

Group-Based Individualized Comprehensive Core Stability Intervention Improves Balance in Persons With Multiple Sclerosis: A Randomized Controlled Trial

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Background. Balance and trunk control are often impaired in individuals with multiple sclerosis (MS). Interventions addressing these issues are needed.

Objective. The objective of this study was to compare the immediate and long-term effects of a 6-week individualized, group-based, comprehensive core stability intervention (GroupCoreDIST) with standard care on balance and trunk control in individuals with MS.

Design. This study was a prospective, assessor-masked, randomized controlled trial.

Setting. The GroupCoreDIST intervention was conducted by 6 physical therapists in 6 municipalities in Norway. Standard care included the usual care for individuals with MS in the same municipalities. Assessments at all time points took place at a Norwegian hospital.

Participants. Eighty people with Expanded Disability Status scores of 1 to 6.5 participated in this trial.

Intervention. Randomized, concealed allocation was used to assign the participants to the GroupCoreDIST intervention ($n = 40$) or to standard care ($n = 40$). The GroupCoreDIST intervention was conducted with groups of 3 participants (1 group had 4 participants), for 60 minutes 3 times per week.

Measurements. Assessments were undertaken at baseline and at weeks 7, 18, and 30. Outcomes were measured with the Trunk Impairment Scale–Norwegian Version, Mini Balance Evaluation Systems Test, and Patient Global Impression of Change–Balance. Repeated-measures mixed models were used for statistical analysis.

Results. One individual missed all postintervention tests, leaving 79 participants in the intention-to-treat analysis. GroupCoreDIST produced significant between-group effects on the mean difference in the following scores at 7, 18, and 30 weeks: for Trunk Impairment Scale–Norwegian Version, 2.63 points (95% confidence interval [CI] = 1.89–3.38), 1.57 points (95% CI = 0.81–2.33), and 0.95 point (95% CI = 0.19–1.71), respectively; for Mini Balance Evaluation Systems Test, 1.91 points (95% CI = 1.07–2.76), 1.28 points (95% CI = 0.42–2.15), and 0.91 points (95% CI = 0.04–1.77), respectively; and for Patient Global Impression of Change–Balance, 1.21 points (95% CI = 1.66–0.77), 1.02 points (95% CI = 1.48–0.57), and 0.91 points (95% CI = 1.36–0.46), respectively.

Limitations. Groups were not matched for volume of physical therapy.

Conclusions. Six weeks of GroupCoreDIST improved balance and trunk control in the short and long terms compared with standard care in individuals who were ambulant and had MS. The intervention is an effective contribution to physical therapy for this population.

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[Arntzen EC, Straume BK, Odeh F, Feys P, Zanaboni P, Normann B. Group-based individualized comprehensive core stability intervention improves balance in persons with multiple sclerosis: a randomized controlled trial. *Phys Ther*. 2019;99:1027–1038.]

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Published Ahead of Print:

February 04, 2019

Accepted: October 23, 2018

Submitted: December 17, 2017



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<https://academic.oup.com/ptj>

Individuals with multiple sclerosis (MS) often report balance problems in both the early and progressed stages of the disease.^{1–3} These dysfunctions are due to a variety of neurological impairments, such as somatosensory deficits, paresis, coordination and visual problems, impaired activation of core/trunk muscles, and impaired anticipatory and compensatory postural adjustments.^{4,5} Learned nonuse and inexpedient compensatory movement patterns are developed over time and can also interfere with balance.⁶ Optimal core/trunk muscle activation is a prerequisite for anticipatory postural adjustments and compensatory postural adjustments. Individuals with MS and both minor and extensive balance problems tend to use more compensatory postural adjustments and fewer anticipatory postural adjustments,^{7,8} a pattern that is associated with reduced movement quality,⁹ increased risk of falling,¹⁰ and restriction of activities.¹¹

A few studies have examined the effects of core stability interventions on balance in individuals with MS. Significant between-group effects on Berg Balance Scale scores were reported in a randomized controlled trial (RCT) comparing CoDuSe (a group-based program comprising Pilates exercises, dual-task and somatosensory challenges) with no intervention in 87 ambulant people with MS (able to walk 100 m) (mean difference = 2.1; 95% confidence interval [CI] = 0.5–3.8; $P = .011$)¹² and in a pilot RCT (mean difference = 3.65; 95% CI = 0.75–6.54; $P = .015$) ($n = 51$, Expanded Disability Status Scale [EDSS] scores of 4–7.5).¹³ Two other RCT studies examining Pilates exercises compared with standardized physical therapy^{10,14} and 4 smaller studies examining Pilates training also demonstrated within-group improvements, although no between-group differences.^{15–18} The results from previous studies examining core stability training in individuals with MS are not conclusive, especially because only 2 studies reported between-group differences. Trunk control was not reported in any of the mentioned studies, which is surprising because they all included Pilates exercises that involve voluntary activation of the deep abdominal muscles.¹⁰ Most interventions were performed individually and not in a group, and none of the studies reported how physical therapist examinations were conducted or how the individualization of exercises was performed. The studies did not include the whole range of ambulant participants (EDSS scores of 1–6.5), and follow-up periods were short.

Concerning balance training in general, a systematic review and meta-analysis reported effects on balance,¹⁹ and another systematic review evaluated the effects of gait, balance, and functional training interventions.²⁰ In general, no intervention has been demonstrated to be more effective than others for balance and trunk control in individuals with MS.^{19–21} High-dose interventions that highlight individualization and interlink core stability training with other aspects of balance are called for,^{22,23} as

are group-based interventions, because such settings are considered motivating^{22,23} and economically efficient.²⁴ There is also a need for studies that clearly describe the content of the intervention.²⁰

A new self-developed, group-based intervention has therefore been developed called GroupCoreDIST: “CoreDIST” describes the coordinated relationship between proximal and distal areas of the body; D = Dual task (motor-cognitive and motor-motor), Dose (high); I = Individualized, Insights; S = Somatosensory, Stability, Selective movement; and T = Training, Teaching. The intervention was previously called GroupCoreSIT;²⁵ however, the name was changed to GroupCoreDIST because this name better describes the content of the intervention. A previous feasibility pilot intervention study of GroupCoreDIST examined balance and walking in 12 persons with MS (EDSS scores of 1–6.5).²⁵ The study demonstrated the feasibility of the intervention and significant within-group effects on balance and walking.²⁵ Based on these findings, the intervention has been further developed and examined in an RCT. The current study investigated trunk control and balance in ambulant individuals with varying disability ranges (EDSS scores of 1–6.5) with a 24-week follow-up after the intervention was completed. The main research question in the current study was: What are the short- and long-term effects of GroupCoreDIST compared with standard care on balance and trunk control in ambulant persons with MS?

Methods

Trial Design

This prospective, 2-armed, single-blind RCT compared GroupCoreDIST with standard care for balance and trunk control in 80 ambulant individuals with MS. The study protocol was registered at ClinicalTrials.gov, and the protocol has been published elsewhere.²⁶ The study was approved by the Regional Committees for Medical and Health Research Ethics in Norway, and the study complied with the Declaration of Helsinki.

Participants and Study Setting

In August 2015, 1 of the MS nurses at the Department of Neurology, Nordland Hospital Trust in Bodø, Norway, sent out invitation letters with a consent form to 160 persons with MS who were registered at the MS outpatient clinic, had EDSS scores of 0 to 7, and lived in 1 of the 6 municipalities included in the study. These municipalities were chosen because they were in both rural and urban areas (between 1200 and 51,000 inhabitants) and had physical therapists who were skilled in neurological physical therapy and wanted to learn GroupCoreDIST. To ensure maximum patient enrollment, 1 reminder letter was sent out to the nonresponders. Ninety-three persons returned signed written informed consent. Among the 67 persons who did not respond, 57% had EDSS scores of 0 to 3.5, 21% had EDSS scores of 4 to 7, and 22% had an

unknown EDSS score. Enrollment started in September 2015, and follow-up was completed in September 2016.

At enrollment, all participants underwent a clinical examination by a neurologist (F.O.) to assess their EDSS scores and review their medical history, noting the type of MS, age, sex, weight, height, and medications. The inclusion criteria were as follows: (1) diagnosed with MS in accordance with the McDonald criteria²⁷; (2) registered at the MS outpatient clinic; (3) living in 1 of 6 selected municipalities; (4) aged 18 years or older; (5) capable of providing signed written informed consent; and (6) EDSS score between 1 and 6.5 (1 = minor disability, 6.5 = able to walk 20 m with or without a walking aid). The exclusion criteria were as follows: (1) pregnancy at time of examination; (2) exacerbation in the previous 2 weeks before enrollment; and (3) other acute conditions compromising balance. Among the 93 individuals who consented to participate, 13 were not included: 5 could not commit the time, 3 scored 0 on the EDSS, 2 did not attend the baseline assessment, 1 was waiting for heart surgery, 1 was pregnant, and 1 had moved out of the catchment area.

Randomization

Eighty persons completed baseline testing. An electronic randomization was conducted 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 (<https://webcrf.medisin.ntnu.no>). The system was stratified by EDSS scores (1–3.5 and 4–6.5) to ensure a mix of people with high and low EDSS scores in both groups, and the participants were randomly assigned to the intervention group or the control group.

GroupCoreDIST Intervention and Standard Care

Six neurological physical therapists conducted the intervention after being trained in GroupCoreDIST for 5 days. The training included practical and theoretical training. The physical therapists received a booklet with descriptions and photos of all exercises and variations, as well as the theoretical framework for the intervention. The physical therapists had varied experience (between 7–25 years) and certification (2 had both a master's degree in neurological physical therapy and were clinical specialists in neurological physical therapy, 1 was a clinical specialist in neurological physical therapy, and 3 were generalists in physical therapy).

Participants allocated to the intervention group were divided into 13 training groups by B.N. and E.C.A. according to geography. The physical therapists conducted an individual clinical examination of each participant. The examinations were followed by group sessions, in which the physical therapists chose from 33 exercises, all with 5 levels of difficulty to address each individual's impairments underlying his or her balance disturbance.

The physical therapists individualized the exercises by tailoring them according to each individual's symptoms, disability level, and general well-being, and they intensified the exercises by increasing number of repetitions, level of difficulty, and/or by adding motor-cognitive dual tasks as movement quality improved. The exercises were performed barefoot in various postural sets, always keeping a focus on dynamic core stability, alignment throughout the body, and optimal movement performance. There is no universal definition of core stability; therefore, the expression "dynamic core stability" is used in GroupCoreDIST to mean the coordinated activation of both local and global muscles of the trunk, pelvis, and shoulder girdle, as well as the muscles attached to these areas.²⁸ These muscles provide coordination and stability for selective movement in the proximal area of the body as well as in the upper and lower limbs.²⁸ Large therapy balls were used in most exercises, and small mobilization balls were used for somatosensory activation of the hands and the feet; see the description of GroupCoreDIST in Table 1 and Normann et al²⁶ for examples. All group members received a booklet with illustrations of the exercises in which the physical therapist prescribed unsupervised home exercises to be conducted twice per week for 30 minutes. Participants in the intervention group were encouraged not to seek any physical therapy other than GroupCoreDIST during the 6 weeks of the intervention. The control group continued their regular routine and were encouraged to maintain their current level of physical activity and to seek any health care required, including physical therapy. Participants in both groups were encouraged to continue their usual medical treatment.

Outcome Measurements and Follow-Up

Assessments were conducted at baseline and at weeks 7, 18, and 30. Two assessors masked with regard to the group allocation carried out the assessments. The assessors had received 3 days of training in the standardized test procedures, and each was trained to apply uniform scoring criteria to all the participants and to perform scoring equivalently to the other assessor. As far as possible, the same assessor followed a given participant throughout all assessment points of the study. The participants were allowed to use a walking aid if preferred and were encouraged to use the same walking aid and shoes for all assessments.

The outcome measures were the Trunk Impairment Scale–Norwegian Version (TIS-NV), the Mini Balance Evaluation Systems Test (Mini-BESTest), and the Patient Global Impression of Change–Balance (PGIC-Balance). The TIS-NV measures dynamic sitting balance and trunk control and includes 6 test items scored from 0 to 2 or 3, with a total score from 0 to 16 (0 = severe problem).²⁹ The TIS-NV is a modified version of the original Trunk Impairment Scale, which has been validated and tested for reliability in people with MS.³⁰ The Mini-BESTest measures

Core Stability Training Improves Balance in MS

Table 1.
Dose and Content of GroupCoreDIST Intervention and Standard Care Over 6 Weeks^a

GroupCoreDIST Intervention		Standard Care Dose and Content
Dose and Equipment	Content and Examples	
Individual clinical examination: 60-min session before the start of the group sessions	<p>History: medical, social, and patient history; symptoms; main issues from the patient's perspective.</p> <p>Analysis: observation and hands-on interaction; consider the patient's resources and constraints for movements.</p> <p>Posture analysis: various positions, eg, standing, sitting, and lying down; consider alignment throughout the body and, for each body area, adaptation to the base of support and interaction with the environment</p> <p>Activities/movement analysis: eg, walking, standing on toes or heels, squatting, standing on 1 leg, and other balance challenges; consider the body's relationship to the base of support, movement patterns of the body as a whole, and specific body parts and their relationship to each other, the task, and the environment; consider the ability for selective movement (to move 1 part of the body while stabilizing other parts) to provide coordination</p> <p>Specific tests: muscle length, muscle activation and strength, tonus, somatosensory function, pain and reflexes.</p> <p>Introduction to GroupCoreDIST exercises: choose and try a few exercises on the basis of the patient's movement problems; introduce hands-on adjustments to improve alignment, adaptation to the base of support, and movement quality; consider the patient's ability for improved performance in the exercises</p> <p>Conclusion: consider the patient's resources and issues, hypothesis of causation, the main problem related to movement and balance, and potential for improved movement control</p>	Optional
<p>Group sessions</p> <p>Duration: 60 min 3 times/wk for 6 wk</p> <p>Equipment: large therapy balls, small mobilization balls, rolled towels, bolsters, plinths, and rubber bands for optimal alignment</p>	<p>Planning the group sessions: consider each participant's main problem and which symptoms are related to it; use the appropriate position and variations of exercises (5 variations for each of the 33 exercises, 6 exercise categories) so that each participant can perform the exercises with optimal movement quality.</p> <p>Goal: teach the participants specific exercises that can be performed both together with a physical therapist and at home; the goal is for participants to perceive improvements in balance and movement control.</p>	Continue the regular routine, which for some involves physical therapy, general physical activity, or training
Beginning and end of all group sessions	<p>The physical therapist should ask how everyone is doing that day and how the performance of home exercises went.</p> <p>Individual balance checkpoints: all participants perform balance challenges simultaneously at the beginning and end of each session, perceive and reflect on their own balance that day, and compare their own balance before and after each session. The physical therapist links a participant's balance challenges with the choice of exercises.</p>	Optional
<p>Exercises:</p> <p>Performed 10 times for up to 3 repetitions according to a participant's capacity and quality of performance.</p> <p>As the quality of movement in the exercise improves, the physical therapist can adjust the dose by increasing the number of repetitions, using a more difficult variant of the exercise, or adding dual-task challenges</p>	<p>Group members concurrently conduct the same exercise but with different variations according to symptoms and quality of performance; all 6 exercise categories should be used at every group session; all exercises should target optimal adjustment to the base of support and activation of the core.</p> <p>The 6 exercise categories are:</p> <p>(exercise 1 or 2) to enhance adaptation to the base of support, eg, by rolling a mobilization ball with the hands or feet;</p> <p>(2) Muscle length: (exercises 3–9) addressing concentric and eccentric activity in muscles of the neck and upper and lower limbs;</p> <p>(3) Selective movement and coordination: (exercises 10–21) selectively moving arms and legs or particular parts of the core, with a focus on dynamic stability, ie, keeping 1 part of the body stable while moving another;</p> <p>(4) Training larger muscle groups: (exercises 22–27) recruiting larger muscle groups in various standing positions, eg, rolling the ball up and down toward the wall with your back;</p> <p>(5) Advanced challenges for balance and postural control: (exercises 28–32), providing advanced challenges for postural control and balance, eg, jumping while bouncing the therapy ball;</p> <p>(6) Relaxation: (exercise 33) systematically performing contraction/relaxation of all parts of the body</p>	Varied; all are encouraged to be active and to seek any health care required

(continued)

Table 1.
Continued

GroupCoreDIST Intervention		Standard Care Dose and Content
Dose and Equipment	Content and Examples	
Additional challenges and adaptations	Motor-motor dual tasks are performed in all exercises, ie, performing more than 1 motor task at once such as keeping the back in contact with the therapy ball while rolling it from side to side. Advanced motor-motor dual tasks, such as throwing a towel or a ball with the other group members, can be added. Motor-cognitive dual tasks, such as singing, rhyming, or calculating while performing exercises, can be added; all dual-task activities can also enhance group dynamics, engagement, and having fun. Both instructions and hands-on facilitation are allowed to improve movement quality, make movement possible or easier, decrease inexpedient compensatory movement patterns, and optimize the movement experience ⁴²	Optional
Home training: Unsupervised GroupCoreDIST exercises for 30 min, 2 times/wk during the 6-wk intervention Equipment: same as for the group sessions	The physical therapist cooperates with each participant to identify exercises for home training; the exercises are individualized and mirror what is highlighted during group training; home training contains all 6 exercise categories; the training progresses in line with the exercises performed in group sessions.	Optional

^aGroupCoreDIST is an individualized, group-based, comprehensive core stability intervention.

balance in standing and walking. The translated Norwegian version has good reliability and validity for people with MS.³¹ It assesses 4 subitems: anticipatory postural control, reactive postural control, somatosensory orientation, and dynamic walking, with 14 tasks altogether. Each task is scored from 0 to 2, with a total score from 0 to 28 (0 = severe problem).³¹ The PGIC-Balance is scored on a 7-point Likert scale, and the question was as follows: “How do you perceive your balance now compared to before the 6-week training period or standard care?” The PGIC-Balance measures how participants perceive a change in balance (1 = much worse, 4 = no change, and 7 = greatly improved).³² A questionnaire was filled in by both groups during the 6 weeks of GroupCoreDIST or standard care; it asked about self-reported level of physical activity (number of half-hours per week), number of physical therapy sessions per week, exacerbation of symptoms, change in medications, and general well-being (level 1–5, with 1 being best). The exercises used in the group sessions were documented by the physical therapist who led the group.

In this study we aimed to explore various effects of the GroupCoreDIST intervention compared with standard care. This article address all balance outcomes, which were: the primary outcomes (TIS-NV and Mini-BESTest) and 1 secondary outcome (PGIC-Balance). Other secondary outcomes addressed were: walking (2-Minute Walk Test, 10-Meter Walk Test, Rivermead Visual Gait Assessment, Multiple Sclerosis Walking Scale-12–Norwegian Version, and Patient Global Impression of Change–Walking); activity level (ActiGraphs Wgt3X-BT activity monitors, ActiGraph, Pesacola, FL, USA);

and health-related quality of life (Multiple Sclerosis Impact Scale-29–Norwegian Version, Multiple Sclerosis Quality of Life-54, and EuroQuol EQ-D5-3L Norwegian Version). The many outcome measures and the 4 repeated assessment points produced a large amount of significant results; therefore, the secondary outcomes are presented in different papers.

Sample Size

The sample size calculation was based on assumptions of change in the Mini-BESTest, where 0.75 standard deviation (SD) between the intervention and the control group was considered clinically significant. For an 80% chance of detecting a 0.75 SD difference between groups with a significance level of .05 (α), 28 individuals with MS in each group were required. Assuming a 30% dropout rate, we aimed to recruit at least 72 participants.

Statistical Analysis

Demographic and clinical characteristics were measured using descriptive statistics in IBM SPSS Version 24 (IBM, Armonk, NY, USA). To examine possible differences between groups over time, we performed an intention-to-treat analysis using repeated-measures mixed models in IBM SPSS Version 24. This approach was preferred because of the model's advantage in addressing missing values and its many options in adjusting for dependence between the repeated measures. All participants with postintervention test assessment scores were included, although some had missing observations. At first all baseline characteristic variables (group/intervention, time, EDSS score, stratification, sex, type of MS, time since diagnosis, age at diagnosis, height, weight, education level, marital status, age, smoking, and

employment) were entered into models as independent variables, with each of the outcome measures (TIS-NV, Mini-BESTest, and PGIC-Balance) as dependent variables to examine significant interactions. The final models (1 for each outcome) included all independent variables that reached significance at $P = .05$ in any of the mentioned models, which included group, time point, EDSS score, sex, type of MS, and age, and an interaction term composed of the time and group variables. The data structure with 4 repeated measurements was coded as a numeric time variable. We calculated differences between groups in each outcome measure at each time point and adjusted for the mentioned independent variables and the baseline variable by keeping the continuous variables as covariates and the categorical variables as factors in the models.³³ The estimated marginal means were used to make plots illustrating the effects of the intervention over time.

Role of the Funding Source

The study was financed by the Northern Norway Regional Health Authority (Project Grant 1240), which is an independent and public funding source that provides funds applicable for hospitals and universities in northern Norway yearly.

Results

The flow of participants through the trial is shown in Figure 1 (flowchart). The 80 participants were randomly allocated to the GroupCoreDIST intervention group ($n = 40$) or the standard care group ($n = 40$). All 80 randomly allocated participants completed the 6 weeks of GroupCoreDIST or standard care. At the 7-week postintervention test, 1 individual from the intervention group dropped out and was excluded from the study due to a lack of postintervention test data. Thus, 79 participants remained in the intention-to-treat analysis. At the 18-week postintervention test, 1 person from the control group became ill and was lost to follow-up, and 3 other participants from the control group missed their assessments. At the 30-week postintervention test, 2 individuals from each group missed assessments. Baseline demographic and clinical characteristics are shown in Table 2.

Group sessions were well attended (mean 2.5 sessions per person per week). The control group reported an average of 0.28 physical therapy sessions per week for the same 6 weeks. Self-reported physical activity levels were equal in the intervention and control groups (mean 4.20 half-hours per week for the intervention group, and 3.56 half-hours per week for the control group), and there was no significant between-group difference in physical activity during the 6 weeks; the mean difference was 4.38 half-hours for the entire period (95% CI = -19.75 to 10.98 ; $P = .57$). General well-being scored a mean of 2.48 points out of 5 for both groups during the 6 weeks and was therefore similar in the GroupCoreDIST and standard

care groups. One person reported a sensory relapse, verified by a neurologist, during the first week of the intervention. No one reported any injury due to the intervention. The control group reported no new relapses. Medications were stable. Thirty-eight participants from the intervention group reported that they were still doing GroupCoreDIST exercises at home at 3 months, whereas only 2 reported performing the exercises at 6 months.

The results of the mixed-model analysis are shown in Table 3. Statistically significant differences between groups were found for the TIS-NV, the Mini-BESTest, and the PGIC-Balance at 7, 18, and 30 weeks. The TIS-NV demonstrated an overall statistically significant difference between the groups ($P = .03$). The TIS-NV results for each time point are shown in Figure 2, demonstrating statistically significant differences between groups at 7 weeks ($P < .001$), 18 weeks ($P < .001$), and 30 weeks ($P = .015$). From baseline to the 7-week postintervention test, the intervention group improved by 19%. The Mini-BESTest demonstrated an overall statistically significant difference between groups ($P < .001$). The Mini-BESTest results for each time point are shown in Figure 3, demonstrating statistically significant differences between groups at 7 weeks ($P < .001$), 18 weeks ($P = .004$), and 30 weeks ($P = .04$). The PGIC-Balance showed an overall statistically significant between-groups effect ($P < .001$). The PGIC-Balance results for each time point are shown in the eFigure (available at <https://academic.oup.com/ptj>), demonstrating significant differences between groups at 7 weeks ($P < .001$), 18 weeks ($P < .001$), and 30 weeks ($P < .001$).

Discussion

To our knowledge, this is the first assessor-masked RCT to evaluate the short- and long-term effects of GroupCoreDIST on balance and trunk control in people with MS. The results demonstrated that 6 weeks of GroupCoreDIST compared with standard care led to significant between-group effects in favor of the intervention group on balance and trunk control at 7, 18, and 30 weeks. The results are in line with the previous pilot study.²⁵

Strengths and Weaknesses in Relation to Other Studies

To the best of our knowledge, no prior studies have conducted a 30-week study and demonstrated long-term effects on balance and trunk control after a core stability and balance intervention in individuals with MS. The TIS-NV, which requires quality of movement and cooperation between body segments in dynamic sitting balance,²⁹ detected a short-term improvement of 19% in the intervention group, which we consider a clinically meaningful change. Moreover, both the TIS-NV and the Mini-BESTest showed a significant between-group effect that lasted for 6 months. This effect could reflect the

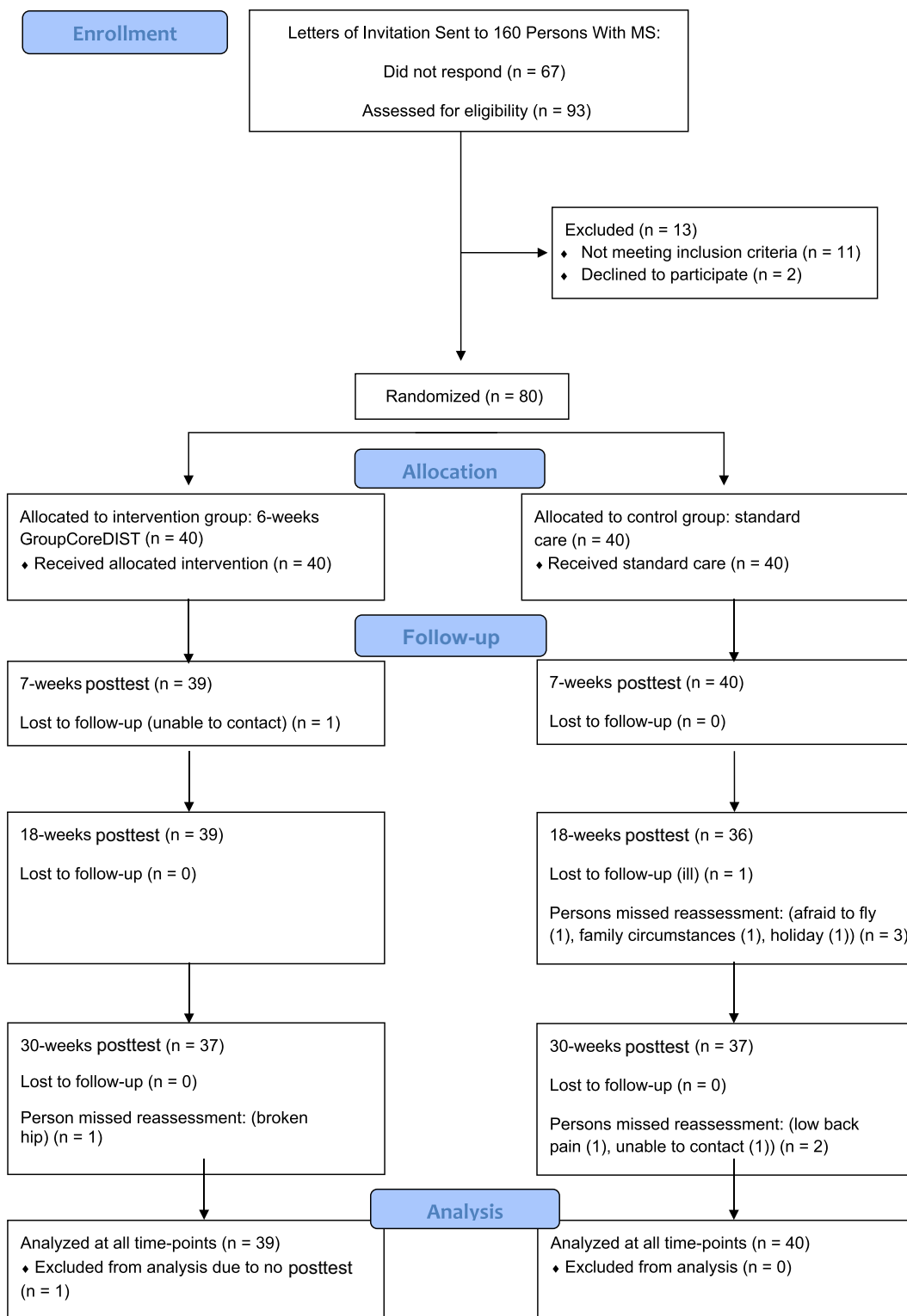


Figure 1. Flowchart of recruitment, allocation, and retention of participants throughout the study.

Table 2.
Baseline Demographic and Clinical Characteristics for Standard Care and GroupCoreDIST Groups^a

Baseline Characteristic	Standard Care (n = 40)	GroupCoreDIST (n = 39)
Age, y, mean [SD]	48 (8.75)	52.2 [12.9]
Height, cm, mean [SD]	171.8 [9.06]	169.26 [7.67]
Weight, kg, mean [SD]	77.7 [14.15]	71.7 [12.16]
Sex, no. (%) of participants		
Women	29 (72.5)	27 (69.2)
Men	11 (27.5)	12 (30.8)
Smoker, no. (%) of participants		
No	30 (75)	36 (92.3)
Yes	10 (25)	3 (7.7)
Type of multiple sclerosis, no. (%) of participants		
Relapsing remitting	36 (90)	32 (82.1)
Primary progressive	2 (5)	5 (12.8)
Secondary progressive	2 (5)	2 (5.1)
EDSS score, mean [SD]	2.28 [1.28]	2.45 [1.65]
Age at diagnosis, y, mean [SD]	37.4 [10.06]	41.9 [10.26]
Years since diagnosis, mean [SD]	10.68 [7.27]	10.04 [7.85]

^aEDSS = European Disability Status Scale; GroupCoreDIST is an individualized, group-based, comprehensive core stability intervention.

content of the intervention and might indicate a transfer to postural control in daily activities.²⁹ The Mini-BESTest assesses anticipatory and reactive postural control and somatosensory orientation, which were all enhanced in the intervention. Several studies have shown that core/trunk control is important for balance,^{1,4,28,34} and the improved scores on both the TIS-NV and the Mini-BESTest could underscore the relationship between optimal core muscle activation and balance. The PGIC-Balance supports the results from the TIS-NV and the Mini-BESTest, because the participants in the intervention group perceived an improvement in balance at all assessment points.

Two systematic reviews have reported effects of balance training in individuals with MS (effect size = 0.34; 95% CI = 0.01–0.67)¹⁹ and effects of gait, balance, and functional training interventions (effect size = 0.82; 95% CI = 0.55–1.10),²⁰ which demonstrate moderate effects on balance, perhaps due to a nonspecific focus on balance in the interventions, lack of intensity, or both.²⁰ The intervention in our study was specifically directed toward trunk control and balance, and achieved greater effect sizes at all assessment points, which might be explained by an individualized, comprehensive, and specific focus. However, a short range in the outcome measures might have made large effect sizes hard to achieve. The combination of high-dose dynamic core training with

somatosensory activation, training muscle length, coordination, postural control, balance, and dual-task has similarities to the studies by Forsberg et al¹² and Carling et al,¹³ who combined core stability with sensory-motor and dual-task challenges, and contrasts with Fox et al,¹⁰ Freeman et al,¹⁸ and Kalron et al,¹⁴ who focused only on low-dose Pilates training. The improvements in balance are also in line with the Forsberg study and in contrast to the Fox study, which revealed no significant effects on balance after Pilates training.^{10,12} Based on these studies, a combination of dynamic core training with other aspects of balance and high doses might be more beneficial for improving balance in persons with MS than low-dose core training alone. Moreover, the initial individual examination and individualization components of GroupCoreDIST are lacking in all of the noted studies. Both a clinical examination and individualization are prevailing principles in neurological physical therapy and should be addressed before the start of any intervention, including group-based interventions.

Explanation of Findings

The 6-week duration of GroupCoreDIST was sufficient for significantly improved balance and trunk control to be retained for 6 months after the intervention. The exercises were individualized to ensure that key impairments contributing to reduced balance and trunk control were

Table 3. Results for the Trunk Impairment Scale–Norwegian Version (TIS–NV), Mini Balance Evaluation Systems Test (Mini–BESTest), and Patient Global Impression of Change–Balance (PGIC–Balance) at Baseline and at Weeks 7, 18, and 30^a

Outcome Measure	Group	Baseline Mean [SD] Score	Week 7			Week 18			Week 30			Overall P Value for Group
			Mean [SD] Score	Mean Difference Between Groups (95% CI)	P	Mean [SD] Score	Mean Difference Between Groups (95% CI)	P	Mean [SD] Score	Mean Difference Between Groups (95% CI)	P	
TIS–NV	Standard care	10.50 [2.03]	9.69 [2.2]	2.63 (1.89–3.38) SE: 0.38	<.001 ^b	9.78 [2.19]	1.57 (0.81–2.33) SE: 0.38	<.001 ^b	9.93 [1.96]	0.95 (0.19–1.71) SE: 0.38	.015 ^b	.03 ^b
	G–Core DIST	9.28 [2.14]	12.32 [1.8]			11.35 [2.01]			10.88 [2.43]			
Mini–BESTest	Standard care	22.65 [3.93]	21.41 [3.63]	1.91 (1.07–2.76) SE: 0.43	<.001 ^b	21.74 [4.26]	1.28 (0.42–2.15) SE: 0.44	.004 ^b	22.38 [3.77]	0.91 (0.04–1.77) SE: 0.44	.04 ^b	<.001 ^b
	G–Core DIST	20.41 [6.05]	23.33 [4.87]			23.02 [5.1]			23.28 [4.37]			
PGIC–Balance	Standard care	Not assessed	4.06 [0.72]	1.21 (1.66–0.77) SE: 0.23	<.001 ^b	3.75 [1.01]	1.02 (1.48–0.57) SE: 0.23	<.001 ^b	3.89 [1.05]	0.91 (1.36–0.46) SE: 0.23	<.001 ^b	<.001 ^b
	G–Core DIST		5.26 [0.90]			4.77 [1.15]			4.81 [1.16]			

^aIn the model, outcome scores were adjusted for baseline, time point, group, group*time, age, sex, European Disability Status Scale score, and type of multiple sclerosis. CI = confidence interval; SD = standard deviation; SE = standard error.
^bStatistically significant effect.

addressed in each individual. Interlinking the core and the distal segments makes GroupCoreDIST more functional than Pilates training, which focuses mostly on the proximal muscles.¹⁰ The motor-motor and motor-cognitive dual tasks might have contributed to less cognitive attention being paid to the core training and, therefore, less cognitive attention on balance, which may be favorable during daily activities. The improved balance can also be explained by the fact that the intervention addresses malalignment in the trunk, hip, ankle, and foot, which are all important elements in adequate ankle and hip strategies.^{9,35} Optimal somatosensory information combined with dynamic adaptation to the base of support is important for adequate anticipatory postural adjustments because they are prerequisites for efficient descending motor systems.³⁶ Sensation is decreased in persons with mild to moderate disability due to MS, and this deficit is related to impaired balance.³⁷ GroupCoreDIST aims to address all of these aspects. Our choice of outcome measurements specifically addressed what the intervention aims to improve.

The high attendance at group trainings can be explained by motivation due to group dynamics,^{22,23} attention from a specialized physical therapist, the individualized exercises, the addition of structure to the week, and the fact that this program was a new physical therapy offering for this group. The social setting could have motivated the participants to increase general physical activities; however, the self-reports indicated the same activity level in both groups during the 6 weeks. The similar scores for well-being in the 2 groups imply that the social aspect of the intervention is unlikely to have caused the improvements. Almost all the participants in the intervention group reported still performing unsupervised GroupCoreDIST exercises at week 18. This could have contributed to the long-term maintenance of improved trunk control and balance.

Strengths and Limitations of the Trial

The current study was an RCT that involved an individual clinical examination and clinical reasoning, which is important given that individuals with MS have various impairments that cause balance problems.^{4,5} Individualization can limit an RCT because a prerequisite is to control the contents of the intervention, which can be compromised by tailoring. However, an RCT with a comprehensive intervention where individualization is embedded has direct relevance to clinical practice.³⁸ The intervention was derived from clinical practice blended with theory, which increased its relevance, and the physical therapists' documentation of all exercises performed avoided deviations from the intervention manual. A limitation of this study was the difference in the dose of physical therapy between the 2 groups, which implied less attention and lower expectations for improvement in the control group. There are no reports of a superior physical therapist intervention for people with

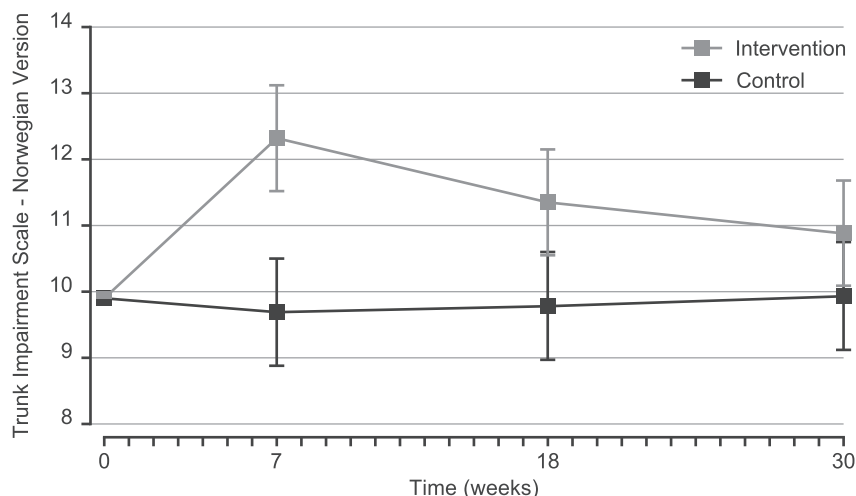


Figure 2. Means and 95% confidence intervals of scores on the Trunk Impairment Scale–Norwegian Version for the GroupCoreDIST and standard care groups at baseline and weeks 7, 18, and 30. In the model, outcome scores were adjusted for baseline, time point, group, group*time, age, sex, Expanded Disability Status Scale score, and type of multiple sclerosis.

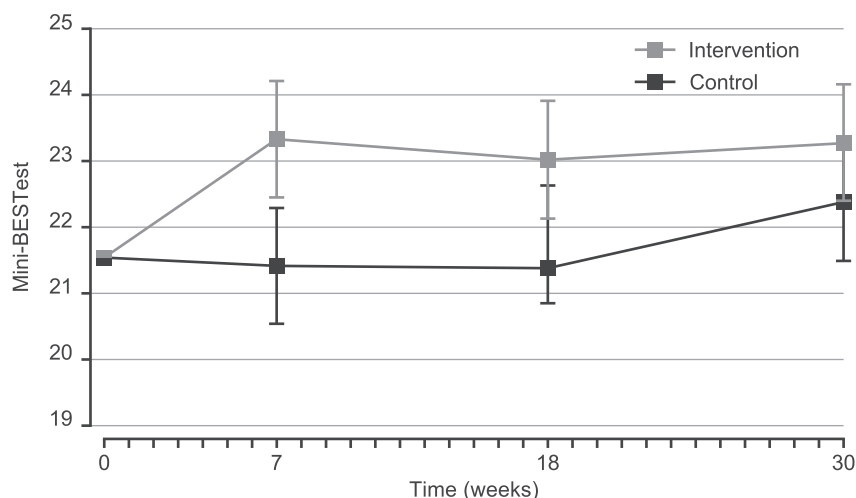


Figure 3. Means and 95% confidence intervals of scores for the Mini-BESTest for the GroupCoreDIST and standard care groups at baseline and weeks 7, 18, and 30. In the model, outcome scores were adjusted for baseline, time point, group, group*time, age, sex, Expanded Disability Status Scale score, and type of multiple sclerosis.

MS²¹; therefore, we chose standard care because this would reflect what these patients are actually offered in general. Standard care is a common comparator in RCTs, and the content of standard care was described.

Computer-based randomization, a new EDSS score for all participants, strict registrations, low dropout rate, and assessor-masked measurements strengthen the results. The GroupCoreDIST intervention is feasible and easy to implement in clinical practice,²⁵ and a group-based approach with 3 persons treated at the same time increases the availability of neurological physical therapy.

No participants reported injury related to the intervention, and only 1 sensory exacerbation was reported (in the first week of the study), which indicates that GroupCoreDIST was well tolerated.

The study recruited individuals with all types of MS, with both moderate and low levels of disability. Moreover, 6 physical therapists from different municipalities contributed. This makes the external validity high, and the results could be transferred to other similar populations and settings.³⁹ Among all the participants, 81% had EDSS scores of 1 to 3.5. This could indicate recruitment bias and

thereby limit generalizability. Among those who did not respond to the invitation to participate in the study, 57% had EDSS scores of 0 to 3.5, and 22% had an unknown EDSS score. This could indicate that the sample in the study was fairly similar to the MS population in the MS outpatient clinic, and that there was no recruitment bias.

A potential limitation is that the study did not include the Berg Balance Scale, which is a common outcome measure and would have allowed direct comparisons with other studies assessing balance in persons with MS. However, our study included other outcome measures, such as walking measures, self-report questionnaires, and activity levels measured by activity monitors (ActiGraph Wgt3X-BT, ActiGraph, Pensacola, FL, USA). Adding even more outcome measures would have increased the risk of fatigue. The results from the other outcome measures will be presented in separate papers.

Implications for Clinical Practice

GroupCoreDIST interlinks dynamic core stability with distal movement control and emphasizes somatosensory activation of feet and hands, muscle length, training larger muscle groups, postural control, and dual task, which are all important elements in optimal balance. In addition, it is important to tailor the exercises to highlight each individual's specific challenges due to the heterogeneous symptoms of MS. This approach will enable individuals with MS to perform individualized exercises during group sessions and also as unsupervised home exercises, and thereby take control of living with a chronic disease. GroupCoreDIST can therefore contribute to self-help and self-management in people with MS.

Individuals with minimal impairment are recommended to perform general training as well as aerobic and progressive resistance exercises.⁴⁰ The current study shows that balance was affected in individuals with both lower and higher EDSS scores and that GroupCoreDIST improved their balance impairments. Therefore, it could be beneficial to start a specific physical therapist intervention early, when neurological dysfunction is limited. This is in line with previous research suggesting that persons with minor balance difficulties often have postural control problems^{1,3} and that intensive training is a prerequisite for improved motor control and neuroplasticity in people with MS.⁴¹

In conclusion, 6 weeks of GroupCoreDIST produced significant short- and long-term effects on balance and trunk control compared with standard care in ambulant individuals with MS, and GroupCoreDIST represents an effective contribution to clinical practice.

Future Research

For future research, we suggest studying whether and how the postural control strategies of people with MS change after GroupCoreDIST, as assessed by electromyography

and a balance force platform. Moreover, the effect of GroupCoreDIST on falls could be reported in future studies. GroupCoreDIST should also be compared with other interventions that aim to improve balance to guide future clinical practice guidelines.

Author Contributions and Acknowledgments

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Providing facilities/equipment: B. Normann

Providing institutional liaisons: B. Normann

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The authors would like to thank all of the individuals with MS who participated in the study, the 6 physical therapists who conducted the group treatment, and the 2 physical therapists who conducted the assessments, as well as the administrations of the participating municipalities. They would also like to thank the Department of Physical Therapy, Nordland Hospital Trust, and the MS nurse at the Department of Neurology, Nordland Hospital Trust. They extend their gratitude to Professor of Statistics Tom Wilsgaard, at UiT The Arctic University of Norway, for help with sample size calculation and statistical analyses.

Ethics Approval

The study was approved by the Regional Committees for Medical and Health Research Ethics in Norway (REK Southeast: 2014/1715-7). The study complied with the Declaration of Helsinki. Participant consent was obtained.

Funding

The study was funded by the Northern Norway Regional Health Authority (Project Grant 1240).

Clinical Trial Registration

This RCT is registered at ClinicalTrials.gov (registration identifier: NCT02522962).

Disclosures

The authors completed the ICJME Form for Disclosure of Potential Conflicts of Interest and reported no conflicts of interest.

DOI: 10.1093/ptj/pzz017

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