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The effects of and experiences from participation in GroupCoreDIST – a new, individualized, group-based, physiotherapy intervention for ambulant individuals with multiple sclerosis.

A mixed methods study including a randomized controlled trial and a qualitative interview study.

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ABSTRACT

Introduction: Balance and walking deviations are common in individuals with multiple sclerosis (MS) due to varied neurological symptoms and impairments. Individualized physiotherapy is common, however individualization in groups is questioned. New knowledge regarding effects and user-experiences from group physiotherapy is needed. This mixed methods study explored the status of balance and walking, short- and long-term effects and user-experiences from participation in GroupCoreDIST – a new, individualized, group-based, physiotherapy intervention for ambulant persons with MS.

Methods: This parallel QUAN+QUAL, mixed method study included a prospective, assessor-masked, randomized controlled trial (RCT) and a qualitative in-depth interview study. The RCT included 80 individuals with MS (European Disability Status Scale (EDSS) 1-6.5, mean 2.36), who were allocated to GroupCoreDIST (n=40) for 60-minuttes, three times per week, for six weeks (18 sessions), or standard care (n=40), both taking place in six Norwegian municipalities. Assessments in the RCT were conducted at baseline, weeks 7, 18 and 30 and included primary outcomes; the Trunk Impairment Scale-Norwegian Version and the Mini Balance Evaluation Systems Test assessing trunk control and balance, and several secondary outcomes assessing walking (distance, speed, quality experience of how MS impact on walking, experience of change in balance and walking, and physical activity). One participant attended no post-tests; leaving seventy-nine subjects for intention-to-treat analysis. A repeated-measures mixed models analysis in IBM-SPSS was conducted. The interview study included a strategic sample of 13 individuals from the GroupCoreDIST group (9 women; age 25-79 years old; EDSS 1-6.5) who participated in interviews at week 7 and 30, all together 25 interviews (one person died before the last interview). The qualitative interviews were systematised using NVivo11.0/12.0 (QSR International, 2016), and analysed by using Malterud´s systematic text condensation, with dynamic systems theory and a phenomenological pattern theory of self as analytical frameworks. The qualitative and quantitative findings were integrated through a systematic analysis where I looked for overlapping findings in the three papers, and also looked for surprising findings that could expand our knowledge from the overlapping themes.

Results: The integrated findings provided three new categories: 1) *Detecting deviations, challenges and possibilities:* The average disability was low (low EDSS), however, the baseline outcome measures and experiences from the clinical examination revealed measured and experienced deviations on trunk control and balance, impaired walking and less physical activity than recommended. Explorations of changes in the clinical examination provided new insights and expectations. 2) *Short-term effects and insights from nesting individual and group elements:* The GroupCoreDIST provided short-term effects and experiences of improved trunk control, balance, walking and new opportunities for activity and participation. The integration of individual elements such as the physiotherapist´s detailed focus on individual challenges, hands-on interactions and adjustments provided experiences of control, ownership and agency towards their own body; and group elements such as equal attention and the supporting dialogue regarding changes, strengthened reflections of own possibilities and were experienced as meaningful. 3) *Long-term changes, affordances and maintenance:* GroupCoreDIST provided long-term effects in balance and walking (three and six-months assessments) and experiences of new affordances and autonomy in activity and participation, which may be due to the intervention and the continuity of conducting home exercises for three months. Physical activity did not change during the study.

Conclusion: In conclusion, the short- and long-term follow-up for individuals with MS should be improved. Balance and walking deviations, challenges and possibilities for change should be detected at an early time-point and even when disability is low. The principles of GroupCoreDIST should be considered to be implemented to clinical practice as only six weeks of group-based physiotherapy provided short- and long-term effects on balance and walking, experiences of changes in all ICF levels, meaning, affordances and autonomy to individuals with MS.

LIST OF PAPERS

Paper 1: Arntzen, E.C., Straume, B.K., Odeh, F., Feys, P., Zanaboni, P. & Normann, B. (2019). Group-Based Individialized Comprehensive Core Stability Intervention Improves Balance in Persons with Multiple Sclerosis: A Randomized Controlled Trial. *Physical Therapy.* 99, 1027-1038. DOI: 10.1093/ptj/pzz01

Paper 2: Arntzen, E.C., Straume, B., Odeh, F., Feys, P. & Normann, B. (2019). 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. *Physiotherapy Research International.* 2019;e1798. https//doi.org/10.1002/pri.1798

Paper 3: Arntzen, E.C., Øberg, G.K., Gallagher, S. & Normann, B. (2019). Group-based, individualized exercises can provide perceived bodily changes and strengthen aspects of self in individuals with MS: a qualitative interview study. *Physiotherapy Theory and Practice.* 26, 1-16. DOI: 10.1080/09593985.2019.1683923

ABBREVIATIONS AND DEFENITIONS

ActiGraph	ActiGraph wGT3x-BT monitors
ADL	Activities of daily living
BOS	Base of support
CNS	Central nervous system
EBP	Evidence Based Practice
EDSS	Expanded Disability Status Scale
GroupCoreDIST	CoreDIST defines the relationship between proximal and distal areas of the body DIST stands for: D: (high) dose, dual task (motor-motor and motor-cognitive) I: individualized, individual assessment, insights S: selective movement, specificity, somatosensory activation T: training, teaching
ICF	the International Classification of Functioning, Disability and Health
Mini-BESTest	Mini Balance Evaluation Systems Test
MRI	Magnetic Resonance Imaging
MS	Multiple Sclerosis
MSWS-12	Multiple Sclerosis Walking Scale-12
PGIC	Patient Global Impression of Change
RCT	Randomized controlled trial
RVGA	Rivermead Visual Gait Assessment
TIS-NV	Trunk Impairment Scale- Norwegian Version
2MWT	2-minute walk test
10MWT	10-metre walk test

1 INTRODUCTION

This thesis addresses balance and walking disturbances in ambulant individuals with multiple sclerosis (MS), group-based physiotherapy, and a newly developed, individualized, group-based physiotherapy intervention called GroupCoreDIST, which aims for participants´ recovery of balance and walking. Participation in GroupCoreDIST is explored through a mixed methods study including a randomized controlled trial (RCT) examining the effects on balance and walking compared to standard care and a qualitative interview study exploring individuals' experiences from participation. The integrated findings from these studies generate new knowledge regarding the varied assessments needed to detect balance and walking challenges in individuals with MS, what aspects of balance and walking were influenced in the short and long term by participation in the six-week GroupCoreDIST intervention, what principles may be advantageous in group-based interventions and the need for long-term follow-up of ambulant individuals with MS.

MS is the leading neurological cause of disability in young adults (Hauser, Oksenberg, & Baranzini, 2015; Ramagopalan & Sadovnick, 2011). Worldwide, 2.3 million people are estimated to be diagnosed (Browne et al., 2014; Multiple Sclerosis International Federation, 2013), and in Norway, approximately 11,000 individuals are affected (Berg-Hansen, Moen, Harbo, & Celius, 2014). This chronic, immune-mediated, inflammatory, demyelinating disease attacks the central nervous system (CNS) and affects the ability of neurons to deliver information within and between the sub-systems in the CNS. Depending on the sites of lesions, a variety of symptoms are common, such as somatosensory impairments, paresis, coordination problems, visual impairments, and reduced core muscle activation (Polman et al., 2011). Balance and walking difficulties are reported in 50-80% of the MS population and may occur even in the early stages when the disability is minor (Aruin, Kanekar, & Lee, 2015; Cattaneo, Jonsdottir, & Coote, 2014; Comber, Galvin, & Coote, 2017; Kalron & Givon, 2016; Langeskov-Christensen et al., 2017; Multiple Sclerosis International Federation, 2013).

Balance and walking problems are often linked to impaired postural control (Aruin et al., 2015; Comber et al., 2017; Comber, Sosnoff, Galvin, & Coote, 2018; Krishnan, Kanekar, & Aruin, 2012a, 2012b), which is defined as the ability to control the body's position in space to maintain stability while simultaneously being oriented towards the environment (Shumway-Cook & Woollacott, 2017, p. 154). Fundamental for this ability are anticipatory and compensatory postural adjustments that take place in the trunk and legs to prepare for predicted perturbations and/or as reactive corrections in response to unexpected displacements (Aruin et al., 2015; Comber et al., 2018; Drew, Prentice, & Schepens, 2004; Horak, 2006; Krishnan et al., 2012a; Schepens & Drew, 2004). Adequate core muscle activation and optimal somatosensory and musculoskeletal conditions in the feet and legs are important prerequisites for postural adaptations and, thus, for balance and walking. Dysfunctions in these body functions and structures, which occur frequently in individuals with MS, may lead to compensations and reduced movement quality and efficiency (Gjelsvik & Syre, 2016), a greater risk and fear of falling (Cameron & Lord, 2010; Gunn, Newell, Haas, Marsden, & Freeman, 2013; Nilsagård, Denison, Gunnarsson, & Boström, 2009) less activity than recommended (Casey, Coote, Galvin, & Donnelly, 2018), and reduced autonomy in participation (Cattaneo, Lamers, Bertoni, Feys, & Jonsdottir, 2017; Coote, Garrett, Hogan, Larkin, & Saunders, 2009; Pirker & Katzenschlager, 2017), and they may influence how individuals with MS feel and think about themselves and their opportunities in their daily life (Normann, Sørgaard, Salvesen, & Moe, 2013). Impaired balance and walking interfere with many aspects of and situations in daily life, and therefore, addressing them is important.

Physiotherapy is recommended as part of an often life-long, multidisciplinary health care follow-up for individuals with MS. A fundamental principle is individualization, that is, adapting therapy to each individual's problems and recourses. Individualization should be addressed at all levels of the International Classification of Functioning, Disability and Health (ICF) to maintain and restore a patient's body functions, structures and movement (impairment level) and to increase or cope with activities (disability level) as well as participation and environmental factors (participation level) in ways that are meaningful for the individual (Barker et al., 2014; Berno, Coenen, Leib, Cieza, & Kesselring, 2012; Coenen et al., 2011; Hukeland University Hospital, 2019; Karhula, Kanelisto, Ruutiainen, Hämäläinen, & Salminen, 2013; RIMS, 2012; World Confederation for Physical Therapy, 2015). Physiotherapy, conducted in individual or group settings, often aims to improve balance and walking (Rasova et al., 2016). The literature indicates that balance and walking challenges often occur early in individuals with MS; however, initiation of physiotherapy often takes place when the disability level is moderate or severe, that is, at a point at which irreversible neuronal damage and degeneration may already have occurred (Riemenschneider, Hvid, Stenager, & Dalgas, 2018). An early start of physiotherapy is recommended since individuals with low disability may have more potential for improvements due to possibilities for change in motor control and plasticity (Flachenecker, 2015; Lipp & Tomassini, 2015;

Riemenschneider et al., 2018). The Norwegian MS register states that the majority of Norwegian individuals with MS are in the low disability range (Expanded Disability Status Scale (EDSS) 0-3.5) (Aarseth, Smedal, Skår, & Wergeland, 2019), which may indicate that they may have potential for change in motor control through physiotherapy. In Norway, however, there is no clear structure to the physiotherapy follow-up of individuals with MS, and this issue should be considered in regard to their balance and walking problems.

Physiotherapy is safe and effective in improving balance, mobility, and quality of life and in reducing fatigue (Amatya, Khan, & Galea, 2019; Khan, Ng, Galea, & Amatya, 2017). In research, the content of interventions is rarely described in detail (Amatya et al., 2019; Khan et al., 2017), and new interventions should be clearly explained to facilitate implementation in clinical practice. Neurological physiotherapy is generally characterized by complexity involving intersubjective verbal, nonverbal and bodily (hands-on) interactions (Levin, Kleim, & Wolf, 2008; Øberg, Normann, & Gallagher, 2015). Professional choices and decision-making should be informed by evidence-based practice (EBP), which encourages the use of the best available evidence from systematic reviews and RCTs, blended with clinical experience, skills, understanding of the body and movement, traditions and intuition, and the patients' interests and resources in the particular environmental setting (Martinková et al., 2018; Veras, Kairy, & Paquet, 2016; World Confederation for Physical Therapy, 2015). Therefore, examinations of the potential short- and long-term effects of new interventions, such as GroupCoreDIST, is needed, and such examinations should be complemented with studies that explore the user perspective and the meaning of participation to guide clinical decision-making.

Group-based physiotherapy for individuals with MS is feasible, has demonstrated effects on balance (Paltamaa, Sjogren, Peurala, & Heinonen, 2012) and is economically efficient (Humphreys, Drummond, Phillips, & Lincoln, 2013). However, effect studies often have small sample sizes and short follow-up periods, and studies with adequate samples and long-term follow-ups are needed. Individualization has been questioned in regard to group-based physiotherapy in individuals with MS (Kalron et al., 2019; Plow, Mathiowetz, & Lowe, 2009), and little is known regarding user experiences from individualization in groups. Since group settings often involve 5-10 individuals, little is known regarding the effects of and user experiences of small groups. Group exercises are nevertheless documented to be motivating and to provide experienced improvements (Learmonth, Marshall-McKenna, Paul, Mattison, & Miller, 2013; Learmonth & Motl, 2016). Qualitative studies are often at a descriptive level, and theoretical generalization should be used to derive new knowledge (Brinkmann & Kvale, 2015; Malterud, 2016). Integrated knowledge from the effects of and user experiences from participation in individualized physiotherapy interventions conducted in small groups, with such effects and experiences being analysed in light of theoretical perspectives, is needed.

To meet the warranted demands for group-based interventions that capture comprehensive elements of balance, individualization and the integration of body functions, structures and activities, my principal supervisor and I have developed a new physiotherapy intervention called GroupCoreDIST (initially called GroupCoreSIT) (Normann, Salvesen, & Arntzen, 2016). In this individualized, high-dose intervention, core muscle (proximal/trunk) activation is addressed in coordination with distal tasks in all exercises. Exercises are performed with optimal movement quality through adequate alignment and adaptation to the base of support (BOS), and elements such as somatosensory activation, muscle length, larger muscle groups and dual-task activities are addressed (Normann, Zanaboni, Arntzen, & Øberg, 2016). To scientifically explore GroupCoreDIST and to fill the knowledge gap regarding its short- and long-term effects on balance and walking, as well as user experiences from participation, a mixed methods study including an RCT and a qualitative interview study was conducted. Concepts from dynamic systems theory and phenomenological elaborations of the pattern theory of self serve as analytical tools to clarify the users' reflections and to inform the general discussion of the integrated findings.

In the following chapter, I present the background of the study, including information of MS; its different types, pathogenesis, cause and diagnosis; and follow-up of individuals with MS in Norway, including neurological screening, medical treatment and possibilities for improvements. A thorough introduction of balance and walking disturbances in individuals with MS, including the postural control and neural sub-systems involved, follows. The background ends with a presentation of the system for physiotherapy for individuals with MS in Norway, including descriptions of individualization and a systematic presentation of the literature on effects and user experiences. Based on this background, the research questions and the integrated results and general discussion at the end of the thesis are presented.

2 MULTIPLE SCLEROSIS

Norway is considered a high-risk area for MS (Benjaminsen, Olavsen, Karlberg, & Alstadhaug, 2014; Browne et al., 2014), and the prevalence of 208 cases per 100,000 persons is reported to be increasing (Grytten, Torkildsen, & Myhr, 2015). In Nordland county, where the current study took place, the prevalence is 182.4 cases per 100,000 persons (Benjaminsen et al., 2014). This high number highlights the relevance of this study that explore new physiotherapy that possibly may improve the health care offer for this population.

2.1 Types of multiple sclerosis and its pathogenesis

MS often occurs between 30-40 years of age (Simonsen, Edland, Berg-Hansen, & Celius, 2017) and twice as often in women than in men (Multiple Sclerosis International Federation, 2013). The disease appears in different forms: 1) relapsing-remitting MS (85-90%), which is characterized by relapses (episodes of neurological dysfunction that last for 24 hours or more), followed by periods of remission; 2) secondary progressive MS, which occurs in 60-80% of those with initial relapsing-remitting MS and involves a gradual change over 10-15 years towards a more progressive course with or without relapses (Meyer-Moock, Feng, Maeurer, Dippel, & Kohlmann, 2014; Multiple Sclerosis International Federation, 2013); and 3) primary progressive MS, which has a progressive course with increased disability from the onset without relapses and occurs in 10-15% of the population (Brownlee, Hardy, Fazekas, & Miller, 2017; Thompson, Banwell, et al., 2018). A fourth form of MS with both a progressive and relapsing course occurs in 5% of individuals with MS (Multiple Sclerosis International Federation, 2013). These facts highlight a growing population with variability in impairments, disabilities and course of disease that may need high-quality follow-up from a young age.

The attacks seen in individuals with relapsing-remitting MS are autoimmune reactions where autoreactive lymphocytes cross the blood-brain barrier in the CNS and target myelin sheaths. Myelin sheaths are sleeves of fatty tissue formed in the CNS by glial cells called oligodendrocytes, which isolate and protect nerve cell axons and speed the transmission of action potentials. Damage to myelin sheaths initiates both impairments of nerve signals and an inflammatory process where the transmission of action potentials is damaged and constrained (Brownlee et al., 2017). Lesions in afferent, efferent and cognitive systems are common and vary in site, size and number, which determines the clinical picture (Dargahi et al., 2017; Grigoriadis & van Pesch, 2015; Houdayer, Comi, & Leocani, 2015). Attacks are followed by phases of remission and remyelinization through the development of oligodendrocytes in the lesion locations, generating myelin sheaths to once again promote rapid neurotransmission and opportunities for recovery. Recovery is not always complete, and when destruction of the neuron itself takes place, the damage is permanent and leads to an increased level of disability (Brownlee et al., 2017). In the progressive forms of MS, there is less inflammation; instead, more diffuse immune mechanisms and neurodegeneration come into play, often causing a more severe clinical status (Ontaneda, Thompson, Fox, & Cohen, 2017). These aspects indicate that the course of all types of MS is unpredictable and individual, and they underscore the relevance of individualized physiotherapy.

2.2 Cause and diagnosis

The cause of MS is not clear and involves a multifactorial integration of environmental and genetic factors (Thompson, Baranzini, Geurts, Hemmer, & Ciccarelli, 2018). Environmental elements such as vitamin D deficiency, obesity in early life, smoking, and infectious conditions that influence the immune system, increase the risk of developing MS (Thompson, Baranzini, et al., 2018). There is an increased heritability within families, and several genes are associated with MS (Thompson, Baranzini, et al., 2018). The diagnosis is based on evaluations of clinical symptoms, characteristic CNS lesions detected by magnetic resonance imaging (MRI) and laboratory findings (Thompson, Baranzini, et al., 2018), which in Norway are obtained in neurological departments at regional hospitals. The McDonald diagnostic criteria are also used to set the diagnosis (Polman et al., 2011; Thompson, Banwell, et al., 2018). The onset of MS usually includes a first episode of neurological dysfunction called a clinically isolated syndrome. A second relapse will indicate the start of a relapsing-remitting MS course (Thompson, Baranzini, et al., 2018). The primary progressive form of MS often starts with a slow onset of asymmetric paraparesis that evolves over months or years (Brownlee et al., 2017; Thompson, Banwell, et al., 2018). In all forms of MS, balance and walking deviations may develop even in the early phases (Aruin et al., 2015). When the diagnosis is set, a plan for medical treatment is established at a neurological outpatient clinic. However, a plan for physiotherapy follow-up is not automatically established, even though doing so may seem to be needed due to the complex clinical picture of individuals with MS.

3 FOLLOW-UP OF INDIVIDUALS WITH MS IN NORWAY

Norway is one of Europe's most sparsely populated countries, with its approximately five million inhabitants living spread over almost four hundred thousand square kilometres (World Health Organization, 2013). Life expectancy of healthy is 81.53 years, and of individuals with MS is on average 74.7 years (Lunde, Assmus, Myhr, Bø, & Grytten, 2017), indicating that long-term follow-up is often needed. In the following sections, I provide an overview of the usual follow-up in specialist and primary health care, the usual screening provided and brief remarks regarding medical treatment for individuals with MS. Plasticity and possibilities for improvements are also outlined, with a special focus on physiotherapy.

3.1 Follow-up in specialist and primary health care

The Norwegian health care system is well developed and built on principles of equal access to services. The system is semi-decentralized, with the state being responsible for specialist health care administered by four regional health authorities and with primary health care being located in municipalities (The Norwegian Ministry of Health and Care Services, 2017; World Health Organization, 2013). In Norway, monitoring the disease activity and function on a regular basis (often yearly) is recommended by monitoring attacks and MRI and EDSS scores. Such monitoring is performed by a neurologist (Aarseth et al., 2019) at a hospital with a neurological outpatient clinic and often also involves meetings with an MS nurse. A multidisciplinary team, including a physiotherapist, an occupational therapist, a speech therapist, and a urologist, is recommended (Barker et al., 2014); however, not all of these professions are routinely involved in treating all patients. Physiotherapy is regulated by law and should be available to the public in municipalities as both a treatment and a preventative service. Physiotherapy is conducted as inpatient treatment during hospitalization through time-limited stays at rehabilitation centres; however, it is most often conducted in outpatient settings in municipalities (The Norwegian Ministry of Health and Care Services, 2017). At the point of the study, physiotherapy was free to individuals with MS; nevertheless, a prior study documented that only 40% of individuals with MS (all EDSS levels) saw a physiotherapist (Svendsen, Myhr, Nyland, & Aarseth, 2012). This low number questions if there is a need for more structure, for improved quality, or for improved access to physiotherapists? Alternatively, perhaps these individuals do not need physiotherapy?

International recommendations state that individuals with MS should have access to a physiotherapist with expertise in MS for a specific assessment and to set individual goals and a realistic treatment plan (Barker et al., 2014). In Norway such access is often not possible since there are only 71 specialists in neurological physiotherapy, and only 21 of them work in the municipalities (Norwegian Physiotherapy Association, 2019). The density of specialists is not uniform throughout this long, rural country, and conducting group interventions may increase access to physiotherapists with competence in neurological physiotherapy.

3.2 Neurological screening

In yearly meetings with neurologists, the EDSS is commonly used to detect the impact of MS on the patient's neurological sub-systems and to record an overview of the person's disability status over time (Meyer-Moock et al., 2014). The EDSS is the most widely used MS-specific outcome measure in both clinical practice and research (Martin et al., 2006), and it was used in the current study. The scale ranges from 0 to 10, where 0 indicates no impairments and 10 indicates death. EDSS scores from 1 to 4.5 refer to individuals who are fully ambulatory, and impairments in 7 neurological systems are examined: 1) pyramidal impairment (weakness or difficulty moving limbs); 2) cerebellar impairment (ataxia, coordination problems or tremor); 3) brainstem impairment (speech, swallow, or eye movement problems); 4) sensory impairments; 5) bowel, bladder and sexual dysfunction; 6) visual function; and 7) cerebral/mental functions and fatigue. EDSS scores over 5 indicate an impact of MS on physical functioning, especially walking, and an EDSS score of 6.5 implies the possibility of walking 20 metres with or without a walking aid (Kurtzke, 1983). This type of screening is important to obtain an overview of the patient's clinical neurological status and may, for instance, indicate whether medications are working well. However, the EDSS scale has been criticized for its insensitivity in detecting functional impairments such as balance and walking abnormalities at lower EDSS levels prior to the onset of clinical disability (Martin et al., 2006). This issue accentuates the potential need for other more sensitive assessments to reveal balance and walking status.

3.3 Medical treatment

Medical treatment has substantially improved over the years, and several disease-modifying treatments are available for individuals with relapsing-remitting MS. These treatments target neuroinflammation and may have an indirect effect on neurodegeneration. New and improved effects of medications have led to a goal of *no evidence of disease activity* (NEDA), defined as no relapses, active MRI lesions or disability progression (Thompson, Baranzini, et al., 2018). Even if medical treatment has improved, evidence pinpoints that balance and walking problems still occur in individuals with MS (Aruin et al., 2015), suggesting that individuals with MS will need physiotherapy, even with the best medical treatment available.

Autologous haematopoietic stem cell transplantation (aHSCT) has received increased attention in recent years and is currently being tested in Norwegian clinical trials (Norwegian Multiple Sclerosis Competence Centre and Research Group, 2019). Even with promising results (Thompson, Baranzini, et al., 2018), individuals who receive aHSCT may already have impairments and disability and may need physiotherapy to regain function. For individuals with progressive forms of MS, there are fewer medications available, and, although fampridine has demonstrated effects on walking, physiotherapy is often the main treatment (Ontaneda et al., 2017). This fact highlights the need for studies that explore the status, effects and user experiences in regard to participation in an intervention that aims to improve balance and walking since individuals with MS may have balance and walking challenges even when the best medical treatment is available.

3.4 Possibilities for improvement: neuroplasticity and timing

Plasticity is the possibility for structural changes in all living tissues in the body, and it is an essential basis for motor learning and recovery (Nudo, 2006), which are often the aim of neurological physiotherapy. Neuroplasticity refers to the ability of the CNS to adapt to new ever-changing internal or external conditions, for instance, through reorganization, which contributes to recovery and/or compensation, development and learning after brain injury (Ibrahim et al., 2011; Lipp & Tomassini, 2015; Morgen et al., 2004; Tavazzi et al., 2018). In the CNS, plasticity takes place through changes in white matter, such changes in the number of axons, axonal diameter, fibre density, and axonal branching, trajectories and myelination;

additionally, plasticity takes place through changes in grey matter, such as neurogenesis, synaptogenesis and changes in neuronal morphology (Lipp & Tomassini, 2015). Such adaptations occur spontaneously after an MS relapse and may result in motor function recovery (Mezzapesa, Rocca, Rodegher, Comi, & Filippi, 2008). In physiotherapy, recovery of function refers to the ability to regain previous (before the attack or gradual progression) ways of performing movement and ADLs to the greatest extent possible (Levin et al., 2008). However, post-injury plasticity may be maladaptive in neuromuscular systems if the quantity of motor experiences is low and/or the quality of movements is characterized by compensatory movement strategies (Nudo, 2006, 2013). Compensation refers to new ways of moving to accomplish tasks, and as a result of compensation, the CNS may be reshaped in maladaptive ways (Kleim & Jones, 2008; Levin et al., 2008). Recovery-oriented interventions have demonstrated possibilities to facilitate reorganization and restoration of altered brain activity patterns (Tomassini et al., 2012). To achieve such neuroplastic changes, a high dose, volume and meaningfulness of experience from physiotherapy are important (Kleim & Jones, 2008). Recovery-oriented physiotherapy need to be individually adjusted, and need to highlight movement quality. These elements were implemented in GroupCoreDIST.

Exercise interventions in individuals with MS have demonstrated positive effects on immune modulation and activity-dependent plasticity, lowering tissue destruction and restoring CNS networks (Prosperini & Di Filippo, 2019; Riemenschneider et al., 2018). Physiotherapy is recommended to be initiated at an early stage, before the onset of large neurological impairments and disability (Riemenschneider et al., 2018), to avoid sustained compensatory ways of moving that may lead to learned non-use and avoidance of use of, for instance, a limb, as described following a stroke (Nudo, 2013; Nudo, Plautz, & Frost, 2001; Taub, Uswatte, Mark, & Morris, 2006). Physiotherapy may reduce the risk of lifestyle-related comorbidities and inactivity (Marck, Neate, Taylor, Weiland, & Jelinek, 2016), and by providing the best bodily conditions for movement, it may prepare individuals with MS for expected upcoming deterioration.

4 BALANCE AND WALKING PROBLEMS IN INDIVIDUALS WITH MS

Balance and walking challenges are well documented in individuals with MS (Comber et al., 2017; Comber et al., 2018). In the following sections, I describe and reflect on various aspects of balance and walking and define the physical activity level and number of steps as one aspect of walking. Outlining postural control, and the neural sub-systems involved in balance and walking may help in understanding the importance of performing a detailed and complex intervention such as GroupCoreDIST and serve as a background for discussing the integrated findings of this mixed methods study.

4.1 Balance

Balance is the ability to control the body´s centre of mass within the BOS (Shumway-Cook & Woollacott, 2017, p. 162). If the centre of gravity moves beyond the borders of the BOS, adjustments must be made to prevent falling (Ivanenko & Gurfinkel, 2018; Shumway-Cook & Woollacott, 2017, pp. 162-168). Adequate balance allows us both to stand still and to move with flexibility, variation and without unnecessary effort. It depends on sensory input (visual, vestibular and somatosensory) and adequate efferent neurological signals to provide postural equilibrium, adequate alignment of body segments with respect to gravity and optimal postural control mechanisms (Comber et al., 2018; Ivanenko & Gurfinkel, 2018). Impaired balance is related to a decreased ability to maintain position, limited and slowed movement towards the limits of stability, delayed adjustments to displacements and perturbation, and a reduced integration of dual-task activities (Cameron & Nilsagard, 2018; Huisinga, Yentes, Filipi, & Stergiou, 2012). Since balance is quite complex, it seems important to explore and address detailed aspects of it, such as sensory input, motor activity, tasks and the environmental setting, to treat balance problems.

4.2 Walking

When we move our body one step or more, the principles of balance are changed, as the goal of walking is to move the body outside the BOS yet prevent falling (Winter, 1995). A normal gait cycle is divided into a stance phase, which is approximately 60% long, and a swing phase, which is approximately 40% long (Pirker & Katzenschlager, 2017). During the stance phase, somatosensory information from mechanoreceptors in the feet provides important information regarding heel-strike, toe-off and weight transfer, and this information initiates extensor muscle activation, especially in the trunk (Gjelsvik & Syre, 2016; Holland & Lynch-Ellerington, 2009). Joint receptors and muscle spindles in the hip of the stance leg initiate the swing phase in the opposite leg as the hip extends, and the Golgi tendon apparatus sends signals that activate extension musculature and inhibit flexor muscles. The swing phase is mostly initiated by the rhythm, pendulum, momentum and acceleration of the body, propelling the body forward without much muscle effort (MacKay-Lyons, 2002; Shumway-Cook & Woollacott, 2017, pp. 318-319). Therefore, to deliver physiotherapy that aim to identify aspects relevant for walking in an individual with MS, it seems necessary for the physiotherapist to explore the feet's ability to adapt to the floor, the somatosensory capacity, the alignment within each body part and the interaction between body parts.

Great variability in gait patterns is reported in individuals with MS (Moon, Sung, An, Hernandez, & Sosnoff, 2016; Socie & Sosnoff, 2013). This variability includes increased use of compensatory postural adjustments and less variation in the movement repertory compared to healthy individuals, who change strategy based on the task and environmental challenges (Gjelsvik & Syre, 2016). A lower centre of gravity, an increased body sway in a quiet stance, delayed postural response latencies to perturbations and a reduced ability to move towards the limits of stability are reported, and these deficits lead to a reduced gait speed, a prolonged double support phase, and a decreased stride length, cadence and joint movement (Cameron, Horak, Herndon, & Bourdette, 2008; Cameron & Wagner, 2011; Huisinga, Mancini, Veys, Spain, & Horak, 2018; Huisinga, St George, Spain, Overs, & Horak, 2014; Krishnan et al., 2012b; Peterson, Huisinga, Spain, & Horak, 2016). One underlying cause of these problems is somatosensory deficits, which are reported in approximately 75% of individuals with MS (Kelleher, Spence, Solomonidis, & Apatsidis, 2009), for instance, decreased sensation under the feet caused by impaired nervous signals (Cameron et al., 2008; Shumway-Cook & Woollacott, 2017, pp. 328-331). This symptom is common even in individuals with mild to moderate disability (Citaker et al., 2011). Therefore, in physiotherapy, including physiotherapy conducted in group settings, it is important to explore and address the prerequisites for walking in individuals with MS, not only the whole task or activity.

4.2.1 Activity

The activity level and the number of steps are one aspect of walking that has received increased attention in recent years, and prior studies have reported that individuals with MS are less active than healthy individuals (Bassett, Toth, LaMunion, & Crouter, 2017; Casey, Coote, Galvin, et al., 2018; Motl, McAuley, Sandroff, & Hubbard, 2015; Motl, McAuley, & Snook, 2005). An average of 18.4 minutes of moderate activity per day is reported in individuals with MS (Casey, Coote, Galvin, et al., 2018). This amount is less than the 30 minutes of moderate activity per day recommended by guidelines (Ezeugwu, Klaren, A. Hubbard, Manns, & Motl, 2015; Garber et al., 2011) and slightly less than the minimum of 150 minutes of moderate activity or 75 minutes of vigorous activity per week recommended by Norwegian health authorities (B. H. Hansen et al., 2015; B. H. Hansen et al., 2019). For mild to moderate MS, the recommendations are as low as 30 minutes of moderate activity twice a week (Latimer-Cheung et al., 2013). It has also been suggested that increasing disability decreases the level of activity (Marck et al., 2014). In individuals with minor disability, the recommendations for MS seem low, especially since a low EDSS score is not an indication of walking problems. Therefore, it is questionable whether the recommendations for persons with low disability should be compared to those for healthy individuals.

The Tudor-Locke and Bassett classification system (2004) categorizes the number of steps per day as follows: <5000 as a sedentary lifestyle, 5000-7499 as physically inactive, 7500-9999 as moderately active, ⊵ 10,000 as physically active and ⊵ 12,500 as very active (Bassett et al., 2017; Tudor-Locke & Bassett, 2004). Studies of individuals with MS report an average of 5903 steps (standard deviation (SD) of 3185, 95% confidence interval (CI) of 5657-6149) (Dlugonski et al., 2013) and an average of 5840 steps (SD of 3096) (Casey, Coote, Galvin, et al., 2018) per day. It has been suggested that such low amounts of physical activity signal a public health problem (Block et al., 2016; Motl et al., 2015) and may create comorbid conditions in individuals with MS (Casey, Coote, Galvin, et al., 2018). No specific recommendations have been made for individuals with MS; however, a value of 7100 steps per day has been recommended for healthy older adults and special group populations (Tudor-Locke et al., 2011). Little is known with regard to whether a balance intervention can influence the number of steps or activity level, and it seems important to record the number of steps and activity level in individuals with MS who have both minor and moderate disability.

4.3 Postural control in balance and walking

Postural control consists of controlling the body’s position in space for the dual purposes of maintaining stability against gravity and coordinating the various parts of the body while simultaneously being oriented towards the environment in ADLs (Shumway-Cook & Woollacott, 2017, p. 154). Normally, all movements start, proceed and end with postural adjustments, which include a fine-tuned interplay between feed-forward mechanisms, also called anticipatory postural adjustments, and feedback mechanisms, also called compensatory postural adjustments (Comber et al., 2018; Horak, 2006; Santos, Kanekar, & Aruin, 2010). Anticipatory postural adjustments are minor adjustments occurring in the trunk and legs that prepare us for predictable perturbations and control for displacements during action (Aruin et al., 2015; Drew et al., 2004; Krishnan et al., 2012a; Schepens & Drew, 2004), for instance, as a person reaches out for a glass in an upper kitchen cabinet. Compensatory postural adjustments are reactive corrections that restore balance in case of sudden or unpredictable displacements (Aruin, 2016), and include larger displacements of the COM (Santos et al., 2010). Anticipatory postural adjustments may be ineffective due to somatosensory impairments, paresis, muscular adaptive shortenings or pathological increased tone, which may compromise the coordination between body parts, and lead to an increased use of compensatory adjustments (Aruin, Ganesan, & Lee, 2017; Ivanenko & Gurfinkel, 2018; Krishnan et al., 2012a, 2012b; Mohapatra, Krishnan, & Aruin, 2012; Santos et al., 2010). Changes in anticipatory and compensatory postural adjustments may interfere with balance and walking in ADLs; therefore, it is important for new physiotherapy interventions for individuals with MS to take such changes into account.

Anticipatory postural adjustments are based on experience and learning, our bodily constraints, our body schemas, internal information regarding the relationship to the BOS and between body parts, and external information and integration of the task and the environment (Ivanenko & Gurfinkel, 2018; Shumway-Cook & Woollacott, 2017, pp. 170-171). Normal walking is highly dependent on adequate postural control mechanisms to be precise, without effort and adapted in regard to the task and the environment (Holland & Lynch-Ellerington, 2009; Nielsen & Sinkjaer, 2002). Movement with adequate power and precision requires sufficient activation of core and leg muscles and optimal biomechanical, somatosensory and musculoskeletal conditions in the trunk, feet and legs. Therefore, interventions that address these prerequisites for balance and walking seem necessary.

4.3.1 Ankle, hip, stepping and reaching strategies

When unexpected displacements occur, compensatory strategies involving synergies of muscle activity come into play to restore balance. These strategies are called ankle, hip, stepping and reaching strategies, and they require good biomechanical and musculoskeletal conditions (Kandel & Mack, 2013). With minor displacements and low frequencies, healthy individuals first use distal to proximal activation starting with muscles near the BOS, called the ankle strategy, to prevent body sway (Shumway-Cook & Woollacott, 2017, p. 165). In the case of larger displacements and higher frequencies, when the COM reaches the border of the BOS, healthy individuals mix the ankle strategy with the hip strategy (Huisinga et al., 2018), which involves a proximal to distal activation of core, back and hip muscles (Shumway-Cook & Woollacott, 2017, p. 166). Individuals with MS are reported to use a mix of ankle and hip strategies regardless of sway frequency (Huisinga et al., 2018). This usage is less favourable, may be a result of inadequate sensorimotor activation and biomechanical conditions, and may lead to the development of inexpedient compensatory movement patterns over time (Francis & Song, 2011). These aspects will have consequences for the the choice of focus in a physiotherapy intervention and choices of outcome measures in a study, as both should emphasize ankle and hip strategies.

When the COM is displaced beyond the BOS, the stepping strategy is used to restore balance, presupposing that we are able to move from double to single stance. Individuals with MS tend to use more compensatory steps than healthy individuals (Peterson et al., 2016), which may increase the risk of falling (Cameron & Lord, 2010; Cattaneo et al., 2017; Nilsagård et al., 2009). Arm strategies are the last chance to prevent falling and involve reaching out at something to establish a new BOS (Gjelsvik & Syre, 2016). To succeed in this strategy, dynamic activation of proximal trunk and shoulder muscles enables the arm to reach out rapidly. In all responses both trunk and lower and upper arm muscles are coordinated (Marigold & Misiaszek, 2009). This fact indicates the need for interventions that address the relationship between body parts and improvements of bodily constraints that make ankle, hip and stepping strategies possible and effective.

4.3.2 Dynamic core stability

Core stability, trunk stability and trunk control are terms that have been used in various ways and that have sometimes been used to describe the same phenomenon in neurological physiotherapy. Even in the 1960s, the Bobath concept used the term trunk stability, emphasizing that alignment of the trunk and proximal stability base was important for effortless movement of the arms and legs (Raine, Meadows, & Lynch-Ellerington, 2009). The "core stability" concept was first theorized by Panjabi(1992a, 1992b) in a model that emphasized core stability as interconnections in the non-contractile tissues, the contractile tissues, and the neural control sub-system (Panjabi, 1992a, 1992b). This concept was expanded in a more comprehensive model where stabilizing systems and mobilizing sub-systems work in an integrated manner and separately to achieve motor control via synergistic neuromuscular relationships (Hoffman & Gabel, 2013). It was theorized that malfunction in any sub-system, for instance, due to neurological impairment, would affect the other systems and impact motor control (Hoffman & Gabel, 2013), especially with respect to delayed timing and recruitment of local stability systems (Gibbons, 2001). No universally accepted definition of core stability has been outlined. The current study and the GroupCoreDIST intervention lean on the definition by Kibler, Press, Sciascia (2006) that core stability is the ability to control the position and motion of the trunk over the pelvis and legs to allow optimum production, transfer and control of force and motion, where both the global[1] and local muscles[2] of the pelvis and trunk, and the joints of the hip, pelvis and spine perform many stabilizing functions required for the distal segments (e.g the limbs) to do specific function. The proximal area contributes in a fine-tuned coordination with the global mobilizers of the upper extremities[3] and lower extremities[4] to achieve optimal movement control (Kibler et al., 2006). I feel that the term "dynamic core stability" captures this coordinated relationship.

The anatomical core in addition to the musculature also includes the bony structures (column, rib cage, shoulder girdle and pelvic girdle), passive tissues (ligaments and cartilage), (Williardson, 2014, p. 3). Different tasks require different activation patterns (Borghuis, Hof, & Lemmink, 2008; Cholewicki & VanVliet Iv, 2002; Williardson, 2014, p. 9). The local core muscles are important for coordination and control of motion segments because they are closer to the spinal column (Kibler et al., 2006). The global core muscles have a larger mass

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[1] The global muscles include m. erector spinae, m. quadratus lumborum, m. rectus abdominis, and the external and internal oblique abdominis.

[2] The local muscles include m. transversus abdominis, m. multividus, m. rotatores, m. intertransversalis, interspinalis, diaphragm and the pelvic floor group.

[3] The global mobilizers of the upper extremities include m. pectoralis major and minor, m. latissimus, m. trapezius, m. serratus anterior, and m. rhomboideus.

[4] The global mobilizers of the lower extremities include m. iliopsoas, m. gluteus maximus and medius, and m. hamstrings.

and a longer moment arm of force and may create more forceful movements (Borghuis et al., 2008). Trunk muscle activation is imperative for monitoring displacements and optimizing steps while walking (Huisinga et al., 2014), and this activation is often impaired in individuals with MS (Comber et al., 2018; Horak, 2006). This impairment may lead to fewer and shorter steps (Sosnoff, Sandroff, & Motl, 2012), a reduced walking speed (Cameron & Lord, 2010) and an increased use of compensatory strategies (Kleim & Jones, 2008). Normally, heel-strike during walking facilitates extensor activity in trunk muscles (Anders et al., 2007; Winter, 1995), meaning that inadequate alignment or adaptation to the BOS or motor activation that causes impaired heel-strike will mean less adequate core muscle activation during walking. This implies that it is important to emphasize the relationship between the core and distal body segments, not only activity in single muscles or the balance or walking task as a whole.

4.4 Neural sub-systems involved in balance and walking

The neural sub-systems involved in balance and walking are organized in networks involving afferent, efferent, perceptual, cognitive and emotional systems. The afferent systems deliver somatosensory information from receptors in the skin, joints and muscles to the CNS through the lemniscus medialis (pressure, touch, vibration, joint position), spino-thalamic (temperature, pain) and spino-cerebellar tracts (muscle spindle, Golgi tendon apparatus) (Brodal, 2010, pp. 183-189). The tracts are organized in a somatotopical manner, meaning that the CNS “knows” – on a pre-reflective level – the position of the body, the projection of the line of gravity, what parts of the body constitute the BOS. The information provide continuously updated body schemas or “inner models” of the body (Brodal, 2010, pp. 164-165). Since individuals with MS often have balance and walking problems related to sensory impairments (Arpin, Gehringer, Wilson, & Kurz, 2017), it is vital to address these systems in physiotherapy.

The efferent systems are informed by continuously updated body schemas and provide motor output (Brodal, 2010, pp. 164-165). The cognitive and emotional systems provide important information to interpret the situation and plan adequate actions directed towards the environment. Proximal and axial activity is provided by the ventromedial system (the cortico-reticulospinal, cortico-rubrospinal and vestibulospinal systems). The reticular formation regulates tone via both crossed and uncrossed tracts, indicating that both sides of the trunk may be affected after the appearance of lesions on one side of the tract (Brodal, 2010, p. 380;

Ivanenko & Gurfinkel, 2018). The vestibulospinal tract is uncrossed and the fastest system, and it provides rapid activation of extensor muscles in extended postures. This system relies on somatosensory and vestibular information and is particularly activated after small displacements (Ivanenko & Gurfinkel, 2018); therefore, it is essential for balance. The cortico-spinal tract is mainly crossed and is closely informed by somatosensory sustems to, provide modulation and selective movement in the hands and mouth (Brodal, 2010, pp. 301-308). The cerebellum receives afferent information from all sub-systems and delivers efferent information to coordinate movements (Brodal, 2010, p. 152; Ivanenko & Gurfinkel, 2018). The recruitment of postural stability prior to movement of the extremities implies that the ventromedial systems are activated prior to the ventrolateral systems and are well coordinated by the cerebellum. This is linked to the size principle of recruitment, also called Henneman's recruitment principle, which suggests that motor units consisting of tonic muscle fibres are recruited before those consisting of phasic fibres (Brodal, 2010, p. 288). Tonic, slow muscle fibres in the trunk and neck are resistant to fatigue and have a low energy cost (Ivanenko & Gurfinkel, 2018). Thus, the network organization support the need for interventions that address coordination between proximal and distal body areas to improve balance and walking and between afferent and efferent systems.

5 PHYSIOTHERAPY FOR INDIVIDUALS WITH MS

Physiotherapy for individuals with MS has changed dramatically over recent decades, from the outdated beliefs that exercise and activity would lead to increased symptoms (Döring, Pfueller, Paul, & Dörr, 2011) and to the current recommendations of a high volume, dose and intensity through activity-dependent interventions that aim to optimize the motor control or physical aspects of balance and walking (Freeman & Gunn, 2018). Norwegian guidelines recommend a detailed physiotherapy follow-up tailored to the individual from the onset of MS (Hukeland University Hospital, 2019). Such physiotherapy may be conducted in individual settings, where the physiotherapist provides full attention to one patient, or in groups, which may vary in size and structure and involve three or more participants who interact to different degrees and in different ways. The content of clinical practice for individuals with MS varies across Europe (Rasova et al., 2010). Both task-specific interventions, such as the motor relearning programme(Carr & Shepherd, 2010), neuro-facilitation approaches, such as the Bobath concept (Bobath, 1990; Gjelsvik & Syre, 2016; Raine et al., 2009; Vaughan-Graham & Cott, 2016), and physical training, such as strength-endurance training and exercise therapy (Dalgas, Stenager, & Ingemann-Hansen, 2008; Kjølhede, Vissing, & Dalgas, 2012) are common. The majority of studies examine varied types of physical training, which often aim to improve balance and walking (Martinková et al., 2018). No intervention has been demonstrated to be superior in regard to its effects on balance and walking (Amatya et al., 2019; Garrett & Coote, 2009; Hogan & Coote, 2009; Khan et al., 2017; Motl et al., 2017). When creating the new GroupCoreDIST intervention, the important principle of individualization was emphasized. I will, therefore, describe individualization in individual- and group-based settings. An overview of the knowledge base regarding the effects of and user experiences from balance and walking interventions will furthermore be highlighted.

5.1 Individualization

Individualization consists of exploring the uniqueness, resources and needs of a person at all levels of the ICF (Gjelsvik & Syre, 2016; Raine et al., 2009; RIMS, 2012). Doing so is particularly important in individuals with MS since in their situation, the variety of symptoms, disability status and progression can rapidly change. Descriptions of how individualization is conducted are rarely emphasized in studies; however, individualization may cover individual adaptations of volume, dose and intensity, the types of exercises, and hands-on adaptations (Normann, 2018; Øberg et al., 2015). All types of individualization require updated knowledge of the patient's ways of moving. Hands-on facilitations are to make movement easier and to improve movement quality (Normann, 2018; Vaughan-Graham & Cott, 2016). Such interactions require the physiotherapist to have explored deviations from normal movement and in the moment respond to the patient´s actions (Normann, 2018; Øberg et al., 2015). Meeting such requirements may be challenging in a group setting where the physiotherapist needs to respond to many persons.

Individualization in group settings has been questioned (Kalron et al., 2019; Plow et al., 2009). In GroupCoreDIST, we decided to implement an individual clinical examination prior to the start of group sessions, which is in line with requirements (The Norwegian Health Economics Administration, 2019) and recommendations (Higgs, 2008). The importance of such an examination was recently documented by Lahelle et al. (2018a, 2018b), who argue that individualization is possible in group settings through a clinical examination including analysis of body and movement in relation to tasks and the environment. Individual knowledge and possibilities to choose from exercises with different levels of difficulty provide options for individual adaptations in small groups (Lahelle et al., 2018a, 2018b). Individualization is important to the symptoms and impairments that limit individuals' autonomy in ADLs and to create the best possible bodily conditions for movement and activity to facilitate life-long participation in age-relevant activities.

Individualized programs may stand in contrast to a standardized set of exercises that is often examined in RCTs. EBP has been criticized for finding effects from standardized interventions more important than addressing the complexity of clinical practice or elements experienced as meaningful for participants (Ekeland, 2009, p. 156). Therefore, it is necessary to develop individualized interventions that are explored in mixed methods studies to create more detailed guidelines for treating balance and walking deviations in individuals with MS.

5.2 Effects of individual- and group-based physiotherapy on balance and walking

Physiotherapy (exercises and physical activity) for individuals with MS improves mobility, balance, muscle strength, aerobic capacity, ADLs and quality of life (Amatya et al., 2019; Khan et al., 2017); however, the evidence that exercise therapy improves balance and symptoms is low in quality (Amatya et al., 2019). Most evaluated interventions provide poor descriptions of their content (Rietberg, Brooks, Uitdehaag, & Kwakkel, 2005) and often lack information regarding settings, intensity and duration, making the studies difficult to implement in clinical practice (Khan et al., 2017). Therefore, more high-quality studies that include details of the content of the interventions are needed.

5.2.1 Individual interventions

I conducted a systematic search for literature that revealed several studies exploring the effects of individual-based physiotherapy and exercise interventions on balance and walking in individuals with MS[5]; however, the searches may not have revealed all studies in this area. Exercise therapy is demonstrated to improve muscle power, exercise tolerance and mobility compared to no exercise, but not to improve activity or participation (Rietberg et al., 2005). The term “exercises” is in review studies often used to cover both non-specific exercises, activity and general training in groups or individually, as well as various forms of core stability or balance interventions. The wide use of the term makes it difficult to implement results from such studies in clinical practice. Detailed balance interventions provide large effects on balance (Gunn, Markevics, Haas, Marsden, & Freeman, 2015; Hogan & Coote, 2009; Paltamaa et al., 2012) and walking (Gunn et al., 2015; Latimer-Cheung et al., 2013). In a review by Gunn et al. (2015), the most effective programmes included exercises in standing and single leg standing, which are already implemented in the GroupCoreDIST.

Aerobic training and resistance training improve walking speed and endurance (Pearson, Dieberg, & Smart, 2015), balance (Paltamaa et al., 2012) and mobility, even in individuals with progressive forms of MS (Campbell et al., 2016). Physiotherapy, aerobic exercise, resistance exercises and yoga demonstrate effects on mobility (Hogan & Coote, 2009). Exercises conducted in supervised settings are significantly more effective than those conducted in unsupervised settings (Paltamaa et al., 2012; Snook & Motl, 2009). GroupCoreDIST involves both supervised group settings and unsupervised home exercises.

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[5] Lates search conducted 1th October 2019 in Ovid’s Medline, Ovid’s Embase, PubMed and PEDro. Search strategy: Subject heading ”multiple sclerosis” AND (physiotherapy OR physical therapy OR ”exercises”). This was separately complimented with AND ”balance” and including AND ”walking as well as AND ”activity”.

Furthermore, progressive resistance training improve lower extremity muscle strength (Dalgas et al., 2008; Kjølhede et al., 2012), mobility and functional capacity (Cruickshank, Reyes, & Ziman, 2015; Latimer-Cheung et al., 2013), effects on walking (Kjølhede et al., 2012) and effects on balance (Edwards & Pilutti, 2017; Hogan & Coote, 2009). The strength element was not considered as a part of the GroupCoreDIST; however, the participants conducted up to 3x10 repetitions of exercises, which may have added an element of strength if they conducted as many repetitions as they could possibly manage. Considering that balance and walking are complex tasks and varied symptoms in individuals with MS, more comprehensive exercises may be needed.

Endurance training, such as cycling, treadmill walking and aquatic exercises provides effects on aerobic capacity and improvements in ADL (Dalgas et al., 2008; Latimer-Cheung et al., 2013). Gait velocity has, however, been reported both to decrease, be unaffected and to improve, and training intensity is reported to be poorly controlled (Dalgas et al., 2008). Gait training on a treadmill improves gait speed and endurance (Robinson, Dennett, & Snowdon, 2019; Swinnen et al., 2012); however, the effects on over-ground walking are unclear (Robinson et al., 2019). These varying results are perhaps not so surprising considering that balance and walking are complex activities and that the problems of individuals with MS initially is not related to endurance but is neurological. The GroupCoreDIST did not have any elements that could potentially lead to increased endurance and did not even involve walking.

Physical activity-directed interventions are furthermore demonstrated to be effective on physical activity in regard to subjective but not objective outcomes (Casey, Coote, Hayes, & Gallagher, 2018; Coulter, Bond, Dalgas, & Paul, 2018). Short-term effects are also demonstrated after web-based physical activity programmes in ambulant individuals with MS (Dennett, Gunn, & Freeman, 2018). However, knowledge of the effects on physical activity level after balance interventions is sparse.

Since an important part of the GroupCoreDIST was activation of core muscles, a detailed search for literature regarding core stability training was conducted[6]. In regard to core stability training, reviews of Pilates training have reported significant improvements in physical function; however, not significantly better than other physiotherapy approaches

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[6] Latest search conducted 1th May 2019 in Ovid's Medline, Ovid's Embase, PubMed and PEDro. Search strategy: Subject heading ”multiple sclerosis” AND (core training OR core stability OR ”Pilates”). This was separately complimented with AND ”balance” and including AND ”walking.

(Byrnes, Wu, & Whillier, 2018; Sánchez-Lastra, Martínez-Aldao, Molina, & Ayán, 2019). Specifically, individual Pilates exercises have demonstrated within-group effects on walking compared to standardized exercises (Duff et al., 2018b; Kalron, Rosenblum, Frid, & Achiron, 2017) and within-group effects on balance (Küçük, Kara, Poyraz, & İdiman, 2016; Marandi, Nejad, Shanazari, & Zolaktaf, 2013) and sensory integration (Soysal Tomruk, Uz, Kara, & İdiman, 2016). No differences were found between Pilates and standardized exercises (Fox, Hough, Creanor, Gear, & Freeman, 2016). Pilates versus home-based exercises provided significant between-group effects on walking (Guclu-Gunduz, Citaker, Irkec, Nazliel, & Batur-Caglayan, 2014), and two smaller studies demonstrated short-term improvements in walking after Pilates (Freeman & Allison, 2004; Freeman et al., 2010). Most of these studies did not report between-group effects, making it difficult to evaluate whether the examined intervention was better than what it was compared to. In contrast to GroupCoreDIST, Pilates exercises involve cognitive attention and voluntary activation of core muscles coordinated with breathing, and they lack the focus on tasks; however, they may have similarities through the focus on posture and precision (Fox et al., 2016; Wells, Kolt, & Bialocerkowski, 2012). GroupCoreDIST is inspired by elements from many individual interventions and is interlinked with important elements from group settings.

5.2.2 Group-based interventions

I conducted a systematic search for literature regarding group interventions that revealed several studies exploring the effects of balance and walking in individuals with MS[7]; however, all studies in this field may not have been revealed. Group exercises have demonstrated small and non-significant overall effects on balance (Paltamaa et al., 2012; Stephens, DuShuttle, Hatcher, Shmunes, & Slaninka, 2001).A few studies have demonstrated effects on balance and/or walking after group-based core stability and balance training (Carling, Forsberg, Gunnarsson, & Nilsagård, 2016; Forsberg, von Koch, & Nilsagård, 2016; Freeman & Allison, 2004; Learmonth, Paul, Miller, Mattison, & McFadyen, 2012; Nilsagård, Von Koch, Nilsson, & Forsberg, 2014; Normann, Salvesen, et al., 2016; Stephens et al., 2001;

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[7] The most recent search was conducted 10 October 2019 in Ovid's Medline, Ovid's Embase, PubMed and PEDro.
The search strategy was as follows: subject heading ”multiple sclerosis” AND (physiotherapy OR physical therapy OR “exercises”) AND (“group”). This strategy was complemented with AND “balance” AND “walking” separately as well as with AND “activity” separately.

Tarakci, Yeldan, Huseyinsinoglu, Zenginler, & Eraksoy, 2013). Most of these studies had short follow-up periods, did not include individuals with minor disability, did not include detailed descriptions of the interventions or the group environment and lacked interventions that addressed the comprehensive prerequisites for balance and walking. Comprehensive interventions (Dodd, Taylor, Denisenko, & Prasad, 2006; Learmonth et al., 2012) and interventions that emphasize individualization in groups are called for (Kalron et al., 2019; Plow et al., 2009). Group-based training is considered economically beneficial (Humphreys et al., 2013). There is a need to create and explore new group-based, individualized interventions such as GroupCoreDIST.

To summarize the evidence, no individual- or group-based intervention has been demonstrated to be superior (Cattaneo, Jonsdottir, Zocchi, & Regola, 2007; Kelleher et al., 2009; Lord, Wade, & Halligan, 1998; Stephens et al., 2001; Wiles et al., 2001). Studies often have small sample sizes, are seldom stratified according to the disability level, have short follow-up periods, and scarcely describe the content of the interventions, making them difficult to reproduce and implement in clinical practice. Studies that address these features are requested (Hogan & Coote, 2009; Paltamaa et al., 2012). Surprisingly, few studies examine balance interventions that focus on integration of sensory and motor systems, which are all core elements of balance. All these elements indicate a knowledge gap and a need for comprehensive, individualized interventions based on the theoretical foundations of balance, such as GroupCoreDIST, examined through short- and long-term follow-up.

5.3 User experiences from individual- and group-based physiotherapy

A systematic search for literature was conducted for qualitative studies exploring user experiences from individual- and group-based physiotherapy[8]. A relatively low number of studies were found, and there may have been studies that were not detected by my searches. It is documented that exercises and physical activity is experienced to maintain physical functions, to increase participation and perceptions of self-management and control,

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[8] The most recent search was conducted 15 October 2019 in Ovid's Medline, Ovid's Embase, PubMed and PEDro.
The search strategy was as follows: subject heading "multiple sclerosis" AND (physiotherapy OR physical therapy OR "exercises") AND "user-experiences".

especially when feelings of accomplishment were perceived. Fatigue and feelings of frustration and loss of control were common negative experiences, (Learmonth & Motl, 2016). Adequate exercises and peer support is experienced to facilitate activity, and less adequate advice to be a barrier (Learmonth & Motl, 2016). Both positive and negative outcomes from exercises are important to take into account in individual and group settings.

5.3.1 Individual interventions

Individual physiotherapy may facilitate higher levels of physical activity and is experienced as motivating and enabling (Smith, Hale, Mulligan, & Treharne, 2013). It is also experienced to improve and maintain function and health, to improve self-efficacy and to provide perceptions of hope and optimism (Kasser, 2009). It has been documented that a feeling of exercise self-efficacy is important for facilitating exercise participation in individuals with MS (Stroud, Minahan, & Sabapathy, 2009). Perceived control provide self-efficacy, and influence the exercise experience (Smith, Hale, Olson, & Schneiders, 2009; Smith, Olson, Hale, Baxter, & Schneiders, 2011). An increasing disability level is found to limit participation in exercises and activity (Borkoles, Nicholls, Bell, Butterly, & Polman, 2008). These individual elements are important to consider in group settings, and in particular, the findings regarding self-efficacy indicate that it is also important to emphasize individual elements and individual feelings of success in a group setting.

One study explored the potential for change in movements through individual physiotherapy sessions, addressed through a combination of hands-on and verbal interactions (Normann et al., 2013). In this study, the perception of improvements in a body part, movement or functional activity, integrated with the physiotherapist's explanations of balance and walking, was emphasized to expand the insights of individuals with MS and to promote autonomy and self-encouragement (Normann et al., 2013). Therefore, perceptions of improvements may be important to address, and such perceptions were emphasized when developing GroupCoreDIST. As a result, we aimed for the physiotherapist and the patients to explore possibilities for change both in the clinical assessment and in the group sessions.

5.3.2 Group-based interventions

Group-based exercise programmes have been reported as being social (Dodd et al., 2006; Learmonth, Marshall-McKenna, et al., 2013), being motivating, to increase energy, empowerment and knowledge of training and to reduce fatigue (Clarke & Coote, 2015). For individuals with MS, the provision of peer support is experienced as valuable in regard to the management of their disease (Aubrey & Demain, 2012; Kasser, 2009). Group settings are also experienced as providing improvements in ADLs and as increasing body confidence and posture (Carling, Nilsagård, & Forsberg, 2018; Crank et al., 2017; Dodd et al., 2006; Van Der Linden et al., 2014). Frustration due to comparison to others in the group, experiences of increased fatigue and lack of service have been reported as barriers (Learmonth, Marshall-McKenna, et al., 2013; Learmonth & Motl, 2016). In summary, group interventions may improve physical and psychosocial factors of both positive and negative nature, and overall, rather few studies are available. The qualitative studies that have been reported were primarily descriptive and lacked analysis in light of theoretical perspectives, which may provide us with more general knowledge. The knowledge base is limited, especially in regard to comprehensive individualized interventions that address the prerequisites for balance.

5.4 GroupCoreDIST

GroupCoreDIST is initiated by an individual examination conducted by the group-leading physiotherapist, including the patient history, observations, movement analysis and hands-on interactions of individual resources for and constraints to movements; immediate improvements in symptoms and movement control are also considered (appendix 5: description of GroupCoreDIST). The assessment is ideally conducted as a collaborative and detailed process through a combination of dialogue and movement analysis, observations of posture, movements and activities, with a specific focus on the trunk in relation to the distal parts of the body with regard to balance and walking. Hands-on interactions to improve alignment and adaptation to the BOS and to thus explore possibilities for change in movement control and balance are integrated to enable the physiotherapist to plan the upcoming sessions.

The group sessions are conducted in groups of three individuals with MS and are led by a physiotherapist. They are conducted for 60 minutes three times per week for six weeks, together with additional home exercises for 30 minutes two times per week. There are 33 exercises that all have 5 levels of difficulty; thus, all group members perform the same exercise simultaneously, though at different levels of difficulty. The exercises are performed barefoot in a variety of postural sets. Verbal instructions and hands-on facilitation are encouraged to improve movement quality, to decrease inexpedient compensatory movement patterns and to optimize the movement experience. In the training, there is a high focus on experiences of immediate changes in performance, which are linked to changes in the individual's constraints to movement and the patient's (and physiotherapist's) experiences of improvements and the meaningfulness of movements.

In all exercises, coordinated and dynamic activation of core muscles is nested with a distal task (CoreDIST) performed in optimal bodily alignment and movement quality. Important parts of the training are DIST, where D stands for high-***D****ose* training and the ***D****ual-task* nature of the training, i.e., motor-motor and motor-cognitive; I stands for ***I****ndividualization*, which specifically relates exercises, variations, adjustments and interactions to each individual's constraints to movement, which is based on an ***I****ndividual physiotherapy assessment*, and which aims to provide new ***I****nsights* through movement changes; S stands for ***S****omatosensory activation* in the hands and feet as well as ***S****elective movement* or the ability to move some parts of the body while keeping others still; and T stands for ***T****eaching* how to conduct ***T****raining* that is specifically tailored to each person´s impairments.

The group sessions start and end with an individual exploration of own balance to perceive and reflect on own balance (balance "check-points"). This provide an opportunity for the physiotherapist to verbalize improvements and to interlink individual resources and impairments to ADLs and the choice of exercises. The exercises are individualized for each person's main challenges by choosing from the five levels of difficulty, hands-on adaptations to make the exercises possible and to improve movement quality, and by adding additional challenges such as advanced motor-motor or motor-cognitive dual tasks. Six exercise categories were included in all sessions: 1) somatosensory activation of the hands or feet by rolling a spiky ball; 2) muscle length-enhancing concentric and eccentric activity in the muscles of the neck and upper and lower limbs; 3) selective movement and coordination by keeping one part of the body still while moving another; 4) activity in larger muscle groups in standing, for instance, performing a calf rise on one leg while holding a large therapy ball in contact with the stomach; 5) advanced challenges for balance and postural control, such as jumping; and 6) relaxation by systematically performing contraction-relaxation of parts of the body (hold-relax).

6 STUDY AIMS AND RESEARCH QUESTIONS

This mixed methods study aimed to explore the participation of ambulant individuals with MS in GroupCoreDIST by studying the effects on various aspects of balance and walking compared to standard care as well as user experiences from participation. We addressed the following overall research question:

"What are the possible advantages of participation in 6 weeks of GroupCoreDIST in terms of balance and walking status, effects and user experiences in ambulant individuals with MS?"

The following secondary research questions were addressed in the three papers included:

Paper 1: *"What are the short- and long-term effects of GroupCoreDIST compared to standard care on balance and trunk control in ambulant persons with MS?"*
Paper 2: *"What are the immediate and long-term effects of GroupCoreDIST compared to standard care on walking in individuals with MS?"*
Paper 3: *"What are the short- and long-term perceptions and reflections of ambulant individuals with MS regarding participation in an individualized, group-based intervention, particularly regarding individualization and potential bodily changes?"*

7 METHODS AND METHODOLOGY

Based on the overall research question and the three secondary research questions, we chose to conduct a mixed methods study. A mixed methods study is a type of study where the researcher or a team of researchers combines components from qualitative and quantitative approaches (e.g., viewpoints, data collection, analysis, inference techniques) to achieve a wider and deeper understanding of a phenomenon (Johnson, Onwuegbuzie, & Turner, 2007). This study contained an RCT to answer the first two secondary research questions and a separate qualitative research interview study to answer the third secondary research question. Integrating the findings from qualitative and quantitative studies may provide a better understanding of a phenomenon than one method alone could provide (Creswell, 2015; Schoonenboom & Johnson, 2017). Mixed methods research is characterized as "the third research paradigm" in addition to qualitative and quantitative research (Johnson & Onwuegbuzie, 2004). A paradigm refers to the constellations of beliefs, values and techniques shared by the members of a given community (Kuhn, 1965). It describes the worldview concerning the nature of reality, the generation of knowledge, what we choose to examine and through what methods (Ford-Gilboe, Campbell, & Berman, 1995). The ontological assumptions, which are the understanding of the nature of being and how to make sense of reality, and the epistemological assumptions, which are the understanding of the nature of knowledge, what knowledge is and how knowledge can be obtained, are quite different in the qualitative and quantitative paradigms (Ford-Gilboe et al., 1995; Malterud, 2016). Therefore, I find it particularly important to describe and reflect on the methods used: the procedures for data collection and analysis used in the RCT (which is a deductive method in which general findings are used to draw a singular conclusion), the qualitative research interview (which is an inductive method in which few empirical findings are used to arrive at general principles) and the mixed methods study. The methodology, the foundations of the theory of science in each method and the principles shared by the methods (Malterud, 2016) are also emphasized. In the following sections, I describe and reflect on the methods and methodological aspects of each part of the study, and demonstrate the mixing of methods along the way.

7.1 Theory of science framework of the mixed methods study

Some researchers have argued that qualitative research, which by nature involves an intersubjective standpoint for exploring meaning and experiences, and quantitative research, which by nature takes an objective and dualistic stance to examine effects, are such radically different paradigms that they cannot be combined (Ford-Gilboe et al., 1995). However, for those who understand the world as including both qualitative and quantitative inquiries, there are possibilities for combining the two paradigms if the phenomenon is complex (Collins, Onwuegbuzie, & Johnson, 2012). The philosophical foundation for mixed methods studies may be critical realism, dialectic pluralism, or pragmatism, which is the most commonly used and is applied in this study (Biesta, 2010). In pragmatism, the ontological view is that there are multiple realities, subjective, objective and intersubjective (Onwuegbuzie, Johnson, & Collins, 2009). Epistemologically, knowledge is constructed and based on the reality of the world we live in and experience, which by nature may also be intersubjective, objective or subjective. Therefore, we can determine what works in a social and interactional context and gain new knowledge that expands past understandings through the integration of findings (Onwuegbuzie et al., 2009). Knowledge will provide possibilities but never certainty (Biesta, 2010). The distinction between objective and subjective knowledge does not exist because the world appears based on what we do. To know the world, we must interact, and we will then know the world as it responds to us. These foundations link together the qualitative and quantitative parts of the current study and make the mixing of two quite different methodological foundations possible.

7.1.1 Theory of science framework of the randomized controlled trial

The experiment originate as early as the 1600s, when hypotheses of the contexts in nature were systematically tested (Skirbekk, Slaattelid, Holst, Granberg, & Gilje, 2007). In further explorations of humans, Rene Descartes (1596-1650) provided the mind-body split and a mechanical view of the body (Skirbekk et al., 2007). This dualistic view is still recognizable in today's quantitative research, which aim for objective knowledge by measuring parts of the body numerically and often do not take bio-psycho-social or situated aspects into consideration (Djulbegovic, Guyatt, & Ashcroft, 2009). Therefore, this split is important to bear in mind when conducting an RCT. Positivism, rooted in Descartes' mind-body dualism, emerged in the late 1800s and early 1900s. It proclaimed that valid knowledge originated through the verification of empirical data and logical relationships expressed in an exact mathematical and physical language. To distinguish between science and pseudo-science, a statement must be verified. The post-positivist philosopher Carl Popper (1902-1994) criticized the concept of verification and proclaimed that scientific knowledge is always preliminary and contextualized and that falsifiability is the criterion for true knowledge because the future may bring new knowledge that falsifies previous theories (Djulbegovic et al., 2009; Onwuegbuzie et al., 2009). Our RCT study is associated with a post-positivist paradigm. The ontological view is that reality is tangible and the epistemological view is that knowledge development is objective and time, context and value free (Djulbegovic et al., 2009), even though total objectivity is not possible in any study. In the RCT, we tried to set aside our pre-assumptions and reduced the participants' balance and walking to a number. Such a reduction may be emphasized as acknowledging an objective and dualistic reality (Sale, Lohfeld, & Brazil, 2002). Through statistical relationships, we emphasized probabilities (for instance, p-values and the confidence level), identified the causal relationships between variables which were generalized to broader populations to produce accurate and unambiguous knowledge (Malterud, 2016; Onwuegbuzie et al., 2009). The results from RCT studies are the gold standard for decision-making in clinical practice and for developing guidelines for clinical practice because of their ability to rule out chance, to minimize bias, and to control confounding variables (Greenhalgh, Howick, & Maskrey, 2014; H. F. Hansen & Rieper, 2009). Conducting an RCT in a new intervention such as GroupCoreDIST is important to explore if this treatments was better than standard care for the MS population.

7.1.2 Theory of science framework of the qualitative research interviews

Qualitative approaches are interpretive and are used to understand, not explain (Malterud, 2016). The ontological standpoint is associated with a subjective and intangible reality, multiple truths and multiple realities that are in constant change in rhythm with people in the changing world (Onwuegbuzie et al., 2009). The epistemological view is that human experience, actions, values and meaning are a source of knowledge both in regard to how experiences are described by those who are interviewed and how researchers describe and analyse the experiences (Malterud, 2016). The researcher is a part of the research process and uses him/her self as a tool for constructing knowledge both in the planning, data collection and analysis. The participant and researcher together create meaning through this interactive process, and the findings are accepted as being co-constructed within the setting (Brinkmann & Kvale, 2015). The knowledge production depend in unique ways on the context and the individuals involved (Blaikie, 2010; Malterud, 2016; Mayoh & Onwuegbuzie, 2015).

The embodied experiences of participants are considered to be an adequate and important source of knowledge derived from a continuous hermeneutical process of systematic analysis of the findings (Blaikie, 2007). Hermeneutics is one of the philosophical pillars of the qualitative paradigm, where interpretations of the meaning of a text, actions and discourse are connected to a contextualized whole. In an inductive approach, we assume that there is a connection between many individual cases and develop patterns of descriptions, which are organized into categories. When the findings are raised to an analytical level through theoretical perspectives transferability to other similar individuals and settings is possible (Malterud, 2012, 2016; McEvoy & Richards, 2006). Theoretical perspectives may interpret the depth, richness and authenticity of peoples' meanings and understandings.

7.2 Study design and purpose of the mixed methods study

Mixed methods research is a continuous and dynamic process that can be accomplished in multiple ways (Collins et al., 2012; Onwuegbuzie, Johnson, & Collins, 2011). One basic classification of the purpose is outlined by Greene, Caracelli and Graham (1989), who divide it into 1) triangulation, i.e., seeking correspondence and convergence of the results from different methods; 2) complementary, i.e., clarifying the findings from one method with the results from another method; 3) development, i.e., using the results from one method to develop another method or study; 4) initiation, i.e., seeking new perspectives of frameworks by reorganizing results from one method with the results from another method; and 5) Expansion, i.e., aiming to extend the range of a study by using different methods to explore different elements of the phenomenon (Greene et al., 1989). Johnson and Onwuegbuzie (2004) suggest to use that the type of mixing that best answers the research question (Johnson & Onwuegbuzie, 2004). In this study, the purpose was to explore different elements of participation in GroupCoreDIST. This type of expansion has in another, more comprehensive classification system, been called completeness, which is recently the most used name (Bryman, 2006) and what I choose to call it. Such a search for completeness from varied angles may inform the development of principles for clinical practice (Johnson & Schoonenboom, 2016). Very few studies integrate qualitative and quantitative inquiries, and such mixing seems to be needed to explore the evidenced for group-based physiotherapy for individuals with MS.

7.2.1 The aims of the randomized controlled trial

The aims of the RCT were to answer two of the secondary research questions and, compared to standard care, to examine the possible effects of six weeks of participation in GroupCoreDIST at the group level. By comparing the performance of two randomly allocated groups in standardized outcome measurements assessed before and after an intervention phase, "objective" knowledge may be developed (Moher et al., 2010). Our null hypothesis of no differences in balance and walking between the GroupCoreDIST group and the standard care group may be rejected if there are significant differences between the groups. With our choices of outcome measures, we pre-defined the premises of what qualities of balance and walking we aimed to explore. We decided that elements such as trunk control, various aspects of balance, walking distance and the participants' feelings of how MS impacted walking were important outcomes to measure after participation in GroupCoreDIST.

7.2.2 The aims of the qualitative research interviews

The qualitative interview study aimed to answer one of the secondary research questions to gain scientific knowledge by exploring how, in what ways, and under what circumstances participation in GroupCoreDIST was experienced. Qualitative research interviews aim to obtain a nuanced picture of patients' experiences from and reflections concerning the (here, group-based) setting in which they are situated, with interactions, communication and bodies being at the individual level (Ekeland, 2009; Greenhalgh et al., 2014). By asking the participants open-ended questions, we aimed to elicit answers that were meaningful to them and that could clarify aspects of GroupCoreDIST that we potentially had not thought of prior to the start of the study (Malterud, 2017, p. 190). The interviews may have contributed to confirming the quantitative findings (and vice versa) and to expanding our knowledge of particular elements in the intervention that were important to the participants.

7.3 Theoretical drive

In mixed methods research, the theoretical drive describes what parts of the study are considered the core component (Schoonenboom & Johnson, 2017). The theoretical drive may be deductive and quantitative dominant, mostly relying on a quantitative view of the research process while simultaneously recognizing that qualitative data may also benefit research projects; alternatively, it may be inductive and qualitative dominant, relying on a qualitative view of the research process while simultaneously recognizing that quantitative data may be useful (Schoonenboom & Johnson, 2017). The dominant component is often written in capital letters (QUAN or QUAL), while the part that is less weighted, is written in small letters (qual or quan) (Morse, 1991). In this study, an equal-status QUAN-QUAL mixing was chosen, as both the effects and experiences of participation in GroupCoreDIST were equally important to answering the overall research question (Schoonenboom & Johnson, 2017). Although our research group found both aspects to be equally important, in practice, this equal importance was slightly challenging because the RCT design has received more attention in clinical and research environments, journals and conferences. I found the equal status to be important, as it signals that the different methods simply explore different aspects of the phenomenon.

7.4 Timing and point of integration

All mixed methods studies have at least one point of integration where the quantitative and qualitative elements are brought together (Guest, 2013; Morse & Niehaus, 2009), and it may take place at any point in the study (Schoonenboom & Johnson, 2017). The timing may include two aspects: simultaneity or dependence (Guest, 2013). This study was concurrent or parallel, indicating that the quantitative and qualitative components were conducted almost simultaneously; the interviews at weeks 7 and 30, and the outcome measures were assessed at baseline and weeks 7, 18 and 30. Concurrence is often indicated by a "+" between components, while a sequential design is described by an "→", indicating that one study is dependent on the other (Morse, 1991). This study can be described as an equal-status, concurrent (parallel) QUAN + QUAL study. In such a design, the data collection and data analysis of each component are not dependent on each other (Schoonenboom & Johnson, 2017). The findings of each component answer the secondary research questions and led to the creation of three papers, while the integration of these findings is emphasized in this thesis. Such an integration may provide a broader understanding of the complexity of a phenomenon (Mayoh & Onwuegbuzie, 2015). Through the integration new overall interpretations and conclusions have raised the findings to a higher analytical level and expanded our knowledge of participation in group-based physiotherapy for persons with MS.

7.5 Study context

This study was organized from the Nordland Hospital trust, a medium-to-large Norwegian hospital that serves the 243,385 inhabitants in Nordland county (Statistics Norway, 2019). The assessments of the outcome measurements and most of the interviews took place at this hospital (two interviews were conducted in a participant's home), while the interventions were conducted in six municipalities in Nordland (ranging between 1200 and 51,000 inhabitants). These municipalities were included because they were in both rural and urban areas and because physiotherapists who were skilled in neurological physiotherapy and who wanted to learn GroupCoreDIST were located in them.

In addition to the current RCT and qualitative study, a qualitative observation study examining professional practice, including 12 individual clinical examinations and 13 group sessions, was conducted and complemented with interviews with the group-leading physiotherapists. These parts of the study were conducted by another PhD student, and these results have been published elsewhere (Lahelle, 2019; Lahelle et al., 2018a, 2018b; Lahelle, Øberg, & Normann, 2019). All these different studies made the study setting different from regular clinical practice and may have influenced how the physiotherapists and participants acted and interacted and how the participants rated the effects of standard care or GroupCoreDIST and described their experiences from participation in the new intervention.

7.6 Recruitment and participants

Participant recruitment started in August 2015, when one of the MS nurses in the department of neurology of the Nordland Hospital Trust sent out invitation letters for the RCT and the qualitative interview study, with a consent form, to 160 individuals with MS. These patients were registered at the MS outpatient clinic, had an EDSS score of 0-7, and lived in one of the six municipalities included in the study. One reminder letter was sent out to the non-responders to ensure maximum patient enrolment, which was achieved in September 2015. Ninety-three individuals wanted to participate in the study; 13 of them were excluded from participation before enrolment: five because they did not have the opportunity to commit the time, three because they had an EDSS score of 0, two because they did not show up for the baseline assessment, one woman because she was pregnant, one person because he was waiting for heart surgery, and one person because she had moved from the catchment area (Figure 1. Flow chart of the mixed methods study).

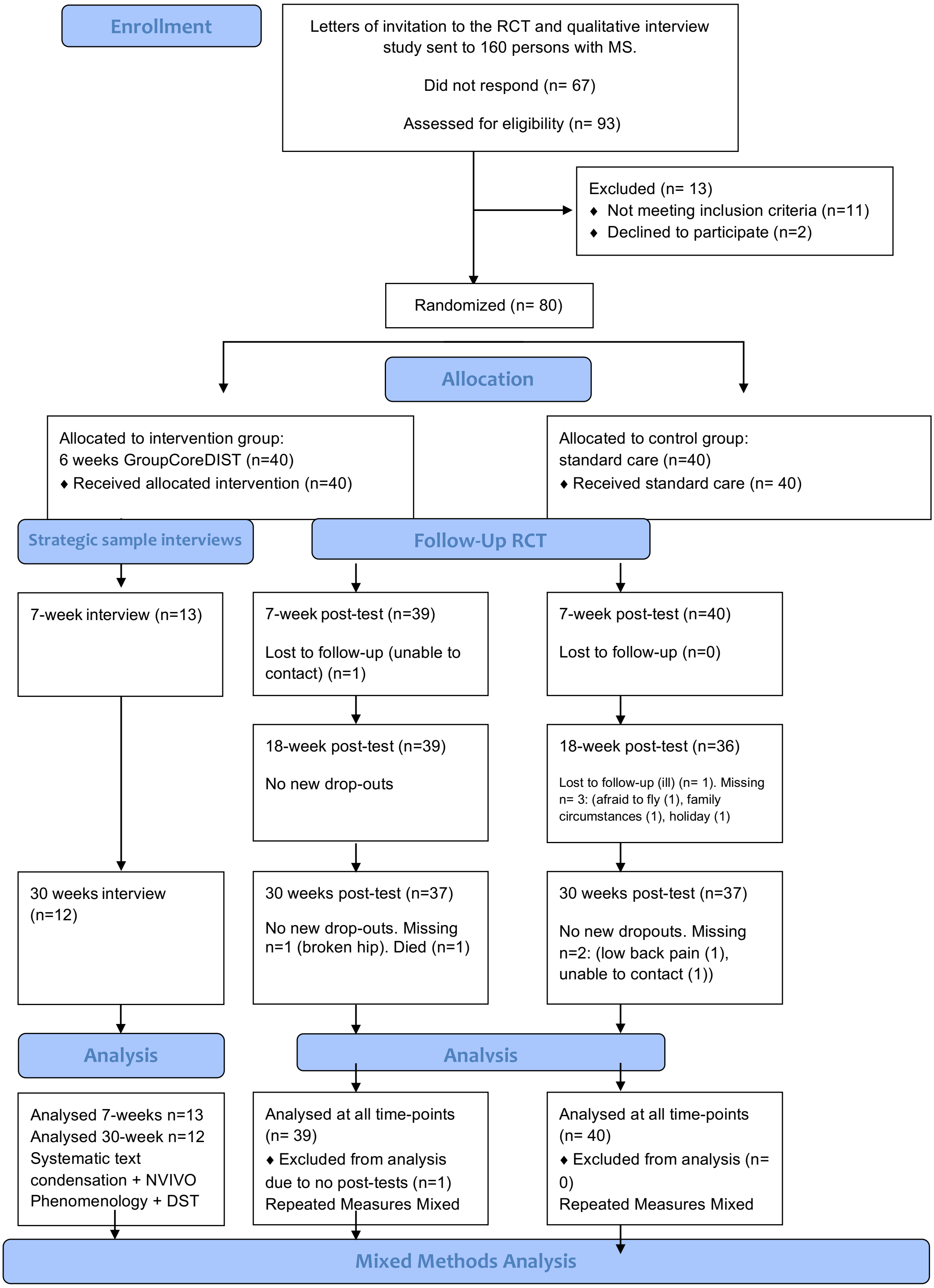

Figure 1. Flow chart of the mixed methods study

7.6.1 Participants in the randomized controlled trial

We tried to calculate the sample size for the RCT study based on the results of the Trunk Impairment Scale-Norwegian Version (TIS-NV) in the pilot feasibility test-retest study. In this study, a within-group mean difference from the pre- to post-test of 7 points in this 16-point scale (n=11) was revealed (Normann, Salvesen, et al., 2016). This large improvement indicated a sample of between 5 and 22 individuals in each group for a larger RCT (power 80%, significance level 5% and SD 1.5). The research group found that it would be unlikely to achieve between-group differences in such a small sample. Therefore, we calculated the sample size based on the assumptions of change in the Mini-Balance Evaluation Systems Test (Mini-BESTest) and considered that a 0.75 SD between the intervention and control groups would be significant. For an 80% chance of detecting a 0.75 SD difference between groups with a significance level of 0.05 (alpha), 28 individuals in each group were required. Assuming a 30% drop-out rate, we aimed to recruit at least 72 persons.

At enrolment, the participants underwent a clinical examination by a neurologist (FO) to assess their EDSS and medical history. The inclusion criteria for the RCT were as follows: 1) being diagnosed with MS in accordance with the McDonald criteria of Polman et al. (2011); 2) being registered at the MS outpatient clinic; 3) living in one of six selected municipalities; 4) being 18 years of age or older; 5) being capable of providing signed written informed consent; and 6) having an EDSS score of 1-6.5 (1=minor disability, 6.5=being able to walk 20 metres with or without a walking aid). The exclusion criteria were as follows: 1) pregnancy at the time of examination; 2) exacerbation in the previous two weeks before enrolment; and 3) acute conditions compromising balance.

We included 80 participants in the study (which was more than the 72 we needed) because we found it unethical to reject individuals who met the inclusion criteria. Electronic randomization was conducted after baseline testing 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; this system stratified by EDSS scores (1-3.5 and 4-6.5) to ensure individuals with high and low disability in both groups. This process led to the allocation of 40 individuals to the GroupCoreDIST group and 40 individuals to the standard care group. One person from the GroupCoreDIST group was excluded after the intervention period due to a lack of follow-up assessments. Therefore, the intention-to-treat analysis included 79 participants.

7.6.2 Participants in the qualitative research interviews

In the qualitative interview study, a strategic sample was recruited from the GroupCoreDIST group. A strategic sample has strengths in exploring participants' varied and nuanced experiences (Malterud, Siersma, & Guassora, 2016). In line with our inclusion criteria, we included participants who varied in age (24-77 years, mean 46 years), gender (9 women and 4 men), EDSS scores (1-6.5, mean 3.5) and time since diagnosis (0.5-24 years, mean 10.8), participants who had expressed positive, neutral or negative experiences and participants from training groups led by all the physiotherapists. The sample size may be chosen for pragmatic reasons and if many similar experiences are repeated by many participants (Malterud et al., 2016). We chose to stop at a sample of 13 participants because many similar stories were described. The participants were interviewed twice, for a total of 25 interviews (one person died of natural causes before the second interview), to explore their short- and long-term experiences. A percentage of 33% (13/40) participating in two interviews was considered to be an adequate sample size.

7.7 The development, training and volume of GroupCoreDIST

The principles of GroupCoreDIST have been developed over several years through practical workshops, clinical experience, knowledge about motor control and learning and systematic searches in the literature regarding individual- and group-based core stability and balance interventions for individuals with MS (Figure 2). A manual with photos and descriptions of all exercises and variations was developed. The six physiotherapists received this manual during the five days of practical and theoretical training. A home training book with pictures of exercises was also created for the participants.

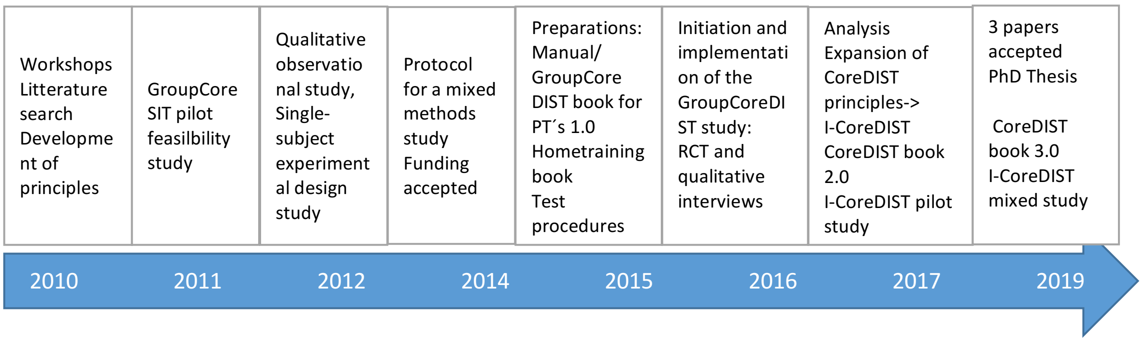

Figure 2. The development of the GroupCoreDIST principles and interventions

The participants in the GroupCoreDIST were divided into groups of three by me and my principal supervisor based on the municipality in which the participants lived. A first appointment for an individual clinical assessment was scheduled with the group-leading physiotherapist, and this appointment was followed by group sessions for 60 minutes three times per week for six weeks (Normann, Zanaboni, et al., 2016). The group sessions were well attended (mean of 2.5 sessions per person/week). Unsupervised home training was recommended to include all six categories, and this training was to be performed for 30 minutes twice per week. Thirty-eight participants reported performing GroupCoreDIST exercises at home at 3 months, while only two reported performing the exercises at 6 months.

7.8 Standard care

The standard care group was encouraged to seek any health care required, including physiotherapy. Self-reports revealed that 5 individuals (12.5%) visited a physiotherapist once per week, 4 individuals (7.5%) did so 2-3 times per week, and one individual visited a personal trainer, and thirty individuals (75%) did not visit a physiotherapist at all over the 6-week period (an average of 0.28 physiotherapy sessions per week for the six weeks of the intervention), which was surprisingly low. The content of physiotherapy was not indicated by this project, and the physiotherapists in standard care were not part of the current study. Reports from the participants revealed that these sessions included strength training (10 individuals), endurance training (8 individuals), Pilates (2 individuals) and yoga (1 individual). The sessions were unsupervised for 4 individuals and were tailored by the physiotherapist for 5 individuals. The self-reported physical activity levels were, furthermore, equal in the intervention and control groups (mean of 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-week period; the mean difference was 4.38 half-hours for the entire period (95% CI (-19.75, 10.98); p=0.57).

7.9 Data collection in the randomized controlled trial

Data collection started in September 2015. Data collection for the RCT included standardized outcome measurements assessed at baseline and weeks 7, 18 and 30. The assessments were conducted by two assessors who were masked to the group allocation and who followed a standardized protocol. The tests were conducted in the same order each time, in the same room, with the same bench and equipment, and with standardized instructions and encouragements by the tester. Before the start of the study, the assessors tested many individuals with MS to see whether the scores were in agreement between the assessors and within each assessor. When the study started, the assessors scored quite similarly, but we did not calculate inter-rater or intra-rater reliability for our assessors, which is a weakness. To the greatest extent possible, the same assessor followed a person throughout the study, which is a strength. All testing was completed in September 2016.

Physical tests and closed-ended questionnaires regarding balance and walking were used in this study. Such tools are essential to track the changes in a group's performance and to evaluate health and effect of an intervention by measuring change over time (Potter, Fulk, Salem, & Sullivan, 2011). We chose outcome measures that could capture aspects of the participants at all ICF levels: *body function and structure,* for instance, to measure trunk control; *activity,* for instance, walking distance; and *participation,* for instance, quality of life questionnaires (is not included in this thesis and will be published elsewhere). We considered that all outcome measurements were feasible for clinical practice in individuals with MS and that they could capture potential changes from participation in GroupCoreDIST, for instance, changes in trunk control and balance, which were a core element in the intervention.

To ensure that a study has good quality, it is important for the psychometric properties of the outcome measurements, including *reliability, validity and responsiveness* (Hobart, Lamping, & Thompson, 1996), to be excellent. *Reliability* is an outcome measurement's ability to produce results that are accurate, consistent, stable over time and reproducible (Hobart et al., 1996). *Validity* is the extent to which a test measures what it intends to measure (Hobart et al., 1996). *Responsiveness* refers to an outcome's ability to capture change. For instance, if a test is too hard and does not have enough easy items to distinguish levels of status, a floor effect may occur. In contrast, if a test is too easy and the majority of participants are able to score within the highest range of the test, a ceiling effect may occur. Responsiveness was not reported in most of our outcome measures but is discussed in regard to the results of the current study for one of the outcome measurements.

To deciding whether a potential change in an outcome measurement is relevant,it is important to consider the minimal clinically important difference (MCID), which is the smallest amount of change in an outcome that is considered relevant for this particular population (de Vet et al., 2006; Potter et al., 2011). Comparing such values is recommended; however, the MCID for outcome measurements is often unavailable (das Nair, de Groot, & Freeman, 2019). This was also the case in the current study. The MCID is discussed in regard to the walking outcomes in the RCT walking paper; however, values were not found for individuals with MS in regard to balance. In the discussion in this thesis, I have added values for other neurological conditions to discuss the balance and trunk control outcomes. Also interesting to consider is the minimal detectable change (MDC) which is the minimal amount of change necessary to exceed measurement error (de Vet et al., 2006). The MDC has limitations in that it estimates thresholds only for true change and does not determine whether changes are clinically important (Potter et al., 2011). Measurement error is reported in the tables in the RCT papers.

7.9.1 The primary outcome measures

The primary outcome measures were the TIS-NV and the Mini-BESTest. Primary outcomes are the outcomes that, prior to the onset of the study, are found to be the most important among the outcomes and a basis for sample size calculation (Andrade, 2015). We chose two because we were equally interested in the possible influence of GroupCoreDIST on trunk control and balance. The two tests complemented each other, as the TIS-NV covers selective movement and coordination in the trunk and pelvis, while the Mini-BESTest covers balance and postural adjustments when the feet are adapted to the floor.

The TIS-NV measures trunk control and includes six test items scored from 0 to 2 or 3, for a total score from 0 to 16 (0=severe problem) (Gjelsvik et al., 2012). The TIS-NV is a modified version of the original Trunk Impairment Scale (TIS), and the original has been validated and tested for reliability in people with MS (Verheyden & Kersten, 2010). The MCID is not reported for the TIS-NV or the original TIS; however, for individuals with stroke, it is reported to be slightly less than three points, meaning that a patient should score at least three points more/less than the previous assessment to be certain that he/she has improved or worsened (Gjelsvik et al., 2012). It is a weakness of the current study that the reliability and validity of the TIS-NV were not tested for individuals with MS, however since it is conducted in individuals with stroke who also may have trunk impairments, we chose to use it. The MCID should be examined in a future study in individuals with MS.

The Mini-BESTest measures balance in standing and walking. The translated Norwegian version has good reliability and validity for individuals with varied neurological conditions, including MS (Hamre, Botolfsen, & Helbostad, 2017). Having a total of 14 tasks, this instrument assesses four sub-items: anticipatory postural control, reactive postural control, somatosensory orientation and dynamic walking. Each task is scored from 0 to 2, for a total score from 0 to 28 (0=severe problem) (Hamre et al., 2017). No MCID is reported for individuals with MS (Di Carlo, Bravini, Vercelli, Massazza, & Ferriero, 2016); however, in elderly individuals with balance disorders, it is 3.5 points, and the MCID is 4 points (standard error of the mean of 1.26) (Godi et al., 2013). It is a weakness of the current study that there was no MCID for individuals with MS that we could use to make comparisons; such calculations should be conducted in a future study.

7.9.2 The secondary outcomes

The secondary outcomes included the 2-minute walk test (2MWT), the 10-metre walk test (10MWT), the Multiple Sclerosis Walking Scale-12 (MSWS-12), the Rivermead Visual Gait Assessment (RVGA), the Patient Global Impression of Change-balance (PGIC-balance) and Patient Global Impression of Chance-walking (PGIC-walking), and ActiGraph wGT3x-BT monitors (ActiGraph). The secondary outcomes were chosen to examine whether the 6 weeks of GroupCoreDIST would have effects on different aspects of walking, including the number of steps per day and activity. Walking was important to assess since it is often of major concern for individuals with MS.

The 2MWT measures walking distance. The participants were instructed to walk as far as they could for a period of two minutes in a 22-metre-long hallway and to turn at the end of the hall. The 2MWT has good reliability and validity (Rossier & Wade, 2001) and is recommended for intervention studies (Domien Gijbels et al., 2012). This outcome is a shorter version of the 6-minute walk test, which captures the same aspects of mobility in ambulant individuals with MS (D Gijbels, Eijnde, & Feys, 2011). The MCID is reported to be an improvement of 9.6 metres and 6.8 metres 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). The MCID was discussed in the RCT walking paper in relation to the results of the current study.

The 10MWT measures walking speed. It has good reliability (test-retest, intra-rater and inter-rater reliability) and validity among individuals with MS (Kieseier & Pozzilli, 2012; Paltamaa, West, Sarasoja, Wikstrom, & Malkia, 2005; Rossier & Wade, 2001). The 10MWT was in this study conducted with a standing start at 1) the preferred, 2) slow, and 3) fast speeds. These three speeds were chosen to look for a similar pattern between speeds. The preferred and slow speed results were inconsistent within each participant, which may indicate that it was difficult for them to decide what a slow or preferred speed was. The instructions for these items should be specified in future studies. Walking speed has been reported to be very responsive to walking impairments (Paltamaa et al., 2012), and long walking tests (2 and 6 minutes) have been reported to be more responsive than the 10MWT in detecting change after rehabilitation (Baert et al., 2014; Baert et al., 2018). An improvement in walking time of approximately 20% is often accepted as an MCID (Nilsagard, Lundholm, Gunnarsson, & Denison, 2007); however, other studies have suggested that a lower change may be calculated by using an anchor-based approach with an external reference such as the EDSS or the Patient Global Impression of Change (PGIC) (Kempen et al., 2011). In patients with sub-acute stroke, an improvement of 0.16 m/s in gait speed is considered an MCID (Tilson et al., 2010). Walking at the preferred speed has demonstrated a within-day variability of 20% independent of the disability level (Feys et al., 2014). The participants were as far as possible tested at the same time of the day, which is a strength.

The MSWS-12 captures how participants perceive limitations in walking as a result of MS over the previous two 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; Learmonth, Dlugonski, et al., 2013; Motl & Snook, 2008). Transforming the total score into a 0-100 scale is recommended (Baert et al., 2014), and this transformation was performed in the current study. There is no consensus regarding the definition of a standard MCID in the MSWS-12, and values between -6 and -11 points have been suggested (Baert et al., 2014; Baert et al., 2018; Hobart et al., 2003; Mehta et al., 2015). The MSWS-12 is associated with changes in walking distance and speed (Pilutti et al., 2013) and is particularly appropriate for capturing changes in individuals with low EDSS scores (Langeskov-Christensen et al., 2017). The MCID was discussed in the RCT walking paper.

The RVGA is a reliable and valid quantitative measure of gait quality in individuals with MS (Lord, Halligan, & Wade, 1998). The RVGA describes how the gait pattern varies from normal and is measured on a four-point scale (0=normal; 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 for each side of the body (Lord, Halligan, et al., 1998). The participants were videotaped while walking and scored based on the film. An 11-point change is associated with a clinically meaningful change (Lord, Halligan, et al., 1998). In the current study, the scores for the right and left side of the body were merged.

The PGIC-balance and PGIC-walking are scored on a 7-point Likert scale with the following question: “How do you perceive your balance/walking now compared to before the 6-week training period or standard care?”. The PGIC measures how participants perceive changes in their clinical status (1=very much worse, 2= much worse, 3= minimally worse, 4=no change, 5= minimally improved, 6=much improved and 7=very much improved). The scale was first published in 1976 by the National Institute of Mental Health (Guy, 1976), is often used in relation to pain (Farrar, Young, Lamoreaux, Werth, & Poole, 2001; Perrot & Lantéri-Minet, 2019) and has been used in regard to balance and walking in individuals with MS (Normann, Moe, Salvesen, & Srgaard, 2012; Smedal et al., 2006). It may also be used as an anchor to determine the MCID (Dworkin et al., 2008). Therefore, we should consider using the results of the current study to calculate the MCID for many of the outcomes used.

The ActiGraph is an activity monitor that registers information regarding the participant’s physical activity level, number of steps and duration of intensity in physical activity (which is divided into different intensity levels: inactive, low, moderate and vigorous) (Block et al., 2016). The ActiGraph has been found to be an reliable measure of community ambulation and physical activity in individuals with MS (Weikert, Motl, Suh, McAuley, & Wynn, 2010). The monitor was worn in a belt around the participants’ waist for 7 days after each assessment time point.

Self-reported physical activity, the number of physiotherapy treatments, perturbations, changes in medications and general wellbeing were recorded for both groups during the 6 weeks of GroupCoreDIST or standard care, and the number of home exercise sessions was also obtained for the GroupCoreDIST group.

7.10 Data collection in the qualitative research interviews

The qualitative in-depth research interviews were conducted at weeks 7 and 30, and data collection was completed in September 2016. The qualitative face-to-face, in-depth research interviews followed a theme-based interview guide with open-ended questions that aimed to explore the positive, negative and neutral aspects of the participants' short-term experiences from and long-term reflections concerning participation in GroupCoreDIST (appendix 6-7: interview guides). The interview guide was developed through discussions between me and my supervisors BN and GKØ in regard to the research questions, through explorations of our professional experience, backgrounds and preconceptions of themes such as individuals with MS, group-based physiotherapy, and individualization, and through a systematic search for literature on these topics, as recommended in the literature (Brinkmann & Kvale, 2015). Prior to the start of the study, the interview guide was tested through two test interviews, which I conducted with individuals with MS who did not participate in the current study. These interviews and my experiences from the interview setting were carefully explored together with my principal supervisor to deal with my preconceptions regarding individuals with MS and their possible experiences from individualized physiotherapy. These discussions resulted in increased awareness with regard to asking open-ended questions, acknowledging both positive and negative stories, formulating follow-up questions, and acknowledging silence. The interview guide was also discussed in light of the current theoretical perspectives to create a distance from the material and for awareness with regard to our pre-assumptions. We found that this discussion was especially important since I and the last author were the creators of GroupCoreDIST.

The themes in the first interview focused on the participant's experiences from the GroupCoreDIST assessment and exercises, the group setting, tailoring, impairments, and potential changes within the body and ADLs. The second interview addressed retrospective reflections concerning the same themes and the impact on daily life during and after the intervention was completed. The following are example open-ended questions: *"How did you experience the individual assessment?"* and *"Could you tell my any particular stories where you did or did not enjoy the group setting?"*. The interviews were audio-recorded and lasted 46-126 minutes (for a total of 1927 minutes), and they had a conversational style that was open with regard to the participants' choice of topics and their free expression of opinions and reflections. The interviews were guided by the research questions. However, it was important to explore whether the participants had experiences other than those which the research team had thought of in advance (Brinkmann & Kvale, 2015). I was open and sensitive to the participants' stories and to capture what was said in a way that related with what was meant.

The participants' answers were validated through probing questions and rephrasing of the participants' answers, also called communicative validation by Brinkmann & Kvale (2015). The following are examples of such rephrasing used during the interviews: *"Did I understand you correctly?"* and *"By saying…did you mean that…?"*.

The participants shared their stories in an open-minded manner, and those few who had negative experiences shared them spontaneously. Since some of the participants knew that the interviewer was also one of the creators of GroupCoreDIST, the interviews outlined that negative experiences would be truly helpful to explore new aspects of the intervention. To ensure that the participants were not afraid of disclosing negative experiences, all participants were directly asked about such experiences, and they were assured that any criticism would stay confidential, would be handled respectfully, would be welcome and would constructively help in further developing GroupCoreDIST. Each participant's 7-week interview was transcribed and reviewed to prepare for the 30-week interview, to illuminate possible topics that had not been fully covered and to prepare follow-up questions that might elaborate and clarify issues from the first interview. This process may have added a more personal touch and may have made it possible to follow the individuals' stories. All interviews ended with an opportunity for the participant to express his/her feelings about being interviewed, which revealed no negative statements.

7.11 Statistical analysis of the RCT data

The demographic and clinical characteristics of the baseline data for the GroupCoreDIST and standard care groups were examined using descriptive statistics in IBM SPSS version 24. The mean and SD are reported for the continuous variables (age, height, weight, EDSS level, age at diagnosis and years since diagnosis), while the sum and percentage are reported for the categorical variables (gender, smokers and type of MS). The between-group differences over time were calculated using repeated-measures mixed models in IBM SPSS version 24 and 25. The mixed-model approach is advantageous for addressing missing values and having many options for adjusting for the dependency between repeated measures (Twisk, 2010, pp. 106-107; 2013, pp. 69-70). All participants with post-assessment scores (n=79) were included in the intention-to-treat analysis. In the repeated-measures analysis, we first restructured our dataset into a long dataset (all post-test values for each person placed one after another). When constructing our model, we adjusted for the baseline scores to avoid possible influence due to regression to the mean (e.g. even if participants in two groups are randomly allocated, assuming no significant differences between groups, there may still be differences at baseline, unless the population is extremely large (Twisk, 2013, pp. 166-170)). The adjusted baseline value for each outcome was, therefore, added as a covariate in the model, as recommended in the literature (Twisk, 2013, pp. 166-170; Vickers & Altman, 2001). By doing so, baseline differences will not influence the results.

When creating a mixed model, building the model step by step is recommended (Twisk, 2013, pp. 69-75). We entered each of the baseline characteristic variables (group/intervention, time points, EDSS level, gender, type of MS, time since diagnosis, age at diagnosis, height, weight, educational level, marital status, age, smoking, and employment) one by one into the mixed-model analysis as independent variables, with each of the outcome measures as dependent variables, to look for confounding factors and to build the most appropriate model. We examining whether any interaction terms (random slopes) became significant ($p<0.05$). When building the model, we examined the significance level if the results for each outcome measurement changed greatly (the regression coefficient and corresponding standard error) and compared the -2 log likelihoods in the different models to find the best model. Since the GroupCoreDIST and standard care period was completed after 6 weeks, we wanted to examine the possible intervention effect at each follow-up time point. We calculated the differences between groups in each outcome measure at each time point and adjusted for the independent variables and the baseline variable. In the final model, we adjusted for all independent variables that reached significance at $p\leq0.05$ in any model. These variables were the time point, group/intervention, gender, type of MS, baseline value for the particular outcome measure, EDSS and age, which were added as main effects in the fixed effects box, and the time point*group, which was added as an interaction term.

In the statistics box, we added parameter estimates for fixed effects, and added time point, group, gender, type of MS and time point*group in the estimated marginal means. In the output, we looked at the estimates of fixed effects to find the intercept and estimated values for the between-group differences at each time point, with corresponding standard error, p-values and 95% CIs. Through the fixed effects we found the overall significance for the intervention for the entire period. We looked at the estimated marginal means to find the mean values for each group at all time points and used these values to create plots illustrating the effects of the intervention over time. SDs were calculated through descriptive statistics.

7.12 Qualitative analysis of the findings from the interviews

The qualitative research interviews contained 433 pages/171 419 words of transcribed material from the 7-week interviews and 216 pages/102 730 words from the 30-week interviews. I conducted the transcribing. I, furthermore, systematized the data using NVivo-11.0/12.0 (QSR International, 2016) to organize and structure the material properly, to recognize patterns in the findings and to get an overview of the material. Systematic text condensation was used to analyse the data (Malterud, 2001, 2012). This is a pragmatic method because it is not restricted to a specific theoretical perspective. It encourages the use of theory, may be used for different types of qualitative data and acknowledges knowledge as situated. The systematic and thematic cross-case analysis included four major steps that helped me keep an overview and systematically analyse the large amount of material in regard to the research questions (Malterud, 2012; 2017, pp. 97-116). The four steps in Malterud's systematic text condensation were conducted as follows:

Step 1) Gaining a total impression of the findings: I transcribed the 7-week interviews in NVivo 11/12 and read the material several times. The last author (BN) read almost all of the qualitative material, and together, we had discussions about the findings where we tried to be open with regard to our pre-assumptions and to set both them and the theoretical framework aside to be open-minded with regard to all the impressions from the material. The second author of the qualitative paper (GKØ) read some of the material, and I presented five provisional themes with provisional names to BN and GKØ. In the initial phase, these themes involved interactions, the meaning of changes during the intervention, lived experience before the intervention, how the physiotherapist affected the participants and how the participants experienced the physiotherapist's competence.

Step 2) Identifying and sorting meaning units: I identified meaning units from the material and sorted together the meaning units with similar contents into codes (names) in a process of de-contextualization. Meaning units are fragments of data which may enlighten the research question. In NVivo, this sorting was performed by highlighting with colours the meaning units that belonged together. I discussed the code groups and meaning units in light of the research questions, the theoretical perspectives of DST and the phenomenological elaborations of the pattern theory of self with my supervisors. The contents of the theoretical perspectives used in the current study are outlined in the next chapter (7.13). The codes were adjusted along with new ideas from the material, as flexibility and adjustments are encouraged (Malterud, 2012; 2017, pp. 97-116).

Step 3) Condensation: I created condensates, i.e., artificial first-person summaries, to highlight that the content was the sum of the participants´ voices. The condensates were written as notes in NVivo and connected to their respective codes. I filtered out the code groups that were not relevant to answering the research questions, which is different from other analysis methods that incorporate all the material (Malterud, 2017, p. 101). This filtration was very important because the material was large. Three code groups were kept and split into two sub-groups each to clarify the main aspects of each code group. These aspects were all illustrated by several quotes that could pinpoint the content of the sub-groups. All members of the research team read the condensates and quotes. In this process, the ways in which the theoretical frameworks could illuminate the findings were discussed with all co-authors. The theoretical perspectives were important to create a distance from the material and to raise the findings from a descriptive level to interpretations to produce a theoretical generalization of the findings.

Step 4) The synthesis of findings: In the fourth step, the de-contextualized condensates were re-contextualized, and the condensates were written in the third-person voice, to tell the story on behalf of the participants. Each piece of text was now placed back together to form a whole analytic text, which was compared to the transcripts to validate the original context and was organized into two main categories with two sub-groups each. Both commonalities and variations of the participants´ stories were summarized and I systematically looked for data that could contradict the main findings.

These steps were repeated for the analysis of the 30-week interviews, and I observed that these findings could expand and colour the findings from the 7-week interviews as well as incorporate more aspects regarding the participants' experiences of how the intervention and their disease impacted their daily life after the intervention phase. Over several rounds, I searched the material again to particularly look for negative findings that could balance the analytic text. The text was read by all authors, and interpretations of it were discussed in meetings and through e-mail correspondence. The quotes from the participants that best illustrated the content were extracted to enrich the analytic text. The names and content of the code groups and sub-groups were discussed again, yielding two main categories, with each containing two sub-groups that were presented in the qualitative paper. All steps were informed by the theoretical perspectives and aimed to answer the research questions.

7.13 Theoretical perspectives used in the qualitative study

To generate general scientific knowledge of user experiences, theoretical concepts are needed as analytical tools (Malterud, 2016). Without theory, the findings will be descriptive, which means that the researcher presumes that his/her private perspectives are general enough to go without explanation (Malterud, 2016). The qualitative interview study was based on a theoretical foundation consisting of dynamic systems theory and Shaun Gallagher's phenomenological elaborations of *the pattern theory of self* (2013; 2018).

The dynamic systems theory was chosen because it is a theory familiar to physiotherapists and is a fundamental principle in neurological physiotherapy for understanding the body, movement, motor control, and the relearning of motor function (Shumway-Cook & Woollacott, 2017, pp. 11-13). We chose to use this theory as a theoretical view for the qualitative study to understand the specific features of the participants' experiences from the GroupCoreDIST intervention. We were interested in how individualization was experienced, the participants' experiences of their body, and possible changes from the training. We were also interested in what potential changes might mean for the participants, their ADLs and their participation and what elements in the group-based setting were meaningful. To explore such existential elements, we chose the pattern theory of self, which interlinks the body as an organism and biomechanical system with pre-reflective and reflective aspects of self as well as interactional aspects that are relevant for group settings. By choosing this combined theoretical framework, we aimed to extract a deeper meaning of the participants' experiences that may illuminate general knowledge regarding the participants' experiences from group-based training.

7.13.1 Dynamic systems theory

Dynamic systems theory is based on the principle of movement as goal directed. There is no ideal way of moving since there is an infinite number of ways to move and tasks to achieve. The CNS self-regulates movement to accomplish a task due to the constraints to movement in the individual, the task, and the environment (Shumway-Cook & Woollacott, 2017, p. 156). Constraints in the individual involve sensory systems (sensory receptors, ascending pathways, sub-cortical processing, cortical perception and cortical integration); action systems (motor planning, extrapyramidal and pyramidal tracts, autonomic and endocrine systems, peripheral neuro-motor systems, and musculoskeletal, cardiovascular and vascular systems); and cognitive systems (memory, motivation, intelligence, problem solving, the ability to learn). Based on these individual constraints, each person develops preferred ways of moving that appear to them to be the most efficient (Shumway-Cook & Woollacott, 2017, p. 157). Impairments in any of the individual systems, due to MS, imply that a person's goals must be achieved in new ways. These new ways may lead to abnormal or compensatory and sometimes ineffective movement patterns that may interfere with possibilities for accomplishing ADLs. For instance, somatosensory disturbance in the feet and impaired core muscle activation, as often seen in individuals with MS, may provide a less accurate perception of the BOS and less efficient postural responses and may provide movement patterns that do not meet the changing demands of the environment.

The sub-systems in the individual, the task and the environment are all open to manipulation, and the physiotherapist may for instance impact the patient's balance and walking by changing biomechanical, musculoskeletal and neurological systems through hands-on interactions (Normann, 2018). Different kinds of tasks may be addressed by functional activities or exercises, which can be manipulated through the choice of exercises and level of difficulty. The environment includes physical characteristics such as light and temperature, floor characteristics, visual surroundings and noise, the socio-emotional context including stress, fear, anxiety, safety and support, and levels of predictability, distractions and complexity (Shumway-Cook & Woollacott, 2017, p. 158). These environmental aspects can be manipulated to make an activity easier or harder. For instance, a well-lit room is easier to walk in for an individual with somatosensory impairments in the feet.

Dynamic systems theory theorizes that new, more effective movement patterns can develop through manipulations of the individual, task and environmental sub-systems. Varied repetition may result in a new attractor status or a preferred movement strategy (Thelen, 2005), all based on principles of neuroplasticity (Kleim & Jones, 2008; Nudo, 2006). Dynamic systems theory provides an important third-person view of the physical body and an analytical tool that may deepen our understanding of individuals with MS´ experiences of balance problems and detailed, individualized group physiotherapy.

7.13.2 Phenomenological elaborations of the pattern theory of self

The phenomenological elaborations of the pattern theory of self are based on a core understanding of the body as the centre of experience and expression, where the "body-as-subject" or "being a body" has primacy and experiences the world from a first-person perspective (Gallagher, 2013; Merleau-Ponty, 2013, pp. 55-57). The ambiguity of the body implies that I simultaneously "have a body", the body-as-object, which may be observed from a third-person perspective (Merleau-Ponty, 2013, pp. 82-85). As healthy individuals, we are always directed towards something and experience what appears or is given to us, also called intentionality (Gallagher, 2012, pp. 63-80; Merleau-Ponty, 2013, pp. 112-113). Intentionality is embodied and composed of the entity of motility, sensation and perception, which consists of both pre-reflective (unconscious) and reflective levels (Gallagher, 2012, pp. 127-130; Merleau-Ponty, 2013, pp. 112-113) and includes the self, also called the embodied self (Gallagher, 2013; Gallagher & Daly, 2018). Since motility, sensation and perception are entities that are often impaired in individuals with MS, this view could explicate the deeper meaning of the participants' experiences of the body and movement, possible improvements from participation in the GroupCoreDIST and stories of ADLs and participation. The pattern theory of self delineates the factors that may constitute the embodied self:

A) The experiential factors are pre-reflective aspects of the self that imply 1) bodily experiences related to body schema and somatosensory components; 2) a sense of ownership of the body and movement, which is a feeling of being the owner of one's own movement (somatosensory components) (Gallagher, 2012, pp. 131-135); and 3) a sense of agency or a feeling of control over one's own movements (motor components) (Gallagher, 2012, pp. 168-171). Here, the body schema not only is the neurophysiological processes and areas in the brain but also contains bodily and intersubjective aspects where, in an experiential way, the body is present in perception or action (Merleau-Ponty, 2013, pp. 100-105). Somatosensory and motor impairments are common in individuals with MS, leading to fewer possibilities to regulate movement and posture, which may affect both the pre-reflective aspects of self and intentionality (Gallagher, 2012, pp. 132-136). Improvements may strengthen the same aspects (Normann, Fikke, & Øberg, 2015; Sivertsen & Normann, 2015; Øberg et al., 2015).

B) *The reflective factors* include body image, which is a reflective awareness involving a person's perception, attitudes and beliefs regarding his/her own body, and the stories I tell about myself (Gallagher, 2013). The narrative self is constituted through our own and other people's stories about us (Gallagher, 2012, pp. 172-180), and may change as MS often influence bodily experiences and reflections concerning what a person can or cannot do.

C) *The intersubjective factors* involve meaning-making and the way I see myself in relation to others (Gallagher, 2013). In individual physiotherapy settings, such factors have been emphasized as both a physical interaction and communication between individuals (e.g., the patient and therapist) and involve "inter-corporeity" between two body-as-subjects, an experiential and physical coupling (Normann, 2018). Interactions may provide viewpoints other than those when alone (Sokolowski, 2000) and may be relevant in group settings.

D) *The extended factors* include how I identify myself, for instance, through the activities in which I participate (Gallagher, 2013). Such extended factors are directly relevant for individuals with MS, since disability can gradually change their perceived opportunities or the range of affordances in their daily life, thus changing how a person identifies him/herself.

E) *The situated factors* of self highlight how I define myself in relation to cultural practices and the environment in which I live, with the things I own and use (Gallagher, 2013). All these aspects of the self-pattern may be rocked when a person has an unpredictable disease such as MS; but the pattern of self remains as long as a sufficient number of factors continue to have a dynamic relationship (Daly & Gallagher, 2019). Through the phenomenological elaborations of the pattern theory of self, the participants' physical, experiential and interactional aspects of participating in group-based physiotherapy may be highlighted.

7.14 The integration of the qualitative and quantitative findings

The integration of data is the hallmark of mixed methods research (Creswell, 2015). The integration process in the current study was led by me, with support from my supervisors. Conducting a systematic analysis, we looked for overlapping findings in the three papers and looked for surprising findings that could expand our knowledge based on overlapping themes. An integration of data through thematic analysis of the mix of data leads to interpretations of new categories (Onwuegbuzie et al., 2009). In each of the three papers, I found three major overlapping findings. These findings were integrated into three new categories that could clarify the phenomenon of participation in GroupCoreDIST and led to three new overall discussions. The key messages for each category were outlined, and an overall conclusion was created. These integrated findings and discussions are presented in chapter 9.

7.15 Methodological considerations of the mixed methods study

The knowledge developed based on qualitative and quantitative methods is by nature different, answers different research questions and, therefore have different quality criteria (Malterud, 2001). Different approaches to quality assessments have been outlined: the generic research approach, which uses generic tools that fit all study designs; the individual components approach, which assesses the quality of the qualitative and quantitative components with separate criteria; and an approach that attempts to address the quality of the whole mixed methods study (O´Cathain, 2010). In the current study, I conducted a separate examination of the quality criteria for the qualitative and quantitative studies. These aspects are emphasized, and a joint section reflects on the ethics of the whole mixed methods study.

7.16 Methodological considerations of the RCT

For an RCT to provide evidence of effects in interventions, it is important to reflect on the allocation process, blinding, inclusion and exclusion criteria, reliability and internal validity (bias or systematic errors), external validity (generalizability) and precision (possible random errors) (Higgins et al., 2011; Lee & Kang, 2015). We followed appropriate guidelines from protocol to publications, such as the Consolidated Standards for Reporting Trials (CONSORT) guidelines (Boutron et al., 2017; Moher et al., 2010; Schulz, Altman, & Moher, 2010; Zwarenstein, Treweek, & Loudon, 2017; Zwarenstein et al., 2008) and the Pragmatic Explanatory Continuum Indicator Summary (PRECIS-2) guidelines (Loudon et al., 2015; Zwarenstein et al., 2017). Other recommendations for reporting RCTs were also considered in the critical writing of this thesis (das Nair et al., 2019; Lee & Kang, 2015). I have also considered the Cochrane collaboration tools for assessing the risk of bias in RCTs (Higgins et al., 2011; Higgins, Svavovic, Page, & Sterne, 2019) and the Grading of Recommendations Assessment, Development and Evaluation (GRADE) guidelines (Alonso-Coello et al., 2016; G. Guyatt et al., 2011; G. H. Guyatt et al., 2008).

7.16.1 Preparations, allocation and inclusion

Based on the findings from the three small GroupCoreSIT studies (Balseth, 2014; Dybesland & Normann, 2018; Normann, Salvesen, et al., 2016), clinical experience and an updated and systematic search in the literature, the creators of GroupCoreDIST identified the knowledge gap and formulated the objectives and research questions of the current study. Collaborators with competency in both qualitative and quantitative methods were found and I took courses addressing both qualitative, quantitative and mixed methods approaches.

Adequate statistical power is important to document the effects of an intervention (Lee & Kang, 2015), and adequate statistical power was achieved in the current study. A computer-based randomization with allocation concealment provided equal groups and, therefore, an argument that any differences between groups after the intervention were caused by differences in the effects of the treatments. When the participants allocated to GroupCoreDIST were to be split into groups of three, we realized that one group had to include four participants due to practical and geographical reasons, and this setting may therefore have been slightly different from the groups of three.

7.16.2 Internal validity and evaluation of risk of bias

Our systematic search for bias included six areas: *selection bias, performance bias, detection bias, attrition bias, reporting bias and other bias*. Bias indicates systematic errors in the research process or method that may influence the conclusions (Higgins et al., 2011). It is important for the compared groups to be as similar as possible, to lead to the same explanations, and to be assessed a similar number of times by similar outcome measures (Greenhalgh, 2019; Lee & Kang, 2015), and all this was accomplished in this study.

Selection bias is the systematic differences in two groups due to incomplete randomization (Greenhalgh, 2019). This bias was avoided by an electronic randomization process and stratification by EDSS scores of 1-3.5 and 4-6.5. We calculated the differences between groups using a t-test at baseline and observed that there were statistically significant differences between the groups in regard to a higher number of smokers and a higher weight as well as better performance on the TIS-NV in the standard care group. The differences were adjusted for in the repeated-measures mixed model calculations to avoid bias. We discussed the possibilities for recruitment bias, which concerns whether or not the recruited participants are similar to the general MS population in our area. This issue was particularly discussed because of the high number of participants with low EDSS scores. We found that the EDSS scores of those who were invited to participate in the study but chose not to participate were similar to those who participated and similar to the reports from the Norwegian MS register (Aarseth et al., 2019), indicating that there was no recruitment bias.

Performance bias is the systematic differences in care apart from the intervention (Greenhalgh, 2019). In the current study, the assessors were masked to group allocation and used standardized procedures from our self-developed book, which indicates a low risk of performance bias in the test situations. In MS rehabilitation studies, double blinding is often not possible (das Nair et al., 2019). In the current study, the participants were informed that we were examining a new intervention compared to standard care. The participants were therefore not masked. The physiotherapists who led the groups were also not masked because they had to learn the intervention. A clear limitation of this study is the difference in the dose of physiotherapy between the two groups. For the control group participation implied less attention to and lower expectations for improvement, and for the GroupCoreDIST, participation increased attention, excitement and structure of the week, which may have posed a risk of performance bias. We knew that no superior physiotherapy intervention for individuals with MS has been found (Hogan & Coote, 2009), and we wanted to keep the study close to real life; thus, we decided to compare GroupCoreDIST to standard care. We possibly could have standardized the standard care and required this group to have the same volume of physiotherapy. By letting those in the standard care group do whatever they wanted, we captured an important picture of what is offered in standard care in our region. We were surprised by how few people saw a physiotherapist and by the low volume reported by those who saw a physiotherapist, which further underlines the need for this study. Furthermore, the individualization in GroupCoreDIST may have limited the RCT because the prerequisite in this design is to control the contents of the intervention and doing so may be compromised by tailoring. However, RCTs with comprehensive interventions have direct relevance to clinical practice (Zwarenstein et al., 2008) and are needed (das Nair et al., 2019). In a future study, we should compare GroupCoreDIST to an equal-dose intervention.

One risk of bias is the performance of group sessions. Although the physiotherapists reported what exercises were conducted, we do not know how they were conducted, whether the participants' particular problems were addressed or the exact number of repetitions that each person performed in each exercise. Such information could have made it easier to implement the intervention in clinical practice and studies. This kind of intervention fidelity is important in intervention studies. Recommendations for highlighting intervention fidelity in an even more systematic manner should be followed in future studies (Lambert et al., 2017;

Rew, Banner, Johnson, & Slesnick, 2018; Walton, Spector, Tombor, & Michie, 2017). An advantage is that another PhD student conducted a qualitative observational study of assessments and group sessions and interviews with the physiotherapists (Lahelle, 2019; Lahelle et al., 2018a, 2018b, 2019). From these papers, we have an impression of what took place in these settings, generally was in line with the intention.

Attribution bias is the systematic differences in drop-outs (Greenhalgh, 2019). In the current study, the drop-out rate was very low, and therefore, it was not seen as a problem. *Detection bias*, i.e., systematic differences in the determination of outcome measures (Greenhalgh, 2019), was carefully examined for each outcome and in regard to the testers. The outcome measurements were standardized, and the options for inadequate scores in the balance and walking outcomes were limited. The reliability and validity of the TIS-NV were tested only for individuals affected by stroke and not MS, leaving the possibility of bias. We chose to use this test because it captures trunk control and may therefore capture one of the intentions of the intervention; we also chose it since we had used this test in our pilot study.

Random errors, i.e., errors unrelated to the process or method (Lee & Kang, 2015), were also searched for. There were cases where the assessor reported that an individual's daily life experiences may have influenced the test situations. Examples included a few individuals who had had a fight with their spouse the morning before testing, one person who was suspected of having issues with alcohol, or those who generally felt that they were having a bad day. However, the appropriate sample size would take this issue into consideration, and therefore, we do not identify this as a random error. When scoring the self-evaluation schemas, the participants sat alone in a hallway or in a quiet room (whichever they preferred), which would indicate that they were not influenced by others when answering. In a few cases, the participants did not answer all the questions. The assessor then called them, asked the questions outlined in the questionnaire, and tried not to impact on their choices.

Notably, in regard to *reporting bias*, all results of the current study have not yet been published. This fact could possibly be perceived as selective reporting. Since we used a broad spectrum of outcome measurements, and the high number of significant results from three follow-up test points, we found it difficult to report all the results in one manuscript. A paper on health related quality of life will be published. Splitting the RCT results could make it more difficult for readers to obtain a full overview of the results, but we considered that it would be easier to follow our interpretations if they were reported in separate papers.

7.16.3 Generalization and usefulness

RCT studies are sometimes criticized for being not useful in practice because they are conducted in an ideal environment and include only individuals who are suspected to suit the intervention perfectly, limiting the generalizability of the results to other settings (Johnson & Schoonenboom, 2016). This study recruited individuals with all types of MS and with both moderate and low levels of disability and who were treated by six physiotherapists from six different municipalities. The levels of disability in the participants (EDSS scores of 1-6.5) and the low average EDSS level reflect the population both in the area and in Norway (Aarseth et al., 2019). The participants reflected the population, which makes the external validity high and the results transferable to other similar populations and settings (Lee & Kang, 2015; Zwarenstein et al., 2017). Generalization is limited to individuals with MS who have an EDSS score of 1-6.5. Further research is warranted to explore those with higher EDSS scores.

The *usefulness* of a study, furthermore, concerns the ways in which knowledge is useful in practical situations (Stige, Malterud, & Midtgarden, 2009). In this RCT, the intervention and the study context were close to real clinical practice, and therefore, they have high relevance and may be useful for clinical practice. The RCT may contribute to the base of evidence and to creating guidelines for clinical practice; therefore, it may be of direct relevance for physiotherapists, patients and policy makers. It should be taken into consideration that the RCT design measures effects on a group level, and there may be individual differences, such as individuals who do not benefit as much as others from the intervention. Such individual aspects were explored in the qualitative part of the study.

7.17 Methodological considerations of the qualitative interview study

In qualitative research, there has been a debate regarding how to evaluate the quality of a study for instance judging qualitative research based on the same criteria as quantitative studies; using a different set of criteria; and an evaluation agenda (Rolfe, 2006; Stige et al., 2009). To achieve quality, integrity and trustworthiness in the current study, I have described the research process systematically and in detail. Guidelines specifically created for qualitative studies, such as the Consolidated Criteria for Reporting Qualitative Research (COREQ) checklist (Tong, Sainsbury, & Craig, 2007), the Standards for Reporting

Qualitative Research (SRQR) (O'Brien, Harris, Beckman, Reed, & Cook, 2014) and the Enhancing Transparency in Reporting the Synthesis of Qualitative Research (ENTREQ) guidelines (Tong, Flemming, McInnes, Oliver, & Craig, 2012), were followed to ensure high quality throughout the research process. Such recommendations allow readers to critically read the published material and to understand the design, performance, findings and analysis of the study. Standardized checklists are referred to in the peer-reviewed qualitative paper as recommended. However, these checklists are criticized for being too rule based and narrow in regard to the expansiveness of qualitative research processes (Stige et al., 2009). Therefore, in the current study, the EPICURE evaluation agenda was followed.

EPICURE is useful for reflexivity throughout a study (Stige et al., 2009). Reflexivity is the researcher's acknowledgement that he/she is inseparable from the study field and should therefore reflect on his/her own position and how his/her background and position affect the research process (Brinkmann & Kvale, 2015). EPIC stands for Engagement, Processing, Interpretation and self-Critique throughout the research process, while CURE stands for social Critique, Usefulness, Relevance and Ethics of the interpretations and consequences of the study and its findings. These items include self-inquiry and exploration of the research process, the study's potential readers and the social and moral consequences of the research (Stige et al., 2009). Researchers' theoretical awareness through theoretical frameworks for interpretation and analysis is a core aspect of reflexivity, as it creates a distance from the findings (Malterud, 2017, pp. 26-28), for transparency, which concerns operating openly to make it easy for others to see all actions throughout the study (Malterud, 2016). In the following, the EPICURE items are discussed with respect to the current study.

7.17.1 Engagement

Engagement in a study refers to the researchers' interactions with the phenomenon and how personal involvement may affect the research process (Stige et al., 2009). Therefore, the research team's personal characteristics, relationships with the participants and theoretical perspectives were carefully described in the qualitative paper. We aimed to have an active and open-minded position with room for doubt, unexpected findings and critical reflection concerning our own process and conclusions, as recommended by Malterud (2016). In our study, this aspect was particularly necessary since both I and the project leader were the creators of GroupCoreDIST. This meant that we had personal interests in the research topic that could possibly have affected the participants' responses and understandings of the phenomena during the interviews. Having personal interests may influence experiences, reactions and questions during the research process and interpretations (Malterud, 2001). However, experience and knowledge regarding an explored phenomenon may also be positive, and Paulgaard (1997) calls this "positioned insight". In the current study, this aspect may have been an advantage, as my engagement with and knowledge of GroupCoreDIST, neurological physiotherapy, and individuals with MS were important for developing a targeted interview guide and understanding the participants' stories and meanings. For instance, I was able to ask adequate follow-up questions when the participants talked about their experiences of specific exercises, situations in the group, for instance, the balance check points, or how they experienced hands-on interactions that led to immediate improvements. Someone without experience in this type of neurological physiotherapy may not have understood the meaning of such experiences, may have asked about different aspects of GroupCoreDIST and may have missed elements that were important for clinical practice. On the other hand, someone with less knowledge in the field could have asked about things that I might have overlooked or found trivial, as insights and knowledge may create "blind spots".

Although my engagement and personal interests may indicate that I wanted the participants to have fruitful and positive experiences from participation, the expanded search for negative experiences also indicates that I wanted the principles of GroupCoreDIST to further develop in the best interests of the participants. Regarding my engagement, a potential negative aspect for individuals with MS was that the interviews lasted a very long time and included themes that did not directly answer the research questions (such as the participants' experiences from receiving the diagnosis). These themes were in line with Malterud (2017) and were filtered out in the analysis, and they are available for analysis in a future paper.

The theoretical perspectives guided my engagement towards the participants' experiences of body and movement and their experiences of the specifics of the intervention, the interactions with the physiotherapist and adaptations, and the group setting. BN, GKØ and SG have published theoretical papers using phenomenology (Daly & Gallagher, 2019; Normann et al., 2015; Normann et al., 2013; Øberg et al., 2015), and BN has also used a combination of embodiment and dynamic systems theory in a recent paper exploring facilitation of movement (Normann, 2018). Such an experienced project group provided interesting and meaningful discussions of the qualitative findings.

7.17.2 Processing

Processing refers to the organization and analysis of the material and the writing process (Stige et al., 2009). Since I and my principal supervisor were at risk of being too close to the material, it was advantageous to include the other two co-authors in the process and to address the material by taking a systematic analytic approach in line with Malterud (2001). We actively strived to set aside our pre-understandings throughout the study by being curious about the participants' expressions during the interviews and by asking questions about what the findings could mean. We ensured that the interviews were conducted before the testing sequences at both 7 and 30 weeks to prevent the participants from being influenced by their perceptions of success or non-success in the assessments. Nevertheless, conducting the RCT study and the interview study in parallel created a special setting and possible positive feelings because receiving a new treatment offer and more attention was difficult to avoid. We discussed actively how to highlight the negative findings, even if they were emphasized by only a few individuals. In regard to transcribing, organizing and analysing the data, NVivo 11/12 (QSR International, 2016) was important for keeping the big picture and systematizing the findings and thus capturing the meaning of the participants' experiences. The systematic organization of data in NVivo and the structured analysis make the process transparent.

We discussed sample size in line with Malterud, Siersma and Guassora (2016) and took into account the research questions, sample, theoretical approach, quality of data and analysis strategy. I selected participants from groups led by all physiotherapists since I believed that the interaction between the participants and each of the physiotherapists (because of clinical skills, experience, education, personality and so on) would affect the participants' experiences. When I had reached 13 participants in the 7-week interviews, I observed the appearance of many similar stories; additionally, all the interviews were rich and long, and our theoretical approach could clarify the categories that emerged in the analysis. In the study protocol, we decided to follow the same participants up to the 30-week interviews to obtain long-term reflections, potential development or change. These interviews revealed some new experiences of daily life and retrospective reflections of participation; however, these interviews were shorter, as we had already talked about most themes. These considerations of sample size are more comprehensive than the debated term "saturation", which describes a state attained when adding more data does not impact the analysis (Green & Thorogood, 2018, pp. 3-34). In all qualitative studies there is a question if some of those who were not selected potentially could have added additional aspects (Malterud et al., 2016).

7.17.3 Interpretation

The *interpretation* of the material involves how the research team generate meaning from the participants' descriptions of their experiences (Stige et al., 2009). The authors tried to be open and attentive regarding interpretations of the material. For instance, we discussed how the theoretical approaches would enrich the understanding of the material and whether were aspects of the few challenging situations that still needed to be highlighted to understand essential elements of GroupCoreDIST. We continually challenged the interpretation of the material by asking *"what does this mean?"* and *"what else could it mean?"*. Both SG and GKØ provided external views that were truly important in this regard, and the theoretical framework served as our lens during this process. I alternated between the empirical data and the theoretical perspectives to clarify the meaning of the participants' experiences from GroupCoreDIST. Such a process may balance the interpretation of findings and raise them to a higher, transferable level (Tong et al., 2007). In line with the Northern Norway Regional Health Authority, we had two patient representatives in the study. These representatives provided important insights and added their understandings of the condensed material.

7.17.4 Critique

Critique involves reflections concerning the study's strengths and weaknesses both throughout and after the study is completed (Stige et al., 2009). *Self-critique* involves reflexivity regarding my position as an interviewer and is already partly discussed in the "engagement" section. My position may have influenced the interview situation. Although I directly asked about negative experiences, my reactions and gazes in the setting might have influenced the participants' answers, and perhaps someone felt obligated to be positive. Therefore, transparency throughout the detailed descriptions of all parts of the study, the published protocol (Normann, Zanaboni, et al., 2016) and the interview guide is important. The two individuals who shared negative experiences and those with neutral experiences did so without hesitation, which may indicate that the participants felt safe in the situation and that my background and position actually facilitated elaborations of their experiences. However, the interviews of the two dissatisfied participants might have further turned their focus towards their own problems. On the other hand, talking about their tough experiences and receiving support by being told that their experiences were important for improving the content of group-based training for individuals with MS may have made their experiences meaningful to the participants.

Social critique concerns how a study is evaluated by others and the influence of research in social and political contexts. The qualitative paper is published in a high-level peer-reviewed physiotherapy journal, and throughout the review process, it is critically read by other researchers. The paper is open access and can be read by other researchers and clinical physiotherapists who may interpret the meaning of the findings.

7.17.5 Usefulness

The *usefulness* of a study concerns the ways in which knowledge is useful in practical situations (Stige et al., 2009), such as for physiotherapists, patients and policy makers. The qualitative paper may provide insights into how a new individualized, group-based intervention is experienced, which may be implemented in physiotherapist´s clinical practice and thus provide improved competence in the municipalities. For ambulant individuals with MS, this study may be indirectly useful if physiotherapists take the findings into consideration, and it may also represent an opportunity to make demands of the physiotherapist concerning specificity and individualization in a group setting. In this regard, we especially found the few negative experiences to be important for emphasizing the principles that are important for success in group physiotherapy.

Usefulness may develop over time. The study may be used by leaders in a municipality to strive for EBP and to set requirements for physiotherapists in regard to knowing advantageous principles for group physiotherapy. In the wake of this study, GroupCoreDIST has been further developed into I-CoreDIST and has been explored in a pilot study examining acute stroke patients (Normann, Arntzen, & Sivertsen, 2018) as well as an ongoing larger mixed methods study that further addresses its usefulness. In regard to political contexts, this paper may contribute to new knowledge for EBP, which together with other research on this topic may influence both decision-making in clinical practise and future guidelines for physiotherapy in ambulant individuals with MS.

7.17.6 Relevance

R*elevance* concerns the study context, knowledge development and how a study contributes new knowledge compared with the previous literature (Stige et al., 2009). Our findings provide valuable insights in the social settings in which they were obtained: in group-based physiotherapy practice in six municipalities, where the participants' general social context consisted of living in their homes with their family and participating in their daily life as usual. At a descriptive level, some of the findings are recognized in the prior literature. Since we have added an analytical level and theoretical perspectives, new insights beyond the prior literature have been provided. The study's findings, interpretations and conclusions should be understood in regard to the fact that the study took place in Norway, which has a good health care system, and the findings may be relevant to similar countries and possibly less relevant to countries or cultures with other health care structures.

7.17.7 Trustworthiness, conformability and transferability

T*rustworthiness* refers to confidence in the data, interpretation and the use of methods to ensure quality in a study, and it is associated with validity in quantitative studies (Malterud, 2017). Trustworthiness is linked to our situatedness in the world with regard to physical, social and ethical aspects and whether the richness of the participants´ stories has the potential to make a change (Stige et al., 2009). In our study, the stories were rich, including both positive and negative findings, and the analysis opened up a new and extensive understanding of the experiences from group-based training of individuals with MS. Trustworthiness may also be accounted for through openness and transparency throughout the study. Since trustworthiness is also claimed to be a matter of the reader's judgement (Sandelowski, 1993), it was crucial that the readers could easily track the whole research process.

Furthermore, *credibility* is often outlined in relation to trustworthiness and may correspond to internal validity in quantitative research, referring to standard procedures such as our study protocol and the interview guide. *Dependability* corresponds to reliability in quantitative studies and refers to the stability of the data over time, which in this study was obtained by keeping a log of activities and debriefings/reflections together with my principal supervisor. Some techniques for dependability include member checking, which means that the participants' read the findings of the data analysis, and peer validation, which means that experts re-analyse some of the data (Brinkmann & Kvale, 2015, p. 242). I preferred not to use such techniques because they are criticized for signalling the opposite of a multi-faceted and constructed reality (Sandelowski, 1993). *Conformability* is the extent to which the findings can be repeated. In qualitative studies, the researcher will influence the content and development of the material (Malterud, 2001). Instead of aiming to repeat the findings, together with the participant, a new setting with new people may lead to the discovery of new insights regarding group-based physiotherapy.

T*ransferability* is related to generalization. In a qualitative study, the focus is on the individual's stories, including rich descriptions of the situations and individuals in these situations. The possibility of transferability lies within the discussion of the findings through a higher analytical level driven by the theoretical framework. A strategic sample is essential in qualitative, in-depth interview studies and has strengths in regard to the search for the nuanced experiences of participants.

7.18 Ethics

A study's ethics is important to address in qualitative and quantitative studies and in mixed methods studies. The participants signed a written informed consent form that involved both the RCT and the interview study (appendix 1). This study was approved by the Regional Committee for Medical and Health Research Ethics in Northern Norway (REK South-East: 2014/1715-7) (appendix 2-4) and complied with the Declaration of Helsinki (World Medical Association, 2013). Both the RCT and the qualitative part of this study were registered in ClinicalTrials.gov, and the protocol has been published (Normann, Zanaboni, et al., 2016).. There could potentially have been individuals who felt pressured to participate in the study to help me or the research leader since some knew us from clinical practice. However, participation was voluntary and they were informed that they could withdraw from the study at any time point without consequences. The interviews and assessments were anonymized, and sensitive personal information was omitted. The audio recordings of the interviews, scoring schemas and video recordings of the RCT are stored in a secure, locked cabinet on a password-protected external hard drive. The clinical physiotherapists may be identified if someone sets his/her mind to search for them since this study is organized in a narrow geographic area. The participants in the study were treated with respect and cannot be identified, and the findings were handled with discretion and confidentiality.

8 RESULTS

8.1 Paper 1

"Group-based individualized comprehensive core stability intervention improves balance in persons with MS: A randomized controlled trial"

Aim: This paper examined the short- and long-term effects of the 6-week GroupCoreDIST intervention compared to standard care on trunk control and balance in individuals with MS.

Methods: A prospective, assessor-masked RCT including 80 individuals with MS (EDSS scores of 1-6.5, mean of 2.36). Forty persons received GroupCoreDIST for 60 minutes three times per week for six weeks (18 sessions), and 40 followed standard care, which for most individuals involved general activities and was not dose matched regarding physiotherapy. The interventions took place in six Norwegian municipalities. Assessments were conducted at baseline and at 7, 18 and 30 weeks, including the following primary outcomes: the TIS-NV and the Mini-BESTest. One secondary outcome; the PGIC-balance, was reported. A repeated-measures mixed-model analysis in IBM SPSS was conducted.

Results: The results demonstrated between-group differences at all follow-up time points in balance, trunk control and perception of improved balance compared to standard care ($p<0.05$) and overall effects for all outcome measures ($p<0.05$). The average difference between the adjusted baseline values (9.9/16 points) and the 7-week value of the TIS-NV for the GroupCoreDIST was 2.4 points, which is slightly less than the 3 points reported as the MCID in stroke patients. In the Mini-BESTest, a 1.8-point difference from baseline to the 7-week assessment was found, which is less than the MCID (3.5 points) reported in elderly individuals. The results demonstrated that 16 individuals from both groups (41% of the total sample) scored 25 points or higher on the Mini-BESTest (maximum score of 28 points). The performance of unsupervised home exercises continued for three months.

Conclusion and implications: The findings indicate that 6 weeks of participation in GroupCoreDIST is effective in regard to short- and long-term improvements in trunk control and balance compared to standard care. Standard care included surprisingly low doses of physiotherapy. The performance of unsupervised home exercises may have contributed to the sustained effects. In later studies, GroupCoreDIST should be compared to interventions with equal doses.

8.2 Paper 2

"Group-based, individualized comprehensive core stability and balance intervention provides immediate and long-term improvements in walking in individuals with MS: An RCT"

Aim: This paper reported the secondary outcomes from the RCT study on the short- and long-term effects of GroupCoreDIST compared to standard care on walking in persons with MS.

Methods: This prospective, assessor-masked RCT included 80 individuals with MS (EDSS mean 2.36). Forty individuals performed GroupCoreDIST for 60 minutes 3 times per week for 6 weeks, and 40 joined standard care, which involved general activities and was not dose matched regarding physiotherapy. The assessments at baseline and 7, 18 and 30 weeks included the 2MWT, the 10MWT-fast, -preferred, and -slow speed, the MSWS-12, the PGIC-walking, the RVGA and ActiGraph. A repeated-measures mixed-model analysis was conducted in IBM SPSS.

Results: The results demonstrated significant between-group differences in the 2 MWT and PGIC-walking at all follow-up time points and between-group effects for the 10MWT-fast and the MSWS-12 at 7 and 18 weeks and for the RVGA at 7 weeks (all $p<0.05$). Overall effects were demonstrated for the 2MWT, 10MWT, MSWS-12 and PGIC-walking (all $p<0.05$). The mean difference from baseline to the first post-test demonstrated improvements similar to MCID for the 2MWT and MSWS-12. No effects were demonstrated for the 10MWT-preferred or -slow, the number of steps per day or the physical activity level. The walking distance at baseline was on average shorter than in healthy individuals, and the number of steps were lower than those recommended by health authorities.

Conclusion and implications: The results indicate that 6 weeks of participation in GroupCoreDIST provides short- and long-term effects on walking distance and speed, the perception of change and MS impact on walking. The effects may have been sustained due to the participants' continued home exercises for three months. Neither the activity level nor the number of steps improved, which clearly indicates that it was the intervention and not the participants' general activity level that influenced the enhancements. The EDSS level was on average low in both groups (a mean of 2.36). This finding indicates that the impairment level alone could not explain why the number of steps were below national and international recommendations. GroupCoreDIST should be compared with equal-dose interventions, and physical activity may be an additional focus in a future study.

8.3 Paper 3

"Group-based individualized exercises can provide perceived bodily changes and strengthen aspects of self in individuals with MS: A qualitative interview study"

Aim: In this paper, we reported the findings from a qualitative interview study investigating individuals' experiences from and reflections concerning participation in GroupCoreDIST.

Methods: We interviewed 13 individuals twice (at 7 and 30 weeks) for a total of 25 interviews (one person died before the last interview) and analysed them in line with the principles of systematic text condensation (Malterud, 2012). Dynamic systems theory and phenomenological elaborations of the pattern theory of self were used as a theoretical framework to uncover the latent content of the meaning of participation in GroupCoreDIST.

Results: The findings revealed two main categories: 1) movement control, orientation and insights and 2) the individual within the group. 1) The participants experienced the intervention as being very detailed. Their impairments were clarified during the individual assessment and balance check points and explained in regard to daily activities. Individual hands-on adjustments and performance of exercises were experienced to contributed to immediate bodily improvements, which were emotional, created experiences of control and agency towards their own body. Such embodied experiences opened for opportunities and expectations for new activities and participation that lasted long term. 2) The group setting capitalized on the changes experienced and strengthened positive reflections of movement possibilities when the participants experienced appropriate adjustments by and attention from the physiotherapist and group members; however, unequal attention, fewer adjustments and a perception of no changes provided a focus on the participants' own disability.

Conclusion and implications: The participants experienced deviations at impairment, activity and participation levels, and new understandings of their own body as their individual challenges were detected and explained and, possibilities for changes explored. Tailored hands-on interactions, and an equal amount of attention was emphasized as advantageous. Experiences of bodily changes due to addressing the individual's prerequisites for balance created control and ownership of own body. The changes involved physical elements, and pre-reflexive elements, as they felt that they were more in control, and reflexive elements, as the group's verbalization capitalized on improvements and new opportunities. Both physical and existential elements should be considered in group physiotherapy for persons with MS.

9 INTEGRATION AND GENERAL DISCUSSION

The overall aim of this study was to derive new knowledge regarding the advantages of participation in GroupCoreDIST by exploring its possible effects and participants' experiences from six weeks of this new intervention. In accordance with the mixed methods design, I have conducted a systematic integration of the key findings from the qualitative and quantitative studies and integrated special and surprising features that could contribute to answering the overall research question: *"What are the possible advantages of participation in 6 weeks of GroupCoreDIST in terms of balance and walking status, effects and user experiences in ambulant individuals with MS?"*. I found that in all papers there were overlapping findings regarding the participants´ status before the interventions (baseline findings and clinical examination), there were overlapping short-term findings and overlapping long-term findings. The integration of these findings led to three new categories:

1) Detecting deviations, challenges and possibilities: This category emphasizes the integrated findings from the baseline outcome measures regarding balance and walking status and the average EDSS level found in the RCT papers, as well as the findings of the qualitative paper regarding the participants' experiences from the individual clinical assessment conducted by the group-leading physiotherapist before the start of the group sessions.

2) *Short-term effects and insights from nesting individual and group elements:* This category accentuates the integrated findings of the short-term effects on various aspects of balance and walking found in the two RCT papers and the short-term experiences from participation in GroupCoreDIST found in the qualitative paper.

3) *Long-term changes, affordances and maintenance:* This category highlights the integrated findings of the long-term effects (three- and six-month assessments) on various aspects of balance and walking found in the two RCT papers and the long-term experiences from participation in GroupCoreDIST found in the qualitative paper.

An overview of the whole mixed methods analysis is presented below (table 1). In the following sections, the three new categories are presented systematically with a short integrated summary of the findings, followed by two discussions to answer the overall research question.

	Findings in each paper	New category		Integration of findings	Overall discussion	Key messages
Paper 1	**A Baseline:** EDSS 2.36. Impaired trunk control(TIS-NV), balance(Mini-BESTest)	A: Detecting deviations, challenges and possibilities	A: Detecting deviations, challenges and possibilities	Participants had low average EDSS, but still impaired trunk control, balance, walking, physical activity/steps per day, and experience of detailed deviations at all ICF levels. Detecting different types of deviations and challenges provided varied types of meaning; embodied feelings, thoughts and reflections	Varied assessments are needed to detect balance and walking status. Varied assessments provide different aspects of meaning.	It is important to detect varied aspects of balance and walking to identify deviations at an early stage, even with low disability. Outcome measures and a clinical examination capturing all ICF levels, relationship between levels and changes may provide different dimensions of meaning leaning to a positive mind-set, and expectations for future possibilities and should be considered in the MS follow-up at an early stage.
	B Short-term: Effects trunk control (TIS-NV), balance (Mini-BESTest), perception of change (PGIC-balance). MCID: TIS-NV(stroke)	B: Short-term effects and insights from nesting individual and group elements				
	C Long-term: Effects TIS-NV, Mini-BESTest and PGIC-balance for 6-months. Home-exercises conducted for 3-months	C: Long-term changes, affordances and maintenance				
Paper 2	**A Baseline:** EDSS 2.36. Shorter walking distance (2MWT), experience of MS impact on daily walking (MSWS-12) fewer steps and lower activity than recommended (ActiGraph)	A: Detecting deviations, challenges and possibilities	B: Short-term effects and insights from nesting individual and group elements	Short- term effects on trunk control, balance, walking and emotional experiences of changes at all ICF levels were linked to varied types of meaning; embodied feelings of control, ownership, agency and insights of changes. Important principles in the GroupCoreDIST: individual elements: detailed pre-requisites for balance in exercise tasks, adaptations of symptoms. Group elements: equal attention, highlight changes. Strengthens feelings and reflections of possibilities for activity and participation.	Integrating pre-requisites for balance and walking in exercise tasks. The power of changes.	The GroupCoreDIST provided short-term effects and experiences of detailed changes at all ICF levels. Calculated and embodied perceptions of change both may provide meaning and should be considered in MS follow-up. The principles in the GroupCoreDIST, including individualized addressing of pre-requisites for balance and walking integrated in task exercises to explore change in a group setting should be considered in interventions as it strengthens feelings of change, control, ownership and agency to body and movements and reflections of activity and participation.
	B Short-term: Effects walking; distance(2MWT), speed(10MWT-fast), quality (RVGA) MS impact (MSWS-12), perception of change (PGIC-walking). MCID: 2MWT and MSWS-12	B: Short-term effects and insights from nesting individual and group elements				
	C Long-term: Effects 2MWT for 6-months. 10 MWT-fast, MSWS-12, PGIC-w for 3-moths. No change:steps/phys act. No change in steps and activity	C: Long-term changes, affordances and maintenance				
Paper 3	**A Clinical examination:** Relationship between symptoms detected in the detail, explained through all ICF levels. Exploration and perception of change leads to expectations!	A: Detecting deviations, challenges and possibilities	C: Long-term changes, affordances and maintenance	GroupCoreDIST provided long- term effects on balance and walking that lasted up to 6-months and experiences of new affordances, possibilities for activity and participation Effect sizes deceased over time and no new changes were experienced Participants continued doing unsupervised home exercises for 3-months, but experienced this as less motivating. Physical activity level or number of steps was unchanged throughout the study	Sustained improvements and stories of daily life activities and participation. Changes in balance and walking and new affordances does not necessarily match activity level.	The GroupCoreDIST created long-term changes in balance and walking in terms of effects, experience of sustained improvements, new affordances and possibilities for daily life activities and participation, and may be an advantageous supplement to clinical practice and the long-term follow-up of individuals with MS. Most effect sizes decreased over time and no new changes were experienced which imply that individuals with MS need a structured long-term follow-up of their balance and walking challenges. Physical activity and steps did not change, and a focus on this should be considered.
	B Short-term: Emotional change at all ICF levels. Individual: pre-requisites for balance tasks, adjustments related to individual sympt. Group: equal attention, highlight changes: strengthens feelings+reflections	B: Short-term effects and insights from nesting individual and group elements				
	C Long-term: Experience new affordances, activity and participation. No new changes from home--exercises	C: Long-term changes, affordances and maintenance				

Table 1. The integration of findings and mixed methods analysis.

9.1 Detecting deviations, challenges and possibilities

The integration of the findings from the EDSS screening, standardized outcome measurements, and the participants' experiences from the clinical examination with the group-leading physiotherapist validated each other, demonstrated interesting contrasts and discoveries that may expand our knowledge. The participants had, on average, low EDSS scores, indicating a low disability level (average EDSS score of 2.36) and no disability in terms of walking. In contrast to these results, the standardized outcome measurements detected balance and walking deviations, including impaired trunk control (TIS-NV) and balance (Mini-BESTest), a shorter walking distance than that in healthy individuals (2MWT), a reduced speed (10MWT), a lower physical activity level, and fewer steps than recommended (ActiGraph), and the participants experienced that MS impacted walking in their daily life (MSWS-12). The descriptions of explicit bodily impairments and balance and walking challenges in daily life given by the participants in the GroupCoreDIST group were similar to these findings. These findings add extra details, especially regarding the participants' experiences of deviations at the impairment level, for instance, impaired sensibility in their feet and reduced core activation. The participants experienced their impairments were detected in detail and explained in a recognizable matter by the physiotherapist in regard to ADLs and participation during the clinical examination.

Identifying balance and walking challenges in ambulant individuals with MS through the EDSS, outcome measures and a clinical examination may be meaningful for understanding deviations from normal, both for the patient and for the physiotherapist. Furthermore, the verification of deviations in the individual examination led to explorations of possibilities for change by trying out GroupCoreDIST exercises and engaging in adjusted hands-on interactions. This seemed to be an embodied route to the meaning of balance and walking deviations, as it led to initial feelings of improved control over one's own body and movements. The participants, furthermore, expected that the physiotherapist would choose adequate exercises and adaptations that suited them in the upcoming group sessions. In summary, the new category "detecting deviations, challenges and possibilities" emphasizes that varied assessments are needed to detect diverse balance and walking deviations and may provide different aspects of meaning for the participants. In the following, these integrated key findings are discussed.

9.1.1 Varied assessments are needed to detect balance and walking status

A core element in the integrated findings was the contrast between the low average disability level (EDSS scores) and the balance and walking challenges documented through outcome measures and the participants' experiences of detailed deviations at all ICF levels. The EDSS is an important tool for monitoring a person's disability status over time, and it aims to detect the impact of MS on the patient's CNS (Kurtzke, 1983; Meyer-Moock et al., 2014). The wide range of disability levels in our study (EDSS scores of 1-6.5) implies that various sub-systems and symptoms were involved, which is usual in individuals with MS (Polman et al., 2011). Various levels of disability were also experienced by the participants since their stories ranged from minor impairments such as decreased sensation in the feet to those stating that they mostly walked indoors. The average low EDSS scores indicate no balance or walking problems. Such a finding at a yearly follow-up at an MS outpatient clinic, would most likely not lead to the initiation of physiotherapy. This way of underestimating or in many cases not detecting balance and walking deviations may also be one explanation for the surprisingly low number of participants in the standard care group who saw a physiotherapist during the intervention period (22.5%).

Critics claim that the EDSS is insensitive in detecting walking and balance deviations when the disability is low, and they indicate that more specific assessments are needed to reveal such challenges prior to the onset of clinical disability to ensure that individuals with initial problems are found and referred to a physiotherapist at an early stage (Martin et al., 2006). This reasoning is in line with our findings and seems particularly important, as it is well documented that 50-80% of individuals with MS experience balance and walking disturbances and that these disturbances often occur when the disability is low (Aruin et al., 2015; Cattaneo et al., 2014; Comber et al., 2017; Kalron & Givon, 2016; Langeskov-Christensen et al., 2017; Multiple Sclerosis International Federation, 2013). Our findings pinpoint the advantage of adding more detailed detections of balance and walking status. Such detections should be conducted at an early time point, such as at the time of diagnosis and in the yearly follow-up at MS outpatient clinics, even if the disability is low.

In regard to what assessments are needed to detect balance and walking challenges, the findings from the standardized outcome measures and the participants' experiences from the clinical examination revealed different aspects of balance and walking deviations at different ICF levels. The impairment level was captured by the TIS-NV, which measured the participant's trunk control (Gjelsvik et al., 2012), with our participants demonstrating deviations from normal at baseline (average 10/16 points). The impairment level was also captured by the participants' detailed descriptions, such as experiences of impaired trunk muscle activation and decreased sensibility in their feet, which they felt were carefully assessed in the one-on-one examination. The scores from outcome measures such as the TIS-NV provided an important basis to make comparisons after 6 weeks of GroupCoreDIST. When findings from all ICF levels were linked together, it seemed to connect the participants´ experiences and the more objective findings. In this way, also the embodied details from the clinical examination and findings from the outcome measures complemented each other.

The activity level was validated by the participants' experiences of balance and walking challenges in the clinical examination and in their daily life and by outcome measures demonstrating balance and walking deviations. The Mini-BESTest captured postural control and balance (Hamre et al., 2017) and detected deviations in our participants (average 21.5/28 points at baseline). In 16 of the 79 participants, the scores were 25 points or higher, which may indicate that these individuals had no or rather small balance problems. The Mini-BESTest measures only *whether* a person manages various balance challenges and not *how* the tasks are performed. Some tasks may have been performed with fixations or compensations in, for instance, the participants' gaze, head, neck, arms or trunk, which may have been advantageous for obtaining a full score on the test; however, they may be disadvantageous for effective movements in daily life and if the aim of physiotherapy is recovery. In this regard, the individual clinical examination seems to expand the knowledge of activity challenges, as even participants with minor disability experienced that deviations from normal motor control were detected by the physiotherapist. It is well known that balance and walking may be affected by ineffective anticipatory and compensatory postural adjustments caused by a variety of impairments, such as somatosensory impairments, paresis, muscular adaptive shortenings or pathological increased tone (Aruin et al., 2017; Krishnan et al., 2012a, 2012b; Mohapatra et al., 2012; Santos et al., 2010). Therefore, capturing such challenges through outcome measures and an individual clinical examination focusing on an analysis of bodily impairments and a movement analysis of motor control in balance and walking seems to be advantageous.

By integrating the baseline findings, we also observed that the participants' experiences of having stopped participating in activities such as cycling, hiking and exercising with their friends were validated by the walking outcomes. The participants walked a significantly shorter indoor distance (43 metres shorter in the 2MWT) compared to healthy age-matched individuals (average 211 m; 95% CI (191, 234 metres) (Selman, de Camargo, Santos, Lanza, & Corso, 2014)). The ActiGraph also detected a lower number of steps per day (an average of 6460 steps for both groups) than the recommended level of 10,000 steps in healthy (Bassett et al., 2017) and 7100 steps per day for special group populations (Tudor-Locke et al., 2011). Other studies of individuals with MS have reported a fairly lower number of steps than that in the current study (5903 steps per day (SD of 3185, 95% CI of 5657-6149 (Dlugonski et al., 2013) and 5840 steps per day in another study (SD: 3096) (Casey, Coote, Galvin, et al., 2018)). However, this difference may be explained by the lower disability level in our study and knowledge that the activity level decreases with increased disability (Marck et al., 2014). With the extended knowledge that 5000-7499 steps are classified as physical inactivity (Bassett et al., 2017; Tudor-Locke & Bassett, 2004), it seems clear that even though their disability level was low, our participants had walking difficulties and walked less than the recommended amount. By only performing a clinical examination, listening to the patient's stories of activity or screening the EDSS level, we would not have captured these important deviations. Specific walking and physical activity assessments are needed to capture these factors, and comparisons to recommendations and the values for healthy individuals are important to pinpoint the extent of the problem.

The level of moderate activity measured in the current study (average of 26.75 minutes of moderate activity per day) was surprisingly close to the guidelines (30 minutes of moderate activity per day) (Ezeugwu et al., 2015; Garber et al., 2011) and the recommendations by the national health authorities of 150 minutes of moderate activity each week for healthy individuals (B. H. Hansen et al., 2015; B. H. Hansen et al., 2019). The level of moderate activity measured in the current study was higher than the unambitious recommendations for people with mild to moderate MS of 30 minutes of moderate aerobic activity twice a week (Latimer-Cheung et al., 2013). The contradictions between the lower number of steps and the participants' feelings of being less active and the activity levels being close to recommendations should be further investigated. Other studies have associated impaired physical activity with comorbid conditions such as contractures, osteoporosis, decubitus ulcers, venous thrombosis, bowel and bladder problems and heart problems in individuals with MS (Casey, Coote, Galvin, et al., 2018; Kelleher et al., 2009; Marck et al., 2016) and have suggested that impaired physical activity is a public health problem (Block et al., 2016; Motl et al., 2015). Physiotherapy is often initiated at a later stage as a symptomatic treatment (Riemenschneider et al., 2018), which may very well be because balance and walking deviations are not detected before the onset of moderate and severe disability. New findings suggest that exercises can have both neuro-protective and disease-modifying effects, be beneficial for immune modulation and activity-dependent plasticity (Prosperini & Di Filippo, 2019; Riemenschneider et al., 2018) and prevent compensatory ways of moving and learned non-use (Nudo, 2013; Nudo et al., 2001; Taub et al., 2006). These facts support the need for early detection of balance and walking status to initiate physiotherapy at an early stage, even when the disability is minimal.

In summary, the current study suggests that varied assessments are needed to reveal different aspects of the balance and walking status of individuals with MS, which implies that an integration of EDSS screening, standardized balance and walking outcomes and a clinical examination is advantageous and should be considered in early stages and at the time of diagnosis as well as in the follow-up of individuals with MS.

9.1.2 Varied assessments provide different aspects of meaning

A common feature of all papers was that the EDSS screening, outcome measures and the participants' experiences of the physiotherapist examining them, all provided more or less "objective" recognitions of the patients' balance and walking deviations (for both the patient and the physiotherapist). The disability status measured by the EDSS is meaningful for ensuring that the effects of medications are in line with the NEDA principle (Thompson, Baranzini, et al., 2018). The EDSS serves as one of the signs of whether the disease activity is steady, is increasing or is decreasing. The standardized outcome measures provided specific numbers for balance and walking that were comparable to the reference values. The clinical examination provided the participants with experiences of impairments in parts of their body, and the activities. All these assessments may add meaningful knowledge to understand the severity and details of patients' balance and walking difficulties. The literature emphasizes that such information is meaningful for the *physiotherapist* with regard to the patient's constraints to movement (Gjelsvik & Syre, 2016; Raine et al., 2009; Shumway-Cook & Woollacott, 2017, pp. 432-433), the *physiotherapist's* clinical reasoning processes (Higgs, 2008; Normann et al., 2013; Øberg et al., 2015) and the *physiotherapist's* adequate choice of exercises and adaptations in GroupCoreDIST (Lahelle et al., 2018b). In the current study, these assessments also seemed to be meaningful for the *patient*, for instance, as the physiotherapist explained his/her impairments in relation to ADLs. In cases where scorings and perceptions of deviations match it may provide a relieving acknowledgement of having an actual problem, even if it is a minor one, which may feel safe. Objective assessments of the body may involve a mind-body dualism and a mechanical view of the body, as we measure parts of the body without taking situated aspects into consideration (Djulbegovic et al., 2009). In contrast, the participants' experiences of the physiotherapist integrating detailed bodily deviations with subjective feelings of the body and stories from activity and participation may have bridged the objective findings with subjective feelings of balance and walking deviations. This integration may have increased the importance of detecting balance and walking deviations for the patient and not only for the physiotherapist.

As an expanded feature, this bridging may have been strengthened by the explorations of changes in motor control by trying out exercises and through hands-on interactions in the clinical examination. These interactions may serve as an embodied route to knowledge in balance and walking and are in line with a core element in GroupCoreDIST involving new insights through perceptions and reflections on bodily and movement changes. In those who experienced immediate changes in the clinical examination, this aspect was expressed as being even more important since it directly meant something to them and was not only a basis for the physiotherapist's knowledge. Immediate changes may be linked to an experience of being more in control and being the owner of one's own body and movements (sense of ownership and agency) and the experiential factors of the self-pattern (Gallagher, 2013). Furthermore, this led to expectations for the group sessions to come and for movement possibilities in the future. Such reflections may be linked to the reflective factors of the self-pattern (Gallagher, 2013). Similar findings have been emphasized in regard to individual settings (Normann et al., 2013) and GroupCoreDIST groups from a professional perspective (Lahelle et al., 2018b). Since experiences of meaning are strongly connected to what a person can do (Gibson, 1986) and meaningfulness is an important principle of neuroplasticity (Kleim & Jones, 2008), it seems important to add explorations of changes to assessments in individuals with MS prior to group sessions. Doing so requires the physiotherapist to have the skills to do more than just screen the balance and walking status, indicating the need for increased competence since there are few specialists in neurological physiotherapy in Norway (Norwegian Physiotherapy Association, 2019). Feelings of change may create an early change in mindset towards one's own body and movement and positive thoughts regarding responsibility for self-care and further training and be a motivational before starting an intervention such as GroupCoreDIST. These aspects seems to be advantageous since individuals with MS often receive their diagnosis at an early age and may experience unpredictable deteriorations throughout life.

In summary, the current study highlights the advantage of varied balance and walking assessments and explorations of change since they may provide both an embodied route and a verbal, cognitive route for meaning and insights into one's own body, deviations and possibilities for changes. The result may be increased feelings of ownership and agency, an early change in mindset and reflections concerning future physiotherapy sessions and movement possibilities.

Main messages of "Detecting deviations, challenges and possibilities":

It is important to detect various aspects of balance and walking to identify deviations from optimal movement at an early stage, even when the disability status is low.

Outcome measures that capture all ICF levels and a detailed clinical examination that addresses the relationship between specific impairments and activities as well as explorations of possibilities for change are needed. These different assessments and interactions may provide different dimensions of meaning to patients, a positive mindset and expectations for future possibilities, which are important for individuals with a chronic disease and when initiating physiotherapy.

9.2 Short-term effects of and insights from nesting individual and group elements

The integration of findings regarding short-term user experiences and effects demonstrated convincing advantages of GroupCoreDIST and expanded knowledge regarding particular components of the intervention that may have been valuable for improvements. The six weeks of GroupCoreDIST provided improvements experienced at all ICF levels, such as improved sensation in the feet and more automatic core muscle activation (impairment level), improved propulsion while walking and the ability to carry two cups of coffee while walking (activity level) and having more energy to participate in domestic obligations (participation level), which led to feelings of being more in control and being the owner of one’s own body and movements. These findings were in line with the significant short-term effects on trunk control (TIS-NV), balance (Mini-BESTest), the indoor walking distance (2MWT), the fast walking speed (10MWT-fast), quality of walking (RVGA) and the experience of improved balance and walking (MSWS-12, PGIC-balance and PGIC-walking) compared to standard care that this study found. Standard care included a low dose of physiotherapy and, above all, general activity. Clinically meaningful changes were revealed in the 2MWT and MSWS-12, and borderline meaningful changes were found in the TIS-NV (compared to stroke).

The participants emphasized both individual and group elements in GroupCoreDIST as advantageous for the changes that they experienced. The individual elements included addressing individual symptoms and the prerequisites for balance and walking in an integrated manner, for instance, through exercises where core muscle activation and somatosensory activation of the feet were coordinated, and the optimal performance of adequate exercise variants was addressed through detailed instructions and hands-on interactions. These elements served as an embodied route to meaningful changes in the 6-week period. The group setting strengthened the feelings of change through reflections on each group member’s improvements. Such conversations led to further reflections on the possibilities for new daily life achievements; however, when a person experienced unequal attention, fewer individual adjustments and fewer changes, his/her reflections turned towards his/her own disability. In summary, the new category “short-term effects and insights from nesting individual and group-based elements” emphasized the advantages of integrating prerequisites for balance and walking in exercise tasks and the power of changes. In the following, these integrated key findings are discussed.

9.2.1 Integrating the prerequisites for balance and walking in exercise tasks

One common feature was that the integrated findings of experienced and measured improvements in trunk control validated each other and seemed to be in line with the felt and measured changes in balance and walking. Such validation strengthens our findings, as it is a reliable fact that the participants actually achieved changes and that the felt changes were not only reflections of the increased attention due to participation in a study. The improvements in trunk control support the idea that the participants potentially achieved a more dynamic and coordinated activation of their core muscles. Dynamic core muscle activation was a fundamental element in all GroupCoreDIST exercises and was integrated with a distal task (Normann, Zanaboni, et al., 2016). The coordination of proximal activation while performing a distal task was highlighted from the user perspective. This ingredience of the GroupCoreDIST was also highlighted in a prior study providing a professional perspective and capitalizes on the sequenced instructions while performing the exercises (Dybesland & Normann, 2018). Such coordinated activation sequences are in line with the size principle of recruitment (Henneman's recruitment principle) according to which tonic muscle fibres, such as deep core muscles, are recruited before phasic fibres (Brodal, 2010, p. 288). Traditional core stability training has been criticized for addressing local core muscles in isolation and with no relationship to functional activity (Lederman, 2010). Pilates training, which is a frequently used type of core stability training among individuals with MS, is slightly more complex than addressing only core muscles, but it includes instructions that imply a cognitive route for activating core muscles such as *"pushing the bellybutton into the spine"* (Di Lorenzo, 2011; Duff et al., 2018a; Sánchez-Lastra et al., 2019). In contrast, the comprehensive motor-motor dual tasks in GroupCoreDIST may have turned the participants' focus towards the task and thus facilitated the use of less cognitive routes for core muscle activation. This may be a good idea since the proximal to distal activation pattern is the natural route for postural stability (ventromedial systems prior to ventrolateral systems) (Brodal, 2010, p. 379) and since postural tone originates from supraspinal centres such as the reticular formation, vestibular nuclei, cerebellum and mesodiencephalic nuclei that exhibit sustained activity, which are less voluntarily activated (Ivanenko & Gurfinkel, 2018). When increasing the difficulty of exercises, such as adding motor-cognitive dual tasks, the facilitation of less cognitive routes may have been strengthened because the focus turned towards the cognitive task.

The focus on a task may also be linked to phenomenological elaborations of the self-pattern since a focus away from impaired body parts may strengthen intentionality (Leder, 1990, pp. 25-27). The outward directedness may also be associated with the observed improvements in postural control, balance and walking based on the Mini-BESTest and walking outcomes since an orientation towards the environment is important for optimal control in balance and walking. Furthermore, the participants' descriptions of managing daily life tasks, such as standing on their toes to reach upper kitchen cabinets, balancing over backpacks lying on the floor, and walking with more propulsion, are examples of activities that require outward directedness while simultaneously coordinating the proximal to distal areas through anticipatory and compensatory postural adjustments. In different tasks and positions, this coordination will require activation of different proximal and distal muscles (Borghuis et al., 2008); therefore, performing exercises in various positions and tasks in GroupCoreDIST may also have been advantageous.

One finding that expanded our knowledge was the participants' experiences of bodily changes at the impairment level, such as improved sensorimotor conditions in the feet after rolling a mobilization ball, which the participants linked to experiences of changes in balance and walking. Prior studies have emphasized that the mechanoreceptors in the feet are important for information regarding heel-strike, toe-off and weight transfer (MacKay-Lyons, 2002; Shumway-Cook & Woollacott, 2017, pp. 49-53), and neuromuscular conditions in the feet and legs are essential for postural control (Lederman, 2010). In the participants' experience, their feet were better adapted to the BOS, which potentially indicates a strengthening of the body schema. Such inner models are updated from efferent and afferent routes and networks, and the somatotopical organization of somatosensory tracts implies that the CNS continuously, on a pre-reflective level, "knows" the body and the position of body parts (Brodal, 2010, pp. 264-265). Such information is essential for adaptation to the BOS and provides easier access to external information about and integration of the task and the environment (Ivanenko & Gurfinkel, 2018; Shumway-Cook & Woollacott, 2017, pp. 156-158); it is also a well-known foundation for optimal balance. These elements may account for the improved motor outcomes and feelings of improvements documented in this study.

Integrating this neurobiological view with an embodied view of body schema, which constitutes a pre-reflective aspect of self and nourishes what the person thinks and where feelings of the body are present in perception and action (Gallagher, 2012, pp. 131-135). This may emphasize the need for interventions that tie neuromuscular prerequisites for balance and walking to existential aspects of life itself. The participants' experienced improvements in somatosensory and motor components support the improved sense of control and ownership over their own movements (Gallagher, 2012, pp. 131-135), where the improved motor components also imply a strengthened sense of agency with regard to their own movements (Gallagher, 2012, pp. 168-171). Such subjective perceptions of change are seldom highlighted as an outcome of physiotherapy but provide important insights in regard to possibilities for movement and action. Therefore, integrating the neurobiological and embodied views of the body may be advantageous in future interventions.

The current study's findings expand the prior evidence of effects on balance and walking from exercises (Amatya et al., 2019; Khan et al., 2017), group exercise (Paltamaa et al., 2012; Stephens et al., 2001), and specific group-based core stability and balance training (Carling et al., 2016; Forsberg et al., 2016; Freeman & Allison, 2004; Learmonth et al., 2012; Nilsagård et al., 2014; Normann, Salvesen, et al., 2016; Stephens et al., 2001; Tarakci et al., 2013), as well as the findings of social benefits (Dodd et al., 2006; Learmonth, Marshall-McKenna, et al., 2013), increased motivation, empowerment, and knowledge regarding training and valuable peer support (Aubrey & Demain, 2012; Clarke & Coote, 2015). For instance, all the changes in impairment and activity ICF levels may indicate that addressing the interactions between proximal and distal prerequisites for balance and walking is advantageous. This result is in contrast to the leading view of motor learning, which capitalizes on the need for specific training, that is, the necessity of gait training to improve walking (Carr & Shepherd, 2010). In this view, the focus is on manipulating the task to succeed in the task. In contrast, GroupCoreDIST represents a different type of specificity. GroupCoreDIST focuses on manipulating the constraints in the individual's sub-systems, for instance, through hands-on adaptations integrated with the task, for instance, rolling a mobilization ball, in the safe and enthusiastic group setting, which is in line with training motor control in DST (Shumway-Cook & Woollacott, 2017, p. 156). The integration of the individual´s sub-systems in task exercises may be advantageous for balance and walking.

In summary, the current study supports the idea that a detailed individual focus on integration of proximal and distal prerequisites for balance and walking in task exercises is advantageous for achieving changes in balance and walking in individuals with MS. Changes may provide experiences of improved control and ownership over one's own body and movements and reflections concerning new possibilities for activity and participation. These principles should be considered in future group interventions.

9.2.2 The power of changes

A core element in our findings was that different aspects of meaning were demonstrated through calculated clinically meaningful changes and the participants' feelings of change or lack thereof. Expanding these findings, particular elements in GroupCoreDIST seemed to strengthen the participants' feelings of meaningful changes. One core element was the participants' emotional experiences of changes at all ICF levels, which were in line with the clinically meaningful changes demonstrated in the MSWS-12 compared to the reference values (Baert et al., 2014; Baert et al., 2018; Hobart et al., 2003; Mehta et al., 2015) and in the 2MWT compared to the reference values (Baert et al., 2014; Learmonth, Dlugonski, et al., 2013). Regarding the other outcome measures, reference values for individuals with MS were lacking. I compared the results from the TIS-NV to the reference values for individuals with stroke (Gjelsvik et al., 2012), where our participants were close to the reference value. Compared to the reference value in the Mini-BESTest for elderly individuals (Godi et al., 2013), our participants did not reach clinically meaningful values, which seems to stand in contrast to the emotional, detailed and sometimes life-rocking experiences of improved balance and walking, which provided feelings of increased autonomy in daily life.

The same type of expanded features was detected for the RVGA, which demonstrated significant effects on gait quality but only very small improvements (only 0.41 points in the GroupCoreDIST group and a deterioration of 0.88 points in the standard care group). The participants' highly emotional experiences of improved control, for instance, while walking over backpacks and outside, which felt meaningful as improved control made their daily life achievements easier, contrasted the minor changes on the RVGA. This result may be explained by the fact that movement control during walking involves a high number of aspects that were not captured by the RVGA, such as sensorimotor integration and the fine-tuned interplay between proximal and distal areas, which also involves rhythm, flow and fixations in the gaze or neck. Similar contrasts between what was measured and what was experienced were demonstrated regarding walking speed. The 10MWT demonstrated significant between-group differences and a 10% improvement in the GroupCoreDIST group; however, it did not reach 20% improvement, which is often accepted as a clinically meaningful change (Nilsagard et al., 2007). The participants reported detailed changes in propulsion and walking speed, which seemed to provide strong and emotional meaning for them, as they reflected positive thoughts of having new possibilities for walking in their daily life. Although we must take into consideration that the outcome measures including the

10MWT were measured on a group level and the participants' experiences were measured at an individual level, it still seems that aiming for embodied feelings of change is a powerful tool for creating positive thoughts for future activity and that these aspects of experiencing changes should be considered in future interventions.

The calculations of meaningful changes measure meaning numerically to reflect valid improvements in importance for the participants' function (de Vet et al., 2006; Potter et al., 2011). Numbers can provide meaningful information for the patient regarding his/her own effort and progress during the intervention period, and they can also be meaningful for the physiotherapist to measure the impact of an intervention. Using numbers to measure feelings is in the post-positivistic tradition, which highlights that knowledge is objective and time, context and value free (Greenhalgh et al., 2014). This characteristic reduces the meaning of changes to something that we can grade and a persons' reality to something that is possible to objectively measure (Sale et al., 2002). However, in a mixed methods study such as the current study, where pragmatism is a foundation, knowledge is based on the view that the world is intersubjective, objective and subjective and that we can integrate knowledge of what works in a social and interactional context (Onwuegbuzie et al., 2009). This view implies that the participants' feelings of meaningful changes are just as important as the number of meaningful changes, and our QUAN+QUAL design values both parts equally.

The participants' reports of meaningful changes were linked to some of the elements of GroupCoreDIST, especially the specific hands-on adjustments in combination with detailed instructions addressing the individual's constraints to movement. Such combined interactions address motor control through consciousness and pre-reflective bodily experiences and less cognitive systems (Normann et al., 2013). Hands-on facilitations are a form of communication through inter-corporeity where the patient and physiotherapist establish a shared sense of agency that, through bodily perceptions of increased opportunities for self-initiation of movement and motor control, has been suggested to strengthen reflections concerning the body and movement and to create new insights (Normann, 2018; Vaughan-Graham & Cott, 2016). Such interactions were emphasized by the participants as shared enthusiasm with the physiotherapist when a person suddenly managed to move, for instance, his/her toes, followed by verbalizations of what just happened and why this movement was suddenly possible. Perceived changes have been reported to facilitate other comments and questions from both the patient and the physiotherapist (Normann et al., 2013). Through such one-on-one interactions, even if in a group setting, each individual may have reached better conditions for movement. Increased movement quality may create possibilities for relearning through real recovery strategies (Levin et al., 2008) and new insights regarding one's own movement opportunities. It is perhaps optimistic to conclude that perceived changes at the impairment or activity level during a group session automatically provide meaning; however, as the body shapes the mind, (Gallagher, 2005), the changes felt may have formed the participants' thoughts. Perceived changes also created a positive dialogue in the group, as reflections and conversations focused on all the changes in each participant. In regard to GroupCoreDIST sessions, it has been documented that both individual interactions and encouragement provided by the physiotherapist to share bodily experiences are advantageous for group dynamics (Lahelle et al., 2019). The evidence in this regard is in line with the literature, which suggests that the awareness of changes is a powerful clinical tool that is strengthened by encouragement from the physiotherapist to share with others and to communicate feelings of change (Ajjawi & Higgs, 2012). Shared insights within the group may increase the meaning of change and may be seen as a behavioural change technique (Ajjawi & Higgs, 2012). As meaning and emotions are important for learning, these elements of embodied and verbal communication should be considered in future group interventions.

However, in a few individuals, the reflections in the group were negative, as they felt less individual adjustments and fewer changes compared to the others in the group. In these cases, the participants started doubting their own possibilities and reflected that "I cannot" do the same things as they can. This finding reminds us that a group setting is a vulnerable situation in regard to the construction of meaning and that self-awareness through inter-corporeity within the group will strengthen positive and negative meanings, insights and reflections. These aspects extend the prior knowledge that group-based interventions are sometimes frustrating and include inadequate individual service (Learmonth, Marshall-McKenna, et al., 2013; Learmonth & Motl, 2016). We now know that equal attention and one-on-one interactions are important for feelings of change and meaning. These ways of interlinking individual elements in a group setting underline the importance of detailed individualization in groups, which has previously been questioned (Kalron et al., 2019; Plow et al., 2009). Previous studies have emphasized that individualization is possible due to the thorough clinical examination prior to GroupCoreDIST sessions, the physiotherapist´s skills in movement analysis and if exercises allow for adaptations (Lahelle, 2019; Lahelle et al., 2018a, 2018b, 2019). These aspects seem to be verified from a user point of view as well.

In summary, the current study indicates that both calculated changes and embodied perceptions of change may provide meaningful insights to the participant (and the physiotherapist). Integrating the individual prerequisites for balance and walking in groups, where equal attention and individual adaptations are emphasized, may be advantageous principles in group-based settings. The physiotherapist's and group members' verbalization of individual changes may strengthen perceptions of change; however, when no changes are perceived or when unequal attention and inadequate adaptations are perceived, negative feelings are also strengthened by the group setting. These various aspects of meaningful change would not have been captured in a qualitative or quantitative study alone, which indicates the need for further mixed methods studies in individuals with MS.

Main messages of "Short-term insights and effects from nesting individual and group elements"

GroupCoreDIST provided short-term effects and experiences of detailed changes at all ICF levels. Both the calculated changes and the embodied perceptions of changes may provide meaningful insights to the participant and the physiotherapist, and they should be considered in future interventions and in the follow-up of individuals with MS.

The principles of GroupCoreDIST, which include addressing the individual prerequisites for balance and walking (embracing all individual sub-subsystems, for instance, neuromuscular and somatosensory constraints and emotions) integrated in task exercises to explore changes, should be considered for other group-based settings since they may lead to changes and feelings of control, ownership and agency towards one's own body and movements. The group environment strengthened both positive and negative feelings and reflections, and to facilitate positive thoughts, the principles of equal attention and individual adaptations should be considered in future group settings.

9.3 Long-term changes, affordances and maintenance

The integration of long-term findings demonstrated that the effects on improving trunk control, balance and walking distance were sustained for as long as six months, that the effects on improved walking speed and the measured experience of daily walking were sustained for three months, and that the participants experienced sustained long-term improvements that were mostly directed at new possibilities for activity and participation. The participants seemed to have discovered new affordances in life and to have gained increased opportunities to do whatever they liked. The sustained improvements involved less emotional descriptions than the feelings of short-term improvements, perhaps because no new bodily improvements occurred and some participants experienced new or recurring symptoms. The results also demonstrated that the effect sizes decreased over time and that no outcome measures demonstrated sustained clinically meaningful changes.

As one common feature reported in the self-reports and interviews that may have facilitated the sustained improvements, most participants continued unsupervised home exercises for three months after the intervention was completed. The participants performed the home training even though they experienced that training without the adjustments and adaptations by the physiotherapist was less meaningful since no new improvements occurred. Only two individuals performed home exercises at six months.

An important contrast in the material was the participants' feelings of having increased possibilities for activity and participation while the measured activity level and the number of steps (ActiGraph monitors) were unchanged throughout the study. This contrast indicates that sustained changes in balance and walking and the experience of new possibilities for activities are not equivalent to an actual increased activity level or increased number of steps.

The findings of the new category "long-term changes, affordances and maintenance" emphasize sustained improvements in balance and walking and stories of daily activities and participation. The findings also emphasize that such changes and feelings of new affordances do not necessarily match the physical activity level. In the following, these integrated key findings are discussed.

9.3.1 Sustained improvements and stories of daily life activities and participation

A core element of our integrated findings was the many long-term effects on balance and walking and the participants' experiences of sustained changes, which validated each other. This element indicates long-term advantages from this short 6-week intervention, that is, changes potentially caused by improvements in motor control and motor learning. Through the GroupCoreDIST exercises, the individual, task and environmental sub-systems were manipulated with the goal of impacting the participants' bodily sub-systems, such as the biomechanical, musculoskeletal and neurological systems. Therefore, the documented improvements from the outcome measures and the participants' emphasis on improved impairments and that balancing and walking had become easier may have been a result of new, more effective movement patterns. Through repetition, for instance, during exercises and ADLs, a new attractor status or preferred movement strategies may have emerged, as highlighted in the literature (Thelen, 2005). The focus of GroupCoreDIST on performing the exercises with movement quality that is as good as possible is in line with the literature regarding the principles of neuroplasticity due to a recovery-based intervention (Kleim & Jones, 2008; Levin et al., 2008; Prosperini & Di Filippo, 2019). These principles provide possibilities for facilitating the reorganization and restoration of altered brain activity patterns (Prosperini & Di Filippo, 2019; Tomassini et al., 2012), which are the basis of sustained improvements, as seen in the current study. We do not have MRI data to prove this point, and such data would have improved the current study; however, from prior studies, we know that exercises has demonstrated positive effects on the brain, including improvements in brain volume and cognition (Dalgas, 2017). The sustained improvements may point in that direction.

Meaning and the emotional experience of improvements are closely linked to plasticity and motor learning, and therefore, they are a basis for permanent improvements (Hylin, Kerr, & Holden, 2017). This point adds further importance to situations of emotional exploration, awareness and reflections concerning both balance control and one's own challenges, such as balance check points. Here, the group and physiotherapist had a chance to verbalize the observable changes, which may have strengthened the person's reflections and expectations of what he/she could do. These intersubjective factors within the group may have provided even stronger emotional insights into his/her own body and provided new stories of possibilities for new activities and participation. This result may indicate that future interventions should consider adding emotions interlinked with optimal movement performance for a positive integration of sub-systems and networks for changes in motor control that last over time.

These characteristics direct us to another integrated feature that expands our knowledge regarding the participants' long-term stories, which were mostly directed at activity and participation, while the measured sustained effects were at both the impairment and activity levels. The feelings regarding sustained improvements were not as emotional as the stories of short-term changes; however, they focused on a new feeling of autonomy, for instance, emphasized by individuals who once again started going to the gym with their friends or started cycling, hiking or aerobic dancing, which seemed to lead to reflections concerning everything they could do ("I can"). The linkage between how improvements in the physical body may open up a world of opportunities and affordances has been previously described in relation to individuals with chronic diseases (Gibson, 1986; Leder, 2016, pp. 36-40) but not in relation to the advantages of group-based balance training. This linkage may be an important feature in a chronic population such as individuals with MS, who are often diagnosed early in life and who often have low levels of disability and should thus aim to participate in age-matching activities. Such reflections may contribute to fewer restrictions on what an individual can accomplish, which may influence a person's choices in his/her daily life and the autonomy to choose enjoyable activities.

It is interesting to consider a group-based intervention with long-term improvements in regard to costs and benefits. GroupCoreDIST included only 18 sessions shared by three participants, making it three times less expensive than 18 one-on-one sessions. Since health care systems worldwide are under constant economic pressure (Nicholls, 2017), group-based interventions with long-term effects should be considered. On the other hand, the current study also documented that standard care involved almost no physiotherapy, which, of course, in the short run is cheaper. In the long run, however, the lack of physiotherapy may lead to inactivity, which may provide comorbidities and increased disability (Marck et al., 2016) that will indirectly be much more expensive for society. These aspects should be explored in detail in future studies, especially in regard to exploring whether there are additional advantages from a sustained functional level, such as work and employment. Furthermore, the low dose of physiotherapy in the standard care group was even lower than that in reports from another study where 40% of individuals with MS (all EDSS levels) saw a physiotherapist (Svendsen et al., 2012). This fact may support why the participants' experiences from prior physiotherapy were less detailed and less directed at their particular symptoms and impairments, which may be due to the low number of specialists in neurological physiotherapy in Norway (Norwegian Physiotherapy Association, 2019). This fact may indicate that the physiotherapy offered to individuals with MS in our area needs to be improved.

Another feature where the qualitative and quantitative findings validated each other was the fact that the effect sizes, meaningful changes measured and feelings of change decreased over time. This finding reminds us that MS is a chronic disease, and both recurring and new symptoms are expected. Some participants emphasized recurring symptoms, which may have felt like a loss and brought back old thoughts of an unpredictable future and feelings of a lack of control, similar to the descriptions in Leder (2016) and Toombs (1987). This phenomenon accentuates the need to further structure the physiotherapy follow-up of individuals with MS. At this point, physiotherapy follow-up occurs by chance in Norway, which can easily be changed by, for instance, a more structured physiotherapy follow-up in MS outpatient clinics and a direct link to physiotherapists in the community health service. In this regard, a challenge is once again posed by the lack of competence in neurological physiotherapy. The Norwegian Ministry of Health and Care Services has emphasized individuals with neurological diseases as a group with large needs for future rehabilitation and, in this regard, the need for capacity, new offers and improved organization for this population (The Norwegian Ministry of Health and Care Services, 2015). This report pinpoints that the waiting list to see a physiotherapist with specialist competency is long and that increased competency is needed (The Norwegian Ministry of Health and Care Services, 2015). Implementing the principles found in this study may improve the physiotherapy offered to individuals with MS. The structures of the long-term follow-up of individuals with MS are also important to highlight, preferably with intensive periods of physiotherapy and structured individualized home exercises in between.

In summary, the findings of the current study indicate that GroupCoreDIST provided long-term effects and experienced changes in impairment at the activity and participation levels, with some lasting as long as six months. Over time, both the effect sizes and meaning of changes decreased. Nevertheless, the participants experienced new affordances and possibilities for activity and participation. One reason for the sustained changes may have been the participants' maintenance of unsupervised home exercises for three months after the intervention was completed. The principles of this short and low-cost intervention should be considered a contribution to the long-term follow-up of individuals with MS.

9.3.2 Changes in balance and walking and new affordances do not necessarily match the activity level

The integrated findings provided an interesting contrast. Despite the many long-term effects and experiences of sustained improvements in balance and walking and the feelings of new affordances in daily life, the physical activity level and the number of steps (measured by ActiGraphs) were unchanged throughout the study. This result means that having increased opportunities for physical activity is not simply the key to being more active, at least not in terms of the number of steps and moderate activity per day. GroupCoreDIST did not address physical activity as such and did not encourage the participants to be more active, however it changed the experience of autonomy in daily life. The literature emphasizes that a person's experiences of affordances in his/her surroundings are closely interlinked with bodily constraints (Gibson, 1986). The experienced long-term changes in body and movements may have influenced the participants to perceive more options in the world, which may have made them feel more like they did when they were healthy.

Despite the improvements in their balance and walking, it is likely that the participants still had some symptoms after the six weeks of training. It has been emphasized that symptoms and impairments influence how a person feels and thinks about his/her own body and the opportunities in his/her daily life (Normann et al., 2013), as well as what activities a person chooses (Carel, 2008; Gallagher, 2013). When improvements in balance and walking occur, as in the current study, the extended factors of the self-pattern, i.e., how a person identifies him/herself through participation in activities, may perhaps have changed as a result of the new feeling of autonomy to choose activities. Several studies have reported that balance and walking challenges reduce autonomy in participation (Cameron & Lord, 2010; Cattaneo et al., 2017; Coote et al., 2009; Nilsagård et al., 2009; Pirker & Katzenschlager, 2017). In contrast, improvements in balance and walking may have increased the participants' experiences of having an opportunity to choose activities. In this regard, the possibility of taking the recommended 10,000 steps (healthy individuals) (Bassett et al., 2017; Tudor-Locke & Bassett, 2004) or 7200 steps (elderly and special groups) (Tudor-Locke et al., 2011) may perhaps be more important for a person than actually reaching such a number of steps.

Another explanation for the contrasts between the unchanged activity level and the improved balance and walking may be the situated aspects of self, which involve culture and habits in the domestic environment (Gallagher, 2013). If a low activity level has been the case for many years, a person may have lowered his/her expectations for activities and participation as well as any actual action.

A low activity level is a general challenge in both individuals with MS (Block et al., 2016; Motl et al., 2015) and the healthy population (B. H. Hansen et al., 2019). Since physical activity is important for improving neuromuscular and physical function at all stages of MS (Rooney et al., 2019), it should be a focus of future interventions and clinical practice. In this regard, it has been reported that physical activity interventions such as exercise prescriptions, behavioural change interventions, combined interventions and education may improve physical activity (Coulter et al., 2018). GroupCoreDIST included both exercises and strategies for behavioural change, such as emphasizing changes in movement control and learning how to perform exercises at home. In regard to physical activity, prior research also suggests that group training that emphasizes group dynamics led to improved physical activity compared to standard exercise classes and home training (Burke, Carron, Eys, Ntoumanis, & Estabrooks, 2005). Therefore, in future interventions, it may be important to construct group-based interventions that facilitate more physical activity, perhaps by strengthening the element of group interactions and the verbalization of improvements.

Another core feature was the continuity of unsupervised home exercises in the GroupCoreDIST group for as long as three months after the intervention was completed. This factor may have contributed to the sustained improvements and thus point to the value of learning exercises suited to one’s own impairments. The long-term continuity of exercises may imply that they were meaningful to the participants, that they had an inner drive to keep performing the unsupervised training, or that the participants may have felt somehow forced to continue exercising due to their participation in a study. However, the lack of a direct response, especially in regard to no particular improvements experienced, may have provided less motivation over time compared to the six-week intervention, where direct responses were provided by the immediate improvements and from the group and physiotherapist accentuating improvements. The lack of response may be a reason why almost all participants had quit the home training at six months. A reduced adherence to home training over time is reported both by Tallner et al. (2016), who show that adherence decreased from 73% at 1-3 months to 36% at 4-6 months after the completion of a home programme (Tallner et al., 2016), and by Molt et al. (2011), who show an approximately 50% reduction in adherence from week two to week eight (Motl et al., 2011). Support that facilitates engaging in performing exercises is well recognized (Learmonth, Marshall-McKenna, et al., 2013), which may inform us that new contact with the physiotherapist some months after completing a high-dose intervention is needed in a chronic population such as individuals with MS.

In summary, the current study indicates that the improvements in balance and walking and the long-term affordances did not influence the physical activity level or the number of steps, which is interesting since the participants seemed to have both the physical and experiential possibilities to be more active and felt more autonomy to do whatever they liked in their daily life. Physical activity is important, as it is a general problem in individuals with MS, and this element should be more directly addressed in future group-based interventions for ambulant individuals with MS.

Main messages of "Long-term changes, affordances and maintenance"

The GroupCoreDIST intervention created long-term changes in balance and walking in terms of effects, feelings of sustained improvements and new affordances in daily life. This short, high-dose, individualized, group-based intervention, which included unsupervised home exercises that the participants performed after the intervention was finished, may be an advantageous supplement to clinical practice and the long-term follow-up of individuals with MS. Most effect sizes and experiences of change decreased over time, as expected in a chronic population, which implies that individuals with MS need structured long-term follow-up in regard to balance and walking challenges. As neither the physical activity level nor the number of steps per day was influenced by this intervention, an additional focus on physical activity should be considered in future interventions.

10 CONCLUSION AND IMPLICATIONS

In this thesis I have presented and discussed the integration of findings from a mixed methods study exploring effects and user-experiences from participation in a new, individualized, group-based physiotherapy intervention called GroupCoreDIST for ambulant individuals with MS conducted in a municipality setting. The findings revealed that even though the disability level was on average low, the participants had both measured and experienced impairments in trunk control, balance, walking and physical activity before the intervention started. It is, therefore, important to detect balance and walking status in detail, even if disability is low. This should be considered done at an early time-point to detect those individuals that need physiotherapy when the potential for change is good. Various standardized assessments, movement analysis and the exploration of change may provide different forms of meaning both for the patient and physiotherapist, including an awareness of the balance and walking status, and an embodied access to new possibilities for movement. Such knowledge may provide expectations and a positive mind-set before the start of the follow-up in individuals with MS.

The six weeks of GroupCoreDIST provided short- and long-term effects on trunk control, balance and walking, and experiences of improvements at all ICF levels. Clinical meaningful changes were emphasized both by calculations for the MSWS-12, 2MWT and borderline for the TIS-NV, and as embodied perceptions of changes, which provided meaning in terms of feelings of autonomy in daily life. The experiences of changes led to an increased sense of ownership and agency towards their own body and movements, a strengthened outward directedness (intentionality), reflections of new opportunities for activity and feelings of increased affordances in daily life (participation). Individual and group elements in the GroupCoreDIST were from the user-perspective emphasized as important. The individual elements were the integration prerequisites for balance and walking in exercise-task, performance of exercises with optimal movement quality and the physiotherapists detailed hands-on interactions. The group elements of importance were from the user perspective equal attention, detailed addressing of individual challenges, and the supporting dialogue with the group regarding changes, which strengthened reflections of own possibilities. When unequal attention, inadequate adjustments and less changes were perceived, the participant´s focus turned towards their own disability. The integration of individual elements in group settings should be considered in future interventions.

In the long-term the effect sizes decreased and feelings of sustained improvements focused on new affordances and autonomy in ADLs and participation. Physical activity did not change throughout the study, even though the participants seemed to have improved their opportunities for being active. This indicate that physical activity has other mechanisms and these should be addressed in future interventions. The participants´ continuity of unsupervised home exercises for three months after the intervention was completed indicate a change in everyday life maintenance. As MS is a chronic disease more structure should be added to the long-term follow-up in regard to balance and walking challenges, for instance through high-dose periods of physiotherapy, and unsupervised exercises in between.

In conclusion, the short- and long-term follow-up for individuals with MS should be improved to detect balance and walking deviations, challenges and possibilities for change in at an early time-point and even when disability is low. The principles of GroupCoreDIST should be considered to be implemented to clinical practice as only six weeks of training provide short and long-term effects on balance and walking, experiences of changes in all ICF levels, meaning, affordances and autonomy to individuals with MS.

10.1 Future studies

In order to expand the knowledge base for physiotherapy directed at individuals with MS who have balance and walking problems, more mixed methods studies that examine effects and user experiences of well described comprehensive interventions are needed. Detailed individual adaptations and hands-on interactions is feasible within small groups, and these features should be explored in larger groups. More studies that reflect real-life clinical practice are also needed. The GroupCoreDIST furthermore should be compared to an equal dosed intervention, and the user-experiences from standard care should be explored. From the current study we have revealed a need for interventions that both highlight prerequisites for balance and walking and also aim to increase physical activity. More knowledge is also needed regarding physiotherapy follow-up from the onset of the disease and over longer periods in individuals with MS, for instance screening functional abilities over years, and examining how implementing a more structured physiotherapy follow-up from the onset of MS might influence on balance and walking over time. Very little is also known regarding individuals with MS participation in society, such as work and employment, and interventions that capture these important part of individuals lives should also be explored in future studies.

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PAPERS 1-3

Paper 1

Arntzen, E.C., Straume, B.K., Odeh, F., Feys, P., Zanaboni, P. & Normann, B. (2019). Group-Based Individialized Comprehensive Core Stability Intervention Improves Balance in Persons with Multiple Sclerosis: A Randomized Controlled Trial. *Physical Therapy.* 99, 1027-1038. DOI: 10.1093/ptj/pzz017

Original Research

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

Ellen Christin Arntzen, Bjørn Kåre Straume, Francis Odeh, Peter Feys, Paolo Zanaboni, Britt Normann

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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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 criteria[27]; (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 al[26] 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

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	History: medical, social, and patient history; symptoms; main issues from the patient's perspective. Analysis: observation and hands-on interaction; consider the patient's resources and constraints for movements. 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 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 Specific tests: muscle length, muscle activation and strength, tonus, somatosensory function, pain and reflexes. 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 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	Optional
Group sessions Duration: 60 min 3 times/wk for 6 wk Equipment: large therapy balls, small mobilization balls, rolled towels, bolsters, plinths, and rubber bands for optimal alignment	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. 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.	Continue the regular routine, which for some involves physical therapy, general physical activity, or training
Beginning and end of all group sessions	The physical therapist should ask how everyone is doing that day and how the performance of home exercises went. 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.	Optional
Exercises: Performed 10 times for up to 3 repetitions according to a participant's capacity and quality of performance. 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	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. The 6 exercise categories are: (exercise 1 or 2) to enhance adaptation to the base of support, eg, by rolling a mobilization ball with the hands or feet; (2) Muscle length: (exercises 3–9) addressing concentric and eccentric activity in muscles of the neck and upper and lower limbs; (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; (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; (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; (6) Relaxation: (exercise 33) systematically performing contraction/relaxation of all parts of the body	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

[a] GroupCoreDIST 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, ActiGaph, 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

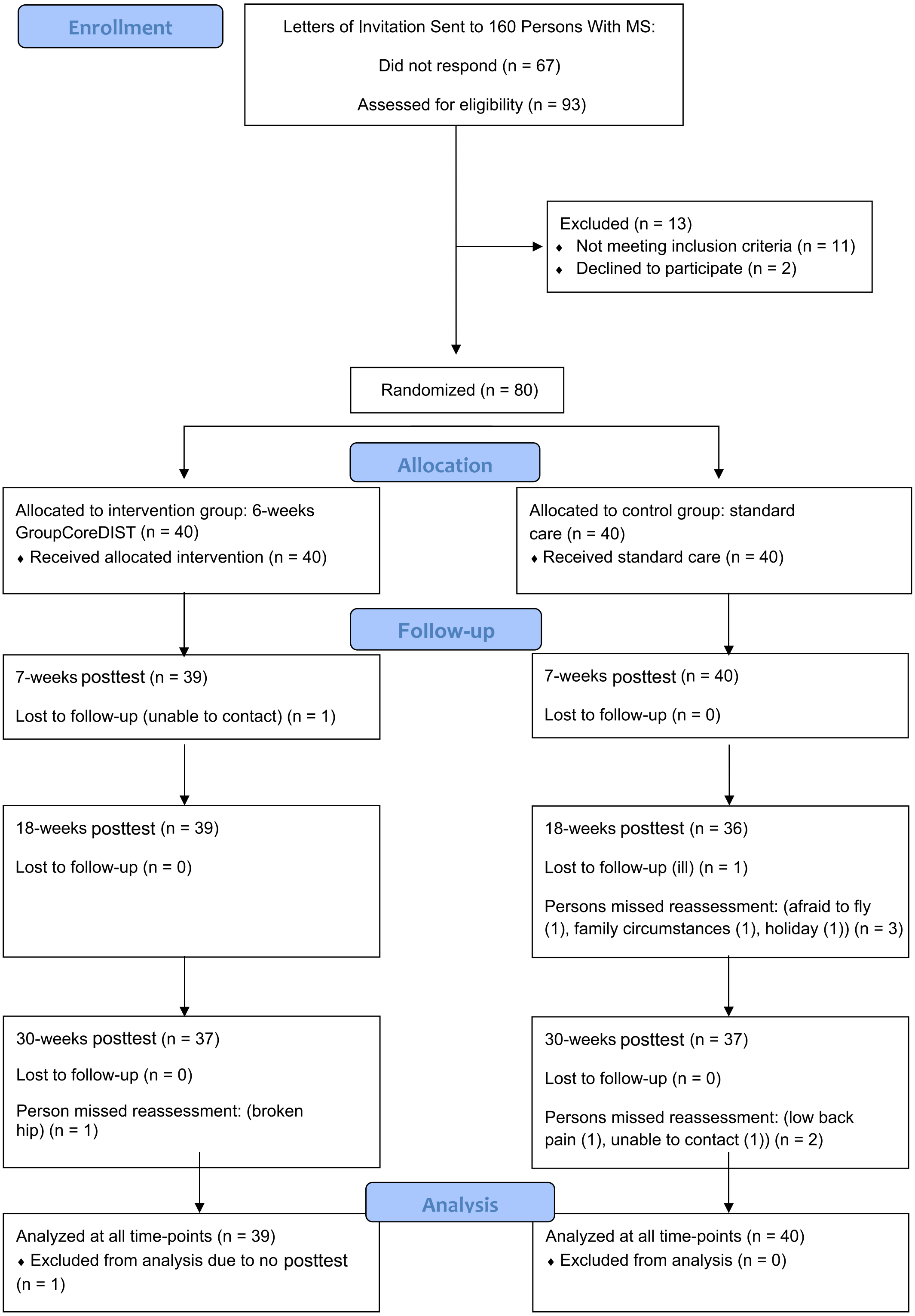

Figure 1.
Flowchart of recruitment, allocation, and retention of participants throughout the study.

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]

[a] EDSS = 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 al[12] 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 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

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]			

[a] In 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.

[b] Statistically significant effect.

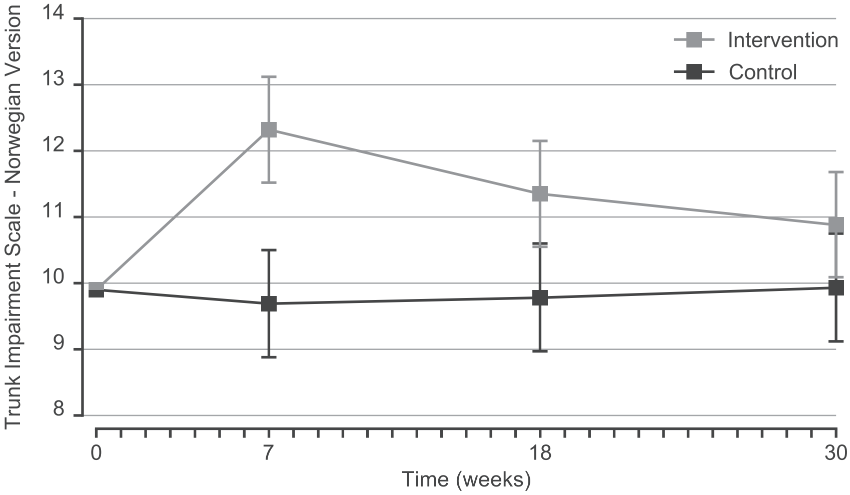

Figure 2.
Means and 95% confidence intervals of scores on the Trunk Impairment Scale–Norwegian Version for the GroupCoreDIST and standard care groups at baseline and weeks 7, 18, and 30. In the model, outcome scores were adjusted for baseline, time point, group, group∗time, age, sex, Expanded Disability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

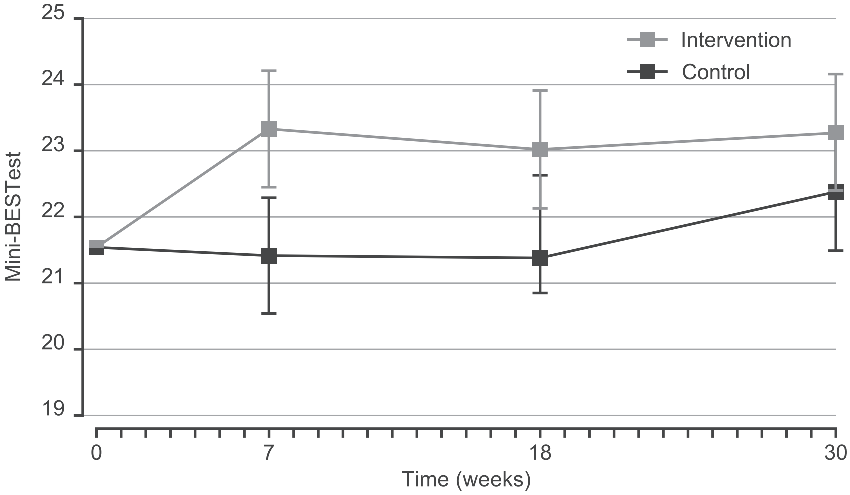

Figure 3.
Means and 95% confidence intervals of scores for the Mini-BESTest for the GroupCoreDIST and standard care groups at baseline and weeks 7, 18, and 30. In the model, outcome scores were adjusted for baseline, time point, group, group∗time, age, sex, Expanded Disability Status Scale score, and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

MS[21]; 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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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.

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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.

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PAPER 2

Arntzen, E.C., Straume, B., Odeh, F., Feys, P. & Normann, B. (2019). 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. *Physiotherapy Research International.* 2019;e1798. https//doi.org/10.1002/pri.1798

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RESEARCH ARTICLE

WILEY

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 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, Irkec, 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 Evaulation 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, tonus, 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 litterature (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

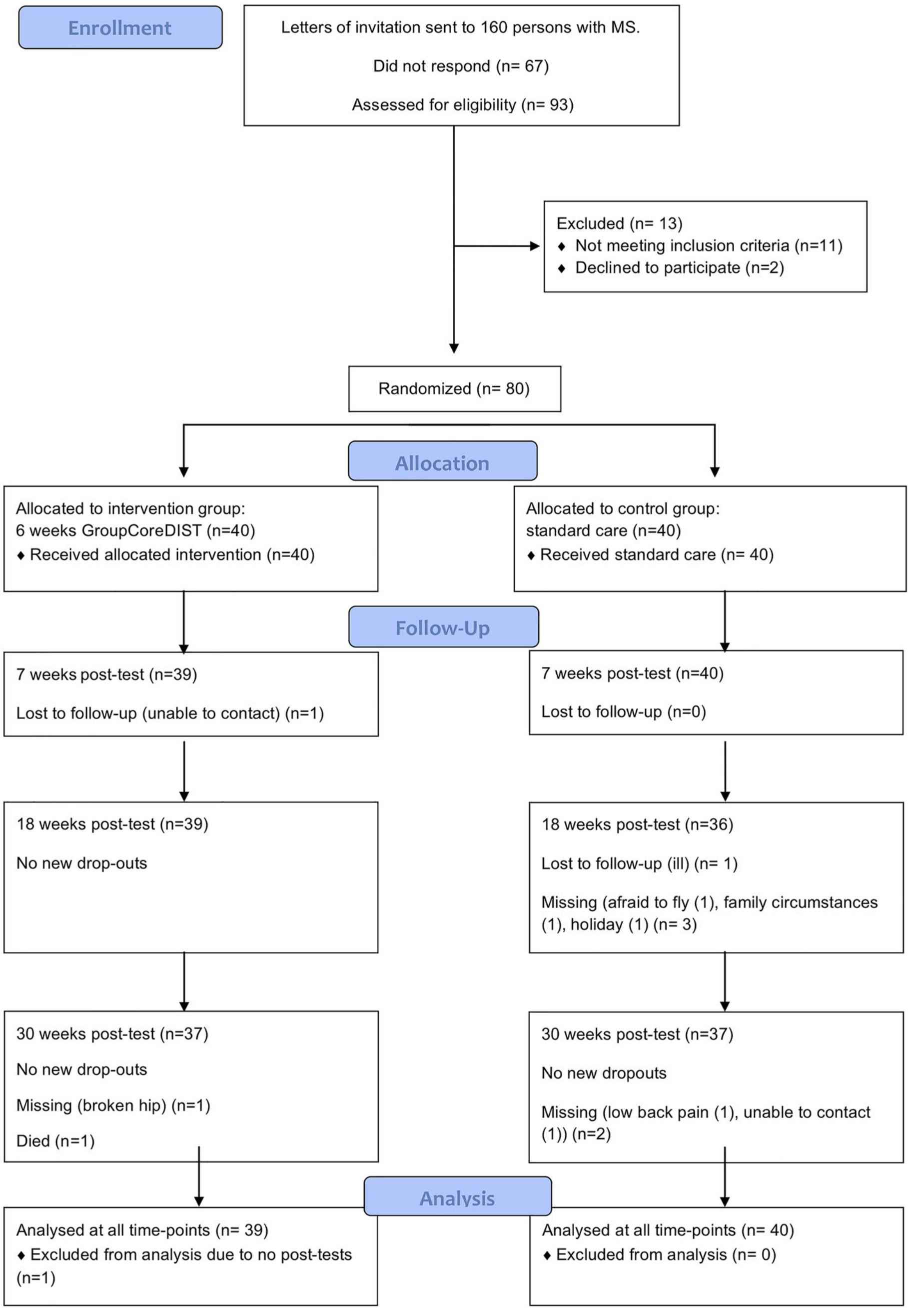

FIGURE 1 Flowchart of the recruitment, allocation and retention of participants throughout the study. MS, multiple sclerosis

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)

			7 weeks			18 weeks			30 weeks			Overall
Outcome measure	Group	Base line Mean (*SD*)	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	*p* value group
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	
				SE: 3.3			*SE*: 3.37			*SE*: 3.37		
PGIC-walking	Standard care	Not assessed	4.00 (0.73)	0.89 CI [1.34, 0.45] *SE*: 0.22	<.00*	3.51 (1.01)	0.97 CI [1.42, 0.52] *SE*: 0.23	<.00*	3.66 (1.08)	0.93 CI [1.39, 0.48] *SE*: 0.23	<.00*	<.00*
	GroupCoreDIST	Not assessed	4.89 (0.98)			4.50 (1.06)			4.61 (1.15)			
RVGA	Standard care	9.9 (4.34)	11.45 (3.37)	1.28 CI [0.17, 2.40] *SE*: 0.57	.03*	10.91 (3.10)	0.09 CI [−1.07, 1.24] *SE*: 0.58	.89	11.28 (3.75)	0.08 CI [−1.07, 1.24] *SE*: 0.58	.89	.29
	GroupCoreDIST	11.24 (5.52)	10.16 (4.18)			10.82 (4.41)			11.20 (5.06)			
ActiGraph Steps	GroupCore DIST	6454.33 (3856.16)	5924.52 (2978.23)	478.93 CI [−1296.20, 338.34] *SE*: 413.59	.25	6086.34 (3020.52)	275.01 CI [−1123.01, 572.98] *SE*: 429.36	.52	6562.26 (3458.89)	35.97 CI [−808.11, 880.05] *SE*: 427.35	.93	.47
	Standard care	6467.50 (3366.67)	5445.59 (2962.10)			5811.32 (2852.52)			6598.23 (3797.50)			
ActiGraph inactivity (minute)	GroupCoreDIST	1086.77 (100.96)	1112.17 (105.09)	13.63 CI [−22.73, 49.98] *SE*: 18.42	.46	1122.96 (76.04)	5.76 CI [−31.25,42.77] *SE*: 18.76	.21	1105.62 (86.86)	8.48 CI [−29.06, 46.01) *SE*: 19.02	.66	.50
	Standard care	1083.08 (92.96)	1125.80 (91.56)			1128.72 (91.56)			1114.10 (109.56)			
Actilight activity(minute)	GroupCore DIST	323.25 (88.91)	303.68 (83.59)	11.14 CI [−45.20, 22.92] *SE*: 17.25	.519	293.11 (65.60)	5.46 CI [−40.12, 29.20 *SE*: 17.56	.76	304.17 (75.58)	8.56 CI [43.71, 26.59] *SE*: 17.81	.63	.51
	Standard care	330.45 (81.57)	292.54 (93.04)			287.65 (83.13)			295.61 (93.72)			
ActiGraph Moderate activity (minute)	GroupCore DIST	29.46 (31.65)	22.31 (21.76)	2.18 CI [−8.87, 4.51] *SE*: 3.39	.52	22.42 (21.44)	0.64 CI [−7.45, 6.16] *SE*: 3.45	.85	27.53 (25.94)	0.78 CI [−6.10,7.67] *SE*: 3.49	.82	.79
	Standard care	24.05 (21.01)	20.13 (16.91)			21.78 (20.03)			28.32 (26.42)			
ActiGraph Vigorous activity (minute)	GroupCore DIST	1.10 (3.10)	2.19 (4.20)	0.73 CI [−2.55, 1.08] *SE*: 0.92	.43	1.87 (2.89)	0.44 CI [−2.28, 1.39] *SE*: 0.93	.64	3.27 (7.25)	1.34 CI [−3.19, 0.52] *SE*: 0.94	.16	.29
	Standard care	2.48 (6.08)	1.46 (2.75)			1.43 3.14)			1.93 (5.18)			

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.

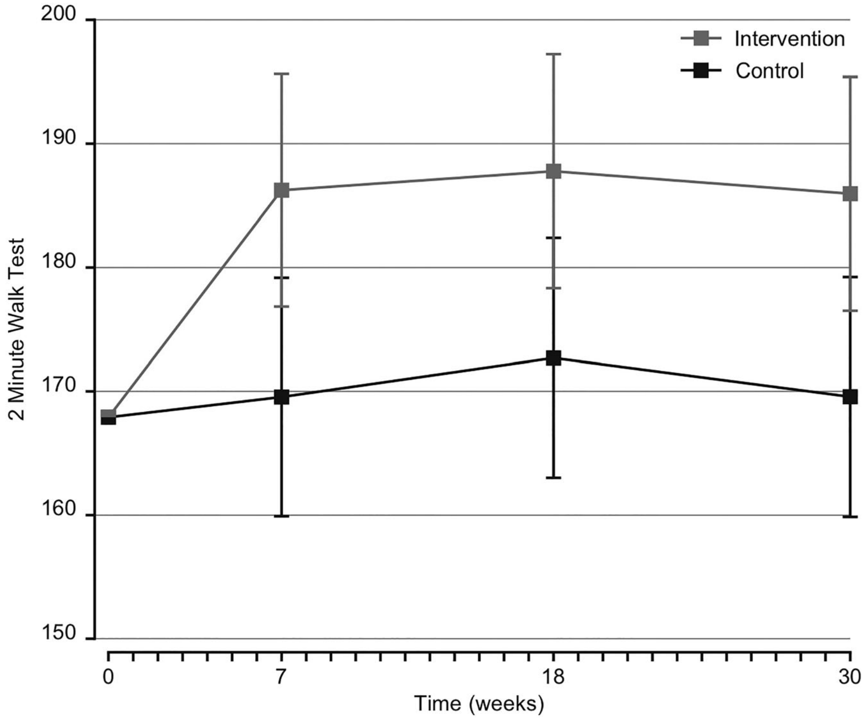

FIGURE 2 Mean and 95% CI of the 2-min walk test in the GroupCoreDIST and standard care groups at baseline and Weeks 7, 18, and 30

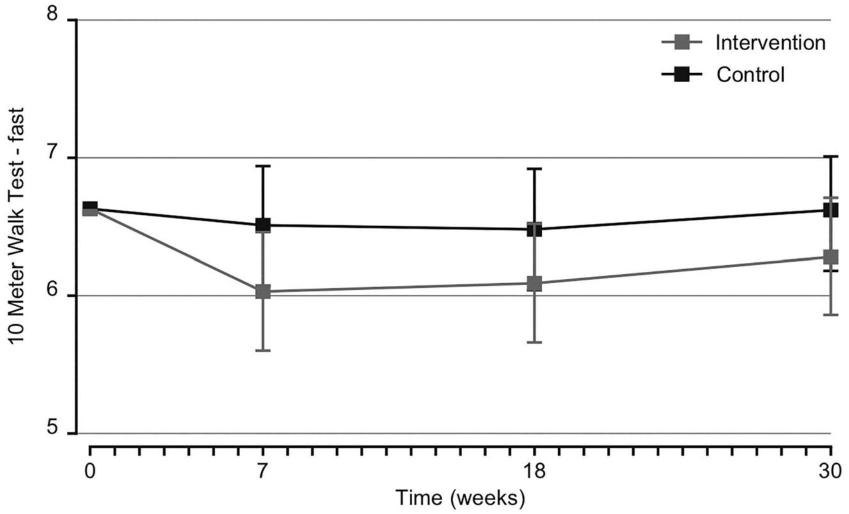

FIGURE 3 Mean and 95% CI of the 10-m walk test-fast speed in the GroupCoreDIST and standard care groups at baseline and Weeks 7, 18, and 30

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

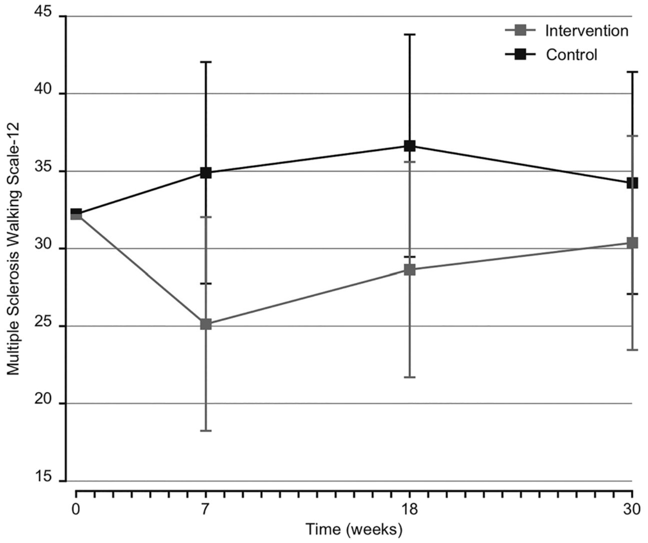

FIGURE 4 Mean and 95% CI of the Multiple Sclerosis Walking Scale-12 100 scale in the GroupCoreDIST and standard care groups at baseline and Weeks 7, 18, and 30

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; Kjølhede, Vissing, & Dalgas, 2012; Pearson, Dieberg, & Smart, 2015) or distance (Freeman & Allison, 2004; Gunn et al., 2015; Kalron et al., 2017; Kjølhede et al., 2012; Pearson et al., 2015); however, some studies have shown no effect on walking (Fox et al., 2016; Kjølhede 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

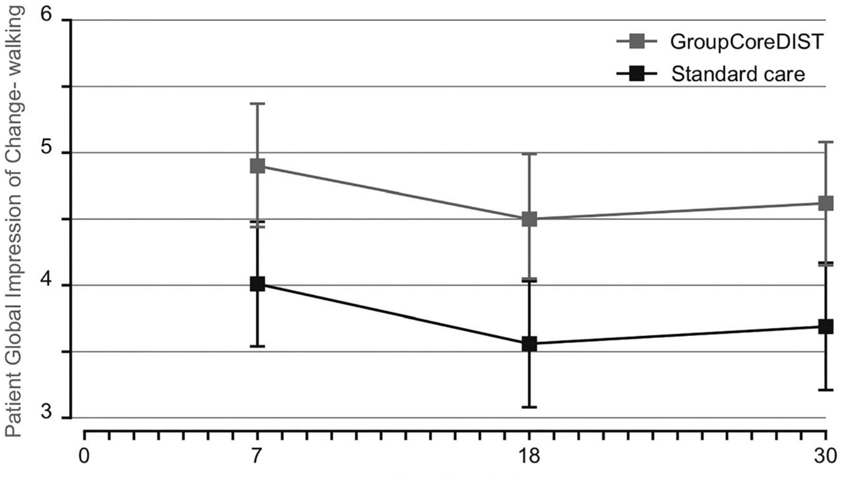

FIGURE 5 Mean and 95% CI of the Patient Global Impression of Change-walking in the GroupCoreDIST and standard care groups at Weeks 7, 18, and 30

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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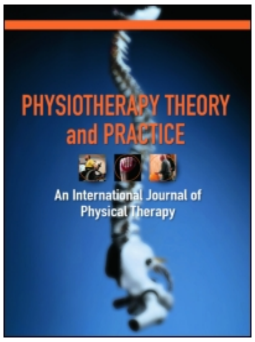
PAPER 3

Arntzen, E.C., Øberg, G.K., Gallagher, S. & Normann, B. (2019). Group-based, individualized exercises can provide perceived bodily changes and strengthen aspects of self in individuals with MS: a qualitative interview study. *Physiotherapy Theory and Practice.* 26, 1-16. DOI: 10.1080/09593985.2019.1683923



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Group-based, individualized exercises can provide perceived bodily changes and strengthen aspects of self in individuals with MS: a qualitative interview study

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Group-based, individualized exercises can provide perceived bodily changes and strengthen aspects of self in individuals with MS: a qualitative interview study

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ABSTRACT

Background: Group-based physiotherapy is effective for individuals with MS; nevertheless individualization within groups is questioned and little is known regarding individuals´ experiences with individualization in small groups.

Objective: We aimed to explore the short- and long-term experiences of individuals with MS participating in a 6-week, group-based, individualized physiotherapy-intervention.

Methods: Within a randomized controlled trial (RCT), 25 in-depth interviews with a strategic sample of 13 people (9 women; age 25–79 years old; European Disability Status Scale (EDSS) 1–6.5) were conducted at weeks 7 and 30 using systematic text condensation, with dynamic systems theory and phenomenology as analytical frameworks.

Results: The main categories were: 1) movement control, orientation and insights: Bodily improvements were associated with targeted exercises, specific adjustments by the physiotherapist, emotional engagement and re-access to activities; and 2) the individual within the group: Equal distributions of one-to-one interactions and attention were important for experiencing success. Less attention and improvements turned attention toward own disability. Physical changes felt particularly emotional short term, implying that individuals' feelings of ownership and control of body and movement, new views of themselves and changed affordances in daily life were involved.

Conclusion: Equally distributed attention and engagement, targeted exercises and hands-on adjustments resulting in visible and perceived bodily changes were experienced as key factors of individualization in small groups.

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Introduction

Individuals with multiple sclerosis (MS) often have balance problems in both the initial and later phases of the disease (Aruin, Kanekar, and Lee, 2015; Huisinga et al., 2014; Kalron et al., 2016) due to a variety of somatosensory, motor, postural control and vision impairments (Cameron and Lord, 2010; Krishnan, Kanekar, and Aruin, 2012). Balance dysfunctions are associated with an increased risk of falling (Comber, Sosnoff, Galvin, and Coote, 2018) and less participation in daily activities (Cameron and Lord, 2010; Cattaneo et al., 2017), and can influence aspects of self (Normann, Sørgaard, Salvesen, and Moe, 2013). Individual exercise therapy is associated with improvements in walking (Dalgas, Stenager, and Ingemann-Hansen, 2008; Hogan and Coote, 2009; Snook and Motl, 2009) and balance (Gunn et al., 2015; Paltamaa, Sjogren, Peurala, and Heinonen, 2012; Rietberg, Brooks, Uitdehaag, and Kwakkel, 2005); and the same association has been reported for group-based interventions for individuals with MS (Arntzen et al., 2019; Forsberg, von Koch, and Nilsagård, 2016; Tarakci et al., 2013).

Studies on users' experiences from group-based exercise programs for individuals with MS have reported social benefits (Dodd, Taylor, Denisenko, and Prasad, 2006), improvements in daily activities, and increased body confidence (Carling, Nilsagård, and Forsberg, 2018; Van Der Linden et al., 2014). Training in groups is a motivational factor for empowerment, improved energy, reduced fatigue, and the gaining of knowledge in self-assisted training (Clarke and Coote, 2015). A review of qualitative studies of individual interventions revealed similar positive findings; however, commonly perceived adverse consequences were increased fatigue and feelings of frustration and lost control (Learmonth and Motl, 2016).

Although the prevailing principle of individualization (European Multiple Sclerosis Platform, 2012) has been questioned in group settings (Kalron et al., 2019; Plow, Mathiowetz, and Lowe, 2009), an individualized intervention conducted in small groups was recently

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introduced and found feasible and effective on trunk control, balance and walking in individuals with MS (Arntzen et al., 2019; Dybesland and Normann, 2018; Normann, Salvesen, and Arntzen, 2016) From a professional perspective individualization within small groups is dependent on an initial individual assessment (Lahelle, Øberg, and Normann, 2018b), ongoing movement analyzes and adaptations through hands-on interactions (Lahelle, Øberg, and Normann, 2018a). Knowledge gained from the participant´s perspective regarding small groups is however limited.

The interest in new theoretical conceptualizations for more diverse and inclusive views of the body has increased among physiotherapist (Nicholls and Gibson, 2010; Nicholls and Holmes, 2012). Conceptions of body and movement that emphasize physical interaction as communication and allow integration of neuro- and movement science and embodiment, have previously been introduced in regard to one-to-one neurological physiotherapy (Normann, 2018; Normann, Fikke, and Berg, 2015; Normann, Sørgaard, Salvesen, and Moe, 2013; Øberg, Normann, and Gallagher, 2015; Sivertsen and Normann, 2015). No prior studies have used such comprehensive conceptions in order to investigate and analyze individualization within groups. In order to generate new insights regarding this topic, we turned to a combination of dynamic systems theory (DST) (Shumway-Cook and Woollacott, 2017) and phenomenology (Gallagher, 2012; Merleau-Ponty, 2013), with a particular focus on Gallagher (2013) "Pattern Theory of Self", to emphasize both physical aspects and deeper meaning of the participant´s bodily experiences.

DST is a commonly used model for understanding motor control and learning (Shumway-Cook and Woollacott, 2017), and it involves adopting a third-person perspective on the body (Normann, 2018). DST comprehends movement as self-regulated due to three factors: 1) constraints for movement in the individual; 2) task; and 3) environment (Shumway-Cook and Woollacott, 2017). Each factor contains subsystems that are open for manipulation, for instance, by the physiotherapist's specific handling (individual), choice of exercise (task) and training equipment within the situation (environment). Through manipulations of the subsystems, a new, more effective movement pattern can develop, resulting in a new attractor status or preferred movement strategy (Thelen, 2005), which is often a goal of neurological physiotherapy. DST provides an analytical tool to deepen our understanding of the participants' individual actions and experiences concerning individualization or lack thereof, as well as potentially perceived positive or negative changes in constraints regarding bodily impairments, activities and participation. Such a third-person view of the physical body is fundamental to physiotherapy in order to understand movement control, biological and biomechanical aspects of the body (Normann, 2018). However, this view might also imply that the body is separated from the mind (Nicholls and Gibson, 2010) and thereby also from subjectivity (which according to DST is associated with the cognitive subsystems) (Normann, 2018). In order to explore what individualization within a group and potential positive or negative bodily changes mean to a participant, a first-person perspective on bodily experience is justified and may be emphasized by phenomenological and more existential theoretical aspects (Normann, 2018).

The key to the possibility for combining such quite different theories lies foremost in one of phenomenology´s core element; the ambiguity of the body. That is the fact that the body is the centre of experience and expression, and simultaneously is a biological and biomechanical organism (Merleau-Ponty, 2013). The "lived body" or the body-as-subject, experiences the world from a first-person perspective, and concurrently may be perceived or observed from a third person perspective (the body-as-object) for instance in a clinical examination (Merleau-Ponty, 2013; Normann, 2018; Øberg, Normann, and Gallagher, 2015). Phenomenology gives primacy to the lived body, which incorporates and is modulated by movements (both pre- and post disease and therapy) and is characterized by intentionality or an outward orientation in processes of perception, sensation and movement/motility (Merleau-Ponty, 2013). Since intentionality is primarily motor, this affords the possibility for integrating the participant´s subjective phenomenological experiences of the body with the DST´ objective analyses the body. We note that some precedent for combining DST and phenomenology can be found in enactivist approaches to cognition especially in the work of Varela, Thompson, and Rosch (1991).

In instances of physical interaction and communication between individuals (e.g. therapist and patient) the body-as-subject involves 'inter-corporeity' an experiential and physical coupling (Merleau-Ponty, 2013), previously emphasized in relation to hands-on interactions in neurological physiotherapy (Normann, 2018). Impairments and symptoms due to MS can disturb the lived body, with the result that one's outward orientation is also affected for instance in a decline of the quality and quantity of one's affordances (Gibson, 1986), and in the feeling of the "I can" (the sense that I can engage in some action) becoming the "I cannot" (Gallagher, 2017; Gibson, 1986). This change involves a loss of autonomy and one's sense of agency (Gallagher and Daly, 2018).

To explicate a deeper meaning of the participants' feelings of self in regard to body and movement, or the embodied self, we turned to the "Pattern Theory of Self"

(Gallagher, 2013; Gallagher and Daly, 2018) and focused on the following factors: A) The experiential factors which imply: 1) bodily experiences related to body-schematic and somatosensory functions; 2) sense of ownership for body and movement, which has strong somatosensory components; and 3) sense of agency or control of one´s movement, with strong motor components (Gallagher, 2012, 2013; Merleau-Ponty, 2013). Since these body functions and structures are often addressed in physiotherapy for individuals with MS, these insights could enlighten bodily experiences from the training. B) The reflective factors, which include body image are defined as a reflective awareness of one ´s body,involve how I perceive myself and the stories or narratives that I and others tell about me (Gallagher, 2013). Changes in bodily experiences; both in regard to increasing disability or improved possibilities for movement may shape the individual's stories and reflections of what they can ("I can") or can not do ("I cannot"). C) The intersubjective factors involve the way I see myself in relation to others. This statement reflects the fact that all group members and the physiotherapist are embodied selves and will perceive and express meaning through their physical interactions, gazes, gestures and words, constituting "intercorporeity" (Merleau-Ponty, 2013). These interactions may provide other viewpoints compared to when being alone (Sokolowski, 2000). D) The extended factors include how I identify myself by, for instance, the activities in which I participate. Such extended factors are directly relevant for individuals with MS, in which disability can gradually change opportunities or the range of affordances in daily life.

Combining analytic tools of DST and phenomenology may reflect the complexity of neurological clinical practice and can help us gain knowledge about all of these factors in regard to individuals with MS´ experiences from group-based physiotherapy. With this background, the aim of the study was to investigate the users' experiences of individualized physiotherapy (GroupCoreDIST) in group-based settings. We ask the following research question: What are the short- and long-term experiences and reflections of ambulant individuals with MS regarding participation in an individualized, group-based intervention, particularly regarding individualization and potential bodily changes?

Methods

Design and choice of method

Based on the research question and the theoretical framework, a qualitative in-depth interview study (Brinkmann and Kvale, 2015; Malterud, 2016) was chosen to target the phenomenological experiences of individuals with MS concerning their short-term insights and long-term reflections regarding their experiences from participation in a 6-week, group-based physiotherapy-intervention.

Context of the study

The interview study was nested within a randomized, controlled trial (RCT) with 80 ambulant participants (EDSS-level of 1–6.5; 1 = minor disability, 6.5 = being able to walk 20 meters with or without a walking aid) and was conducted in six municipalities in Norway between 1200 and 51,000 inhabitants, examining the effects of a new, individualized, group-based intervention called GroupCoreDIST compared to those of standard care with respect to trunk control, balance, walking, activity level and health-related quality of life (Normann, Zanaboni, Arntzen & Øberg, 2016). Six physical therapists (who had 7–25 years of experience, three as specialists in neurological physiotherapy and three as generalists) conducted the intervention after being trained in GroupCoreDIST for five days and receiving a booklet with descriptions and photos of the 33 exercises, all having 5 levels of difficulty.

GroupCoreDIST-intervention

GroupCoreDIST emphasizes the multifaceted aspects of balance. CoreDIST stands for the coordinated interplay between proximal and distal parts of the body, and DIST stands for D = dose (high), dual task; I = individualization, insights; S = stability, specificity, somatosensory activation; and T = training, teaching. The intervention includes an initial individual clinical examination performed by the physiotherapist (group leader). The group sessions consisted of three participants for pragmatic reasons having diverse or similar EDSS values and lasted for 60 minutes, three times per week for six weeks. All of the group members performed the same exercise concurrently, however with difficulty tailored by the physiotherapist to each individual. Table 1 describes the GroupCoreDIST intervention, and the protocol article provides details of the exercises (Normann, Zanaboni, Arntzen, and Øberg, 2016).

Participants and sample

One of the MS nurses at the hospital sent invitation letters with a consent form concerning both the RCT and the interview study. The participants signed the written informed consent form and were informed that they could withdraw at any point. The study was approved by the Regional Committee for Medical and Health Research Ethics in Norway (REK South-East: 2014/1715-7) and complied with the Declaration of Helsinki.

Table 1. Description of the GroupCoreDIST intervention.

GroupCoreDIST Dose and equipment	GroupCoreDIST Content and examples
Individual clinical examination 60-minute session before the start of the group sessions	History: Medical, social and patient history; symptoms; main issues from the patient's perspective Analysis: Observation and hands-on interaction. Consider the patient's resources and constraints for movements. Posture analysis: Various postural sets; for example, standing, sitting and lying down. Consider the alignment throughout the body and for each body area, adaptation to the base of support and interaction with the environment. Activities/movement analysis: For instance; walking, standing on the toes or heels, squats, one-leg standing and other balance challenges. Consider the body's relation to the base of support, movement patterns of the body as a whole, and specific body parts and their relation to each other, the task and the environment. Consider the ability to perform selective movements (to move one part of the body while stabilizing other parts) to provide coordination. Specific tests: Muscle length, muscle activation and strength, tonus, somatosensory function, pain, reflexes. Introduction to GroupCoreDIST exercises: Choose and try out a few exercises in relation to the individual's movement problems. Hands-on adjustments to improve alignment, adaptation to the base of support and movement quality. Explore the participant's ability for improved performance in the exercises. Conclusion: Consider the patient's resources and issues, hypothesis of causation and the main problem related to movement and balance and potential for improved movement control.
Group sessions Duration: 60 minutes, 3 times per week for 6 weeks Equipment: Large therapy balls, small mobilization balls as well as rolled towels, bolsters, plinths and rubber bands for optimal alignment.	Planning the group sessions: Consider each participant's main problem and which underlying impairments are related to it. Choose exercises that suit the three participants and choose the appropriate postural set and variation of exercises (5 variations for each of the 33 exercises, 6 different exercise categories) for each participant to be able to perform the exercise with optimal movement quality. Goal: Teaching the participants specific exercises that can be performed both together with a physical therapist and at home. It is a goal that participants should perceive improvements in balance and movement control.
Beginning and end of all group sessions	The physiotherapist asks how everyone is doing that day and for experiences regarding the performance of home exercises. Individual balance challenges are performed simultaneously for all participants at the beginning and end of each session, to perceive and reflect on their own balance that day, compare their own balance before and after each session, and provide an opportunity for the physical therapist to interlink the individual's balance challenges with the choice of exercises.
Exercises Perform up to 3 × 10 repetitions according to the individual's capacity and quality of performance. As the quality of movement in the exercise improves, the physiotherapist may adjust the dose by increasing the number of repetitions, using a more difficult variation of the exercise or adding dual task challenges.	Group members concurrently conduct the same exercise but with different variations according to symptoms and quality of performance. All six exercise categories should be used at every group session. All exercises target optimal adjustment to the base of support and activation of the core while performing the exercise. The 6 exercise categories are: 1) Somatosensory stimulation/activation of the hands or feet: exercises 1–2, somatosensory activation of the feet or hands to enhance adaptation to the base of support, for instance, by rolling a mobilization ball with the hands or feet. 2) Muscle length: exercises 3–9, addressing concentric and eccentric activity in muscles of the neck, upper and lower limbs. 3) Selective movement and coordination: exercises 10–21, selectively moving the arms and legs or particular parts of the core. Focus on dynamic stability, keeping one part of the body stable while moving another. 4) Training larger muscle groups: exercises 22–27, recruiting larger muscle groups in various standing positions for instance rolling the ball up and down toward the wall with your back. 5) Advanced challenges for balance and postural control: exercises 28–32, giving advanced challenges for postural control and balance for instance jumping while bouncing the therapy ball. 6) Relaxation: exercise 33, systematically performing contraction/relaxation of other parts of the body.

(*Continued*)

Table 1. (Continued).

GroupCoreDIST Dose and equipment	GroupCoreDIST Content and examples
Additional challenges and adaptations	Motor-motor dual tasks are performed in all exercises while performing more than one motor task at once for instance 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 to the other group members could be added. Motor-cognitive dual tasks may be added, for instance, singing, rhyming or calculating while performing exercises. All dual task activities may 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 (Vaughan-Graham and Cott, 2016).
Home training Unsupervised GroupCoreDIST exercises for 30 minutes, 2 times per week during the six weeks of the intervention	The physical therapist cooperates with each participant to identify exercises for home training. The exercises are individualized and mirror what is highlighted during group trainings. Home training contains all six exercise categories. The training progresses in line with the exercises performed in the group sessions. Equipment: The same as for the group sessions

Table 2. Participants' demographic background data. The mean or % and (min-max) are presented.

Variable	Total (n = 13)
Age	Mean 46 (25–78)
Gender	9 women/4 men, 69%/31%
Type of MS	Relapsing remitting 9/69% Primary progressive 2/15.5% Secondary progressive 2/15.5%
EDSS	Mean, 3.5 (1–6.5) years
Time since diagnosis	Mean, 10.8 (0.5–23) years

From the 40 participants in the GroupCoreDIST-group, ECA and BN chose a strategic sample for the interview study with the following criteria: variation in age (24–-77 years); gender (9 women and 4 men); EDSS-values (1 and 6.5); and time since diagnosis (0.5–24 years) (Table 2). The selected participants were from training groups led by all the PTs. We also purposely selected participants reported by the physiotherapists to be dissatisfied, satisfied or neutral regarding the intervention. For pragmatic reasons, and because many similar experiences were repeated by different participants (Malterud, Siersma, and Guassora, 2016) we ended up with a sample of 13 patients who were interviewed twice, for a total of 25 interviews (one person died of natural causes before the second interview).

Data collection

The audio-recorded, face-to-face interviews were conducted by the first author (ECA) at study-week 7 and 30 (from December 2015-September 2016); they took place in a quiet room at the hospital (23 interviews) or in one participant's own home (2 interviews) and lasted for 46–126 minutes (altogether 1927 minutes). The interviews were anonymized, and sensitive personal information was omitted. A theme-based interview guide with open-ended questions was used to explore the participants' experiences and reflections, actively asking also for negative experiences (Tables 3 and 4). The interview guide was tested on two individuals with MS prior to the study, and adjustments were made to meet specific ethical standards. In the first interview, the participants were invited to describe and reflect on their experiences from the GroupCoreDIST-assessment and exercises, the group setting, tailoring, impairments, and potential changes within the body and daily activities. The second interviews addressed retrospective reflections regarding the same themes and the impact on their daily lives after the intervention was completed. During the interviews, the participants' answers were rephrased for communicative validation (Brinkmann and Kvale, 2015). For ethical reasons, the interviewer was sensitive regarding the participants' stories and attempted to capture what was said in a way that correlated with what was meant (Brinkmann and Kvale, 2015). All interviews

Table 3. Interview guide: 7-week interviews.

Theme	Possible questions
Background information	Could you tell me a little bit about yourself, please? Time of diagnosis, type of MS, EDSS status, where you live, are you employed, your social status, physical activity, and have you been seeing a physiotherapist before the study?
Opening question	Is there anything you would like to point out and tell me about your participation in the GroupCoreDIST training?
Experiences from the first meeting with the physical therapist and the individual clinical examination	How did you experience the first meeting with the physiotherapist and the individual clinical examination? What did the individual clinical examination before the group training started mean to you?
Experiences from the 6 weeks of group-based training	How did you experience the GroupCoreDIST training? How did you perceive and respond to the training? How did you perceive the group?; the content of the training?; individualization?; hands on interactions and and instructions? How did you experience the physiotherapist`s role and competence? How did you perceive the dose and intensity of the training? What did the training mean to you? Did you learn anything from the training period? Were there any challenges during the training? Could you tell me what happened in these challenging situations? Did you experience some things that went really well? Some things than did not work out so well?; Or some things that you would like to change? Could you tell me if there were any episodes in particular that made a special impression on you? Was there anything you did not like, something that made you feel uncomfortable or was not as expected? Have you reflected on the group-based training compared to previous experiences with physical therapy?
Experiences from home training	How did you experience the obligation for home training? Can you describe one of your regular home-training sessions, how you experienced this and what it meant to you? Were there any challenges? Things that went well or not so well? Are there things you would like to change? How did you experience performing the exercise on your own?
Experiences of impairments, daily function, activities and participation	Can you describe how you experience your function, impairments and disability? Can you describe daily activities you normally participate in? Did you experience any changes? How was family life and life in general during the period?
Experience of quality of life	Is there anything you would like to pinpoint concerning your daily life? Did you experience the training as having a negative or positive influence in your daily life?
Closing question	Are there any experiences from the group-based training that you would like to share that other individuals with MS or physiotherapists could learn from? How did you experience being interviewed?

ended with an opportunity for the participant to express his or her feelings about being interviewed, which revealed no negative utterances.

Data analysis

The data were transcribed and systematized using NVIVO-11.0/12.0 (QSR International) by ECA, and were analyzed by systematic text condensation, a thorough process of decontextualization and recontextualization (Malterud, 2001, 2012). All of the transcribed material was read in an open-minded way by ECA and BN, and most parts were read by GKØ to obtain an overall impression of the material, followed by discussions of provisional themes. Subsequently and guided by the research question, ECA identified meaning units, which were coded in accordance with their meaning, followed by organization of the coded meaning units into groups based on their content and finally into subgroups (decontextualization) organized by an active search in the material for both negative and positive findings. Following negotiations between ECA and BN on every step in the process and regular workshops between ECA, BN and GKØ, regarding the organization and interpretation of findings, the meaning units in each subgroup were agreed on and rewritten by ECA in a condensed 1st-person form. ECA transformed the condensates to analytic texts in 3rd-person format, which was compared with the transcripts to validate the original context (recontextualized) (Malterud, 2017). SG joined regular e-mail correspondence and one workshop regarding interpretation of the theoretical framework in relation to the findings. All the authors verified each analyzing step and critically reviewed the manuscript. In line with guidance from the Northern Norway Regional Health Authority two user representatives participated in the project group, contributed in both the planning of the study and a workshop where the findings and what these could mean to individuals with MS were discussed. The analysis yielded two main categories, each containing two subgroups. An example of the analysis process is shown in Table 5.

Table 4. Interview guide: 30-week interviews.

Theme	Possible questions
Opening question	Is there anything you would like to point out and tell me about your participation in the GroupCoreDIST? Do you have any reflections of the period after the training was completed?
Experiences of impairments, daily function, activities and participation	Can you describe how you experience your function, impairments and disability? What daily activities do you normally participate in? Did you experience any changes in daily activities during or after the training period? Were there any challenges? How did you experience family life and life in general after the training period was completed?
Experiences from home training	Did you perform home training after the intervention was completed? How did you experience this? Were there any challenges? Things that went well or not so well? Or things you would like to be different?
Retrospective reflections from the 6 weeks of group-based training	How did you experience the training? How did you respond to the training? How did you experience the group? The content of the training? Individualization? Hands on adaptations and instructions? How did you experience the physiotherapist`s role and competence? How did you perceive the dose and intensity of the training? What did the training mean to you? Did you learn anything from the training period? Were there any challenges during the training? Could you tell me what happened in these situations? Did you experience some things that went really well? Or not work out so well? Would you like to change something? Could you tell me if there were any episodes in particular that made a special impression on you (positive or negative)? Have you reflected on the group-based training versus previous experiences with physical therapy?
Experience of quality of life	Is there anything you would like to pinpoint concerning your daily life/life quality in the period after the training finished? Did you experience the training to have any influence in your daily life long term (positive or negative)?
Thoughts about the future	Do you have any thoughts concerning future physical therapy, group-based training, or activity in the future? Any challenges?
Closing question	Are there any experiences from the group-based training or the period after the intervention was completed that you would like to share that other individuals with MS or physiotherapists could learn from? Do you have anything else you would like to share? How did you experience being interviewed?

Reflexivity

The research team included different competencies: ECA and BN are clinical specialists in neurological physiotherapy for adults and the creators of GroupCoreDIST, GKØ is a specialist in pediatric physiotherapy, and SG a philosopher and an expert in phenomenology. The two patient representatives both participated in the RCT part of the study, but were not interviewed. They provided important insights, for example as they spontaneously reported similar experiences to what was extracted from the material of that feelings of improvements in strength or sensibility meant that they felt more in control and had lead to easier access to daily life activities, and expressed a congruency of group settings sometimes being hard.

Experience and knowledge regarding neurological physiotherapy, GroupCoreDIST and individuals with MS gave the interviewer (ECA) and the last author (BN) positioned insight (Paulgaard, 1997). This background, combined with the research team´s insights in DST, phenomenology and experience from performing interview studies enforced the team to create a targeted interview-guide, which through discussions served to illuminate our preconceptions regarding the phenomenon in advance. Moreover, the interview guide was prior to the study adjusted through two test interviews with individuals with MS. These were transcribed and discussed in order to increase the quality of the interview guide and the interview competency of ECA, including to ask adequate open-ended questions and follow-up questions allowing for surprises to occur, such as the unexpected strong emotional feelings related to positive bodily changes in individuals with minor disability as well as others who experienced less improvements. The research team furthermore discussed the interview guide and verbalized what we thought could be potential answers, what would be relevant to ask for and how to ask in a way that opened for stories and reflections that we haven't thought of before. We considered the interview guide to be balanced, allowing the participants to lead the direction of their answers. Since the participants mostly highlighted positive situations, they were also asked directly for negative experiences (Tables 3 and 4).

During the interviews the first author tried to understand the meaning of the participants´ statements and to ask adequate follow-up questions to capture each person´s uniqueness; for example: could you tell more about that? could you describe what you and the PT did in the situation? What do such experiences mean to you? Was there anything you did not like, something that made you feel uncomfortable or was not as expected?

The risk of being too close to the material and overlook blind spots was addressed by the systematic analytic approach to the material in line with Malterud (2001), which included the discussions to develop the

Table 5. Description and examples of the analytical process.

Preliminary themes	Feeling a change Changes in everyday life and activity Confirmation of change The examination The physiotherapist's one-to-one interactions, adaptations and engagement	
Theory: Dynamic systems theory	Manipulation of constraints in the individual, the task and the environment. Changes in the individual´s subsystems make the whole movement pattern change which leads to improved movement control.	
Theory: Phenomenology of the body	Changes influence the self-pattern: both pre-reflective and reflective aspects, how each individual looks at themselves and becomes attached to own movement possibilities: body schema, sense of ownership and agency. Body image and narrative self. "I can" or, in some cases, "I can't."	
Meaningful units	*"The changes feel fantastic; it makes me feel like there is hope, that it is actually possible to improve something that has been totally pacified and to move easier."*	*"Suddenly, I experienced myself walking up the stairs without holding the handrail."*
Code group	Changes in bodily impairments and activities are meaningful for the participant	
Sub-groups	Bodily changes and engagement	Reaccessing opportunities
Condensates (short summaries)	The participants reported the intervention to have a major impact, both immediately and in the long term, involving the absence of headaches, improved sensation in the hands and feet, improved activation of core muscles and better balance, as well as a faster gait with longer steps, more power and propulsion, and more endurance. They highlighted the importance of specific and engaged verbal instructions for exercises combined with hands-on facilitations by the physiotherapist during the group sessions.	The participants highlighted that living with a progressive disease such as MS meant gradually giving up activities. They were therefore astonished by the way the improvements in impairments and movement control had enhanced daily life activities and the performance of domestic obligations such as doing laundry without taking breaks and being able to stand on one's toes to reach the upper kitchen cabinets and to carry two cups of coffee while walking. The participants expressed emotionally that increased energy allowed them to spend more time with their children and other family members.
Category	Movement control, orientation and insights	

interview guide, the presented literature review and the applied theoretical framework. This enabled us as a research team to be more conscious of our pre-understandings, which we actively strived to set aside throughout the study.

Throughout the analyses the authors tried to be open and attentive, and had discussions where alternative interpretations of the material were considered, for instance was the participants´ strong focus on their own performance emphasized in relation to the fact that this was a group setting, and the high focus on positive improvements discussed in relation to the small amount of negative experiences. We discussed if there could be aspects of the few challenging situations that still needed to be highlighted in order to understand significant elements of GroupCoreDIST, and continually challenged the interpretation of the material by asking: what does this mean? what else could it mean?

The four researchers had different competencies, experiences and tasks in the research process, which enriched the discussions and interpretations of the material and provided adequate distance. For instance, two of the authors read all and another read much of the transcribed material in order to discuss and validate that the content of the categories and subgroups were in line with the themes that the majority highlighted. Furthermore, the consistent use of theoretical perspectives throughout the whole process was validated by all authors, with special insights from the third author who has an extensive overview of the literature in this area.

None of the authors were involved in the group trainings or assessments in the RCT, which was an advantage in that it did not exert pressure on the participants to emphasize only positive experiences. The interviews were conducted before the testing sequences at both 7- and 30-week interviews, to avoid the participants being influenced by their perceptions of success or nonsuccess in the balance and walking tests. Being a part of the intervention group may though in it self have strengthened the feeling of success as participants received a new treatment offer, more attention and additional structure to the week.

Results

The findings are presented as analytic text condensed from the interviews (Table 6, overview of categories and subgroups) and are supported by illustrative quotations involving most of the participants and marked with informant identification (number), gender (M/W), age (years) and EDSS value (EDSS).

Table 6. Overview of the categories and subgroups.

Category	Movement control, orientation and insights		The individual within the group	
Subgroup	Bodily changes, and engagement	Re-access to opportunities	Acceptance and interactions	Adjustments and attentiveness to the individual

Movement control, orientation and insights

Overall, the participants' provided strong and emotional short term experiences from the GroupCoreDIST regarding improvements in bodily impairments and movement control, which enhanced positive views of themselves, strengthened outward orientation and allowed them to join new activities. New accomplishments were continued in the long term but reported with less emotional excitement. Absence of improvements was associated with increased awareness of their own impairments by two participants.

Bodily changes and engagement

> *… Even during the examination, I felt that it became easier to walk! And then I looked forward to what was coming; I felt something happen. (ID 3, M (65), EDSS 5.5)*

The participants emphasized that the individual assessment prior to the group sessions was important for the physiotherapist to choose suitable variants of exercises. Both participants with high and low EDSS-values were surprised that even their minor but perceptible symptoms were detected. Seven individuals reported perceiving immediate changes in performance in the initial examination, which created positive expectations for the training. All participants reported that the high dose of training was well tolerated; however, eight participants said that getting there, organizing their travel from home or work and finding a parking space, was a bit energy consuming.

All participants emphasized that the GroupCoreDIST-intervention addressed their movement problems more specifically than prior experiences from physiotherapy, where many described being offered a general training program and insufficient adjustments. Twelve individuals described perceiving varied bodily improvements during and immediately after the intervention such as: cessation of headache; improved sensation in the hands and feet; improved activation of core muscles and balance; faster gait with longer steps; and more power, propulsion, and endurance. These short-term experiences were described as feeling fantastic, being emotional and meaningful.

The participants, furthermore, highlighted the importance of specific and engaged verbal instructions combined with hands-on facilitations by the physiotherapist. Although all participants reported sometimes struggling in the start of a new exercise, most reported that one-to-one situations with the physiotherapist during a group session including fine-tuned hands-on adjustments, enabled them to move easier and to feel and understand how to perform an exercise adequately. One such one-on-one situation was described like this:

> *"I noticed the changes, yes, and she [the physiotherapist] noticed the changes, and she became so excited! I mean, it was so exciting!" " … She mobilized, massaged and moved my foot at the same time … ." "Suddenly, I managed to move my toes, and I was not able to do that in the beginning." "So it seems to pay off, even in a leg that you think is of no value." (ID2, W (70), EDSS 6)*

Two participants reported that the physiotherapist sometimes did not tailor the exercises according to their perceived needs, which led to experiencing difficulties in performing, not noticing any changes, and an increased focus on their own disability. Nevertheless, all but one participant reported that their active contribution and bodily improvements made them feel proud and in control. This outcome generated hope and less concern regarding the future. One participant used these words:

> *" … This is the best thing that has happened since I got the diagnosis! Yes! I get so emotional when thinking about it [tears in her eyes] … ." "Ever since I got the diagnosis, I have had a huge M-S on my shoulders; it has unintentionally dragged me down." " … . Can you imagine! It [the training] had such an effect! If I had only known … " " … When I perceived how good it was for my entire system, for my body, I got so motivated!" (ID 4, W (49), EDSS 1.5)*

Reaccessing opportunities

> *Suddenly, I experienced myself walking up the stairs without holding the handrail.*
> *(ID 12, W (40), EDSS 1.5*

All participants highlighted that living with a progressive disease such as MS felt unpredictable in regard to future mobility, and many had gradually given up activities. They were therefore astonished by the way their bodily improvements enhanced their daily life activities and domestic obligations, such as doing the laundry without taking breaks, being able to stand on their toes to reach the upper kitchen cabinets and being able to carry two cups of coffee while walking. Those who had kids or grandkids emotionally expressed having more energy to play with them. Employed individuals reported that job tasks had become easier both during and after the intervention was completed (as expressed both at the 7- and 30-week interviews). They stated that working made them feel healthier and more normal. One participant (a teacher) said:

> *I have especially struggled with keeping my balance at my job. When I walk in the hallways, I have to step over like 100 backpacks along the way. However, now I have noticed that if something is on the floor, I don't think about how to walk. I actually manage to walk over or beside it, without taking sidesteps or having to stop and think about how to get past this area and without losing my balance completely, and that feels so great! (ID 12, W (40), EDSS 1.5)*

All but two participants reported at the 30-weeks interviews, performing unsupervised home-based GroupCoreDIST exercises during and up to three months after the intervention. All stated that unsupervised exercises felt less meaningful because, without the physiotherapist's hands-on adjustments and instructions, fewer immediate changes appeared and the training got boring. Five participants added, with sorrow, that some of the bodily improvements achieved during the training-period reversed after some months. Eight participants though reported, both at 7 and at 30 weeks, to have started new activities or activities they had once quit, such as aerobic training, hiking, cycling and jogging. Earlier, even minor impairments had caused them to quit exercising together with others because they were afraid that their deficiencies would show. One participant, who previously loved to exercise, said that he had once again started going to the gym with friends, and believed that he could "accomplish anything" when experiencing such meaningful bodily improvements from only six weeks of training. He said:

> *"As I felt my body started functioning again, and I managed to do things again, I wanted to try once more the things I couldn't manage previously. So my self-confidence has improved, along with my bodily improvements." … "Previously, I didn't dare to try anything because I was afraid to fail, but now, I have decided to go for it – no matter what!" (ID 6, M (25), EDSS 1)*

The individual within the group

Overall, the group setting was reported as safe and fruitful at both the 7- and 30-week interviews, especially when the participants experienced tailored adjustments by the physiotherapist, perceived positive bodily changes, and experienced appropriate attention from the group and physiotherapist. These factors enriched the experience of being in a group and strengthened the feeling of individual success. When attention and adjustments were not obtained, the group setting became challenging, and the focus turned toward their own disability compared to the others in the group.

Acceptance and interactions

> *"We are in the same boat." … . "It felt safe. We didn't judge each other – what I can do and what you can't do." (ID 7, M (78) EDSS 6)*

The majority emphasized the value of meeting other individuals with MS and reported that the group's expectations for them to show up made it easier for them to attend. Even if they had the same diagnoses, they noted each other's different impairments during group sessions and highlighted the importance of performing tailored variants of the same exercise. Sharing a diagnosis meant gaining acceptance and understanding when having bad days and not being embarrassed about balance difficulties, being misunderstood as drunk, or blamed for being lazy when becoming tired. One individual described the group atmosphere as follows:

> *… It is just something about the unity in a way, and well, we got to know each other, and we all understand. We all have MS, and we understand what it is like to have MS.(ID 4, W (49), EDSS 1.5)*

The balance checkpoints at the beginning and end of every session, where the aim was to explore one's own balance, were particular situations when the participants reported observing each other's performance. These parts of the session were described with excitement and interest, particularly when focusing on their own performance and if the group verbalized observable improvements. Seeing others perform better than oneself was, however, described as frustrating. Both those with severe and mild disabilities, emphasized that noticing other group members struggle with exercises at their level, increased the perception of one's own success. One severely disabled woman expressed this as follows:

> *He [another participant] was one of those guys who woke up at 7 in the morning three times a week to go to the gym and exercise, exercise, exercise … but when he was set to do these small movements that the physiotherapist instructed, then he didn't perform them any better than me. This was difficult for him, even though he could walk perfectly [compared to me]. (ID 9w, W (72), EDSS 6.5)*

Adjustments and attentiveness to the individual

> *"It is very individual what each and every one can accomplish." … "She [the physiotherapist] was constantly ensuring that we all performed correctly." (ID 3, M (65), EDSS 5.5)*

The physiotherapists were described in various ways; some as skillful and enthusiastic, others as strict but firm or as warm. Three participants reported that the physiotherapist looked in the manual to remember the exercises, which led to less attention toward each participant and slower progression in the session. All but two participants described excitement when someone improved at their individual level, and that sufficient attention to everyone in the group and hands-on tailoring to enhance each individual´s problems were important for their perception of success within the group. One participant described this as follows:

> *There were several exercises where all three of us were struggling, and then she [the physiotherapist] came around and adjusted us in different ways, and suddenly, we all succeeded! I am truly aware of that interaction, how good it feels, the group, that we succeeded – all of us – and that felt so great. (ID 5, W (26), EDSS 4.5)*

The group setting was, however, sometimes challenging. The same two participants who said that the physiotherapist did not tailor the exercises sufficiently also thought that the physiotherapist seemed to be more interested in the group member who performed "best," which made them feel like outsiders in the group. One participant described how skewed attention and fewer adjustments provided negative experiences:

> *"I couldn't do it because my body doesn't listen. I don't have the skill and balance and strength to perform the exercises from instructions, and I had to give up, and I felt like watching the ship go down." "… When you are invited to do the same as the group and you can't do it, you just cannot do it! Then, I moved backwards in time and remembered so strongly when I had that functional level." (ID 13, M (64), EDSS 5.5)*

Discussion

Specificity provides bodily changes and new opportunities

The participants' perceptions of improved symptoms, movement control and easier access to daily activities are not surprising and in line with significant effects on balance in the RCT, in which this interview study is nested (Arntzen et al., 2019). It is also in agreement with previous reviews of effects in balance and walking (Byrnes, Wu, and Whillier, 2018; Gunn et al., 2015; Hogan and Coote, 2009; Paltamaa, Sjogren, Peurala, and Heinonen, 2012; Rietberg, Brooks, Uitdehaag, and Kwakkel, 2005; Snook and Motl, 2009) and qualitative studies of group-based training in individuals with MS (Carling, Nilsagård, and Forsberg, 2018; Clarke and Coote, 2015). Targeted hands-on adjustments, combined with instructions and engagement, were emphasized as essential for experiencing bodily improvements. One example is a participant who described that the physiotherapist's mobilization combined with active movement of her foot suddenly enabled her to move her toes. In line with DST, these interactions could be associated with manipulations of constraints in the individual´s biomechanical, motor and somatosensory subsystems, which also seemed to influence the emotional and cognitive systems, as the participants enthusiastically noticed the changes. According to DST, all the reported improvements in sensibility, core stability, balance, walking, motivation, etc., could be linked to effected changes in the individual's constraints for movement.

Improvements in walking and daily activities were reported both in the short and long term. Since gait training was not part of the intervention, these changes may be due to changed constraints in individual subsystems, that influenced the whole self-regulated system, indicating new attractor statuses regarding these activities (Shumway-Cook and Woollacott, 2017; Thelen, 2005). Specificity in tasks and optimizing the individual's constraints are required in neurological physiotherapy (Frykeberg and Vasa, 2015), and are important for recovering optimal movement strategies following lesions in the CNS (Kleim and Jones, 2008; Levin, Kleim, and Wolf, 2009; Lipp and Tomassini, 2015). A focus on movement control and movement quality has traditionally stood in contrast to task orientation (Carr and Shepherd, 2010). Our findings suggest that specificity in the therapeutic approach addressing the prerequisites for an activity, for instance hands-on mobilization, was meaningful to the participants and created improvements. Even if gait training as such was not conducted, partial tasks were introduced, such as instructions of rolling the ball from side to side, addressing lateral weight transfer, which is an important prerequisite for walking (Gjelsvik and Syre, 2016). This suggests that a detailed focus on prerequisites and tasks simultaneously may be important elements for successful individualization within a group setting. This fruitful mixing of movement and task has previously been emphasized in regard to individual settings (Normann, Sørgaard, Salvesen, and Moe, 2013).

For the few participants who did not experience bodily changes and adequate adjustments regarding specific hands-on interactions or exercises, the total system might have remained unchanged, with the result that the individual's movement strategies remained the same. Experiencing their own failure in performance compared to the others´ success may have lead to a verification of own disability and a negative influence on the cognitive and emotional subsystems. Such feelings of frustration and lost control has also been accentuated in a review study (Learmonth and Motl, 2016).

In our study, participants with both high and low EDSS values claimed that another essential element of individualization was the physiotherapist's choice of adequate exercises for the group, with different variants for each individual. We consider these actions as manipulations of constraints in the tasks (Shumway-Cook and Woollacott, 2017). The specificity in the choice of actions for each individual´s within the group was furthermore highlighted as possible due to the initial clinical assessment. This finding is in line with studies examining the physiotherapist's perspective regarding GroupCoreDIST (Lahelle, Øberg, and Normann, 2018a, 2018b). Individualization has been questioned within group settings both in regard to feasibility and effects (Kalron et al., 2019; Plow, Mathiowetz, and Lowe, 2009). In strength and endurance training individualization is often emphasized in relation to intensity, duration, diverse number of repetitions or load (Dalgas, Stenager, and Ingemann-Hansen, 2008). The current study of participants in small groups points out that in addition to these aspects, addressing the individual`s underlying constraints for movement by choosing from the 33 exercises, levels of difficulty, the use of hands-on adjustments and exploring immediate changes (Normann, Zanaboni, Arntzen, and Øberg, 2016) creates both physical improvements and deeper meaning.

Turning to phenomenology, the one-to-one situations where the physiotherapist and a participant worked together to improve sensory-motor function and performance through a mix of instructions and hands-on interactions, may be seen as a form of bodily communication mediated through inter-corporeity and an establishment of a shared agency (Merleau-Ponty, 2013) Such interactions made possible both a pre-reflective, subjective awareness of their lived body and a reflective awareness on their own possibilities and sometimes a deviation and lack of possibilities (Gallagher, 2012). For instance, might both the improvements regarding sensibility in the feet, core activation or feelings of increased movement control be considered a strengthening of "I can" and intentionality, as their outward directedness generated more affordances in daily life, while the lack of such changes affirmed the status quo. Specific bodily changes were emotional and meaningful. This stands in contrast to other approaches in neurological physiotherapy, in which the achievement of whole activities and not impairments or the quality of the task is considered meaningful (Carr and Shepherd, 2010). In this study, bodily improvements were emphasized as becoming incorporated into daily activities, for instance, by being able to walk past backpacks at work and to balance on one's toes to reach the upper kitchen cabinets. These findings suggest that the participants' body schemas, sense of ownership and agency regarding body and movement the prereflective experiential aspects of the self-pattern (Gallagher, 2005, 2012, 2013) were updated, giving individuals improved opportunities to regulate movement and posture in daily life. This interpretation implies that bodily changes are meaningful, and are not only about neurophysiological processes but also about the pre-reflective aspects of self-experience.

Since what we can or cannot do helps to shape our thoughts (Gallagher, 2005), the short- and long-term reports of new activities, such as cycling or carrying coffee-cups while walking, generated among the participants a "new look" at themselves and gave insights into future possibilities and affordances (Gallagher and Daly, 2018). These experiences indicate that the reflective aspects of the individuals' self-pattern (including the narrative aspect) were updated and might have influenced how they identified themselves, which is in line with descriptions from individual settings (Gallagher, 2013; Normann, 2018; Normann, Sørgaard, Salvesen, and Moe, 2013). The extended factors of the self-pattern seem also to be in play, since the participants managed daily activities more easily, such as having energy to play with their children. The increased focus on own disability reported by two individuals could be due to fewer perceived improvements generating lower expectations of possibilities which may explain the distress among these individuals, and also among those who felt impairments returning some months after the intervention. Such return of symptoms are highlighted by Leder (2016) to possibly increase the feeling of loss and lack of control that comes with a chronic disease, and would be important to have in mind in physiotherapy in regard to content and timing of future follow-up.

The group setting reinforced the participants' self-reflections

The participants highlighted that training together with others who had MS made the training situations feel safe, motivated them and gave them a perception of accomplishment, in line with other studies (Clarke and Coote, 2015; Dodd, Taylor, Denisenko, and Prasad, 2006; Learmonth and Motl, 2016). As emphasized by our findings, the interactions between the physiotherapist and a group member made new possibilities for movement visible to all the group members. When such interactions with a shared sense of agency were equally distributed among all participants, it strengthened the individuals' feelings of being acknowledged within the group. The interactions between other group-members especially involved positive comments during the balance checkpoints and awareness of the others struggling. These situations created a shared agency between all members of the group and thereby strengthened each single person´s sense of agency, as well as the reflective factors of the self-pattern, including the individual's body image (Gallagher, 2013; Merleau-Ponty, 2013). This implies that the multimodal communication between all embodied subjects of the group co-constructed insights that were incorporated in their lived bodies and brought forward "pre-MS" experiences and self-narratives, and oriented them toward a focus on activities that they could accomplish (increasing the feeling of "I can"). In contrast, when skewed attention, inappropriate tailoring, fewer changes and task accomplishment were experienced there was an increase in the feeling of "I cannot", including recollection of previous experiences of giving up activities and losing control, which often is described in relation to having a chronic disease, in which bodily restrictions gradually appear (Carel, 2008; Toombs, 1987). This underscores vulnerability regarding group situations, and that together with others we also compare ourselves with others and create meaning through the others (Sokolowski, 2000). Conversely, identifying your own specific symptoms and addressing them in relevance to function can demonstrate your specific needs and uniqueness within the group, which might be of relevance for motivation and meaningfulness during the training period- at least if improvements in performance are pinpointed simultaneously. Seeing the other participants' performances might furthermore be linked to identifying oneself in relation to one's own and other participants' abilities, associated with both the intersubjective and extended factors of the self-pattern (Gallagher, 2013). Positive or negative attitudes in therapeutic situations might extend to the perceived opportunities and affordances in daily life, for instance, the participants' descriptions of feeling more normal due to managing their jobs better or, in contrast, avoidance of participating because the "body doesn't listen." These aspects of physiotherapy involving an individual's sense of self are important, although rarely emphasized in clinical practice or prior studies within the field.

Methodological considerations

This study involved a strategic sample of thirteen participants, which might be considered a small number. A strategic sample is essential in qualitative depth-interview studies, and has its strengths in the search for participants´ nuanced experiences, including both positive, neutral and negative experiences, in order to answer the research question. Limitations may be that some of those who were not selected might have been able to add additional aspects to the phenomenon. Considering a population of 40 individuals in the GroupCoreDIST intervention-group, 33% (13/40) participated in two interviews, for a total of 25 extensive interviews that produced a large amount of nuanced data of the investigated phenomenon, which is in line with Malterud's (2016) characteristics of sample sizes in qualitative studies (Malterud, Siersma, and Guassora, 2016). The interview study being nested in an RCT makes the study context special, involving repeated measures, which might have influenced participants' experiences and expectations. The fact that one of the creators of GroupCoreDIST conducted the interviews may have stressed the participants and influenced the large amount of positive expressions. Negative experiences were therefore also highlighted in the findings even if they were emphasized by only a few individuals. The study was conducted in six different municipalities, involving different clinical physiotherapists, which improved the relevance and transferability of the results (Malterud, 2001). Different physiotherapists conducted interviews, RCT assessments and interventions. A detailed protocol was used (Normann, Zanaboni, Arntzen, and Øberg, 2016) with thorough descriptions of the methods and reports of all of the items of the Consolidated Criteria for Reporting Qualitative Research (COREQ) (Tong, Sainsbury, and Craig, 2007) and Standards Reporting Qualitative Research (SRQR) (O'Brien et al., 2014) checklists, all of which improved the trustworthiness of the study. The participants had EDSS scores of 1–6.5, and the groups consisted of only three participants, which would limit the transferability to ambulant individuals with MS and small groups.

Implications for clinical practice

The findings support integration of elements known from individual physiotherapy with social elements known from group settings. This indicate that group interventions aiming for improved balance should consider including an initial individual examination, specific one-on-one adaptations and exercises that allow for individualization in order to address the individuals' specific symptoms and positive verbalization of improvements among the group-members.

By the use of a mix of analytical tools we have gained a deeper understanding of the participants bodily experiences and why these were so important to the them- it was not just about the body as biomechanics, neurophysiological processes, muscle strength or balance, but how it mattered to them as individuals, how they experienced themselves and their opportunities. These aspects may be important and general features in physiotherapy, because the way you perceive your own body is closely related to how you experience yourself and own possibilities in the world. Studies are warranted of the possibilities for individualization and experiences of bodily changes within larger training groups containing participants with equal EDSS.

Conclusion

Most of the participants in GroupCoreDIST experienced physical improvements in body functions and structures, activities and participation in the short and long terms. The changes felt emotional and meaningful, involving increased feelings of ownership and control of body and movement. This changed how they looked at themselves, at their opportunities and affordances in daily life, implying that both pre-reflexive and reflexive aspects of the self-pattern were influenced. Changes and success were linked to different elements of individualization: detailed exercises that targeted each individuals' constraints for movements; one-to-one situations with the physiotherapist including hands on adjustments and; the group setting, as long as there was equal amount of on-to-one interactions, and positive attention from the physiotherapist and the other group members occurred. Skewed attention, inadequate choices of exercise variance or lack of adjustments were associated with less changes and an increased focus on own disability.

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APPENDIX 1- 7

Appendix 1

Informed consent form for participants (in Norwegian)

Gruppebasert trening av balanse for personer med MS – Hoveddel – 28.8.2014

Forespørsel om deltakelse i forskningsprosjektet

"Innovative Physiotherapy and Coordination of Care in People with MS: A Randomized Controlled Trial and a Qualitative Study"

Bakgrunn og hensikt

Dette er et spørsmål til deg om å delta i en forskningsstudie for å få ny kunnskap om virkning av gruppetrening og standard oppfølging for personer med multippel sklerose (MS). Hensikten med studien er å undersøke om individuelt tilpasset gruppebasert intensive trening, har effekt på balanse, gangfunksjon, daglige aktiviteter og helserelatert livskvalitet sammenlignet med standard oppfølging for personer med MS. Det søkes også etter å få innsikt i deltakernes erfaringer med å delta i dette treningsopplegget, samt erfaringer med standard oppfølging i kommunen og samhandling mellom MS-poliklinikken og kommunehelsetjenesten. Videre søkes innsikt i hvordan treningen gjennomføres og hvilke erfaringer fysioterapeutene har med å gjennomføre denne gruppetreningen. I tillegg undersøkes det om den nye fysioterapiformen er samfunnsøkonomisk. Du er valgt ut til å forespørres om å delta i studien fordi du har diagnosen MS, og bor i en av kommunene som studien skal hente deltakere fra: Bodø, Fauske, Meløy, Rana, Rødøy eller Vågan. Nordlandssykehuset er ansvarlig for studien, som foregår i samarbeid med Universitetet i Tromsø Norges Arktiske Universitet.

Hva innebærer studien?

72 personer med MS planlegges tatt med. Disse vil, ved loddtrekning fordeles i to grupper. Den ene gruppen gjennomfører individuelt tilpasser gruppebasert trening av balanse i lokalene til en fysioterapeut i kommunen. Den andre gruppen følges opp med standard oppfølging i kommunen og utgjør kontrollgruppen. Det er vanlig at standard oppfølging varierer. Noen har ulike former for fysioterapi eller deltar på andre aktiviteter, mens andre ikke gjør det. Alle deltakerne følger sin ordinære medisinske oppfølging.

For å delta i studien må du ha MS (uansett type), ditt funksjonsnivå kan være fra at du har minimale gang og balanseproblemer til at du kan gå minimum 20 meter med krykker (EDSS 1-6,5), og det må være mer enn 14 dager siden siste sykdomsforverring (atakk). Du kan ikke delta dersom du er gravid når studien starter, eller har akutte ortopediske skader som påvirker balanse og gange.

Treningsprogrammet for intervensjonsgruppen innebærer:

- Individuell undersøkelse hos kommunefysioterapeut med spesialkompetanse innen nevrologi, slik at gruppe-behandlingen kan tilpasses den enkelte deltaker.

- Deretter følger trening i grupper på tre deltakere, hvor balanse og bevegelseskontroll vektlegges. Den enkelte deltaker følges tett opp av fysioterapeuten. Hver gruppetrening varer i 60 minutter, 3 dager per uke i 6 uker. Deltakerne utfører i denne perioden egentrening hjemme i 30 minutter, to dager i uken, basert på øvelser fra gruppetreningen. Egentreningen kan deles opp og all trening tilpasses den enkeltes dagsform.

Før loddtrekning til intervensjons eller kontrollgruppe blir alle deltakerne testet hos nevrolog og fysioterapeut ved Nordlandssykehuset HF, Bodø. Reiseutgiftene til testing dekkes av Pasientreiser. Nevrologen skårer EDSS som viser ditt funksjonsnivå. Ved første testing vil alle deltakere også gi kort informasjon om høyde, vekt, alder, yrke, utdanning, om du er i jobb, om du røyker og standard oppfølging i kommunen. Fysioterapeuten vil teste deltakerne med ulike standardiserte balanse- og gangtester samt fire spørreskjema vedrørende gange, daglige aktiviteter og helserelatert livskvalitet. En av gangtestene vil bli videofilmet slik at fysioterapeuten kan skåre testen etterpå. Alle deltakere, også de som ikke mottar behandling, vil testes på nytt med de samme balanse- og gangtestene samt spørreskjema etter 6 uker, samt etter tre og seks måneder. Testing vil foregå ved Nordlandssykehuset HF, Bodø. Hver testsekvens tar inntil 60 minutter. For å registrere daglig aktivitetsnivå i avgrensede perioder vil alle deltakerne få låne en "aktivitesmåler" som er et lite armbånd/klokke. Denne skal brukes i uka etter at første testing er gjort, og deretter en uke etter hver testing hos fysioterapeuten. Deltakerne må sende aktivitesmåleren i ferdig utfylt og frankert konvolutt til prosjektleder etter bruk. I treningsperioden (6 uker) skal deltakerne føre en enkel treningsdagbok med avkryssingsskjema. Alle deltakerne skal registrere forverringer i sykdomsaktivitet i løpet av hele prosjektperioden i et skjema. Fysioterapeuten som gjennomfører alle målingene/testene vet ikke om deltakerne er i treningsgruppene eller kontrollgruppen.

Åtte til ti personer fra intervensjonsgruppen og fra kontrollgruppen vil bli intervjuet to ganger, første gang på slutten /rett etter at gruppetreningen avsluttes og det neste seks måneder senere. Samtalene vil dreie seg om deltakerens erfaringer med å delta i gruppetreningen, tiden etter avsluttet gruppetrening og samhandlingen mellom MS-poliklinikken og kommunehelsetjenesten. Samtalene med deltakere i kontroll-gruppen vil dreie seg om innhold og erfaringer med standard oppfølging. Intervjuene vil foregå i ditt nærmiljø eller ved Nordlandssykehuset HF, tas opp på lydband, og vil vare i maksimum 1 time.

For å utvikle ny kunnskap om det nye gruppebaserte fysioterapitilbudet skal 12 førstegangsundersøkelser hos kommunefysioterapeuten som skal lede gruppetreningen observeres og vidofilmes og det samme gjelder 12 gruppebehandlinger. Det vil til sammen bli 12 treningsgrupper, hver på tre deltakere. Observasjon og videofilming fordeles slik at alle gruppene blir dekket og gjennomføres så diskre og lite forstyrrende som mulig av en fysioterapeut.

Mulige fordeler og ulemper

Det er ingen risiko å delta i studien. Mulige fordeler ved å delta i intervensjonsgruppen er at treningen kan gi bedre balanse, gangfunksjon og funksjonsnivå i det daglige samt innsikt i trening og hva som påvirker balanse og daglige bevegelser. Videre kan det oppleves som en fordel å trene sammen med andre. Deltakerne i intervensjonsgruppen vil gå gjennom en intensiv periode med trening noe som kan føles krevende. Treningen vil imidlertid til en hver tid tilpasses den enkelte når det gjelder funksjonsnivå, symptomer og dagsform. Testingen, registrening av sykdomsforløp, treningsdagbok samt å ha aktivitetsmålerklokken på armen i til sammen fire uker kan oppleves som en ulempe. Imidlertid kan det være inspirerende å delta på slike målinger, da det gir den enkelte innsikt i egen situasjon. Det er gratis å delta. Utgifter til transport til og fra testing og behandling dekkes av pasientreiser. Observasjon og videofilming kan oppleves som forstyrrende og være en belastning. Imidlertid vil fysioterapeuten gjennomføre dette så skånsomt som mulig for deltakerne ved å oppholde seg i periferien av rommet og bevege seg minst mulig slik at forstyrrelsen blir minst mulig. Videre vil fysioterapeuten åpne for at deltakerne etterpå får si noe om hvordan det var å bli observert og filmet.

Frivillig deltakelse

Det er frivillig å delta i studien. Dersom du ønsker å delta, undertegner du samtykkeerklæringen på siste side. Du kan når som helst og uten å oppgi noen grunn trekke ditt samtykke til å delta i studien. Dette vil ikke få konsekvenser for din videre behandling. Dersom du nå sier ja til å delta, kan du senere trekke tilbake ditt samtykke uten at det påvirker din øvrige behandling. Dersom du trekker deg fra prosjektet, kan du kreve å få slettet innsamlede opplysninger, med mindre opplysningene allerede er inngått i analyser eller brukt i vitenskapelige publikasjoner. Dersom du senere ønsker å trekke deg eller har spørsmål til studien, kan du kontakte prosjektleder Britt Normann, Tlf. 99614941, e-post britt.normann@uit.no

Gruppebasert trening av balanse for personer med MS – Hoveddel – 28.8.2014

Hva skjer med informasjonen om deg?

Testresultatene og informasjonen som registreres om deg skal kun brukes slik som beskrevet i hensikten med studien. Du har rett til innsyn i hvilke opplysninger som er registrert om deg og rett til å få korrigert eventuelle feil i de opplysningene som er registrert. Alle opplysningene og testresultatene vil bli behandlet uten navn og fødselsnummer, eller andre direkte gjenkjennende opplysninger. En kode knytter deg til dine opplysninger og testresultater gjennom en navneliste. Det er kun autorisert personell knyttet til prosjektet som har adgang til navnelisten og som kan finne tilbake til deg. Bruk av helsetjenester og kostnader ved disse vil bli innhentet gjennom kobling mot sykehusenes journalsystem (DIPS), Norsk pasientregister og HELFOs system for kontroll og Utbetaling av Helserefusjoner. Alle data lagres forsvarlig ved Nordlandssykehuset HF, Bodø. Lyd- og bildefilene slettes ved prosjektets slutt 31.12.2019, og avidentifiserte data og øvrige opplysninger vil bli slettet 5 år etter prosjektslutt, 31.12.2024. Det vil ikke være mulig å identifisere deg i resultatene av studien når disse publiseres.

Ytterligere informasjon om studien finnes i kapittel A – utdypende forklaring av hva studien innebærer.
Ytterligere informasjon om biobank, personvern og forsikring finnes i kapittel B – Personvern, biobank, økonomi og forsikring.

Samtykkeerklæring følger etter kapittel B.

Gruppebasert balansetrening for personer med MS – Kapittel A og B – 28.8.2014

Kapittel A- utdypende forklaring av hva studien innebærer

Kriterier for deltakelse

- Ha diagnosen MS
- Bo i kommunene Bodø, Fauske, Meløy, Rana, Rødøy eller Vågan
- Være 18 år eller eldre
- EDSS 1-6.5 (fra minimale symptomer til de som kan gå minimum 20 meter med to krykker)
- I stand til å gi informert samtykke
- Ikke gravid
- Ikke ha akutte ortopediske skader som påvirker balanse og gange

Gruppebasert balansetrening for personer med MS – Kapittel A og B – 28.8.2014

Bakgrunnsinformasjon om studien

I Norge er det ca. 10000 personer med MS. Gange og balanse er ett av hovedproblemene for denne pasientgruppen. Individuelt tilpasset fysioterapi med moderat høy intensitet anbefales. Vi har i dag noe kunnskap om betydningen av trening av balanse og gange gjennom å styrke stabiliteten i mage/rygg, hofte/bekken og overkropp. Imidlertid er denne kunnskapen mangelfull, særlig når det gjelder trening i grupper. I forkant av denne studien er det gjennomført en liten studie som prøvde ut intervensjonen, og denne viste at alle gjennomførte treningen og viste lovende resultater med tanke på endret balanse og gange. Tilgang til spesialisert fysioterapi i kommunene er begrenset og gruppetrening vil kunne øke tilgjengeligheten til fysioterapeuter som er spesialisert i nevrologisk fysioterapi. MS-poliklinikken har en nøkkelfunksjon i forhold til koordinering av helsetjeneste-tilbudet til personer med MS. Foreløpig er det kun i spesialisthelsetjenesten de kan henvise videre til intensive treningsopphold. Studien søker å bidra med utvikling og innsikt i nye pasientforløp.

Behandling/oppfølging som pasienten får dersom personen velger å ikke delta i studien

Dersom du velger å ikke delta i studien vil du få den vanlige oppfølgingen i din hjem-kommune. Oppfølging av personer med MS varierer fra kommune til kommune og fra person til person. Standard oppfølging kan innebære en eller annen form for fysioterapi.

Undersøkelser den inkluderte må gjennom i studien

Det vil gjennomføres standardiserte tester på alle undersøkelsestidspunkter i studien. Testene er relevante og pålitelige for å måle balanse og gange. Videre er spørreskjemaene som brukes i forhold til å få innsikt i deltakernes opplevelse av endring i balanse, gang og daglige aktiviteter beregnet for personer med MS. Aktivitetsmålerne som deltakerne skal ha på armen er liten og lett og gir pålitelig informasjon om aktivitetsnivå. På et overordnet nivå kan vi si at vi måler både hvor fort deltakerne går, hvordan de går og hvordan de selv opplever at de går og hvordan balansen er både i ro og under bevegelse. De deltakerne som intervjues vil kunne komme fram med erfaringer fra deltakelse i gruppebasert trening av balanse eller standard oppfølging. Videre vil noen førstegangsundersøkelser hos kommunefysioterapeut og en gruppebehandling fra hver treningsgruppe på tre deltakere observeres og video-filmes.

Tidsskjema – hva skjer og når skjer det?

Etter at man har takket ja til å være med i studien blir man innkalt til første testing hos nevrolog og fysioterapeut på Nordlandssykehuset HF, Bodø. Deretter brukes aktivitetsmåleren i en uke og returneres så til prosjektleder i ferdig utfylt konvolutt. Deretter trekkes deltakerne tilfeldig av en datamaskin til treningsgruppen eller kontrollgruppen. Når en treningsgruppe i en kommune er har fått tre deltakere starter intervensjonsperioden med individuell undersøkelse hos kommunefysioterapeut etterfulgt av treningsperioden som varer i seks uker. Så følger ny testrunde. Denne gjentas etter tre måneder og etter 6 måneder. Observasjon og videofilming foregår når kommunefysioterapeuten gjør den individuelle undersøkelsen før treningsgruppene starter og observasjon og videofilming av gruppetreninger skjer i løpet av treningsperioden. Deltakere som bor i Fauske kommune får sin gruppetrening i Bodø kommune. Deltakere som bor i Meløy og Rødøy kommune får sin gruppetrening av på Nordtun i Meløy kommune. Øvrige deltakere får sin trening hos kommunefysioterapeut i hjemkommunen.

Pasientens/studiedeltakerens ansvar
Alle deltakerne har ansvar for å møte til tesing og registrere sykdomsforløp. Deltakerne i behandlingsgruppen har ansvar for å delta i treningsopplegget, gjøre egentrening og registrere dette. For øvrig skal alle deltakere følge opp de medisinske anbefalinger som de har fått.

Informasjon underveis

Dersom ny informasjon blir tilgjengelig som kan påvirke din villighet til å delta i studien vil du så raskt som mulig bli orientert om dette. Du vil få opplysning dersom mulige beslutninger/situasjoner gjør at din deltagelse i studien kan bli avsluttet tidligere enn planlagt

Som deltaker i intervensjonsgruppene vil du få dekket treningen på vanlig måte, siden personer med MS har full refusjon. Reiseutgifter til og fra testing og behandling dekkes av Pasientreiser.

Kapittel B - Personvern, økonomi og forsikring

Personvern

Opplysninger som registreres om deg er navn, fødselsdato, kjønn, høyde, vekt, tidspunkt for diagnosen MS, type MS og funksjonsnivå registrert gjennom European Disability Score Scale (EDSS), medikamentbruk, fysioterapi og annen aktivitet de siste seks måneder, oppfølging i sykehus og kommunehelsetjeneste siste seks måneder, andre diagnoser, om du er gravid, bosteds-kommune, yrke, om du er i jobb, utdanning, om du røyker og sivil status. Videre registreres resultatene fra de standardiserte balanse- og gangtestene, spørreskjemaene og data fra aktivitetsmåleren. Andre opplysninger som vi ønsker å registrere om deg er opphold på rehabiliteringsinstitusjoner, sykehusinnleggelser, legekonsultasjoner i primærhelsetjenesten og spesialisthelsetjenesten, akuttinnleggelser, samt diagnostiske undersøkelser. Denne informasjonen vil bli hentet fra din pasientjournal, Norsk pasientregister og HELFO. All informasjonen du gir om deg vil anonymiseres, og vil bli lagret sikkert og beskyttet. Lydfilene og videofilmene vil bli lagret sikkert og beskyttet. Kobling mot sykehusenes journalsystem (DIPS), Norsk pasientregister og HELFOs system for kontroll og Utbetaling av Utbetaling av Helserefusjoner gjøres for å beregne om intervensjonen er samfunnsøkonomisk

Nordlandssykehuset HF, Bodø ved administrerende direktør er databehandlingsansvarlig.

Utlevering av materiale og opplysninger til andre

Hvis du sier ja til å delta i studien, gir du også ditt samtykke til at avidentifiserte opplysninger utleveres til forskere i prosjektet som arbeider ved Nordlandssykehuset HF, Universitetet i Tromsø; Norges Arktiske Universitet, Nasjonalt kompetansesenter for Telemedisin Universitetssykehuset Nord Norge, University of Hasselt i Belgia og University of Memphis i USA .

Rett til innsyn og sletting av opplysninger om deg og sletting av prøver

Hvis du sier ja til å delta i studien, har du rett til å få innsyn i hvilke opplysninger som er registrert om deg. Du har videre rett til å få korrigert eventuelle feil i de opplysningene vi har registrert.

Dersom du trekker deg fra studien, kan du kreve å få slettet innsamlede opplysninger, med mindre opplysningene allerede er inngått i analyser eller brukt i vitenskapelige publikasjoner.

Økonomi

Studien er finansiert av Helse Nord HF og Universitetet i Tromsø. De økonomiske ytelsene er lønn til prosjektleder, en prosjektmedarbeider og to doktorgradsstudenter (fysioterapeuter), samt driftsmidler og midler til utstyr. Det er ingen interessekonflikter mellom finansieringskilde og gjennomføring av studien.

Forsikring

Deltakerne i studien er dekket gjennom pasientskadeloven.

Informasjon om utfallet av studien

Dersom du sier ja til å delta i studien har du rett til å få informasjon om utfallet/resultatet av studien. Informasjon om resultatet og publiserte artikler vil du kunne få ved å henvende deg til prosjektleder Britt Normann telefon: 99614941 eller e-post britt.normann@uit.no

Samtykke til deltakelse i studien

Jeg er villig til å delta i studien

(Signert av prosjektdeltaker, dato)

....

(Blokkbokstaver, prosjektdeltakers navn)

Jeg bekrefter å ha gitt informasjon om studien

(Signert, rolle i studien, dato)

Appendix 2

Approval from the Regional Committee for Medical and Health Research Ethics in Norway (in Norwegian)

REK
REGIONALE KOMITEER FOR MEDISINSK OG HELSEFAGLIG FORSKNINGSETIKK

Region:	**Saksbehandler:**	**Telefon:**	**Vår dato:**	**Vår referanse:**
REK sør-øst	Gjøril Bergva	22845529	11.11.2014	2014/1715 REK sør-øst D
			Deres dato:	**Deres referanse:**
			23.09.2014	

Vår referanse må oppgis ved alle henvendelser

Britt Normann
Universitetet i Tromsø

Institutt for helse og omsorgsfag
9037 Tromsø

2014/1715 Gruppebasert trening av balanse til personer med MS: effekt, erfaringer og samhandling

Forskningsansvarlig: UiT Norges Arktiske Universitet
Prosjektleder: Britt Normann

Vi viser til søknad om forhåndsgodkjenning av ovennevnte forskningsprosjekt. Søknaden ble behandlet av Regional komité for medisinsk og helsefaglig forskningsetikk (REK sør-øst) i møtet 22.10.2014. Vurderingen er gjort med hjemmel i helseforskningsloven (hfl.) § 10, jf. forskningsetikkloven § 4.

Prosjektomtale

Studien skal frembringe kunnskap om en ny gruppebasert trening av balanse for personer med MS og samhandling mellom MS-poliklinikker og kommunehelsetjenesten. Formålet er å undersøke om intensiv individuelt tilpasset trening utført i 1) grupper hos kommunale fysioterapeuter og 2) i pasientenes hjem ved bruk av telemedisin har effekt på balanse, gange, dagliglivets funksjoner og livskvalitet sammenlignet med standard oppfølging i kommunehelsetjenesten. Videre søkes svar på hvordan pasientene erfarer å delta i treningen og samhandling mellom helsetjenestenivåene. En randomisert kontrollert studie med 108 deltakere, intervju med 30 deltakere og 10 helsepersonell gjennomføres. Samfunnsøkonomiske analyser utføres. Dersom intervensjonen viser effekt vil den kunne tas i bruk i ordinær praksis, stimulere til interkommunalt samarbeid, gi økt tilgang til spesialisert trening for personer med MS og kan være økonomisk samfunnsbesparende. I studien inngår et PhD prosjekt..

Vurdering

Komiteen har vurdert søknaden og har ingen innvendinger mot at prosjektet gjennomføres som beskrevet i søknad og protokoll.

Vedtak

Med hjemmel i helseforskningsloven § 9 jf. 33 godkjenner komiteen at prosjektet gjennomføres.

Godkjenningen er gitt under forutsetning av at prosjektet gjennomføres slik det er beskrevet i søknad og protokoll, og de bestemmelser som følger av helseforskningsloven med forskrifter.

Tillatelsen gjelder til 28.02.2018. Av dokumentasjonshensyn skal opplysningene likevel bevares inntil 28.02.2023. Forskningsfilen skal oppbevares avidentifisert, dvs. atskilt i en nøkkel- og en opplysningsfil. Opplysningene skal deretter slettes eller anonymiseres, senest innen et halvt år fra denne dato.

Forskningsprosjektets data skal oppbevares forsvarlig, se personopplysningsforskriften kapittel 2, og Helsedirektoratets veileder for «Personvern og informasjonssikkerhet i forskningsprosjekter innenfor helse og omsorgssektoren».

Dersom det skal gjøres vesentlige endringer i prosjektet i forhold til de opplysninger som er gitt i søknaden, må prosjektleder sende endringsmelding til REK.

Prosjektet skal sende sluttmelding på eget skjema, senest et halvt år etter prosjektslutt.

Klageadgang
REKs vedtak kan påklages, jf. forvaltningslovens § 28 flg. Klagen sendes til REK sør-øst D. Klagefristen er tre uker fra du mottar dette brevet. Dersom vedtaket opprettholdes av REK sør-øst D, sendes klagen videre til Den nasjonale forskningsetiske komité for medisin og helsefag for endelig vurdering.

Vi ber om at alle henvendelser sendes inn på korrekt skjema via vår saksportal: http://helseforskning.etikkom.no. Dersom det ikke finnes passende skjema kan henvendelsen rettes på e-post til: post@helseforskning.etikkom.no.

Vennligst oppgi vårt referansenummer i korrespondansen.

Med vennlig hilsen

Finn Wisløff
Professor em. dr. med.
Leder

Gjøril Bergva
Rådgiver

Kopi til: postmottak@iho.uit.no
Universitetet i Tromsø ved øverste administrative ledelse: postmottak@uit.no

Appendix 3

Approval from the Regional Committee for Medical and Health Research Ethics in Norway (in English)

REK
REGIONALE KOMITEER FOR MEDISINSK OG HELSEFAGLIG FORSKNINGSETIKK

Britt Normann
UiT – Norges arktiske universitet

Regional Committee for Medical
& Health Research Ethics
South East Norway, Section D
Postbox 1130 Blindern
NO-0318 Oslo
Norway

Phone: + 47 22 84 55 23
E-mail: ingrid.donasen@medisin.uio.no
Webportal: http://helseforskning.etikkom.no

Our ref.: 2014/1715d
IRB ref: IRB00006245

Date: 29th of June 2016

To whom it may concern,

Re: REC Letter of Confirmation

I am writing in reference to a request from Project Manager Britt Normann via e-mail dated the 23rd of June 2016, regarding a Letter of Confirmation in English.

Confirmation

We hereby confirm that the Regional Committee for Medical and Health Research Ethics, Section D, South East Norway, approved the Research Project "Innovative Physioterapy and Coordination of Care for People with MS: a Randomized Condtrolled Trial and a Qualitative Study" (Norwegian title: *Gruppebasert trening av balanse til personer med MS: effekt, erfaringer og samhandling*) at its Committee Review Meeting on the 22nd of October 2014. The Project Manager for the study is Britt Normann and the Institution Responsible for Research is Nordlandssykehuset HF.

An Amendment to the Project, including extension of the end date until the 31st of December 2019, was approved by REC on the 7th of July 2015.

The approval has been given on the basis that Research Project will be implemented as described in the Research Protocol.

Ethics Committee System

The Ethics Committee System in Norway consists of seven Independent Regional Committees with authority to either approve or disapprove Medical Research Studies conducted within Norway, or by Norwegian Institutions, in accordance with the Act on Medical and Health Research (2008).

Please do not hesitate to contact the Regional Committee for Medical and Health Research Ethics Section South East D (REK Sør-Øst D) if further information is required, as we are happy to be of assistance.

Yours faithfully,

Finn Wisløff
Chair of the Regional Committee for Medical
& Health Research Ethics of South East Norway,
Section D

Ingrid Dønåsen
Higher Executive Officer

Appendix 4

Confirmation of changes from the Regional Committee for Medical and Health Research Ethics in Norway (in Norwegian)

REK
REGIONALE KOMITEER FOR MEDISINSK OG HELSEFAGLIG FORSKNINGSETIKK

Region:	Saksbehandler:	Telefon:	Vår dato:	Vår referanse:
REK sør-øst	Gjøril Bergva	22845529	07.07.2015	2014/1715/REK sør-øst D
			Deres dato:	**Deres referanse:**
			01.07.2015	

Vår referanse må oppgis ved alle henvendelser

Britt Normann
Universitetet i Tromsø

2014/1715 Gruppebasert trening av balanse til personer med MS: effekt, erfaringer og samhandling

Forskningsansvarlig: UiT Norges Arktiske Universitet
Prosjektleder: Britt Normann

Vi viser til søknad om prosjektendring datert 01.07.2015 for ovennevnte forskningsprosjekt. Søknaden er behandlet av leder for REK sør-øst på fullmakt, med hjemmel i helseforskningsloven § 11.

Endringene innebærer:
- Ny forskningsansvarlig institusjon: Nordlandssykehuset HF. Kontaktperson er direktør Paul Martin Strand

- Utvidelse av prosjektperioden til 31.12.2019

- Endring i design fra trearmet til toarmet studie (telemedisindelen utgår)

- Antall forskningsdeltakere er redusert til 72 (36 i intervensjonsgruppen og 36 i kontrollgruppen)

-Innhenting av nye data fra samme utvalgsgrupper: nytt spørreskjema, observasjoner - inkludert bruk av video, intervju med fysioterapeutene som utfører intervensjonen, endring av måleinstrument.

-Endring i inklusjons- og eksklusjonskriterier

- Endring i rekrutteringsprosedyre

-Ny prosjektmedarbeider (fysioterapeut) knyttes til prosjektet

- Navnet på studien er endret til Innovative Physioterapy and Coordination of Care for People with MS: a Randomized Condtrolled Trial and a Qualitative Study

Vurdering
REK har vurdert endringssøknaden og har ingen forskningsetiske innvendinger mot endringen av prosjektet.

Vedtak

REK godkjenner prosjektet slik det nå foreligger, jfr. helseforskningsloven § 11, annet ledd.

Tillatelsen er gitt under forutsetning av at prosjektet gjennomføres slik det er beskrevet i søknaden, endringssøknad, oppdatert protokoll og de bestemmelser som følger av helseforskningsloven med forskrifter.

REKs vedtak kan påklages, jf. forvaltningslovens § 28 flg. Klagen sendes til REK sør-øst. Klagefristen er tre uker fra du mottar dette brevet. Dersom vedtaket opprettholdes av REK sør-øst, sendes klagen videre til Den nasjonale forskningsetiske komité for medisin og helsefag for endelig vurdering.

Vi ber om at alle henvendelser sendes inn med korrekt skjema via vår saksportal: http://helseforskning.etikkom.no. Dersom det ikke finnes passende skjema kan henvendelsen rettes på e-post til: post@helseforskning.etikkom.no.

Vennligst oppgi vårt referansenummer i korrespondansen.

Med vennlig hilsen

Finn Wisløff
Professor em. dr. med.
Leder

Gjøril Bergva
Rådgiver

Kopi til: *postmottak@iho.uit.no; postmottak@nlsh.no;Paul.martin.strand@nordlandssykehuset.no*

Appendix 5

Description of the GroupCoreDIST intervention.

GroupCoreDIST Dose and equipment	GroupCoreDIST Content and examples
Individual clinical examination 60-minute session before the start of the group sessions	History: Medical, social and patient history; symptoms; main issues from the patient's perspective Analysis: Observation and hands-on interaction. Consider the patient's resources and constraints for movements. Posture analysis: Various postural sets; for example, standing, sitting and lying down. Consider the alignment throughout the body and for each body area, adaptation to the base of support and interaction with the environment. Activities/movement analysis: For instance; walking, standing on the toes or heels, squats, one-leg standing and other balance challenges. Consider the body's relation to the base of support, movement patterns of the body as a whole, and specific body parts and their relation to each other, the task and the environment. Consider the ability to perform selective movements (to move one part of the body while stabilizing other parts) to provide coordination. Specific tests: Muscle length, muscle activation and strength, tonus, somatosensory function, pain, reflexes. Introduction to GroupCoreDIST exercises: Choose and try out a few exercises in relation to the individual's movement problems. Hands-on adjustments to improve alignment, adaptation to the base of support and movement quality. Explore the participant's ability for improved performance in the exercises. Conclusion: Consider the patient's resources and issues, hypothesis of causation and the main problem related to movement and balance and potential for improved movement control.
Group sessions Duration: 60 minutes, 3 times per week for 6 weeks	Planning the group sessions: Consider each participant's main problem and which underlying impairments are related to it. Choose exercises that suit the three participants and choose the appropriate postural set and variation of exercises (5 variations for each of the 33 exercises, 6 different

Equipment: Large therapy balls, small mobilization balls as well as rolled towels, bolsters, plinths and rubber bands for optimal alignment.	exercise categories) for each participant to be able to perform the exercise with optimal movement quality. Goal: Teaching the participants specific exercises that can be performed both together with a physical therapist and at home. It is a goal that participants should perceive improvements in balance and movement control.
Beginning and end of all group sessions	The physiotherapist asks how everyone is doing that day and for experiences regarding the performance of home exercises. Individual balance challenges are performed simultaneously for all participants at the beginning and end of each session, to perceive and reflect on their own balance that day, compare their own balance before and after each session, and provide an opportunity for the physical therapist to interlink the individual's balance challenges with the choice of exercises.
Exercises Perform up to 3x10 repetitions according to the individual's capacity and quality of performance. As the quality of movement in the exercise improves, the physiotherapist may adjust the dose by increasing the number of	Group members concurrently conduct the same exercise but with different variations according to symptoms and quality of performance. All six exercise categories should be used at every group session. All exercises target optimal adjustment to the base of support and activation of the core while performing the exercise. The 6 exercise categories are: 1) Somatosensory stimulation/activation of the hands or feet: exercises 1-2, somatosensory activation of the feet or hands to enhance adaptation to the base of support, for instance, by rolling a mobilization ball with the hands or feet. 2) Muscle length: exercises 3-9, addressing concentric and eccentric activity in muscles of the neck, upper and lower limbs. 3) Selective movement and coordination: exercises 10-21, selectively moving the arms and legs or particular parts of the core. Focus on dynamic stability, keeping one part of the body stable while moving another. 4) Training larger muscle groups: exercises 22-27, recruiting larger muscle

repetitions, using a more difficult variation of the exercise or adding dual task challenges.	groups in various standing positions for instance rolling the ball up and down towards the wall with your back. 5) Advanced challenges for balance and postural control: exercises 28-32, giving advanced challenges for postural control and balance for instance jumping while bouncing the therapy ball. 6) Relaxation: exercise 33, systematically performing contraction/relaxation of other parts of the body.
Additional challenges and adaptations	Motor-motor dual tasks are performed in all exercises while performing more than one motor task at once for instance 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 to the other group members could be added. Motor-cognitive dual tasks may be added, for instance, singing, rhyming or calculating while performing exercises. All dual task activities may 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 (Vaughan-Graham & Cott, 2016).
Home training, unsupervised GroupCoreDIST exercises for 30 minutes, 2 times per week during the six weeks of the intervention	The physical therapist cooperates with each participant to identify exercises for home training. The exercises are individualized and mirror what is highlighted during group trainings. Home training contains all six exercise categories. The training progresses in line with the exercises performed in the group sessions. Equipment: The same as for the group sessions

Appendix 6

Interview guide: 6-weeks interviews

Theme	Possible questions
Background information	Could you tell me a little bit about yourself, please? Time of diagnosis, type of MS, EDSS status, where you live, are you employed, your social status, physical activity, and have you been seeing a physiotherapist before the study?
Opening question	Is there anything you would like to point out and tell me about your participation in the GroupCoreDIST training?
Experiences from the first meeting with the physical therapist and the individual clinical examination	How did you experience the first meeting with the physiotherapist and the individual clinical examination? What did the individual clinical examination before the group training started mean to you?
Experiences from the 6 weeks of group-based training	How did you experience the GroupCoreDIST training? How did you perceive and respond to the training? How did you perceive the group?; the content of the training?; individualization?; hands on interactions and and instructions? How did you experience the physiotherapist`s role and competence? How did you perceive the dose and intensity of the training? What did the training mean to you? Did you learn anything from the training period? Were there any challenges during the training? Could you tell me what happened in these challenging situations? Did you experience some things that went really well? Some things than did not work out so well?; Or some things that you would like to change? Could you tell me if there were any episodes in particular that made a special impression on you? Was there anything you did not like, something that made you feel uncomfortable or was not as expected? Have you reflected on the group-based training compared to previous experiences with physical therapy?

Experiences from home training	How did you experience the obligation for home training? Can you describe one of your regular home-training sessions, how you experienced this and what it meant to you? Were there any challenges? Things that went well or not so well? Are there things you would like to change? How did you experience performing the exercise on your own?
Experiences of impairments, daily function, activities and participation	Can you describe how you experience your function, impairments and disability? Can you describe daily activities you normally participate in? Did you experience any changes? How was family life and life in general during the period?
Experience of quality of life	Is there anything you would like to pinpoint concerning your daily life? Did you experience the training as having a negative or positive influence in your daily life?
Closing question	Are there any experiences from the group-based training that you would like to share that other individuals with MS or physiotherapists could learn from? How did you experience being interviewed?

Appendix 7

Interview guide: 30-weeks

Theme	Possible questions
Opening question	Is there anything you would like to point out and tell me about your participation in the GroupCoreDIST? Do you have any reflections of the period after the training was completed?
Experiences of impairments, daily function, activities and participation	Can you describe how you experience your function, impairments and disability? What daily activities do you normally participate in? Did you experience any changes in daily activities during or after the training period? Were there any challenges? How did you experience family life and life in general after the training period was completed?
Experiences from home training	Did you perform home training after the intervention was completed? How did you experience this? Were there any challenges? Things that went well or not so well? Or things you would like to be different?
Retrospective reflections from the 6 weeks of group-based training	How did you experience the training? How did you respond to the training? How did you experience the group? The content of the training? Individualization? Hands on adaptations and instructions? How did you experience the physiotherapist`s role and competence? How did you perceive the dose and intensity of the training? What did the training mean to you? Did you learn anything from the training period? Were there any challenges during the training? Could you tell me what happened in these situations? Did you experience some things that went really well? Or not work out so well? Would you like to change something? Could you tell me if there were any episodes in particular that made a special impression on you (positive or negative)? Have you reflected on the group-based training versus previous experiences with physical therapy?

Experience of quality of life	Is there anything you would like to pinpoint concerning your daily life/life quality in the period after the training finished? Did you experience the training to have any influence in your daily life long term (positive or negative)?
Thoughts about the future	Do you have any thoughts concerning future physical therapy, group-based training, or activity in the future? Any challenges?
Closing question	Are there any experiences from the group-based training or the period after the intervention was completed that you would like to share that other individuals with MS or physiotherapists could learn from? Do you have anything else you would like to share? How did you experience being interviewed?