Functional Independence Measure, or the MS Quality of Life-54 questionnaire [16].

Broad conclusions can be drawn from the body of research on rehabilitation in MS. First, physical activity in MS is not associated with symptom exacerbation or increased rates of relapse [17]. Second, while rehabilitation in MS does not reverse the progression of neurological impairment, it may yield benefits in physical and neurological functioning and QoL [6,9,18].

Body-Weight-Supported Treadmill Training

Body-weight-supported treadmill training (BWSTT) enables individuals to walk on a treadmill while a portion of their body weight is supported by a parachute-style harness linked to an overhead pulley system. This system allows people with motor deficits that render them unable to completely support their own body weight to practice and experience locomotion at physiological speeds. Depending on the extent of the person's impairment, one or more physical therapists may be required to help maintain appropriate posture and move the person's legs through as temporally and kinematically physiological a gait pattern as possible [19]. More recently, electromechanical devices such as the Lokomat robot-driven gait orthosis (Hocoma AG; Volketswil, Switzerland) have been introduced [20] with the aim of reducing the physical labor demands on therapists by using a computer-controlled exoskeleton to repeatedly and consistently guide lower-limb movements, which in turn renders BWSTT more feasible for long-term and widespread use. The present study on QoL outcomes was conducted as part of a pilot study on the effect of robot-assisted and unassisted BWSTT on gait for people who are ambulatory but have progressive forms of MS. At the inception of this project, BWSTT had not been investigated as a mode of therapy for people with MS; therefore, the effect of BWSTT on QoL was not known. Since this study was conceived and completed, three articles have been published on treadmill training in the MS population, but they provide only limited QoL information. We recently reported that task-repetitive BWSTT resulted in significant within-participant improvements in gait parameters and disability (EDSS) in this same study sample [21]. Van den Berg et al. examined the effect of aerobic treadmill training without body-weight support on walking and fatigue in 16 persons with MS and reported improved walking outcomes and no change in fatigue [22]. In another study, Giesser et al. examined the effect of BWSTT with manual assistance on mobility in four patients with severe MS-related disability and reported improved muscle strength, spasticity, endurance, balance, and walking speed [23]. Additionally, while improved HRQoL was noted in three out of four study participants, as measured by the Multiple Sclerosis Impact Scale, only one participant demonstrated a significantly improved EDSS score.

Thus, our goal in this study was to examine the effect of BWSTT on QoL for people with MS. Our primary hypotheses were that (1) robot-assisted BWSTT (R) would result in greater improvements in QoL than unassisted BWSTT (T); (2) BWSTT training, regardless of training protocol, would result in improved QoL among persons with MS; and (3) R preceding T would result in greater improvements than T preceding R.

METHODS

Participants

We recruited persons with either the relapsing-remitting secondary progressive (RRSP) or primary progressive (PP) subtypes of MS. The study's inclusion and exclusion criteria have been previously reported [21] and are also listed on ClinicalTrials.gov (NCT00156676). In summary, inclusion criteria for participants were an MS diagnosis by McDonald criteria [24] and a gait problem but the ability to walk 25 ft. without assistance. Potential participants were excluded if they had a recent myocardial infarction; uncontrolled hypertension or diabetes; symptomatic orthostasis; or body-weight, joint, or lower-limb musculoskeletal injuries that limited the range of motion necessary for safe use of the Lokomat.

Study Design

The study design has been described previously [21]. Briefly, enrolled participants were stratified by baseline (T1) EDSS score (≤5 or >5) [25] and sequentially randomized into one of two treatment groups: (1) T followed by R or (2) R followed by T. After completion of the first phase (T2) and a 6-week washout period (T3), participants crossed over to the alternate treatment. Completing the second phase marked the end of the study (T4). The target training time for each session was 40 minutes. The training sessions were scheduled twice a week for 3 weeks, for a total of six sessions per phase (R or T). Participants were instructed not to change their normal physical activities or exercise routines during the study.

Outcome Variables

QoL was assessed at four points during the study: at T1, after T2, after T3, and after T4. QoL was assessed by three self-report questionnaires: the MS Quality of Life Inventory (MSQLI) [4], the Fatigue Severity Scale (FSS) [26], and a single-item measure of general Life Satisfaction (LS) [27]. Additional information about the MSQLI scales is presented in **Table 1**.

Multiple Sclerosis Quality of Life Inventory

The MSQLI is a modular psychometric instrument comprising a well-established general HRQoL measure, the 36-Item Short Form Health Survey (SF-36) from the Medical Outcomes Study (MOS) [28], and nine symptom-based scales that represent areas of specific concern to people with MS. Of the symptom-specific scales, previously established instruments were used when possible to allow comparison across diseases [4]. The nine MS-specific scales used in the MSQLI were the Modified Fatigue Impact Scale (MFIS), the MOS Pain Effects Scale (PES), the Sexual Satisfaction Scale, the Bladder Control Scale, the Bowel Control Scale, the Impact of Visual Impairment Scale (IVIS), the Perceived Deficits Questionnaire (PDQ), the Mental Health Inventory (MHI), and the MOS Modified Social Support Survey (MSSS). To minimize participant burden and time constraints, we used the validated abbreviated versions of the PDQ, MHI, and MSSS (PDQ-5, MHI-5, and MSSS-5, respectively) in this study.

The SF-36 is a 36-item instrument with eight subscales that are scored to yield two summary scores: a Physical Component Summary (PCS) and a Mental Component Summary, each ranging from 0 to 100. These scores were normalized to the general population of the United States, such that a score of 100 represents optimal HRQoL while a 90 represents the 90th percentile.

Table 1.
Scales of Multiple Sclerosis Quality of Life Inventory (MSQLI).

MSQLI Scale	No. of Items	Score Range	Content
Physical Component Summary (PCS)*	21	0–100	Weighted sum of subscales reflective of physical well-being.
Mental Component Summary (MCS)*	—	0–100	Weighted sum of subscales reflective of mental well-being.
Modified Fatigue Impact Scale (MFIS)	21	0–84	Physical, cognitive, and psychosocial components of fatigue.
MOS Pain Effects Scale (PES)	6	6–30	Impact of pain on mood and physical/psychosocial function.
Sexual Satisfaction Scale (SSS)	5	4–24	Satisfaction within monogamous sexual relationships.
Bladder Control Scale (BLCS)	4	0–22	Lifestyle restriction secondary to bladder dysfunction.
Bowel Control Scale (BWCS)	5	0–26	Lifestyle restriction secondary to bowel dysfunction.
Impact of Visual Impairment Scale (IVIS)	5	0–15	Functional limitation secondary to visual impairment.
Abbreviated Version of Perceived Deficits Questionnaire (PDQ-5)	5	0–20	Perceived deficits in attention, memory, and planning.
Abbreviated Mental Health Inventory (MHI-5)	5	0–100	Overall emotional functioning.
Abbreviated MOS Modified Social Support Survey (MSSS-5)	5	0–100	Perceived availability of emotional and logistical support.

*Derived from Medical Outcomes Study (MOS) 36-Item Short Form Health Survey (SF-36), which contains 36 questions that pertain to eight domains of general health.

Fatigue Severity Scale

The FSS is a 9-item scale that assesses fatigue and its impact on daily functioning [26]. The scale was originally developed and validated for use in MS and systemic erythematous lupus and, in recent years, has been used to study a wide variety of neurological and chronic systemic conditions [29–33]. Possible scores range from 9 to 63, with higher scores representing a greater negative impact of fatigue on QoL.

Life Satisfaction

At each of the four time points, participants were asked a single item about overall LS: “How would you describe your satisfaction with life in general?” Scores ranged from 1 (“extremely satisfied”) to 6 (“extremely dissatisfied”) [27].

Statistical Analyses

Baseline demographic and gait characteristics of the two treatment groups were compared to assess adequacy of randomization [21]. The study was originally designed as a crossover trial, with participants randomly assigned to receive one of the treatments during the first phase and then crossed over to the other treatment after a 6-week washout period during the second phase [21]. However, as noted previously [21], the improvements in gait parameters did not revert to T1 measures by the end of T3, indicating that sufficient washout over the 6 weeks did not occur; as a consequence, we could not analyze the second-phase treatment effects independently. Therefore, statistical analyses compared treatment effects for T versus R only during the first phase or for the entire (first through second phase) randomized treatment group (T-R vs R-T). The first analysis directly compares T and R, and the second analysis examines treatment-ordering effect of the two forms of BWSTT. The latter comparison sought to evaluate the extent to which robot-assisted training provided a foundational advantage for subsequent BWSTT without robotic assistance, relative to the alternative treatment order. Because of the small sample size, nonparametric tests of association were performed with a significance level cutoff of $p < 0.05$. Between-group differences were tested with the Kruskal-Wallis test. Within-subject comparisons of overall changes in each QoL outcome and EDSS relative to T1 for all participants from both groups combined were examined by calculation of change scores for each variable such that a positive number indicated improvement and were tested with the Wilcoxon signed rank test. EDSS was collected at T1 and T4, and thus, only one time period (T1 to T4) was analyzed. All analyses were performed using SAS version 9.1.3 (SAS Institute Inc; Cary, North Carolina) and Microsoft Excel 2007 for Windows (Microsoft Corporation; Redmond, Washington).

RESULTS

The baseline study population demographics are shown in **Table 2**. A total of 13 participants were enrolled, of whom 6 were randomized to R-T and 7 were randomized to T-R [21]. Eight participants had the RRSP MS subtype (four males, four females), and five participants had the PP MS subtype (three males, two females). No participant had experienced a relapse within 6 months of enrollment. All participants completed the entire 12 training sessions, and no adverse events occurred during the study period. The baseline characteristics of the participants randomized into the two experimental groups (T-R, R-T) were similar and not statistically different, with the exception of the 6-Minute Walk ($p = 0.03$) and IVIS ($p = 0.04$).

Randomized Treatment Comparison

Changes in QoL measures between T and R in T2 were not significantly different (**Table 3**). The effect of treatment order (T-R vs R-T) on QoL for the two variations of BWSTT (alone or with robotic assistance) were analyzed by comparison of T1 to T4 data (**Table 4**). The PCS change scores significantly improved for participants randomized to R-T (15.6% increase) compared with T-R (2.0% increase) ($p = 0.008$).

Longitudinal Treatment Effects

Shown in **Table 5** are the within-participant longitudinal changes in QoL measures and EDSS score for all participants. From T1 to T2, significant improvements were seen in the FSS ($p = 0.01$), MFIS ($p = 0.03$), and PES ($p = 0.04$).

For both groups combined, from T1 to T4, significant within-participant longitudinal improvements were seen on 5 of the 13 QoL measures: PCS ($p = 0.03$), MFIS ($p = 0.03$), PES ($p = 0.02$), PDQ ($p = 0.03$), and LS ($p = 0.03$) (**Table 5**). A significant ($p = 0.003$) 1-point improvement in EDSS from T1 to T4 was also seen.

Table 2.
Characteristics of study sample.

Characteristic	All Subjects	R-T	T-R	*p*-Value*
Total (*n*)	13	6	7	—
Sex (*n*)				
Male	7	3	4	>0.99
Female	6	3	3	
				***p*-Value**†
Age (Mean ± SD)	49.8 ± 11.1	50.2 ± 11.4	49.6 ± 11.8	0.67
Baseline Total EDSS Score (Mean ± SD)	4.9 ± 1.2	5.3 ± 1.3	4.6 ± 1.2	0.28
Baseline QoL Scores (Mean ± SD)				
FSS	47.0 ± 11.8	48.2 ± 13.2	46.0 ± 11.4	0.76
PCS	39.5 ± 6.5	38.3 ± 6.8	40.2 ± 6.7	0.79
MCS	56.0 ± 8.5	51.2 ± 12.0	58.8 ± 5.0	0.41
MFIS	39.2 ± 12.3	38.3 ± 14.0	40.0 ± 6.7	0.86
PES	15.0 ± 4.8	14.8 ± 4.3	15.1 ± 5.5	0.80
SSS	10.9 ± 8.6	8.3 ± 5.5	13.0 ± 10.5	0.42
BLCS	7.3 ± 4.4	8.0 ± 5.7	6.7 ± 3.4	0.56
BWCS	4.0 ± 4.7	5.7 ± 6.1	2.6 ± 2.8	0.46
IVIS	1.1 ± 2.5	0.0 ± 0.0	2.0 ± 3.3	0.07
PDQ	6.5 ± 5.6	5.8 ± 4.1	7.0 ± 7.0	0.97
MHI	79.7 ± 13.0	77.3 ± 15.5	81.7 ± 11.3	0.56
MSSS	79.2 ± 27.2	86.7 ± 15.4	72.9 ± 34.4	0.55
LS	2.8 ± 1.3	3.3 ± 1.5	2.4 ± 1.1	0.30

*Fisher exact test.
†Wilcoxon two-sample exact test.
BLCS = Bladder Control Scale, BWCS = Bowel Control Scale, BWSTT = body-weight-supported treadmill training, EDSS = Expanded Disability Status Scale, FSS = Fatigue Severity Scale, IVIS = Impact of Visual Impairment Scale, LS = Life Satisfaction, MCS = Mental Component Summary, MFIS = Modified Fatigue Impact Scale, MHI = Mental Health Inventory, MSSS = Modified Social Support Survey, PCS = Physical Component Summary, PDQ = Perceived Deficits Questionnaire, PES = Pain Effects Scale, QoL = quality of life, R-T = BWSTT with robotic assistance followed by BWSTT alone, SD = standard deviation, SSS = Sexual Satisfaction Scale, T-R = BWSTT alone followed by BWSTT with robotic assistance.

DISCUSSION

The effect of either form of BWSTT on QoL outcome measures was similar and without consistent statistical significance for one form over another. Overall, some evidence of treatment order favoring R-T over T-R was found, with the only significant difference in the PCS score. However, large within-participant changes from T1 to T4 for all participants combined were found for several QoL measures. Analysis comparing T1 with T4 showed that task-repetitive gait training with either variation of BWSTT resulted in significant longitudinal improvements from study start to end in 5 of the 13 QoL measures: the PCS, MFIS, PES, PDQ, and LS. In addition, a 1-point improvement in EDSS score occurred over this period, as has been noted previously [21].

Limited evidence of treatment ordering effects favoring R-T versus T-R was found, with significant differences in the PCS measure. This finding is potentially important and may reflect the early training benefits of robot-assisted treadmill training. We hypothesize that early robot-assisted training gives the patient the opportunity to develop necessary initial coordination as a foundation for more independent BWSTT.

Significant longitudinal within-group improvements from T1 to the end of T2 were seen in 3 of the 13 QoL measures: the FSS, MFIS, and PES. Examination of all study participants overall from T1 to T4 showed that BWSTT, either alone or with robotic assistance, resulted in improvements. The positive effects of BWSTT in general appear most robust in the domains of LS, pain (PES), fatigue (MFIS), perceived deficits (PDQ), physical well-being (PCS), and disability (EDSS), which reached

Table 3.
Change in quality of life measures from baseline to end of first phase for participants with multiple sclerosis who received BWSTT alone (T) versus BWSTT with robotic assistance (R).

Measure	T (n = 7)		R (n = 5)		Wilcoxon Two-Sample Test	p-Value*
	Baseline Mean	Change	Baseline Mean	Change		
FSS	46.00	4.14	48.17	9.00	27.0	0.43
PCS	40.21	0.76	38.16	1.28†	25.0	0.93
MCS	58.76	–1.86	51.19	9.26†	31.0	0.23
MFIS	40.00	4.29	38.33	5.20	30.0	0.72
PES	15.14	1.14	14.83	4.20	25.0	0.24
SSS	13.00	–1.17	8.33	4.00	25.5	0.46
BLCS	6.71	1.57	8.00	2.60	35.0	0.75
BWCS	2.57	0.14	5.67	1.80	29.0	0.59
IVIS	2.00	0.29	0.00	–0.20	40.0	0.26
PDQ	7.00	2.14	5.83	1.00	37.0	0.54
MHI	81.71	0.57	73.33	6.40	37.5	0.45
MSSS	72.86	7.14	86.67	1.00	29.5	0.66
LS	2.43	0.29	3.33	1.20	23.5	0.17

Note: Positive change indicates improvement.
*Wilcoxon rank sum test exact p-value.
†n = 4 in R group.
BLCS = Bladder Control Scale, BWCS = Bowel Control Scale, BWSTT = body-weight-supported treadmill training, FSS = Fatigue Severity Scale, IVIS = Impact of Visual Impairment Scale, LS = Life Satisfaction, MCS = Mental Component Summary, MFIS = Modified Fatigue Impact Scale, MHI = Mental Health Inventory, MSSS = Modified Social Support Survey, PCS = Physical Component Summary, PDQ = Perceived Deficits Questionnaire, PES = Pain Effects Scale, SSS = Sexual Satisfaction Scale.

statistical significance in spite of the small study size. While FSS did not reach significance from T1 to T4, continued participation in the exercise resulted in a statistically significant within-group improvement in fatigue as measured by the MFIS.

Possible explanations for the improvements in QoL measures include endorphin release, which could reduce the burden of pain, and improved strength and aerobic fitness, which could improve one's sense of physical health and reduce fatigue by improving locomotor efficiency. Lower PDQ scores may reflect increased self-confidence and self-efficacy and be related to an improved sense of physical health resulting directly from the training or the psychosocial effect of participating in a study that promises new hope for control over an unpredictable disease. In line with our previous findings of a 1-point improvement in EDSS, the improvements in PDQ scores suggest a consistency between patient- and clinician-derived outcomes.

Table 4.
Change in quality of life measures and Expanded Disability Status Scale (EDSS) from baseline to end of study for participants with multiple sclerosis who received BWSTT alone followed by BWSTT with robotic assistance (T-R) versus BWSTT with robotic assistance followed by BWSTT alone (R-T).

Measure	T-R (n = 7)		R-T (n = 6)		Wilcoxon Two-Sample Test	p-Value*
	Baseline Mean	Change	Baseline Mean	Change		
EDSS	4.57	1.00	5.33	1.00	42.0	1.00
FSS	46.00	4.57	48.17	5.40†	32.5	1.00
PCS	40.21	0.80	38.16	5.93‡	38.0	0.01
MCS	58.76	0.41	51.19	11.71‡	34.0	0.07
MFIS	40.00	4.71	38.33	13.00	33.5	0.24
PES	15.14	2.29	14.83	6.83	33.5	0.24
SSS	13.00	1.67§	8.33	0.67	42.0	0.69
BLCS	6.71	–1.00	8.00	4.33	29.5	0.08
BWCS	2.57	–1.43	5.67	0.00‡	26.0	0.78
IVIS	2.00	0.29	0.00	–0.17	50.0	0.29
PDQ	7.00	1.29	5.83	2.50	35.5	0.37
MHI	81.71	1.71	73.33	10.67	50.5	0.25
MSSS	72.86	5.00	86.67	–4.00†	26.0	0.34
LS	2.43	0.71	3.33	1.20†	28.0	0.50

Note: Positive change indicates improvement.
*Wilcoxon rank sum test exact p-value.
†n = 5 in R-T group.
‡n = 4 in R-T group.
§n = 6 in T-R group.
BLCS = Bladder Control Scale, BWCS = Bowel Control Scale, BWSTT = body-weight-supported treadmill training, FSS = Fatigue Severity Scale, IVIS = Impact of Visual Impairment Scale, LS = Life Satisfaction, MCS = Mental Component Summary, MFIS = Modified Fatigue Impact Scale, MHI = Mental Health Inventory, MSSS = Modified Social Support Survey, PCS = Physical Component Summary, PDQ = Perceived Deficits Questionnaire, PES = Pain Effects Scale, SSS = Sexual Satisfaction Scale.

The results from this pilot study are consistent with findings from Motl and Gosney's recent meta-analysis of the effects of exercise training on QoL in individuals with MS, which reported a small but significant improvement in QoL and fatigue as a result of aerobic exercise training [15]. The meta-analysis found that the effect of exercise training on QoL was statistically significant when MS-specific measures of QoL and fatigue were used as outcomes, as in the present study. One may speculate that these training benefits are related to the factors previously noted for life satisfaction—endorphins, improved physical health, excitement about the potential benefit of the treatment, the opportunity to feel proactive in managing MS, and the social interactions inherent to study participation.

Table 5.
Overall longitudinal treatment effects: Change in quality of life measures and Expanded Disability Status Scale (EDSS) from baseline (T1) to end of first phase (T2) and from T1 to end of second phase (T4).

Measure	T1 to T2 (*n* = 12)			T1 to T4 (*n* = 13)		
	Change*	Signed Rank Test	*p*-Value†	Change*	Signed Rank Test	*p*-Value†
EDSS	NA	NA	NA	1.00	–33.0	0.001
FSS	6.17	–28.5	0.01	4.92‡	–14.0	0.17
PCS	0.09§	–8.0	0.52	2.67§	–25.0	0.02
MCS	2.18§	–9.0	0.46	4.52§	–17.0	0.15
MFIS	6.31	–27.0	0.03	8.54	–30.5	0.03
PES	2.42	–23.0	0.04	4.38	–29.5	0.02
SSS	1.18	–7.0	0.28	1.17‡	–6.0	0.37
BLCS	2.00	–12.0	0.18	1.46	–14.5	0.22
BWCS	0.00	–2.5	0.72	–0.91§	–1.0	0.87
IVIS	0.08	–1.0	1.00	0.08	–1.5	1.00
PDQ	1.67	–13.0	0.13	1.85	–28.0	0.02
MHI	3.00	–9.0	0.45	5.85	–17.5	0.12
MSSS	4.58	–6.0	0.44	1.25‡	–5.0	0.51
LS	0.17	–12.0	0.12	0.92‡	–15.5	0.04

*Change from T1 for all subjects combined.
†Wilcoxon signed rank exact test.
‡n = 12.
§n = 11.
BLCS = Bladder Control Scale, BWCS = Bowel Control Scale, FSS = Fatigue Severity Scale, IVIS = Impact of Visual Impairment Scale, LS = Life Satisfaction, MCS = Mental Component Summary, MFIS = Modified Fatigue Impact Scale, MHI = Mental Health Inventory, MSSS = Modified Social Support Survey, NA = not applicable, PCS = Physical Component Summary, PDQ = Perceived Deficits Questionnaire, PES = Pain Effects Scale, SSS = Sexual Satisfaction Scale.

Until the end of the twentieth century, exercise was widely believed to exacerbate symptoms of MS, triggering relapses and thus hastening the progression of the disease [17]. As a result, people with MS were cautioned to avoid exercise and excessive expenditures of energy in activities of daily living [34]. In the mid-1980s, however, researchers began to challenge this belief and investigate the potential benefits of aerobic exercise as a mode of therapy for individuals with MS [35–36] and found no detrimental effects of a physical training protocol for people with MS. A turning point in the attitude toward physical activity and the possible benefit from exercise and rehabilitation for MS came in 1996, when Petajan et al. published the results of a randomized controlled trial evaluating the effects of an aerobic fitness program on several parameters of physical fitness and HRQoL [8]. The results indicated that compared with the control group, individuals randomized to the exercise group had significantly greater improvements in physical parameters, including aerobic capacity, strength, skinfold thickness, blood lipids, and self-reported bladder and bowel function. Importantly, analysis of HRQoL data revealed the following: significant benefits of the exercise program for the Physical Dimension summary subscale of the Sickness Impact Profile; transiently significant benefits in the Social Interaction and Emotional Behavior subscales of the Sickness Impact Profile; a positive correlation between gains in aerobic capacity and improvements in the Tension, Vigor, Fatigue and Confusion subscales of the Profile of Mood States; and no significant changes for either group in FSS. The positive results of this trial stimulated excitement about the potential for rehabilitation for MS [17] and helped to further allay fears of exercise-induced exacerbations. The present study lends further credence to the idea that exercise training can improve QoL in those with MS.

LIMITATIONS AND FUTURE DIRECTIONS

These findings should be interpreted with an understanding of the limitations of the study, which include limited sample size, the absence of a traditional physical therapy or a nonexercise control group, and limited generalizability outside ambulatory individuals with MS within the examined EDSS range. All findings should be interpreted with caution, given the low statistical power of the study and the paucity of corroborative data in this still relatively undeveloped field of research. Future studies should include a group of participants undergoing conventional physical therapy to allow for comparisons between types of interventions, which could yield more widely meaningful information about the relative efficacy of this mode of treatment for people with MS. In addition, future studies of BWSTT in persons with MS should also examine the long-term effects on QoL outcomes.

This pilot study—though it did not demonstrate a significant difference between the effects of robot-assisted versus unassisted BWSTT—provides evidence that both types of BWSTT can lead to improved QoL. The QoL analysis augments our previous findings of improved gait performance after treadmill training in this same study population [21].

CONCLUSIONS

This study suggests that task-repetitive gait training is safely tolerated and can effectively improve QoL in patients with chronic MS, even after a brief training period. Among the study participants, no quantifiable differences were found between BWSTT alone and BWSTT with robotic assistance. However, the results of the present study clearly demonstrated a longitudinal improvement in QoL as a result of BWSTT. Overall, the study suggests that task-repetitive gait training is a noninvasive intervention with the potential to help improve QoL in MS.

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