Effects of Pilates-Based Core Stability Training in Ambulant People With Multiple Sclerosis: Multicenter, Assessor-Blinded, Randomized Controlled Trial

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Background. Pilates exercise is often undertaken by people with multiple sclerosis (MS) who have balance and mobility difficulties.

Objectives. The primary aim of the study was to compare the effects of 12 weeks of Pilates exercises with relaxation on balance and mobility. Secondary aims were: (1) to compare standardized exercises with relaxation and (2) to compare Pilates exercises with standardized exercises.

Methods. A multicenter, assessor-blinded, randomized controlled trial was conducted. Participants with Expanded Disability Status Scale scores of 4.0 to 6.5 were randomly allocated to groups receiving 12 weeks of Pilates exercises, standardized exercises, or relaxation. Assessments were undertaken at baseline and weeks 12 and 16 (primary outcome measure: 10-Meter Timed Walk Test [10MTW]).

Results. One hundred participants (mean age=54 years, 74% female) were randomized to study groups. Six participants relapsed (withdrew from the study), leaving 94 participants for intention-to-treat analysis. There was no significant difference in mean 10MTW measurements between the Pilates and relaxation groups. At 12 weeks, there was a mean reduction of 4.2 seconds for the standardized exercise group compared with the relaxation group (95% confidence interval [relaxation group minus standardized exercise group measurements]=0.0, 8.4) and a mean reduction of 3.7 seconds for the Pilates group compared with the standardized exercise group (95% confidence interval [Pilates group minus standardized exercise group measurements]=−0.4 to 7.8). At 16 weeks, mean 10MTW times for the standardized exercise group remained quicker than those for the Pilates and relaxation groups, although the differences were nonsignificant. There were no significant differences between the Pilates and relaxation groups for any secondary outcome measure.

Limitations. In this study, therapists were limited to a standardized basket of exercises that may have affected the study outcomes. Furthermore, choosing measures such as posturography to assess balance, accelerometry to assess walking, or a specific trunk assessment scale might have been more responsive in detecting changes in outcome.

Conclusion. Participants did not improve significantly, either in the short term or at the 4-week follow-up, on the 10MTW after 12 weeks of Pilates exercises compared with 12 weeks of relaxation.

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Multiple sclerosis (MS) is one of the most prevalent causes of neurological disability affecting young adults in the United Kingdom.[1] Impairments in balance and mobility are common even in the early stages of disease.[2] These are often the first reported symptoms, with up to 80% of people experiencing difficulties, highlighting the significance of walking impairments for people with MS.[3] Difficulties with walking are associated with impaired ability to perform activities of daily living and work and with reduced quality of life.[4] Similarly, balance impairments have significant consequences, being associated with an increased risk of falls.[5] The prevalence of falls is estimated at approximately 50%, with a higher risk of fractures compared with the general population.[6] Together, these issues confirm that management of these problems should be a clinical priority.

The trunk constitutes the largest part of the body, and effective activation of trunk muscles is considered crucial to trunk stability and balance.[7] Research has shown that reduced trunk stability occurs in people with MS.[8] The deep abdominal muscles are thought to contribute to trunk stability.[9] Improving trunk stability in people with neurological impairment is a common goal of physical therapy,[8] with different approaches used to address this impairment. These approaches include the use of Pilates; a system of exercises that focuses on training the deep abdominal muscles. Although Pilates originally became fashionable among dancers, modified Pilates courses have recently been established to train physical therapists to apply these concepts within clinical practice.[10] As a consequence, Pilates exercises are frequently used by physical therapists, and people with MS self-finance attendance at Pilates classes, despite a paucity of evidence to support effectiveness.[11]

This multicenter randomized controlled trial (RCT) builds upon pilot work that suggested potential for Pilates-based core stability training to improve balance and mobility in people with MS.[11] The primary aim was to compare the effectiveness of a 12-week program of Pilates with relaxation exercise. Secondary aims were to compare a 12-week program of standardized exercises with relaxation and to compare Pilates with standardized exercises. A further secondary aim was to explore underlying mechanisms of change with ultrasound imaging, which will be reported in a separate article.

Method

Trial Design

This was a 3-arm, multicenter, assessor-blinded, pragmatic RCT. The full protocol is reported elsewhere[12] and can be freely accessed at http://www.biomedcentral.com/1471-2377/12/19.

Participants

One hundred participants were recruited across the United Kingdom. The original protocol was for recruitment from 4 centers; however, slower-than-anticipated recruitment rates required the number of centers to be increased to 7 and the recruitment period to be extended by 6 months. Recruitment commenced on September 1, 2011, and ceased on March 5, 2013.

Participants were eligible if they were aged over 18 years, had a definite diagnosis of MS according to McDonald's criteria,[13] and had an Expanded Disability Status Scale (EDSS) score of 4.0 to 6.5, meaning that, at best, they were able to walk independently without use of an aid or rest for 500 m (EDSS score=4.0) and, at worst, they required 2 walking aids (pair of crutches or canes) to walk about 20 m without resting. Exclusion criteria were: in relapse or having relapsed in the previous 3 months[14]; any medical condition contraindicating participation in Pilates exercises; scoring <6 on the Abbreviated Mental Test,[15] as an indicator of those whose cognitive difficulties could interfere with the informed consent process or the ability to fully engage in the exercise program; current or recent (within previous 6 months) participation in Pilates or core stability exercises; and current involvement in another interventional research study.

Participants were recruited from physical therapy departments at each of the centers and via advertisement in the newsletter of the South West Impact of Multiple Sclerosis Project (SWIMS), which is accessed by more than 1,500 people with MS living in southwest England.[16]

Randomization and Blinding

After providing written consent, participants were randomly assigned (1:1:1) to groups receiving Pilates, standardized exercises, or relaxation. Before the start of the trial, the study coordinator (E.E.F.) prepared sequentially numbered, opaque, sealed envelopes containing the treatment allocation. The random sequence was generated using a computerized random number generator. Block randomization, with each center as the block, was used. The local investigator opened the sealed envelopes sequentially and only after the participant's name and other details were written on the envelope. To further optimize the rigor of randomization, the allocation was confirmed with the study coordinator. Due to the slow recruitment, requiring the addition of trial centers, one error in allocation occurred, resulting in one duplication (Figure).

After allocation, it was not possible to blind the treating physical therapist to each participant's allocated intervention. The assessing therapists, however, remained blind to treatment allocation throughout the trial, and every effort was made to blind the participants to treatment allocation.

Interventions

Following randomization, the allocated intervention was delivered at each center by a neurological physical therapist experienced in managing people with MS and trained in the standard protocols. All therapists had undertaken formal postgraduate Pilates training with an accredited body.

Full details of all interventions have been published previously[12] and are briefly summarized below. Table 1 compares the contents of the interventions.

Pilates

This was a pragmatic trial; therefore, the exercises were selected by the treating therapist from 10 exercises chosen to be

reflective of current clinical practice. This program of exercises[17] was developed for the pilot work by experienced specialist MS physical therapists.[11] Emphasis was placed on voluntary activation of the deep abdominal muscles, and exercises were progressed at each session according to individual's abilities.

Standardized Exercises

These exercises, designed to improve pelvic and trunk stability, lower limb strength, and balance, are detailed in Barrett et al.[18] In line with the pragmatic nature of this trial, these exercises were chosen because they reflect routine exercises carried out in current clinical practice. At each session, appropriate exercises were chosen from the list and progressed according to individual ability.

For participants randomized to either of these exercise interventions, 12 half-hour, individualized, one-to-one training sessions were delivered over 12 weeks. An individualized 15-minute daily home exercise program also was prescribed. The exercise intensity was individualized to the participant, and the level of exercise was progressed over 12 weeks. Participants were given a workbook with written and diagrammatic instructions to facilitate exercise performance and a diary in which to record their adherence.

Relaxation Sessions (Control)

The control was a relaxation activity utilizing contract-relax techniques, wherein the participant was positioned supine and progressively isometrically contracted and relaxed the muscles. Current evidence demonstrates that this activity would not be of sufficient intensity to generate change in muscle strength.[19] Participants attended 3 face-to-face individualized relaxation sessions lasting approximately 60 minutes, at 4 weekly intervals. They were asked to perform 15 minutes of this "exercise" daily at home and were provided with an audio CD to facilitate performance of the home program. A diary was provided to record their adherence to this home program. Weekly telephone contact by the treating therapist was undertaken in an attempt to match for the attention given to the participant by the therapist.

Table 1.
Comparison of Interventions

Variable	Pilates	Standardized Exercises	Relaxation
Description	Exercises in standing, supine, 4-point kneeling, and prone positions Exercises based on the principles of Pilates, which include focusing on voluntarily activating the deep abdominal muscles by drawing the navel toward the spine and combining movement with breathing Gym ball used at discretion of therapist	Exercises in standing, supine, 4-point kneeling, and prone positions Therapists teaching the exercises were expressly asked not to teach voluntary activation of the deep abdominal muscles	A supine relaxation exercise, participants were positioned supine and progressively contracted and relaxed the muscles Therapists used a script for standardization Participants were provided with a CD for practice at home
Frequency and intensity	One session per week with neurological Pilates-trained center therapist plus 15 minutes of home exercises recorded in the diary based on exercises taught in the session Therapists were able to select and progress exercises based on the participants' individual requirements		One session per month with the center therapist, weekly telephone calls to match for attention

Outcome Measures and Follow-up

The standardized, validated outcome measures were administered by a blinded assessor at baseline, immediately following the allocated program of face-to-face intervention (week 12), and 1 month after contact with the treating therapist had ceased (week 16). The primary outcome measure was the 10-Meter Timed Walk Test (10MTW), which has established validity[20] and high interrater reliability (intraclass correlation coefficient=.94)[21] and has been shown to be responsive in people with MS,[20,22] including in those who participated in Pilates as part of our pilot work.[11] At all 3 assessments, participants used their usual walking aid for the 10MTW, which was documented to ensure consistency.

The secondary outcome measures were collected in a protocolized order:

- Walking speed (in meters per second), calculated on the basis of the 10MTW.
- Functional reach (forward and lateral); clinician-rated measures of balance impairment.
- 12-Item Multiple Sclerosis Walking Scale (MSWS-12, version 2); a 12-item self-report questionnaire that measures walking impairment.
- Activities-specific Balance Confidence (ABC) scale; a self-report questionnaire measuring perceived balance confidence.
- 10-point numeric rating scale to determine the participants' perspective of "difficulty in carrying a drink when walking," identified as a common dual-task problem in people with MS.

Adherence Data

Type, level, and repetition of exercises were documented by the therapist. Participants recorded adherence to home exercises in a diary.

Sample Size

The recruitment target was 100 participants. The sample size calculation was based on data from the case series study investigating the effectiveness of a

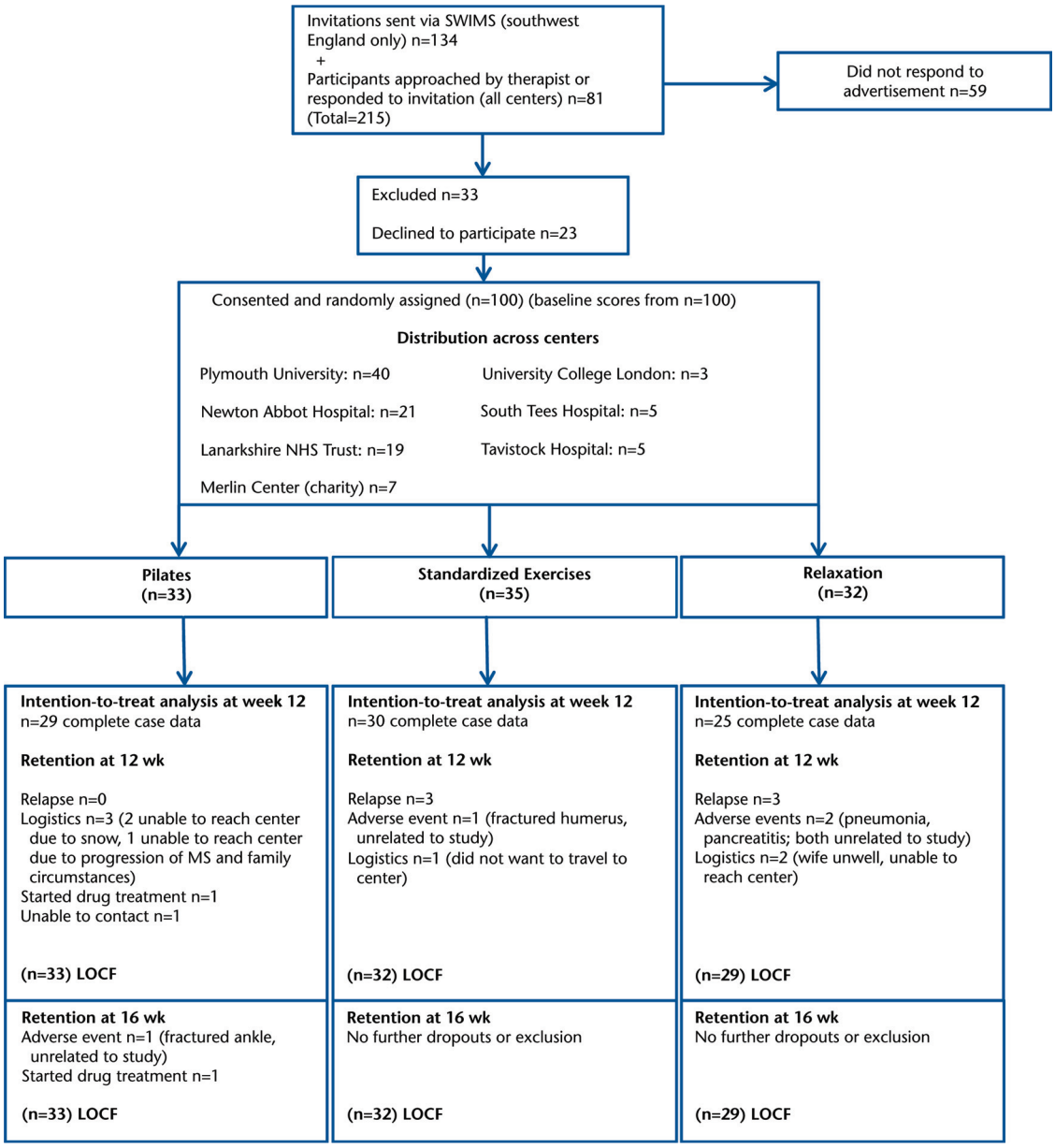

Figure
Recruitment, allocation, and retention of participants. SWIMS=South West Impact of Multiple Sclerosis Project, LOCF=last observation carried forward analysis, MS=multiple sclerosis.

Pilates-based core stability training program on balance and mobility in a similar sample of people with MS.[11] Based on these data, 30 people in each group were required in order to detect a 20% difference between Pilates and relaxation groups in terms of the primary outcome measure (ie, 10MTW), with 85% power and at the 5% significance level. This sample size was inflated to 33 participants per group to allow for a 10% loss due to dropout or relapse. At the time of finalizing the protocol, it was decided to add another 33 participants to allow randomization to 1 of 3 groups.[12]

Data Analysis

The 6 participants who relapsed, none of whom were in the Pilates group, were excluded from the analysis, as prespecified in the protocol[12]; an additional 13 participants were lost to follow-up (Figure). Therefore, to maximize use of the data, and prior to commencing statistical analysis, the decision was made to impute missing outcome values using the last observation carried forward (LOCF) method. This approach was chosen based on existing evidence that a significant decline in overall mobility was unlikely over the time frame of this study.[22,23] Sensitivity analysis was performed on all available data (ie, on complete cases only), which yielded similar

Table 2.
Demographic and Diagnostic Characteristics of the 100 Participants Recruited

Variable	Pilates (n=33)	Standardized Exercises (n=35)	Relaxation (n=32)	All (N=100)
Age (y), $\bar{X}$ (SD) [range]	53.97 (9.19) [31–73]	54.60 (11.54) [35–77]	53.78 (9.72) [40–74]	54.13 (10.14) [31–77]
Female sex, % (n)	84.9% (28)	71.4% (25)	65.6% (21)	74.0% (74)
Type of multiple sclerosis, % (n)				
Relapse remitting	39.4% (13)	37.1% (13)	37.5% (12)	38.0% (38)
Secondary progressive	24.2% (8)	31.4% (11)	34.4% (11)	30.0% (30)
Primary progressive	36.4% (12)	31.4% (11)	25.0% (8)	31.0% (31)
Benign			3.1% (1)	1.0% (1)
Years since first symptoms, $\bar{X}$ (SD) [range]	18.94 (11.29) [2–40]	18.46 (11.59) [3–44]	20.53 (10.96) [4–45][a]	19.27 (11.22) [2–45][a]
Years since diagnosis, $\bar{X}$ (SD) [range]	13.18 (10.06) [1–36]	13.91 (10.97) [0–41]	12.14 (10.68) [0.5–42]	13.11 (10.50) [0–42]

[a] One participant allocated to the relaxation group did not report years since first symptom.

results; for simplicity, only the results based on the imputed data are presented.

Although the original research hypothesis was stated in terms of comparing Pilates with relaxation (the basis on which the study was powered), the final study design allocated participants to 1 of 3 groups (Pilates, standardized exercise, or relaxation), with the comparisons among all 3 groups of interest. Therefore, to make maximal and efficient use of the data structure, repeated-measures mixed models were fitted for each outcome measure, incorporating effects of time (baseline, 12 weeks, 16 weeks), allocated group, and the interaction between time and allocated group. The statistical significance level was set at 5%. All pair-wise comparisons between groups at 12 and 16 weeks were considered to be of potential interest and were calculated using the marginal linear predictions from the fitted models (including the interaction effect between allocated group and time) and are presented with corresponding Bonferroni-adjusted 95% confidence intervals (CI).

Role of the Funding Source

The authors acknowledge The MS Trust for funding the trial.

Results

There were no reported harms or adverse reactions in any of the participants. Four adverse events occurred: a fractured ankle (Pilates group) and a fractured humerus (standardized exercise group) (both as a result of falls in the snow, unrelated to the exercise sessions) and pneumonia and pancreatitis (relaxation group) (unrelated to the exercise sessions). The Figure illustrates the flow of participants through the trial.

Demographics of all participants who were randomized are shown in Table 2. After the removal of the relapsers and imputation for missing outcome data, the outcomes are summarized descriptively in Table 3. Table 4 shows the adjusted mean differences and Bonferroni-corrected 95% CI values for between-group differences at 12 and 16 weeks.

At 12 weeks, for all outcome measures except the visual analog scale (VAS), the repeated-measures mixed models indicated that overall there were statistically significant differences among the allocated groups (all $P<.05$, except for VAS [$P=.363$]). At 16 weeks, there was evidence of statistically significant differences among allocated groups for walking speed, lateral functional reach, MSWS-12 score, and ABC score only (all $P<.05$).

Primary Outcome measure

For the primary outcome measure of 10MTW, there was no statistically significant difference between the Pilates and relaxation groups at 12 weeks. There was some evidence of a reduction in time in the standardized exercise group compared with the relaxation group (adjusted difference [ie, from the fitted model]) (standardized exercise minus relaxation) of −4.2 seconds (95% CI=−8.4, 0.0) and of a slightly smaller reduction in time when comparing the standardized exercise group with the Pilates group (adjusted difference) (standardized exercise minus Pilates) of −3.7 seconds (95% CI=−7.8, 0.4). At 16 weeks, although the standardized exercise group remained, on average, quicker than either the Pilates or relaxation group (mean time=12.9, 14.9, 15.39 seconds, respectively), the magnitude of the mean difference was much reduced.

Secondary Outcome Measures

At both 12 and 16 weeks, there was no evidence of statistically significant differences between the Pilates and relaxation groups for any of the secondary outcome measures.

At 12 weeks, participants in the standardized exercise group did statistically significantly better, on average, than those in the relaxation group in terms of walking speed, forward functional reach, and MSWS-12 and ABC scores, with the difference in lateral functional reach not quite reaching statistical significance. When comparing these 2 groups again at 16 weeks, the differences remained for walking speed and MSWS-12 score, and there was evidence of a statistically significant difference in lateral functional reach.

At 12 weeks, participants allocated to the standardized exercise group, on average, did significantly better than those in the Pilates group in terms of walking speed and MSWS-12 score. At 16 weeks, the difference for MSWS-12 score remained statistically significant, but the difference for walking speed did not reach statistical significance. Attendance at therapy sessions was 66% for the Pilates group, 84% for the standardized exercise group, and 92% for the relaxation group. Adher-

Table 3.
Descriptive Statistics for All Outcome Measures Across Time and Allocated Groups (After Removal of Relapsers and Imputation of Missing Outcome Data for Participants Lost to Follow-up)[a]

Outcome Measure	Baseline			12 Weeks			16 Weeks		
	Pilates (n=33)	Standardized Exercises (n=32)	Relaxation (n=29)	Pilates (n=33)	Standardized Exercises (n=32)	Relaxation (n=29)	Pilates (n=33)	Standardized Exercises (n=32)	Relaxation (n=29)
10-Meter Timed Walk Test (s)[b]	16.16 (7.72) [6.09–39.20]	12.85 (5.05) [6.70–30.00]	15.52 (6.22) [6.00–35.00]	14.43 (7.56) [6.18–41.00]	10.73 (4.46) [5.00–28.00]	14.94 (5.66) [7.54–28.06]	14.90 (8.22) [8.00–39.00]	12.94 (9.18) [5.50–54.00]	15.39 (5.95) [6.00–30.00]
Walking speed (m/s)	0.73 (0.28) [0.26–0.64]	0.87 (0.27) [0.33–1.49]	0.75 (0.31) [0.29–1.67]	0.83 (0.30) [0.24–1.62]	1.04 (0.32) [0.36–2.00]	0.77 (0.28) [0.36–1.33]	0.82 (0.30) [0.26–1.25]	0.96 (0.35) [0.19–1.82]	0.76 (0.34) [0.33–1.67]
Forward functional reach (cm)	21.36 (10.64) [1.00–54.60]	22.23 (7.57) [9.90–42.30]	20.50 (9.41) [4.80–49.30]	24.46 (11.08) [1.00–54.60]	26.54 (7.85) [11.00–43.30]	20.27 (6.24) [4.80–30.60]	23.30 (10.92) [1.00–54.60]	26.19 (7.03) [11.60–42.00]	22.01 (7.98) [4.80–38.30]
Lateral functional reach (cm)	16.29 (6.47) [0.00–31.00]	15.81 (5.17) [5.30–26.00]	15.94 (7.79) [0.00–39.30]	18.37 (7.60) [0.00–43.30]	19.26 (6.32) [8.30–34.60]	15.13 (6.81) [0.00–27.30]	17.92 (8.32) [0.00–43.30]	20.36 (5.35) [9.60–31.50]	15.80 (6.94) [0.00–34.00]
12-Item Multiple Sclerosis Walking Scale	72.15 (19.47) [23.81–100.00]	59.38 (22.90) [14.29–92.86]	70.61 (21.31) [14.29–100.00]	63.49 (23.78) [23.81–100.00]	47.84 (24.61) [4.76–90.48]	68.39 (23.69) [19.05–100.00]	67.39 (24.65) [14.29–100.00]	51.41 (26.79) [4.76–97.62]	71.10 (21.71) [19.05–100.00]
Activities-specific Balance Confidence scale	3.94 (1.53) [1.33–7.07]	4.74 (2.19) [1.67–10.00]	4.20 (1.67) [1.20–8.60]	4.76 (2.14) [1.20–9.07]	5.74 (2.36) [1.93–9.93]	4.27 (1.95) [1.40–8.73]	4.52 (2.15) [1.27–9.07]	5.46 (2.52) [1.93–10.00]	4.21 (1.74) [1.07–8.13]
Difficulty walking while carrying a drink	5.58 (2.42) [1.00–10.00]	5.13 (2.99) [0.00–10.00]	5.72 (2.66) [0.00–10.00]	4.85 (2.44) [0.00–10.00]	4.59 (2.97) [0.00–10.00]	5.56 (2.81) [0.00–10.00]	5.36 (2.60) [0.00–0.00]	4.91 (2.86) [0.00–10.00]	6.07 (2.39) [0.00–9.00]

[a] Data presented as mean (SD) [range] of values.
[b] Primary outcome measure.

ence to home exercises was 80% for the Pilates group, 78% for the standardized exercise group, and 91% for the relaxation group.

Discussion

A 12-week program of Pilates led to small, nonsignificant improvements in clinician-rated balance and mobility compared with relaxation. These small changes, which were typically too small to be deemed clinically significant (20% improvement is considered to be clinically significant), were observed directly after face-to-face intervention but were not retained at the 16-week follow-up assessment. The same period of standardized exercise resulted in statistically and clinically significant improvements in both clinician-rated and patient-reported measures of balance and mobility compared with relaxation, which remained evident at the 16-week follow-up assessment. There were no statistically significant differences between the Pilates and standardized exercise groups immediately after intervention, with the exception of MSWS-12 score and walking speed. A 16 weeks, statistical significance remained only for improvement in self-reported mobility.

Strengths of the Trial

This is the first multicentre, blinded RCT, to our knowledge, to evaluate the effects of Pilates training in people with MS. The trial was performed in a pragmatic setting, and therapists employed to perform the interventions were formally trained in Pilates and experienced in delivering therapy to people with neurological impairments. Previous research investigating Pilates has shown improvements in standing balance and mobility in ambulant people and in sitting balance in wheelchair dependent people with MS[24–26]; however, these studies were less methodologically rigorous (pilot studies, small sample sizes) than this RCT. The high level of interest in Pilates and its relevance to clinical practice is supported by the numbers of people who expressed interest in participation in the trial but were excluded on the basis that they already either attended Pilates classes or performed core stability exercises under the direction of a phys-

Table 4.
Adjusted Mean Differences and Bonferroni-Corrected 95% Confidence Intervals for Between-Group Differences at 12 and 16 Weeks

Outcome Measure	12 Weeks			16 Weeks		
	Pilates Minus Relaxation	**Standardized Exercises Minus Pilates**	**Standardized Exercises Minus Relaxation**	**Pilates Minus Relaxation**	**Standardized Exercises Minus Pilates**	**Standardized Exercises Minus Relaxation**
10-Meter Timed Walk Test (s)	−0.50 (−4.68 to 3.69)	−3.71 (−7.79 to 0.37)	−4.20 (−8.42 to 0.01)	−0.50 (−4.68 to 3.69)	−1.96 (−6.04 to 2.13)	−2.45 (−6.67 to 1.77)
Walking speed (m/s)	0.06 (−0.13 to 0.25)	0.22 (0.04 to 0.40)	0.28 (0.09 to 0.47)	0.05 (−0.13 to 0.24)	0.14 (−0.04 to 0.32)	0.20 (0.01 to 0.38)
Forward functional reach (cm)	4.19 (−1.27 to 9.65)	2.08 (−3.24 to 7.40)	6.27 (0.77 to 11.77)	1.28 (−4.18 to 6.75)	2.90 (−2.43 to 8.22)	4.18 (−1.32 to 9.68)
Lateral functional reach (cm)	3.23 (−0.92 to 7.39)	0.90 (−3.15 to 4.95)	4.13 (−0.05 to 8.32)	2.12 (−2.04 to 6.28)	2.44 (−1.61 to 6.49)	4.56 (0.37 to 8.75)
12-Item Multiple Sclerosis Walking Scale	−4.90 (−19.11 to 9.32)	−15.65 (−29.50 to −1.79)	−20.55 (−34.87 to −6.23)	−3.71 (−17.93 to 10.50)	−15.97 (−29.83 to −2.12)	−19.69 (−34.01 to −5.37)
Activities-specific Balance Confidence scale	0.49 (−0.76 to 1.74)	0.98 (−0.24 to 2.21)	1.48 (0.21 to 2.74)	0.31 (−0.94 to 1.56)	0.95 (−0.28 to 2.17)	1.26 (−0.01 to 2.52)
Difficulty walking while carrying a drink	−0.70 (−2.34 to 0.94)	−0.26 (−1.85 to 1.34)	−0.96 (−2.61 to 0.69)	−0.71 (−2.35 to 0.93)	−0.46 (−2.06 to 1.14)	−1.16 (−2.81 to 0.49)

ical therapist; unfortunately, this affected the speed of recruitment.

Limitations of the Study

Choosing outcome measures such as posturography to assess balance[27] or accelerometry to assess walking[28] may have been more responsive in detecting any changes. It also is debatable as to whether outcome measures focusing on the trunk, such as the Trunk Impairment Scale,[29] may have been a more responsive measure than the chosen primary outcome measure. However, our research question was formulated on the basis that physical therapists use Pilates as an intervention aimed at improving mobility and balance. Our pragmatic study was designed to be reflective of UK clinical practice, after extensive consultation with experienced MS specialist physical therapists and using outcome measures on the basis of pilot work[11] and with established psychometric properties in this patient group.

Although this approach was designed to reflect the types of Pilates exercises used in clinical practice, we acknowledge that this approach may not represent popular Pilates classes where resistance bands and weights may be incorporated. Therapists were limited to 10 mat-based exercises, which did not challenge standing balance or require participants to exercise in an upright weight-bearing position and may be less likely to improve balance and gait. Greater improvements may be achieved if Pilates exercises are based on functional goals of the client (eg, balance, gait) and involve use of specialized equipment to enable exercise in unstable environments, in upright weight-bearing positions, and against resistance. Moreover, although we followed up participants 1 month after they had completed the face-to-face intervention, it is possible that this is too short a duration to provide meaningful information on any retention effects.

The adverse events (all of which were independently determined to be unrelated to the interventions) and relapses were not quantitatively compared in this trial; therefore, no comments can be made on potential harm from either of the exercise-based interventions in rela-

tion to relapses. However, it is notable that there were no reported harms or adverse reactions related to the interventions in any of the participants, in any of the groups.

Finally, the participants in this trial were all ambulant; thus, the results cannot be extrapolated to people with MS who are wheelchair dependent. Currently, research is being performed to evaluate the effects of Pilates in this group.[24]

Explanation of Findings

The Pilates exercise approach teaches people to voluntarily activate the deep abdominal muscles, with the rationale of improving core stability and related function. However, it has been questioned whether focused voluntary activation is necessary to achieve this effect[30] or whether automatic activation, which occurs during movement in both healthy people[31] and people with neurological impairments,[32] may be as effective. It is possible that the larger gains made and sustained by those undertaking standardized exercises were because activation of the core stabilizers was more effectively achieved at an automatic level. Another explanation could be that a greater proportion of the standardized exercises were task specific, in that a number of them were undertaken in a standing position, which has shown to be an effective method for improving function in individuals with neurological impairment.[33] A better understanding of the association between core stability and balance and mobility function is needed to elucidate this explanation of our findings.

In people with MS, demyelination and axonal damage may cause neuromuscular weakness, resulting in problems with foot clearance when walking.[18] Pilates is an exercise intervention that focuses heavily on training the proximal musculature. In clinical practice, therapists can combine interventions such as targeted abdominal and lower limb muscle training with the provision of ankle-foot orthoses and functional electrical stimulation in order to improve walking.[18] Combined interventions were not assessed in this study but could be considered for future research.

It is noteworthy that individuals varied markedly in their response to the exercise interventions; although some demonstrated very large improvements (up to 44% on the 10MTW), others worsened over the 12-week intervention period. This variability is consistent with other studies monitoring mobility over time in similar samples.[22] Future research could be performed to identify people who respond favorably to exercise to help best direct resources.

The small-to-moderate magnitude of change within groups in both the Pilates and standardized exercise groups is congruent with other MS studies evaluating exercise[34] (effect sizes available from the corresponding author on request). A 20% increase in walking speed is considered clinically meaningful in people with MS.[35] The mean percentage of improvement observed within the standardized exercise group was 21.7%. This percentage is comparable with the percentage of improvement reported with a 14-week course of fampridine (25.2%).[36] In addition, a 5.1-point change in the self-report MSWS-12 is considered clinically meaningful.[35] The Pilates and standardized exercise groups had average improvements from baseline of 8.7 and 11.5 points, respectively, at 12 weeks, in contrast to the relaxation group, whose self-reported mobility deteriorated by an average of 2.2 points on this scale. The magnitude of improvements noted in the ABC scale was consistent with that of other physical therapy interventions in this patient group.[37]

Future Research

This study identified that a program of standardized exercise resulted in both statistically and clinically significant improvements in a range of balance and mobility measures in ambulant people with MS compared with relaxation. These improvements were retained 1 month after intervention. Future research could be performed to explore the reasons as to why standardized exercises appear to be more effective than the Pilates intervention in terms of the self-report walking scale. Future research to assess the effects of this type of exercise on measures of disability in people with MS who are wheelchair dependent also is needed. In this study, the adherence to home exercises was recorded for 1 month after face-to-face sessions with the physical therapist had ceased. The mean adherence was 73.5% (for the whole sample), suggesting that research directed at measuring the adherence and effects of home exercise in the longer term is warranted.

Clinical Implications

These results suggest that exercise programs for ambulant people with MS do not need to focus on voluntary activation of the deep abdominal muscles, as proposed in the Pilates method, in order to gain improvements in standing balance and mobility.

In conclusion, a 12-week period of Pilates led to small, nonsignificant improvements in patient-reported and clinician-rated measures of balance and mobility in comparison with relaxation. These small improvements were not sustained at 1 month after the therapist contact time ceased. Standardized physical therapy exercises led to statistically and clinically meaningful changes in both patient-reported and clinician-rated measures of balance and mobility compared with relaxation, which remained evident 1 month after the therapist contact time had ceased.

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