

RESEARCH ARTICLE

Group-based, individualized, comprehensive core stability and balance intervention provides immediate and long-term improvements in walking in individuals with multiple sclerosis: A randomized controlled trial

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Abstract

Objectives: Walking impairments are common in individuals with multiple sclerosis. Trunk control is a prerequisite for walking; however, knowledge regarding whether core stability and balance training influence walking is limited. This study aimed to investigate the immediate and long-term effects of a group-based, individualized, comprehensive core stability and balance intervention (GroupCoreDIST) compared with those of standard care on walking.

Methods: This assessor-blinded, prospective randomized controlled trial included 80 participants (Expanded Disability Status Scale scores 1–6.5) randomly allocated to GroupCoreDIST, conducted in groups of three for 60 min three times per week for 6 weeks (18 sessions) or standard care ($n = 40/40$). One participant attended no posttests, leaving 79 subjects for intention-to-treat analysis. The assessments were performed at baseline and at Weeks 7, 18, and 30. Outcomes included the 2-min walk test (2MWT), 10-m walk test-preferred/fast/slow speed (10MWT), Multiple Sclerosis Walking Scale-12 (MSWS-12), Patient Global Impression of Change-walking (PGIC-walking), Rivermead Visual Gait Assessment (RVGA), and ActiGraphsWgt3X-BT activity monitors (ActiGraph). The statistical analyses included repeated-measures mixed models performed in IBM SPSS Version 24.

Results: There were no significant between-group differences in the outcome measurements at baseline. The mean differences between groups were significant at all follow-up time points in favour of GroupCoreDIST for the 2MWT, 16.7 m at 7 weeks (95% CI [8.15, 25.25], 15.08 m at 18 weeks (95% CI [6.39, 23.77]) and 16.38 m at 30 weeks (95% CI [7.65, 25.12]; and the PGIC-walking, 0.89 points at 7 weeks (95% CI [1.34, 0.45]), 0.97 points at 18 weeks (95% CI [1.42, 0.52]), and 0.93 points at 30 weeks (95% CI [1.39, 0.48]; all $p \leq .001$). The 10MWT-fast speed and the MSWS-12 showed significant between-group differences at 7 and 18 weeks and

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the RVGA at 7 weeks. No between-group differences were found regarding activity level (ActiGraph) or the 10MWT-preferred or slow speed.

Conclusion: Compared with standard care, GroupCoreDIST significantly improved walking immediately after the intervention for up to 24 weeks of follow-up.

KEYWORDS

group, mobility, multiple sclerosis, physiotherapy

1 | INTRODUCTION

Multiple sclerosis (MS) is a chronic, demyelinating disease in the central nervous system that may lead to varied impairments, such as somatosensory deficits, paresis, coordination difficulties, and visual problems. These impairments may lead to walking problems (Freund, Stetts, & Vallabhajosula, 2016), which are common during both the early and later stages of the disease (Comber, Galvin, & Coote, 2017; Langeskov-Christensen et al., 2017). Trunk control, also termed core stability, is imperative for monitoring displacements and optimizing steps while walking (Huisinga, St George, Spain, Overs, & Horak, 2014). Trunk control is accomplished through anticipatory postural adjustments (APAs) and compensatory postural adjustments (CPAs; Krishnan, Kanekar, & Aruin, 2012a, 2012b). Optimal trunk control relies on adequate somatosensory, motor, and musculoskeletal systems, which are frequently compromised in the MS population (Cameron & Lord, 2010). Reduced postural control, impaired core muscle activation, less effective APAs, and increased reliance on CPAs have been reported in individuals with MS (Krishnan et al., 2012a, 2012b). Inexpedient compensatory movement patterns develop over time (Francis & Song, 2011) and may interfere with trunk control due to the inefficient activation of core muscles; for instance, a malalignment in the ankles, knees, and hips may result in the increased use of hip strategy. Core muscle activation is considered important for quality of movement while walking (Gjelsvik & Syre, 2016; Kalron & Givon, 2016), and impairments in this area may lead to fewer and shorter steps (Sosnoff, Sandroff, & Motl, 2012), a reduced walking speed (Cameron & Lord, 2010), increased risk of falls, and restricted activities of daily living (Nilsagard, Denison, Gunnarsson, & Bostrom, 2009) and may increase cognitive attention toward walking (Wajda & Sosnoff, 2015).

Only a few studies examined the effects of core stability interventions on walking in individuals with MS. Three randomized controlled trials (RCTs) compared Pilates exercises and standardized physical therapy (Expanded Disability Status Scale [EDSS] < 7). Two of them demonstrated significant within-group improvements in walking; however, no between-group differences were observed (Duff et al., 2018; Kalron, Rosenblum, Frid, & Achiron, 2017). The third RCT observed differences between standardized exercises and relaxation; however, no differences were observed between Pilates and the mentioned interventions (Fox, Hough, Creanor, Gear, & Freeman, 2016). A controlled trial (EDSS 0–4) comparing Pilates with home-based exercises indicated significant within-group effects on walking (Guclu-Gunduz,

Citaker, Irkeç, Nazliel, & Batur-Caglayan, 2014), and two smaller studies (EDSS 3–6.5) demonstrated short-term improvements in walking parameters after Pilates (Freeman et al., 2010; Freeman & Allison, 2004). In contrast to the current study, none of these studies demonstrated between-group differences, described a physical therapy examination, or presented how the individualization of the exercises was conducted. In the above-mentioned studies, Pilates exercises were considered the voluntary activation of deep abdominal muscles (Fox et al., 2016). Traditionally, Pilates also includes cognitive attention, posture control, movement, precision, flow during transition, and coordinated breathing (Wells, Kolt, & Bialocerkowski, 2012). Only one study presented group training, only two included participants with low EDSS scores (1–2.5), and in all studies, the follow-up periods were absent or short. In general, exercise therapy is associated with improvements in walking; however, no interventions have been shown to be more effective than others in individuals with MS (Hogan & Coote, 2013; Snook & Motl, 2009), and some have demonstrated limited valuable impacts (Motl et al., 2017).

Studies investigating walking using a long-term follow-up are called for (Snook & Motl, 2009), as are group-based interventions, because group settings are considered economically efficient (Humphreys, Drummond, Phillips, & Lincoln, 2013). Studies examining individualized interventions interlinking core stability, dual tasks, and somatosensory retraining have been recommended (Fox et al., 2016; Gunn, Markevics, Haas, Marsden, & Freeman, 2015).

A new group-based, individualized, comprehensive, core stability, and balance intervention called GroupCoreDIST (D = dual task, dose; S = somatosensory, stability, selective movement; I = individualized, insights; T = training, teaching) has been developed (Normann, Zanaboni, Arntzen, & Øberg, 2016). The feasibility of GroupCoreDIST was demonstrated in a qualitative observation study (Dybesland & Normann, 2018) and a feasibility pilot study that showed significant within-group effects on balance and walking in 12 individuals with MS (EDSS 1–6.5; Normann, Salvesen, & Arntzen, 2016). In the current study, GroupCoreDIST was compared with standard care in an RCT. The results from the two primary and one secondary outcomes regarding trunk control and balance have already been published, demonstrating short- and long-term significant between-group effects on the Trunk Impairment Scale-Norwegian Version and the Mini Balance Evaluation Systems Test (Mini-BESTest) ($p < .05$; both primary outcomes) and the Patient Global Impression of Change-balance ($p < .05$; secondary outcome; Arntzen et al., 2019). The

current paper present reports on the secondary outcomes on walking and addresses the following research question: What are the immediate and long-term effects of GroupCoreDIST compared with standard care on walking in individuals with MS?

2 | METHODS

2.1 | Design

This two-armed, prospective, single-blinded RCT included 80 ambulant individuals with MS. The study protocol was registered at ClinicalTrials.gov, and the protocol article has been previously published elsewhere (Normann, Zanaboni, et al., 2016). This study was approved by the Regional Committees for Medical and Health Research Ethics in Norway and complied with the Declaration of Helsinki.

2.2 | Subjects and study setting

In August 2015, letters of invitation with a consent form were sent by the MS nurse at the Department of Neurology, Nordland Hospital Trust, Bodø, Norway, to 160 individuals with MS who were registered at the MS outpatient clinic and lived in one of the six municipalities included in the study. These municipalities were selected because they were located in both rural and urban areas (1,200–51,000 inhabitants) and had neurological physical therapists who were interested in learning GroupCoreDIST. A reminder letter was subsequently sent to ensure maximum patient enrolment. Ninety-three individuals replied with a signed consent form. Of the 67 individuals who did not respond, 57% had EDSS values ranging from 0 to 3.5, 21% had EDSS values ranging from 4 to 7, and 22% had unknown EDSS values. Enrolment was initiated in September 2015, and the follow-up assessments were completed in September 2016.

At enrolment, all participants underwent a clinical examination by a neurologist (F. O.) to assess their EDSS and medical history, including the type of MS, age, gender, weight, height, and medications. The inclusion criteria were as follows: (a) a diagnosis of MS in accordance with the McDonald criteria (Polman et al., 2011); (b) registered at the MS outpatient clinic; (c) living in one of the six selected municipalities; (d) aged 18 years or older; (e) capable of providing signed written informed consent; and (f) an EDSS value between 1 and 6.5 (1 = *minor disability* and 6.5 = *able to walk 20 m with or without a walking aid*). The exclusion criteria were as follows: (a) pregnancy at the time of examination; (b) exacerbation within 2 weeks prior to enrolment; and (c) other acute conditions resulting in compromised balance (such as acute neurological conditions, including stroke). Of the 93 individuals who consented to participate, 13 individuals were excluded, as follows: Two individuals did not attend the baseline assessment, five individuals could not commit the time, three individuals had an EDSS value of 0, one individual was pregnant, one individual was waiting for heart surgery, and one individual had moved from the catchment area.

2.3 | Randomization

The remaining 80 individuals completed the baseline testing and were randomly allocated to the GroupCoreDIST or standard care group by electronic concealed randomization using a web-based system developed and administered by the Unit of Applied Clinical Research, Institute of Cancer Research and Molecular Medicine, Norwegian University of Science and Technology, Trondheim, Norway (www.webcrf.medisin.ntnu.no). The system was stratified on the basis of EDSS values of 1–3.5 and 4–6.5 to ensure a mix of individuals with high and low EDSS values in both groups.

2.4 | Preparation, procedures, and interventions

Six physical therapists conducted GroupCoreDIST after undergoing 5 days of practical and theoretical training. The therapists received a manual containing photos and descriptions of the exercises and registered the exercises that were conducted during the group sessions to ensure standardization of the intervention. These physical therapists were not involved in the treatment of the standard care group.

The participants in GroupCoreDIST were divided into 13 training groups according to municipality by the researchers B. N. and E. C. A. The intervention was initiated with an individual clinical examination conducted by the physical therapist. The examination included the patient history, observations, movement analysis, and hands-on interactions. The patients' resources, movement constraints, and display of immediate improvements in performance related to trunk control and balance were considered. A movement analysis of posture and activities was performed to explore balance, alignment throughout the body, adaptation to the base of support, and interaction with the environment in various positions. The ability to perform selective movement (to move one part of the body while stabilizing the other parts) to achieve coordination was considered with a specific focus on the trunk in relation to the other parts of the body and functional movement. The following specific assessments were performed: muscle length, muscle activation and strength, tone, somatosensory function, pain, and reflexes. On the basis of the patient's symptoms, resources, and limitations, the physical therapist formed hypotheses regarding the main underlying problems related to trunk control and balance.

The group sessions were conducted in groups of three and were led by the physical therapist for 60 min, three times per week for 6 weeks. GroupCoreDIST contains 33 exercises, and each exercise has five optional variations to allow for individualization as the group members concurrently conduct the same exercise (although at different levels of difficulty). All exercises were performed barefoot and addressed dynamic core stability defined as the coordinated activation of local and global muscles of the trunk, pelvis, and shoulder girdle and the muscles attached to these areas (Kibler, Press, & Sciascia, 2006). These areas provide the coordination and stability required for selective movement in proximal body regions and the potential for selective movement in the upper and lower limbs (Kibler et al., 2006). The

physical therapist chose the appropriate exercises and variations according to the participants' symptoms. All exercises addressed core muscle activation; however, the focus in the exercises was on the task, in order to use less cognitive attention directed toward the core. For instance, the participants were instructed to "keep your back in contact with the therapy ball and roll the ball from side to side." The potential for improved core muscle activation was also obtained indirectly during optimal alignment and adjustment to the base of support. These are aspects that differ the GroupCoreDIST from for instance, Pilates and general exercises. The exercises were divided into the following six categories, which were represented in each group session: (a) somatosensory activation of the hands or feet by rolling a spiky ball; (b) muscle length (enhancing concentric and eccentric activity in the muscles of the neck and upper and lower limbs); (c) selective movement and coordination (keeping one part of the body stable while moving another); (d) training larger muscle groups in a standing position; (e) advanced challenges related to balance and postural control, such as jumping; and (f) relaxation (systematically performing contraction-relaxation of parts of the body) Normann, Zanaboni, et al., 2016. Motor-motor dual tasks were performed in all exercises as the activation of the core muscles was coordinated with other motor tasks. The motor-cognitive dual tasks included singing, rhyming, or calculating while performing exercises with the additional goal of promoting group dynamics and engagement. Verbal instructions and hands-on facilitation were allowed to improve the movement quality, decrease inexpedient compensatory movement patterns, and optimize the movement experience (Normann, 2018; Vaughan-Graham & Cott, 2016). The protocol article provides details and further examples of the exercises (Normann, Zanaboni, et al., 2016). All group members received a booklet with illustrations of the exercises, and the physical therapist prescribed unsupervised home-based exercises to be conducted twice per week for 30 min. The participants were encouraged to continue performing the home-based exercises after the intervention was completed for 30 min twice per week; however, these exercises were voluntary and unsupervised. The participants in GroupCoreDIST were encouraged to not seek other physical therapy during the 6-week intervention.

The control group continued their regular routines, and the participants were encouraged to maintain their current level of physical activity. The participants were informed that they could see a physical therapist and seek any health care as required. Physical therapy was free to individuals with MS in Norway (at the time the study was conducted) and offered by both generalists and specialists; most often, physical therapy is received in a private practice or community-based service. The self-reports from the standard care group showed that 30 individuals (75%) did not visit a physical therapist within the 6 weeks of intervention/standard care, five individuals (12.5%) visited a physical therapist once per week, four individuals (7.5%) visited a physical therapist two to three times per week, and one individual visited a personal trainer. The contents of the sessions included strength training (10 individuals), endurance training (eight individuals), Pilates (two individuals), and yoga (one individual). The trainings were unsupervised for four individuals and tailored by the physical therapist for five individuals. The participants in both standard care and

GroupCoreDIST groups were encouraged to continue their usual medical treatment.

2.5 | Outcome measurements and procedure

The assessments were conducted at baseline, after the intervention was completed (Week 7; primary end-point), and at Weeks 18 and 30. Walking aids were allowed, and the participants were encouraged to use the same walking aid and shoes during all assessments. Two assessors who were blinded to the group allocation and adequately trained in the standardized test procedures conducted the assessments.

The outcome measures of walking included the 2-min walk test (2MWT), 10-m walk test (10MWT), Multiple Sclerosis Walking Scale-12 (MSWS-12), Patient Global Impression of Change-walking (PGIC-walking), the Rivermead Visual Gait Assessment (RVGA), and ActiGraphsWgt3X-BT monitors (ActiGraph). The 2MWT measures walking distance, has good reliability and validity (Rossier & Wade, 2001), and is recommended for intervention studies (Gijbels et al., 2012). The participants were instructed to walk as far as they could in a 22-m-long hallway and turn at the end of the hall for a period of 2 min. The 10MWT measures walking speed and was conducted with a standing start at (a) the preferred speed, (b) slow speed, and (c) fast speed. The assessment has good reliability and validity among individuals with MS (Paltamaa, West, Sarasoja, Wikstrom, & Malkia, 2005; Rossier & Wade, 2001).

The MSWS-12 captures how participants perceive their limitations while walking as a result of MS over the previous 2 weeks. Each of the 12 items is scored from 1 to 5 (lowest score 12 = *no limitation*). The MSWS-12 has good reliability and validity among individuals with MS (Hobart, Riazi, Lamping, Fitzpatrick, & Thompson, 2003; Kieseier & Pozzilli, 2012). The total score was transformed into a 0–100 scale as recommended (Baert et al., 2014). The PGIC-walking is scored on a 7-point Likert scale and measures how the participants perceive changes in walking (1 = *very much worse*, 4 = *no change*, and 7 = *very much improved*) compared with walking before the 6 weeks of GroupCoreDIST or standard care (Farrar, Young, LaMoreaux, Werth, & Poole, 2001).

RVGA is a reliable and valid quantitative measure of an individual's gait quality (Lord, Halligan, & Wade, 1998). RVGA describes how the gait pattern varies from normal and is measured on a 4-point scale (0 = *normal* and 4 = *great abnormality*) with a total score ranging from 0 to 59 when conducting two observations of the arms and 18 observations of the trunk and lower extremities (Lord et al., 1998). The participants were videotaped while walking and scored on the basis of the film.

The ActiGraph is an activity monitor that registers information regarding the participants' activity level: number of steps and duration of intensity in activity (divided into different intensity levels: inactive, low, moderate, and vigorous; Block et al., 2016). The monitor was worn in a belt around the participants' waist for 7 days after each assessment time point. The ActiGraph has been found to be an

objective measure of community ambulation and physical activity in individuals with MS (Weikert, Motl, Suh, McAuley, & Wynn, 2010).

General physical activity, the number of physical therapy treatments, perturbations, changes in medications and general well-being were recorded for both groups during the 6 weeks of GroupCoreDIST or standard care, and the number of home exercise sessions was additionally obtained for the GroupCoreDIST group.

2.6 | Sample size

The sample size calculation was based on assumptions of change in the Mini-BESTest, where a 0.75 standard deviation (*SD*) between the intervention group and the control group was considered relevant. The results of the Mini-BESTest are presented in another manuscript (Arntzen et al., 2019). To achieve an 80% chance of detecting a 0.75 *SD* difference between the groups at a significance level of .05 (α), 28 individuals with MS were required per group. Anticipating a 30% dropout rate, we aimed to recruit at least 72 participants.

2.7 | Statistical analysis

Descriptive statistics (frequency, descriptive, and explore) were used to describe the demographic and clinical variables. The between-group differences over time were calculated using repeated-measures mixed models in IBM SPSS Version 24. The mixed-model approach has an advantage in addressing missing values and provides many options for adjusting for the dependence between repeated measures. An intention-to-treat analysis was performed for all participants with postassessment scores; however, some participants had missing observations. In the repeated-measures mixed-model analyses, the data structure involved four repeated measurements coded as a numeric time variable, and each follow-up time point was used as a reference. We adjusted for baseline by maintaining the baseline variable as a covariate in the model as recommended in the literature (Twisk, 2013; Vickers & Altman, 2001). The final model of all outcomes included all independent variables that reached significance at $p = .05$ in any model. Group, time point, EDSS, gender, type of MS, age, and an interaction term composed of the time and group variables were included in the model. Other interaction terms with the intervention indicator were evaluated; however, these interaction terms did not reach significance and, thus, were not included. The estimated marginal means were used to create plots illustrating the effects of the intervention over time.

3 | RESULTS

The 80 participants were randomly allocated to the GroupCoreDIST ($n = 40$) or the standard care ($n = 40$) group after the baseline testing (Figure 1). One participant in the intervention group dropped out before the postassessments and was excluded from the study. Thus, 79 individuals were included in the intention-to-treat analysis. At the 18-week assessment, one individual from the control group was lost

to follow-up due to illness, and three individuals from the control group missed the assessments. At the 30-week assessment, two additional individuals from each group missed the assessments. The demographic and clinical characteristics are shown in Table 1.

The self-reported data collected during the 6 weeks of GroupCoreDIST/standard care demonstrated that the group sessions were attended with a mean of 2.5 sessions (*SD* 0.16) per individual per week. In the standard care group, five individuals reported receiving individually adjusted physical therapy, whereas four individuals conducted unsupervised training at the physical therapist's gym (an average of 0.28 physical therapy sessions, *SD* 0.85, for the whole group during the 6 weeks). There was no significant between-group difference in general physical activity during the 6 weeks; the mean difference was 4.38 half-hours during the entire period (95% CI [19.75, 10.98]; $p = .57$). Both groups recorded a mean general well-being of 2.48 of 5 points (*SD* 0.90). One individual reported a sensory relapse, which was verified by a neurologist, during the first week of the intervention. No injuries occurring as a result of the intervention were reported. The control group reported no new relapses. The medications remained unchanged. During the 6 weeks of the intervention, the GroupCoreDIST group reported a mean of 2.14 home-based exercise sessions (*SD* 1.19). Thirty-eight of the 40 participants in the GroupCoreDIST group reported that they continued to perform home-based GroupCoreDIST exercises at Week 18, and two individuals reported the same at Week 30.

The primary outcomes of this study, that is, the Trunk Impairment Scale-Norwegian Version and the Mini-BESTest, have already been reported in a different paper, which demonstrated statistically significant between-group differences at 7, 18, and 30 weeks ($p < .05$) and overall significant effects by group ($p < .05$; Arntzen et al., 2019).

The results of the mixed-model analyses of the secondary outcomes are presented in Table 2. These results demonstrate statistically significant between-group differences in favour of GroupCoreDIST at all follow-up time points for the 2MWT and the PGIC; between-group differences at 7 and 18 weeks for the 10MWT-fast and the MSWS-12; and at 7 weeks for the RVGA.

At baseline, the GroupCoreDIST and standard care group demonstrated a mean walking distance on the 2MWT of 165.18 m (95% CI [149.74, 180.62] and 170.56 m (95% CI [157.61, 183.51]), respectively. The 2MWT (Figure 2) demonstrated an overall group effect ($p < .00$), and all posttests demonstrated a significant between-group difference ($p < .001$). The 10MWT-fast speed (Figure 3) demonstrated an overall significant difference by group ($p = .016$) and significant between-group effects at 7 ($p = .011$) and 18 weeks ($p = .04$). No significant differences were identified in the 10MWT-slow or 10MWT-preferred speeds or activity (neither number of steps nor activity level) at any time point. The RVGA demonstrated a significant between-group difference at 7 weeks ($p = .03$).

The MSWS-12 100scale (Figure 4) demonstrated an overall significant difference by group ($p = .011$) and significant between-group differences at 7 ($p = .004$) and 18 weeks ($p = .019$). The PGIC-walking (Figure 5) demonstrated an overall significant difference by group ($p < .00$) and significant between-group differences at all time points ($p < .00$).

4 | DISCUSSION

This assessor-blinded prospective RCT evaluated the short- and long-term effects of a 6-week GroupCoreDIST intervention compared with standard care. The results demonstrated significant between-group effects in favour of GroupCoreDIST on walking distance and self-perceived change in walking that lasted for 24 weeks, on fast walking speed and self-perceived walking mobility that lasted for 12 weeks, and on gait quality immediately after the intervention was completed.

4.1 | Strengths and weaknesses compared with those of other studies

Several studies have shown that core control is important for balance (Aruin, Kanekar, & Lee, 2015; Borghuis, Hof, & Lemmink, 2008; Kibler et al., 2006). However, knowledge regarding whether comprehensive core stability and balance training impact walking is limited. In the current study, the participants were mildly impaired given their low EDSS scores (average 2.36). Despite the low overall disability indicated by the EDSS, the participants had substantial walking limitations

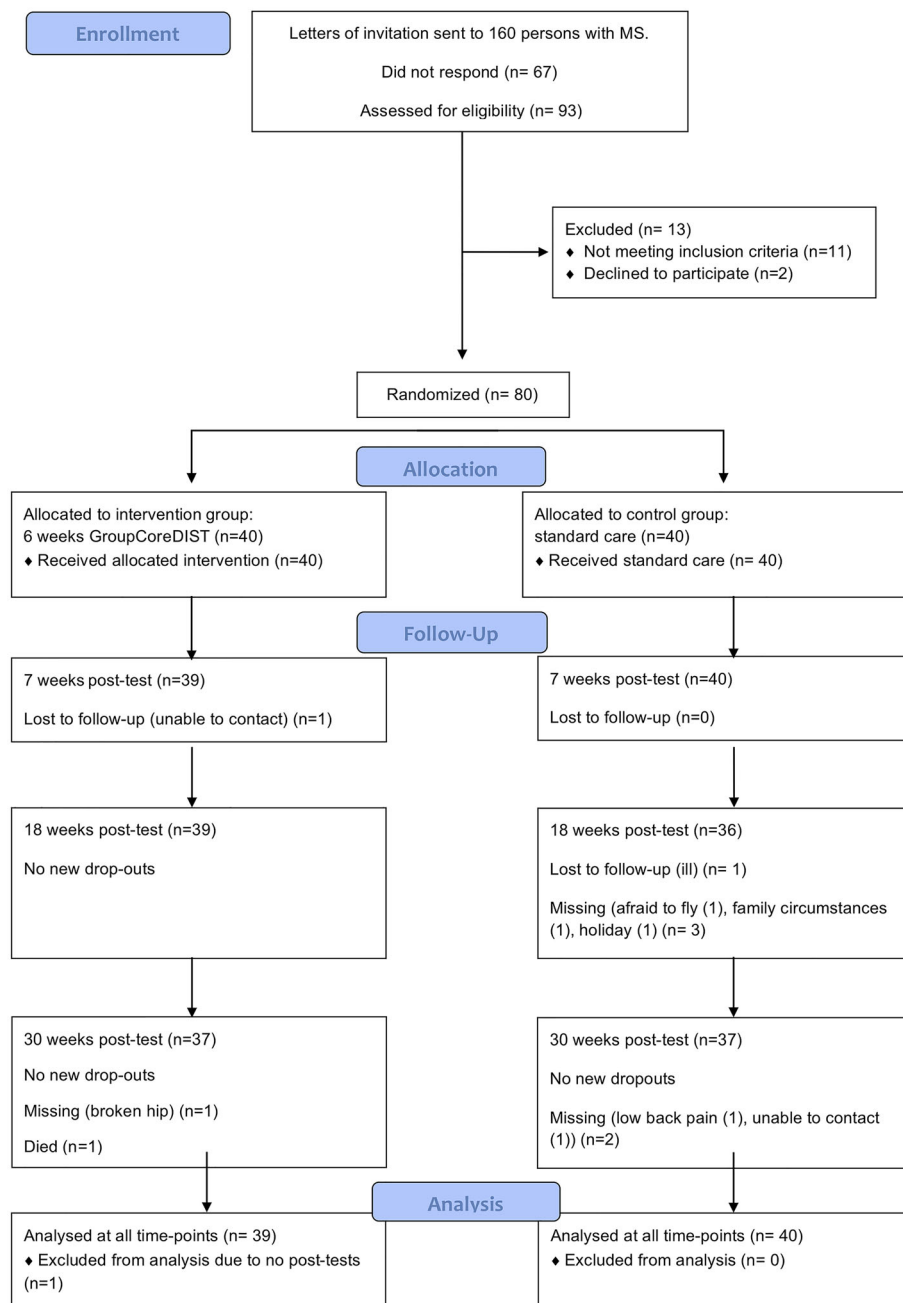


FIGURE 1 Flowchart of the recruitment, allocation and retention of participants throughout the study. MS, multiple sclerosis

TABLE 1 Baseline demographic and clinical characteristics of the standard care and GroupCoreDIST groups as measured by means, standard deviation, and range (in brackets) or %

Baseline characteristics	Standard care n = 40	GroupCoreDIST n = 39
Age	48 (8.75) [31–67]	52.2 (12.9) [24–77]
Height (cm)	171.8 (9.06) [155–191]	169.26 (7.67) [154–185]
Weight (kg)	77.7 (14.15) [53–116]	71.7 (12.16) [44–99.8]
Gender		
Women	29 (72.5%)	27 (69.2%)
Men	11 (27.5%)	12 (30.8%)
Smoker		
No	30 (75%)	36 (92.3%)
Yes	10 (25%)	3 (7.7%)
Type of MS		
Relapsing remitting	36 (90%)	32 (82.1%)
Primary progressive	2 (5%)	5 (12.8%)
Secondary progressive	2 (5%)	2 (5.1%)
EDSS	2.28 (1.28) [1–5.5]	2.45 (1.65) [1–6.5]
Age at diagnosis	37.4 (10.06) [21–64]	41.9 (10.26) [19–63]
Years since diagnosis	10.68 (7.27) [1–28]	10.04 (7.85) [0.5–33]

Abbreviations: EDSS, Expanded Disability Status Scale; MS, multiple sclerosis.

considering their average walking distance at baseline (167.87 m in the 2MWT), which was significantly shorter than the previously published average distance in healthy individuals (211 m; 95% CI [191, 234 m]; Selman, de Camargo, Santos, Lanza, & Dal Corso, 2014). This finding suggests the need for early rehabilitation in mildly impaired individuals to improve walking, which is also indicated in other studies (Langeskov-Christensen et al., 2017). A clinically meaningful change in the 2MWT was defined as an improvement of 9.6 and 6.8 m from the patient and clinician perspectives, respectively, in one study (Baert et al., 2014) and a 12% improvement in another study (Learmonth, Dlugonski, Pilutti, Sandroff, & Motl, 2013). Our results demonstrated a clinically meaningful change in the GroupCoreDIST group at all assessment points as follows: 18-m (11%) improvement at 7 weeks, 20-m (12%) improvement at 18 weeks, and 18-m (11%) improvement at 30 weeks. The 10MWT-fast speed also showed significant effects at 7 and 18 weeks. However, walking at the preferred or a slow speed did not improve, which may be related to the psychometrics of the test as walking at the preferred speed exhibited more within-day variability than walking at a fast speed (Feys et al., 2014). The 10MWT-fast speed is more comparable with long walking tests than walking at the preferred speed, and the 2MWT is more comparable with habitual walking behaviour than the 10MWT (Gijbels et al., 2010).

In contrast to the clinical walking outcomes, the activity monitors (ActiGraph) detected no effects, which is not surprising because the

TABLE 2 Results of the repeated-measures mixed-model analyses of the 2MWT, the 10MWT, the MSWS-12, the PGIC-walking, the RVGA, and ActiGraphsWgt3X-BT (steps, inactivity, light activity, moderate activity and, vigorous activity)

Outcome measure	Group	Base line Mean (SD)	7 weeks			18 weeks			30 weeks			Overall p value group
			Mean score for each group/(SD)	Mean difference/ 95% CI/SE	p value	Mean score for each group/(SD)	Mean difference/ 95% CI/SE	p value	Mean score for each group/(SD)	Mean difference/ 95% CI/SE	p value	
2MWT	Standard care GroupCoreDIST	170.56 (40.5) 165.18 (47.64)	169.537 (40.48) 186.23 (47.68)	16.7 CI [8.15, 25.25] SE: 4.3	<.00*	172.69 (43.6) 187.77 (49.63)	15.08 CI [6.39, 23.77] SE: 4.39	.001*	169.56 (46.63) 185.95 (46.89)	16.38 CI [7.65, 25.12] SE: 4.4	<.00*	<.00*
10MWT-fast speed	Standard care GroupCoreDIST	6.42 (1.75) 6.86 (2.77)	6.51 (1.74) 6.03 (2.09)	0.48 CI [0.11, 0.85] SE: 0.19	.01*	6.48 (1.81) 6.09 (2.37)	0.39 CI [0.02, 0.77] SE: 0.19	.04*	6.62 (1.96) 6.28 (2.30)	0.33 CI [-0.04, 0.71] SE: 0.19	.08	.02*
10MWT-preferred speed	Standard care GroupCoreDIST	8.61 (1.85) 9.04 (3.3)	8.88 (1.65) 8.67 (2.93)	0.20 CI [-0.29, 0.69] SE: 0.25	.42	8.88 (1.81) 8.90 (2.37)	0.02 CI [-0.52, 0.47] SE: 0.25	.93	8.88 (1.93) 8.74 (3.02)	0.39 CI [-0.11, 0.89] SE: 0.25	.12	.39
10MWT-slow speed	Standard care GroupCoreDIST	11.81 (3.3) 11.83 (3.7)	11.15 (3.49) 11.00 (3.43)	0.14 CI [-0.97, 1.26] SE: 0.56	.80	10.26 (2.03) 11.13 (3.99)	-0.87 CI [-2.00, 0.27] SE: 0.58	.14	10.55 (2.28) 10.98 (2.46)	-0.42 CI [-1.57, 0.72] SE: 0.58	.45	.42
MSWS-12 100 scale	Standard care GroupCoreDIST	33.80 (28.09) 30.61 (29.81)	34.90 (27.93) 25.13 (25.56)	9.77 CI [3.19, 16.35]	.004*	36.64 (28.16) 28.64 (27.15)	8.0 CI [1.33, 14.66]	.02*	34.24 (29.04) 30.37 (27.74)	3.87 CI [-2.80, 10.54]	.25	.01*

(Continues)

TABLE 2 (Continued)

Outcome measure	Group	Base line Mean (SD)	7 weeks			18 weeks			30 weeks			Overall p value group
			Mean score for each group/(SD)	Mean difference/ 95% CI/SE	p value	Mean scores for each group/(SD)	Mean difference/ 95% CI/SE	p value	Mean score for each group/(SD)	Mean difference/ 95% CI/SE	p value	
PGIC-walking	Standard care	Not assessed	4.00 (0.73)	0.89	<.00*	3.51 (1.01)	0.97	<.00*	3.66 (1.08)	0.93	<.00*	.93
	GroupCoreDIST	Not assessed	4.89 (0.98)	CI [1.34, 0.45] SE: 0.22		4.50 (1.06)	CI [1.42, 0.52] SE: 0.23		4.61 (1.15)	CI [1.39, 0.48] SE: 0.23		
RVGA	Standard care	9.9 (4.34)	11.45 (3.37)	1.28	.03*	10.91 (3.10)	0.09	.89	11.28 (3.75)	0.08	.89	.29
	GroupCoreDIST	11.24 (5.52)	10.16 (4.18)	CI [0.17, 2.40] SE: 0.57		10.82 (4.41)	CI [-1.07, 1.24] SE: 0.58		11.20 (5.06)	CI [-1.07, 1.24] SE: 0.58		
ActiGraph Steps	GroupCore DIST	6454.33 (3856.16)	5924.52 (2978.23)	478.93	.25	6086.34 (3020.52)	275.01	.52	6562.26 (3458.89)	35.97	.93	.47
	Standard care	6467.50 (3366.67)	5445.59 (2962.10)	CI [-1296.20, 338.34] SE: 413.59		5811.32 (2852.52)	CI [-1123.01, 572.98] SE: 429.36		6598.23 (3797.50)	CI [-808.11, 880.05] SE: 427.35		
ActiGraph inactivity (minute)	GroupCoreDIST	1086.77 (100.96)	1112.17 (105.09)	13.63	.46	1122.96 (76.04)	5.76	.21	1105.62 (86.86)	8.48	.66	.50
	Standard care	1083.08 (92.96)	1125.80 (91.56)	CI [-22.73, 49.98] SE: 18.42		1128.72 (91.56)	CI [-31.25, 42.77] SE: 18.76		1114.10 (109.56)	CI [-29.06, 46.01] SE: 19.02		
Actilight activity(minute)	GroupCore DIST	323.25 (88.91)	303.68 (83.59)	11.14	.519	293.11 (65.60)	5.46	.76	304.17 (75.58)	8.56	.63	.51
	Standard care	330.45 (81.57)	292.54 (93.04)	CI [-45.20, 22.92] SE: 17.25		287.65 (83.13)	CI [-40.12, 29.20] SE: 17.56		295.61 (93.72)	CI [43.71, 26.59] SE: 17.81		
ActiGraph Moderate activity (minute)	GroupCore DIST	29.46 (31.65)	22.31 (21.76)	2.18	.52	22.42 (21.44)	0.64	.85	27.53 (25.94)	0.78	.82	.79
	Standard care	24.05 (21.01)	20.13 (16.91)	CI [-8.87, 4.51] SE: 3.39		21.78 (20.03)	CI [-7.45, 6.16] SE: 3.45		28.32 (26.42)	CI [-6.10, 7.67] SE: 3.49		
ActiGraph Vigorous activity (minute)	GroupCore DIST	1.10 (3.10)	2.19 (4.20)	0.73	.43	1.87 (2.89)	0.44	.64	3.27 (7.25)	1.34	.16	.29
	Standard care	2.48 (6.08)	1.46 (2.75)	CI [-2.55, 1.08] SE: 0.92		1.43 (3.14)	CI [-2.28, 1.39] SE: 0.93		1.93 (5.18)	CI [-3.19, 0.52] SE: 0.94		

Note. The results show the means and SD of the GroupCoreDIST and standard care groups at all time points, and the means, 95% confidence intervals (CI), standard error (SE), and p values of the between-group differences at the 7-, 18-, and 30-week assessments. Significant between-group differences at 7, 18, and 30 weeks and overall differences are indicated. This mixed model adjusts for baseline, time point, group, group × time, Expanded Disability Status Scale, age, type of multiple sclerosis, and gender. Significant effects are marked with *.

Abbreviations: 10MWT, 10-m walk test; 2MWT, 2-min walk test; MSWS-12, Multiple Sclerosis Walking Scale-12; PGIC-walking, Patient Global Impression of Change-walking; RVGA, Rivermead Visual Gait Assessment.

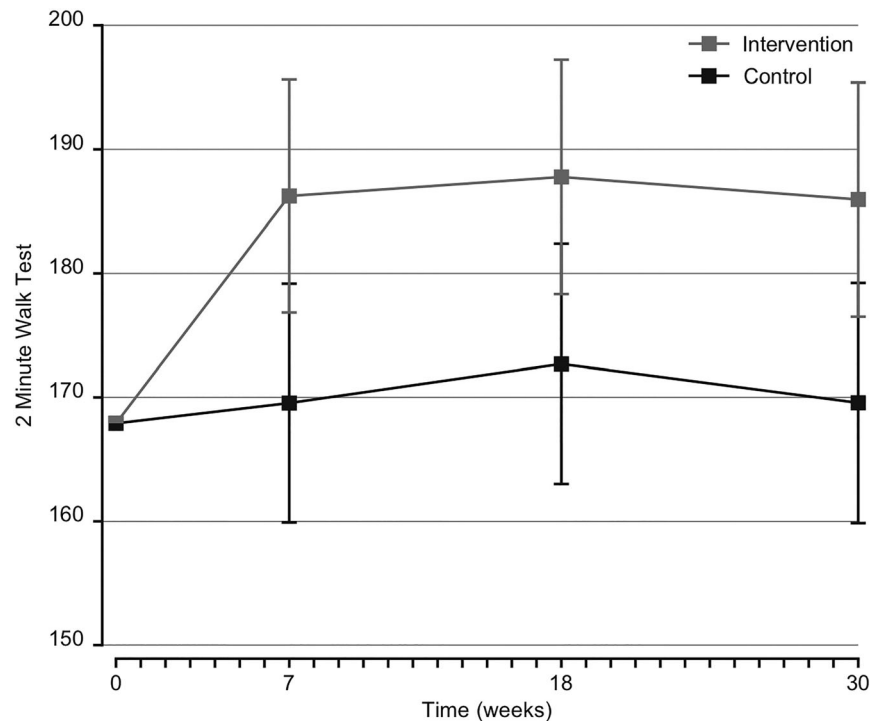


FIGURE 2 Mean and 95% CI of the 2-min walk test in the GroupCoreDIST and standard care groups at baseline and Weeks 7, 18, and 30

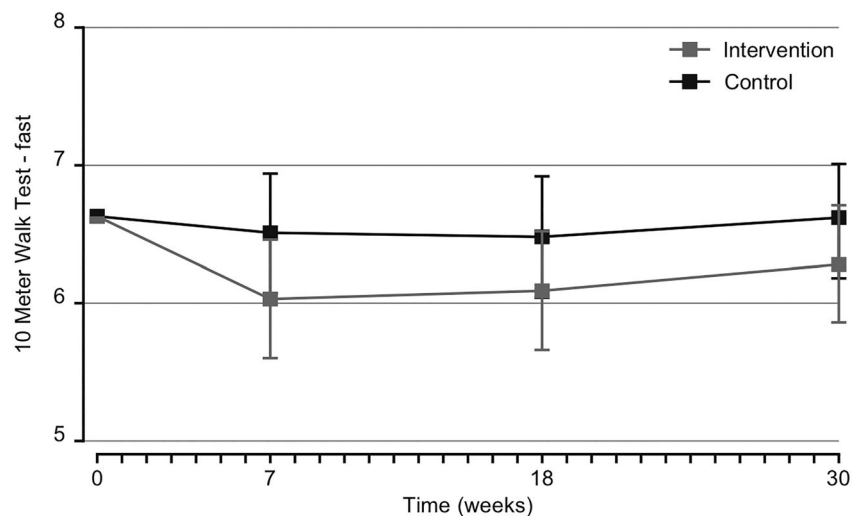


FIGURE 3 Mean and 95% CI of the 10-m walk test-fast speed in the GroupCoreDIST and standard care groups at baseline and Weeks 7, 18, and 30

GroupCoreDIST did not emphasize activity or encourage the participants to increase their activity level. Compared with healthy individuals in Norway, our participants had lower activity levels (Hansen et al., 2019); however, compared with individuals with MS, participants in both groups had higher amount of steps per day than reported in a prior study (Learmonth & Motl, 2016). This may be explained due to the high amount of individuals with EDSS 1–2 in our study and the wide standard deviations in both groups, implying a great variation regarding activity.

The MSWS-12 demonstrated significant effects at 7 and 18 weeks. There is no clear agreement regarding the definition of a standard clinically meaningful change in the MSWS-12; however, values between –6 and –11 points have been suggested previously (Baert et al., 2014; Baert et al., 2018; Hobart et al., 2003; Mehta et al., 2015).

The current study demonstrated a –7-point improvement in the GroupCoreDIST group from baseline to 7 weeks, indicating a clinically meaningful improvement. The MSWS-12 is associated with changes in walking distance and speed (Pilutti et al., 2013), which were observed in this RCT. The MSWS-12 has also been suggested to particularly capture changes in individuals within the low EDSS range (Langeskov-Christensen et al., 2017), which was the case for most participants. The MSWS-12 and the PGIC-walking reflect improvements in assessed walking distance and speed. The RVGA demonstrated that the participants had few abnormalities in the quality of walking or at least abnormalities that were captured by this outcome measurement. The low baseline scores in both groups may indicate a borderline floor effect and, thereby, limited the possibilities for improvement in the RVGA because the creators of this outcome measurement indicated

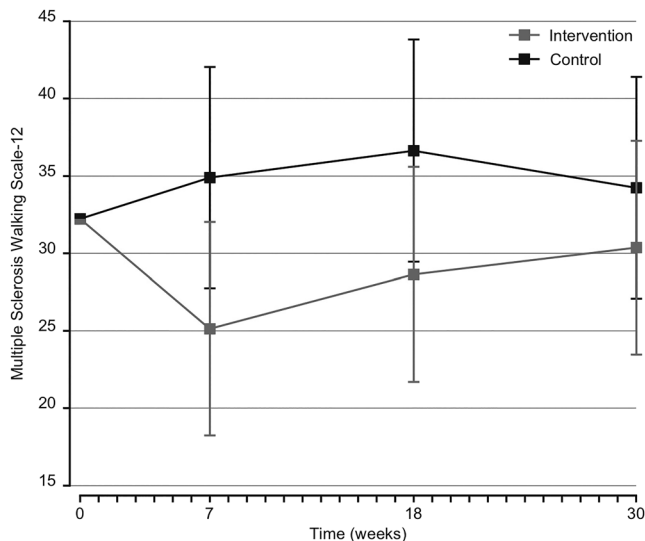


FIGURE 4 Mean and 95% CI of the Multiple Sclerosis Walking Scale-12 100 scale in the GroupCoreDIST and standard care groups at baseline and Weeks 7, 18, and 30

that an 11-point change is a significant change in gait quality (Lord et al., 1998).

The results from this study contradict the view that gait training is required for improving walking (Lederman, 2010) because GroupCoreDIST does not include walking. Other studies assessing walking after Pilates, resistance training, or general exercises have demonstrated effects on walking speed (Freeman et al., 2010; Kalron et al., 2017; Kjølhed, Vissing, & Dalgas, 2012; Pearson, Dieberg, & Smart, 2015) or distance (Freeman & Allison, 2004; Gunn et al., 2015; Kalron et al., 2017; Kjølhed et al., 2012; Pearson et al., 2015); however, some studies have shown no effect on walking (Fox et al., 2016; Kjølhed et al., 2012). The current study is distinguished by the finding that the walking distance, speed, quality, and self-perceived outcome measures of walking all improved, which may indicate that exercises that comprehensively address aspects of core stability and the prerequisites of optimal balance control influence walking.

4.2 | Explanation of findings

GroupCoreDIST highlights trunk muscle activation in coordination with activity in the limbs and other underlying aspects of balance, such as somatosensory activation of the feet, adaptation to the base of support, muscle length, and larger muscle groups. The improvements in walking may be related to the high dose of trunk muscle activation, which is imperative for monitoring displacements and optimizing steps while walking (Huisinga et al., 2014). Moreover, the intervention addresses malalignment of the trunk, hip, ankle, and foot, which are all important elements for adequate ankle and hip strategies and the ability to make longer steps, which may explain the faster walking speed (Gjelsvik & Syre, 2016; Shumway-Cook & Woollacott, 2017). Optimal somatosensory information, alignment, and dynamic adaptation to the base of support were addressed in the exercises because individuals with MS-induced mild to moderate disability tend to have decreased sensation in their feet (Citaker et al., 2011). Although these aspects are essential for walking (Arpin, Gehringer, Wilson, & Kurz, 2017), they were unfortunately not assessed as outcome measures in this study and, therefore, need to be examined in future studies for a mechanistic understanding of the components. Motor-motor dual tasks were important for all exercises, which may have been an advantage as walking involves coordination of both proximal and distal regions of the body. The significant immediate and long-term improvements in trunk control and balance (Trunk Impairment Scale-Norwegian Version and Mini-BESTest; Arntzen et al., 2019) may substantiate that comprehensive core stability and balance exercises are important for walking. The self-perceived improvements may have motivated the participants to continue to perform home-based exercises after the intervention was completed. Nearly all (38/40) of the GroupCoreDIST participants reported performing unsupervised home exercises at the 18-week assessment, which is remarkable and may have provided sustained walking improvements. At 30 weeks, only two of 40 participants reported performing unsupervised home-based exercises, which may have influenced the lack of significant effects in most walking outcomes at this point. This finding may indicate the need for intensive blocks of physical therapy

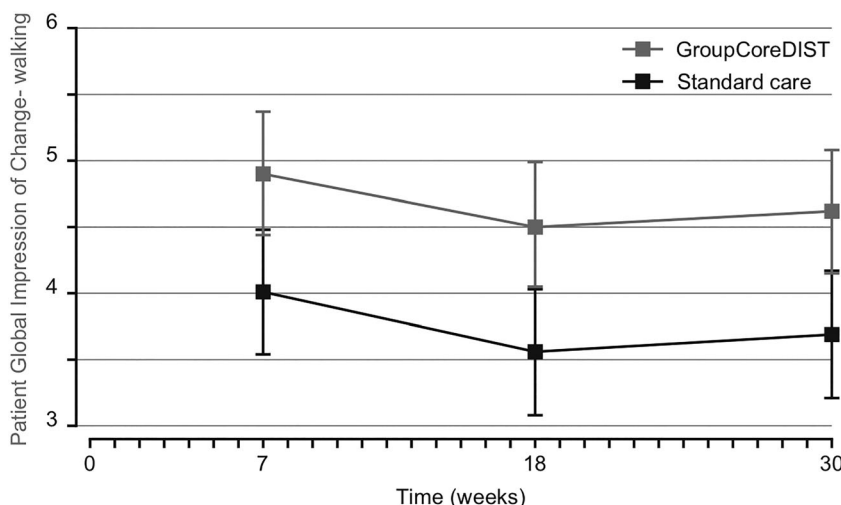


FIGURE 5 Mean and 95% CI of the Patient Global Impression of Change-walking in the GroupCoreDIST and standard care groups at Weeks 7, 18, and 30

with a few months in between and also the need to explore other elements to support adherence.

4.3 | Strengths and limitations of the trial

The group trainings were highly attended, which may have been the result of motivation and group dynamics as social settings are often motivating and may lead to increased general physical activities (Dodd, Taylor, Denisenko, & Prasad, 2006). However, the self-scorings indicated equal activity levels in both groups throughout the 6 weeks. Moreover, the well-being similar scores in the two groups imply that the social aspects of the intervention were unlikely to have caused the improvements in walking. The lacking changes in activity may also underscore that the effects on walking that occurred as a result of the intervention and not due to increased activity level. One methodological consideration is that the groups were not matched for volume of physical therapy, which implies less attention and lower expectations for improvement in the standard care group. However, standard care is a common comparator in RCTs, and the content is well described (Zwarenstein, Treweek, & Loudon, 2017). Because there is no gold standard intervention for individuals with MS (Hogan & Coote, 2013), standard care may reflect what this group is offered in general, which in this study demonstrated to be very little physiotherapy.

This RCT included a physical therapy examination as the basis for individualization, which is important given that individuals with MS have various impairments (Cameron & Lord, 2010). Individualization may limit and create imprecision in an RCT because controlling for the specific contents of the intervention may be compromised; however, the physical therapists were adequately trained in the intervention, followed a detailed manual, and registered the exercises used (Zwarenstein et al., 2008). No injuries related to the intervention were reported, and only one individual reported an exacerbation (sensory), indicating that GroupCoreDIST was well tolerated. Ambulant individuals with all types of MS and varied EDSS scores (1–6.5) participated; however, as a group, their EDSS level was quite low (mean 2.36). This finding demonstrates walking impairments in individuals with low EDSS as previously described in other studies (Sosnoff et al., 2012) and displays the potential for improvements in this group. Among all participants, 81% had an EDSS score of 1–3.5, which could indicate recruitment bias and, thus, limit generalizability. Among those who did not respond to the invitation to participate in the study, 57% had an EDSS score of 0–3.5, and 22% had an unknown EDSS score, indicating that the sample in this study is fairly similar to the MS population in the MS outpatient clinic. We consider the outpatient clinic to be no different from others in Norway, indicating that there was no recruitment bias; however, other countries may have given a different sample.

Multiplicity of analyses may be a limitation because we used many outcome measures to explore walking. However, exploring different aspects of walking is important because GroupCoreDIST is a new intervention. Additionally, physical therapists from six municipalities participated, rendering the external validity high and the results transferable to other similar populations and settings (Zwarenstein et al., 2017).

5 | IMPLICATIONS FOR PHYSICAL THERAPY PRACTICE

The immediate and long-term effects on walking demonstrated in this study support the initiation of GroupCoreDIST in ambulant individuals with MS (EDSS values 1–6.5). The usefulness of this approach among people with more severe MS ought to be investigated further. The prevailing principle of individualization in neurological physical therapy (Rehabilitation in Multiple Sclerosis (RIMS), 2012, April) has previously been questioned in group settings (Kalron et al., 2019; Plow, Mathiowetz, & Lowe, 2009). In our studies, comprehensive and individualized core stability and balance exercises were demonstrated to be feasible (Normann, Salvesen, & Arntzen, 2016) and effective regarding balance (Arntzen et al., 2019) and walking when performed in small groups. Individualization may therefore be an important element to implement in group-based physical therapy. The high dose and intensity of the GroupCoreDIST seemed important for the improvements in walking, and the fact that the standard care follow-up in our area foremost contained low dose and general activities may indicate that a more intensive and structured physical therapy treatment is needed for this population.

In conclusion, compared with standard care, 6 weeks of GroupCoreDIST produced immediate and long-term significant and clinically meaningful effects on walking. The intervention represents an effective contribution to clinical practice. In future studies, GroupCoreDIST needs to be compared with other types of exercise programmes of equal dosage in order to establish any superiority and support the theoretical underpinnings.

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CONFLICT OF INTEREST

The authors declare no conflict of interest.

AUTHOR CONTRIBUTIONS

BN and ECA provided concept, idea, and research design. FO and a blinded tester provided data collection. ECA, BS, BN, and PF provided data analysis. ECA, BN, BS, PF, and FO provided writing. BN and ECA provided project management. BN provided fund procurement, facilities, and equipment.

REGISTRATION AND FUNDING SOURCE

This RCT is registered at ClinicalTrials.gov under registration identifier NCT02522962. This study was financed by the Northern Norway Regional Health Authority (Project Grant 1240). The trial received approval from the Regional Committees for Medical and Health Research Ethics in Norway (REK South-East: 2014/1715-7).

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