Effect of treadmill training versus muscle strength training in gait control in persons with MS

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Abbreviations

RRMS	Relapsing-remitting Multiple Sclerosis
SPMS	Secondary progressive Multiple Sclerosis
PPMS	Primary progressive Multiple Sclerosis
EDSS	Kurtzke Expanded Disability Status Scale (Appendix 5)
CNS	Central Nervous System
COM	Center of mass
COP	Center of Pressure
VO2 max	Maximum oxygen consumption
FAP	Functional Ambulation Performance[2]
TG	Treadmill group
SG	Strength training group
RM	Repetition maximum
ROM	Range of movement
BMI	Body Mass Index
L3	Lumbar spine level 3
APAcc RMS	Anteroposterior root mean square acceleration
MLAcc RMS	Mediolateral root mean square acceleration
VAcc RMS	Vertical root mean square acceleration
APAcc	Anterio-posterior acceleration
MLAcc	Medio-lateral acceleration
Vacc	Vertical acceleration
APIntStrideReg	Anterio-posterior Interstride regularity
MLIntStrideReg	Medio-lateral Interstride regularity
VIntStrideReg	Vertical Interstride regularity
ACSM	American College of Sports Medicine[1]

Abstract

Persons with Multiple Sclerosis experience gait impairment in early state of the disease. Interventions with strength and endurance training have shown divergent effect in gait variables. This study examined if treadmill training had better effect than strength training in gait control.

Intervention: The participants assessed 3 training sessions per week in 8 weeks. Treadmill training group (TG) walked 3 times 7 minutes period with focus on 1)incline walking, 2)focusing on symmetric gait cycle and balance and 3)increased speed The strength training group (SG) had 5 exercises; leg press, plantar flexion, dorsal flexion, hip abduction and rowing or pull-down for the back muscles. The resistance was calculated to 80% of individual 1 RM and performed with 2 sets with 6 repetitions in each. The main outcome was the FAP score measured with Gaitrite Electronic Walkway.

Results: This paper shows the results measured with a tri-axial accelerometer. There was some differences between the groups in baseline in trunk acceleration in AP (p=.029) and ML (p=.019) direction. Also difference in step length was nearly significant (p=.051). The only significant finding between the groups was change in Vertical (V) trunk acceleration (P=.022) with decreased acceleration in TG and increased in SG. Within groups changes were nearly significant in medio-lateral (ML) trunk acceleration in TG (P0.064) and anterio-posterior (AP) asymmetry in SG (P=.051). There was no change in other trunk acceleration variables or spatio-temporal variables measured with an accelerometer.

Conclusion: As the vertical trunk acceleration has shown to decrease with lower energy consumption, we have to assume that TG had better effect of the intervention. The increase in AP symmetry in SG might have an important effort for the progress in walking.

Sammendrag

Personer med Multippel Sclerose opplever problemer med gange allerede i tidlig fase av sykdommen. Nedsatt gangfunksjon fører til nedsatt mobilitet og nedsatt funksjon i daglige aktiviteter. Dette påvirker både sosialt samvær, arbeidssituasjonen og livskvalitet. Rehabilitering av gangfunksjon ved hjelp av styrketrening og kondisjonstrening har gitt avvikende resultater. Denne studien prøvde å finne ut om tredemølle trening hadde bedre effekt i gang funksjon enn styrketrening.

Intervensjon: Intervensjonen varte i 8 uker og deltakerne trente 3 ganger i uken. Tredemølle trening varte i ca. 30 minutt og hadde 3 ulike deler à 7 minutter med fokus på; 1) gangmønsteret, fraspark og balanse i foretrukket ganghastighet; 2)motbakke i foretrukket hastighet; 3)økt ganghastighet. Pause mellom delene varte i 2 minutter og deltakerne kunne velge mellom å sitte, stå eller gå sakte. Styrkegruppe hadde 4 øvelser for underekstremitetene; beinpress og tåhev på beinpress apparat, dorsalfleksjon av ankel med ekstendert kne samt stående hofteabduskjon i MTT apparat. I tillegg hadde de en øvelse for ryggmuskulturen (roing/nedtrekk). Motstanden for ben øvelser ble kalkulert ut fra målt 1RM, og gjennomført i 2 serier med 6 repetisjoner. Hovedmålet for studien var å måle FAP (Functional Ambulation Performance) score på Gaitrite gangmatte.

Resultat: Denne oppgaven ser på målingene gjort med Trask triaksial akselerometer. Det var ingen signifikante forskjeller i utvalg karakteristikkene, men det var forskjell mellom gruppene i trunkal akselerasjon i AP (p=.029) og ML (p=.019) retning. I tillegg var det nesten signifikant forskjell I steglengde (p=.051)i baseline. Etter intervensjonen var den eneste signifikante endringen mellom gruppene i trunkal akselerasjon i vertikal retning (p=0.022). Den trunkale akselerasjonene i vertikal retning ble redusert i tredemøllegruppe mens den økte i styrkegruppe. Innad i gruppene ble trunkal akselerasjon i mediolateral retning nesten signifikant redusert i tredemøllegruppe (p=0.064). I strykegruppe ble anterioposterior asymmetri betydelig redusert som følge av intervensjonen (p=0.051).

Konklusjon: Studiene viser at den vertikale akselerasjonen minsker ved lavere energi forbruk, må vi anta at gange på tredemølle hadde bedre effect på gangfunksjon. Økt AP symmetri i SG kan antyde økt fremdrift i gange.

1 Introduction

1.1 Background for the thesis

Multiple sclerosis (MS) is a chronic disease resulting in mobility impairments among young people. Immune modulating treatments can somewhat slow down the progress of the disease. Rehabilitation has an important role to maintain best possible function and especially walking ability which has an impact in daily living, working situation and the quality of life.

It has been documented that physical activity improve muscle function, mobility, endurance and quality of life in ms (Johansson et al., 2007). Rehabilitation has a goal to improve function, increase the level of activity, participation and the quality of life (Langdon & Thompson, 1999). Exercise can promote to better physical functioning when the level of activity is decreased as a result of reduced motor activation (Kent-Braun et al., 1997).

Impaired gait control is one of the main problems in rehabilitation of MS patients. As a physiotherapist in a clinical environment it is important to address the rehabilitation potential in best possible manner. It is essential to know which treatment has the best effect, and also important to measure the effect of treatment in a reliable way. In the present study we examined whether relatively high intensive resistance training gives better effect than treadmill training in gait control.

1.2 Multiple sclerosis

Multiple sclerosis (MS) is an inflammatory disease that causes demyelination of the Central Nervous System (CNS). Incidence of MS in Norway is approximately 300 persons per year, twice as many women than men. It is mostly young adults who will be affected of MS. People with relapsing-remitting type (RRMS) are mostly diagnosed in their 20s and 30s. 80-90 % of incidences are RRMS. Around half of those with RRMS develop a secondary progressive type (SPMS) after 15-20 years, but they also can have a combination of these with steadily worsening disease but still having attacks as well. 10-15 % have a primary progressive type (PPMS) with onset approximately 10 years later than in RRMS. The PPMS affect lower limbs more often than RRMS and up to 80-90% of them have impaired gait ability. They often experience increased muscle stiffness, often resulting in muscular fatigue

(Gjerstad, Skjeldal, & Helseth, 2007).

The cause of this autoimmune disease is not known, but it is worldwide researched. It is assumed that the cause is a combination between environmental factors and genetic disposal. MS is an unpredictable disease and the symptoms are individual. There exists no curative treatment. People with RRMS can get preventive immune modulating medicine that slows down the course of the disease. It has not shown effect on progressive type of MS. Persons with MS also get symptomatic treatment when needed (Gjerstad et al., 2007).

MS is a disease that affects relatively young people who still are employed and wish to do so as long as possible. Still, many of them drop out from employment and this, among other costs related to the illness, gives socioeconomic expenses (Svendsen, B., 2005). Most of persons with MS experience impaired gait control in the early course of the disease (Givon, Zeilig, & Achiron, 2009); (Martin et al., 2006) Mobility is a critical part maintaining independency and important for quality of life (Shumway-Cook & Woollacott, 2007). Loss of muscle activation and control often impact the daily activities of living and physical activity level. This again affects the social as well as the occupational participation in life (Carr & Shepherd, 2010).

Years ago persons with MS received information that physical activity was harmful for them but fortunately several studies have demonstrated the positive effect of regular physical activity, which now is highly recommended. Persons with MS tolerate both strength training and endurance training although the individual adjustments are needed. Different rehabilitation methods have shown to affect gait characteristics, but results are inconclusive.

1.3 Gait

Gait function is of importance for many activities in daily living. A normal gait is a symmetric motion to move the body mass forward in a controlled and safe manner. The center of mass (COM) is kept inside the Center of Pressure (COP) by moving feet forward in a rhythmic motion. This requires postural control, muscular control and coordination, intact somatosensory system and the ability to adapt to environmental changes (Shumway-Cook & Woollacott, 2007).

1.3.1 Gait cycle

Gait cycle includes two steps (one stride) from heel strike to heel strike with the same foot. Gait cycle has one stride with a stance and a swing phase (Figure 1). Stance phase is divided into double support with both feet touching the ground and single support when only one foot touches the ground. To be able to walk, the body's position in space has to be controlled. Stance phase is further divided into initial contact, loading response, midstance, terminal stance and preswing. The swing phase is divided into initial swing, midswing and terminal swing. The spatio-temporal gait characteristics can differ impaired gait from normal gait during the gait cycle.

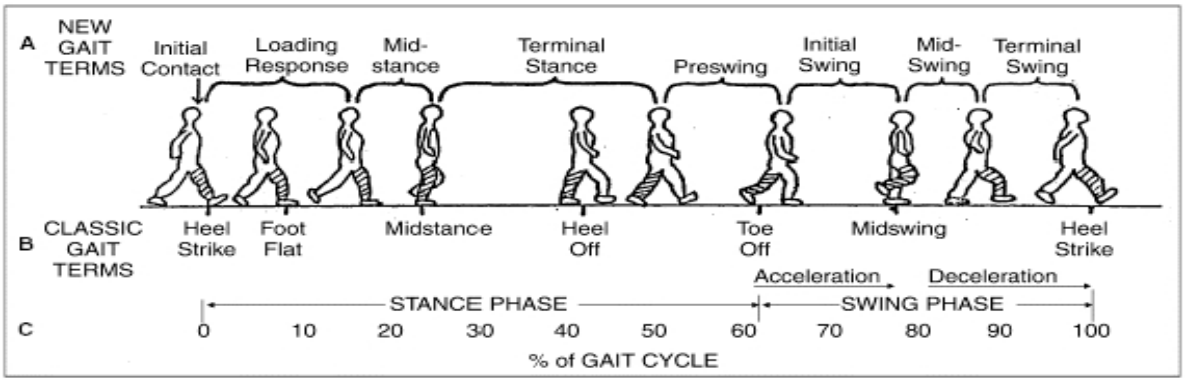


Figure 1. Gait cycle with stance and swing phase.

In normal gait cycle, stance phase lasts abaout 60% of the time while swing phase lasts 40%. (Shumway-Cook & Woollacott, 2007). This ratio changes in impaired gait. Reduced muscle strength in lower limbs effect both stance and swing phase. In impaired gait, the stance phase is extended, especially the double support. Swing phase and the single support time in stance phase get correspondingly shorter. The single support in stance phase is especially vulnerable in terms of balance control (Carr & Shepherd, 2010).

1.3.2 Gait speed

Gait velocity is defined as *the average horizontal speed of the body measured over one or more strides.* A normal gait velocity in unimpaired persons is around 1.3 to 1.4 m/s in

healthy controls (Shumway-Cook & Woollacott, 2007). Gait speed influences gait parameters in healthy population (Kirtley, Whittle, & Jefferson, 1985).With increased speed in unimpaired walking, the stance phase normally gets shorter and step length longer as the hip extension is greater in late stance phase (Carr & Shepherd, 2010). At slower speeds, both double stance and swing phase get longer. The longer single support at lower speed challenges the postural stability during stance phase and increases the variability in gait cycle (Shumway-Cook & Woollacott, 2007). Walking in another than preferred speed increases the energy consumption during walking (Mochon & McMahon, 1980).

1.3.3 Postural control during gait

Postural orientation is needed to maintain postural control, and can be defined as control over the different body segments (alignment, koordination) during task performance and gait. Postural control is important for controlling the posture during the different parts of the gait cycle (Brodal, 2007). Shumway-Cook and Woollacott defines postural control as the ability to control the position of the body related to the task and the environment in interaction between the musculoskeletal system and the CNS (Shumway-Cook & Woollacott, 2007). Reduced muscle strength, power and endurance, reduced coordination and sensory and perceptual impairments as well as cognitive dysfunction affect postural control (Carr & Shepherd, 2010).

Measurement of COM related to BOS gives the amplitude of movement in trunk sway in standing and walking. The gait velocity affects COM in medio-lateral direction by increasing the trunk sway in low velocities (Shumway-Cook & Woollacott, 2007). Brodal says that the postural reflexes are supposed to maintain the upright position of the body and adjust the postural control to ensure a best possible body position for movement and tasks (Brodal, 2007). Both vertical and horizontal forces are recalled to move the body forward and keep the body upright against the gravity during stance phase. The vertical forces stabilize the body while the horizontal forces progress the movement (Shumway-Cook & Woollacott, 2007).

1.3.4 Control mechanisms for gait

The CNS regulates muscle tone, muscle activation and the reflexes making the movement smooth (Shumway-Cook & Woollacott, 2007). Coordination of muscle and joint function in lower limbs and pelvis are important for a smooth movement during gait. Muscles stabilize the body during stance phase against gravity, and thereby enable the next step. They also work as shock absorbers when touching the ground. During swing phase the clearance from the ground is important to be able to move the leg forward and to secure the balance as the COM of the body moves anterior to the supporting limb (Shumway-Cook & Woollacott, 2007).

When the regulating paths in CNS are impaired, the changes in gait pattern occur. Due to damage in the CNS, sensory changes, muscle weakness, change in muscle tone and ataxia can influence and give impaired gait function in persons with MS (Cameron & Wagner, 2011). Reduced muscle recruitment and coordination together with reduced range of motion in joints at lower limb can also impair gait pattern, as well as reduced function in the somatosensory system (Carr & Shepherd, 2010).

While ankle movement is essential for balance control in standing, the hip control becomes more important during gait. Liu et al found that gluteus medius is a large contributor to support and to forward progression especially during single support stance (Liu, Anderson, Pandy, & Delp, 2006). Still, to allow the flexible adjustments during gait, the knee movements are also important (Shumway-Cook & Woollacott, 2007).

1.3.5 Gait kinematics measured with an accelerometer

During the gait cycle, body's movements include linear and angular displacements, velocities and acceleration (Shumway-Cook & Woollacott, 2007). Movement of the body occur in sagittal, frontal and vertical planes, the major joint movements in sagittal plane during gait. Many muscles are active during the gait cycle. Major generation of energy takes place in plantar flexion during push-off and in hip flexors in the end of stance phase and preswing while knee extensors absorbe the energy (Carr & Shepherd, 2010). In impaired gait, measurement of the footfall patterns will not identify asymmetric trunk movements. To get

the whole picture of gait pattern, the trunk movements should be investigated as well as the footfall parameters.

A tri-axial accelerometer quantifies movement patterns by measuring segmental acceleration in sagittal, frontal and vertical plane (Kavanagh & Menz, 2008). Body worn sensors fastened at lower back measure the body's acceleration and deceleration near the COM during gait. The velocity and amplitude of trunk acceleration is expressed in three different directions: anterioposterior (AP), medio-lateral(ML) og vertical(V). Acceleration is the rate at which velocity body moves in time, expressed in m/s^2.

The acceleration pattern during gait cycle differentiates between steps and strides, and enables calculating steplength, step time and cadence. It measures the regularity and symmetry of trunk movements. Impaired gait is often characterized by variability in spatio-temporal gait characteristics and in trunk acceleration. In elderly, interstride variability might represent impaired balance control or the necessary adjustments to be able to walk safely (Moe-Nilssen & Helbostad, 2005; Wilhelmsen et al., 2010). Trunk regularity between strides in AP and V directions were found to decrease with increased variability. In ML direction,

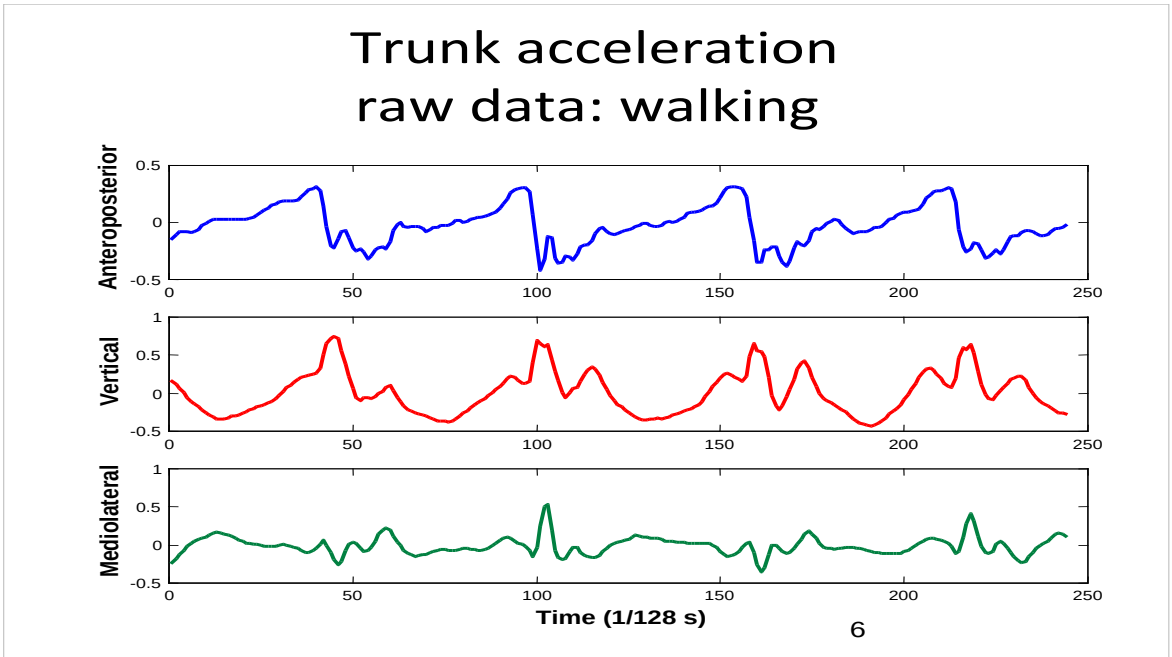


Figure 2. Typical curves of trunk acceleration in 3 different directions. In vertical direction the 1st peak represents heel contact, the 2nd peak flat foot and the 3rd peak mid stance. The lowest point represents the initial push-off in stance phase (Auvinet, Chaleil, & Barrey, 1999).

the regularity increased with decreased variability (Moe-Nilssen & Helbostad, 2005). Yang et al found lower step and stride regularity (more variability) in persons with Parkinson disease with gait abnormalities compared to healthy controls (Yang, Hsu, Shih, & Lu, 2011). The variability in gait has shown to be increased in persons with MS compared to controls, measured in spatio-temporal parameters (Socie et al 2012). This might be due to impaired balance control or decreased muscle strength in persons with MS.

Asymmetry in walking is typical with impaired balance control, muscle weakness or decreased mobility in joints. Divergent spatio-temporal gait characteristics like step length and single support time are often used to measure gait asymmetry, but it is shown that trunk movement asymmetry discriminates better between stroke patients and non-impaired elderly (Hodt-Billington, Helbostad, & Moe-Nilssen, 2008). This is also found in studies between MS patients and healthy controls in (Huisinga, Mancini, St George, & Horak, 2012).

1.4 Rehabilitation of gait function

Gait is a task-specific exercise, and to optimize walking, treadmill and overground walking are recommended. In rehabilitation of the gait cycle, training support and push-off through the lower limbs, coordination of the lower limb and controlling the COM over BOS should be in focus. Weightbearing and limb loading are critical for promoting the muscle function in lower limb. During the gait cycle, hip extension stimulates to hip flexion and for pull-off in late stance phase. Plantar flexors in the ankles also contribute to the push-off and trigger knee flexion in preswing at swing phase. To regain the dynamic balance, walking without support should be part of the training regime (Carr & Shepherd, 2010) In general, treatment effect is highly dependent on the intensity of the training protocol (Eng & Tang, 2007). Interventions over 8 weeks of variation are recommended by the European Multiple Sclerosis Platform[3].

1.4.1 Gait training

Multiple levels of neural control are required to support the body against gravity and move it forward. This system has to be challenged by exercise to train balance control and to be able to adapt the walking pattern due to the goal and environmental demands. In the absence of

sensory input, speed and coordination are impaired (Carr & Shepherd, 2010). Walking on treadmill gives challenging conditions to practice walking. The hip extension and ankle dorsiflexion are maximized by the moving belt. Walking uphill has an effect in muscle strength and endurance. Varying gait speed enable the lower limbs to build up peak force faster by increasing power and speed (Carr & Shepherd, 2010). Studies show increased activation of cortico-subcortical networks produced by repetitive treadmill training in stroke patients (Globas, Macko, & Luft, 2009).

1.4.2 Strength training

Strength training is known to increase muscle mass and to improve neural adaptation (Kraemer & Ratamess, 2004). The hip, knee and ankle extensor muscles should be strengthened when the goal is optimizing the gait function. These muscles generate the basic support, balance and propulsive functions during walking (Carr & Shepherd, 2010) Yahia et al. found that muscle strength in knee extensors and flexors were significantly correlated both to posture and gait speed, cadence and stride length in MS patients (Yahia, Ghroubi, Mhiri, & Elleuch, 2011)), Thoumie et al 2005 found correlation between gait speed and knee flexors and extensors in MS patients with proprioseptive loss (Thoumie, Lamotte, Cantalloube, Faucher, & Amarenco, 2005).

2 Earlier studies

2.1 Gait characteristics in MS

Spatio-temporal gait parameters like velocity, step and stride length and cadence (steps/minute) are often used to describe and measure gait impairment (Shumway-Cook & Woollacott, 2007). The pyramidal affection in MS decreases the muscles strength and changes the muscle tone. Kelleher et al measured muscle activity and joint motion in ankle, knee and hip joints during walking in patients with MS. He found impaired plantar flexion at toe-off, impaired knee flexion at the end of swing phase and in mid stance. They also found impaired hip flexion and hip extension during the gait cycle (Kelleher, Spence, Solomonidis, & Apatsidis, 2010). Crenshaw et al. also found impaired joint movements during walking in persons with MS (Crenshaw, Royer, Richards, & Hudson, 2006). Several studies show that

people with MS have deviation in gait cycle; increased double support and decreased single support time and shorter and wider steps and strides (Yahia, Ghroubi, Mhiri, & Elleuch, 2011); (Kelleher, Spence, Solomonidis, & Apatsidis, 2010); (Martin et al., 2006). Remelius et al. found that changes in gait parameters (double stance time, swing time, wider strides) were independent to the gait speed (Remelius et al., 2012).

Measures registered on Gaitrite electrical gaitway[1] have shown significant differences in Functional Ambulation Performance (FAP) score, step length, cadence, step time and base of support between persons with MS and controls (Givon et al., 2009; (Socie et al., 2012); (Sosnoff, Sandroff, & Motl, 2012). Sosnoff et al. additionally found significantly increased variability single support time and lower gait velocity in minimally impaired persons with MS (EDSS<3,5) compared to healthy controls (Sosnoff et al., 2012). Although Sosnoff found increased variability in step and single support time in person with MS compared to controls, Socie et al. found that spatio-temporale gait parameters are more sensitive in measuring gait dysfunction than gait variability in persons with MS (Socie et al., 2012). Studies also show that impaired postural control results in lower gait velocities, step length and cadence (Cameron et al., 2008)(Cameron, Horak, Herndon, & Bourdette, 2008).

2.2 Gait control

Impaired postural control is widely documented in MS patients. Some studies have found that the impairment occurs already in early course of the disease in persons with MS, compared to healthy controls (Martin et al., 2006). This affects gait control, and especially initiation of gait. This leads, according to Remelius et al., to a slower and less movement of the trunk in anterio-posterior direction compared to healthy controls (Remelius, Hamill, Kent-Braun, & Van Emmerik, 2008).

In MS patients, possible reasons for impaired postural control are the lesions in CNS due to the disease, complex symptomatic impairment (motor, sensor and fatigue) (Corradini, Fioretti, Leo, & Piperno, 1997) or sensory impairment (Cameron, Horak, Herndon, & Bourdette, 2008). Impaired postural control can be characterized by increased trunk sway and delayed balance reactions wider BOS during transfers and walking (Shumway-Cook & Woollacott, 2007).

Use of an accelerometer in studies of gait control with MS patients is in early stage, and the variables measured vary between the studies. Corporaal et al found that EDSS scores were highly correlated to trunk sway showing that increased impairment (higher EDSS) correlated with increased trunk sway. (Corporaal et al., 2013). Huisinga et al. found larger frequency dispersion in ML direction in lower back compared to controls. In AP direction, RMS was lower compared to controls. The acceleration of the trunk showed greater divergence in both ML and AP directions (Huisinga, Mancini, St George, & Horak, 2012).

Moe-Nilssen og Helbostad have studied gait control in elderly with an accelerometer to find out how the postural trunk control relates to risk of falling. They found lower medio-lateral and higher vertical and anterio-posterior trunk variability in frail elderly compared to fit elderly (Moe-Nilssen & Helbostad, 2004). An intervention study in persons with vestibular affection showed that trunk acceleration in lower back increased in AP and ML direction after vestibular rehabilitation assuming a better balance control. Cadence was reduced and the step length increased after the intervention. (Wilhelmsen, Nordahl, & Moe-Nilssen, 2010).

2.3 Reliability of measures with an accelerometer

Daily variation in fitness and fatigue are typical in MS. It is shown that variation in gait variables is higher in persons with MS compared to controls. This is important to take account in the reliability of measures. Relative reliability measures the relation between two measures based on a correlation coefficient.

Trask accelerometer system has been tested earlier by Moe-Nilssen for accuracy and precision. The same study showed high test-retest reliability during walking. An accelerometer with sensors fastened in L3 level gives information of trunk acceleration near the COM. The sensor placed in lower back is found to be a valid and reliable measurement tested in older and healthy population (Moe-Nilssen, 1998). Tri-axial accelerometer gives reliable information with few bias (Kavanagh & Menz, 2008). Henriksen et al. found high reliability in gait variables measured with a tri-axial accelerometer in healthy controls (Henriksen, Lund, Moe-Nilssen, Bliddal, & Danneskiod-Samsoe, 2004). A study with stroke

patients show that accelerometer can differentiate between persons with stroke and healthy controls. They found differences in step length, step cycle, cadence and gait velocity (Mizuike, Ohgi, & Morita, 2009).

Timed tests that are widely used in rehabilitation are reliable, but do not measure specific changes in trunk movements or the quality of movement during gait (Cameron & Wagner, 2011). Studies done with persons with MS also show that the accelerometer differentiate impaired from non-impaired persons better than timed tests and balance tests. Corporaal et al found that peak-to-peak trunk sway angles and velocities showed higher trunk sway in MS patients compared to controls when Romberg's balance test and tandem gait test were normal (Corporaal et al., 2013). Findling et al analyzed trunk sway in lower back in mildly disabled persons with MS with and without subjective balance impairment. The clinical balance tests, like Bergs Balance Scale, Performance Oriented Balance Assessment and Dynamic Gait Index were normal and did not detect the difference between groups. (Findling et al., 2011). Spain et al wanted to determine if tri-axial accelerometer was sensitive enough to show differences in balance and gait control between minimally affected persons with MS and healthy controls. They found greater medio-lateral and rotational range of motion during walking in persons with MS. Like Findling et al., they also concluded that traditional timed tests (Timed up and go, 25 feet walk) did not detect the differences (Spain et al., 2012).

2.4 Gait training in MS

The recommendations for physical activity and exercise for persons with MS have been based on aerobic activity to increase endurance because there has been disagreement of the intensity of strength training. Endurance training interventions show that persons with MS increase VO2-max already with 55-60% of VO2 max intensity while training with arm-leg ergometry. They intended training sessions 3 times a week for 8 weeks (Ponichtera-Mulcare, 1993); (Petajan et al., 1996). Some studies show positive effect on treadmill and endurance training in gait function (Newman et al., 2007); (van den Berg et al., 2006). Studies show that walking on a treadmill have a positive influence in energy consumption during gait in gait speed and fatigue (Newman et al., 2007). Increased energy cost of walking is also associated with decreased gait velocity and stride length, and increased double support (Motl, Sandroff, Suh, & Sosnoff, 2012). Benedetti et al also found reduced energy cost and

changes in foot placement after treadmill training (Benedetti et al., 2009).

Interventions with mild to moderate strength training the last years have been well tolerated of MS patients. Kraft et al. showed improved gait velocity in Timed Up and Go after 12 weeks of resistance training (Kraft et al., 2008), while Taylor et al. found increased gait velocity in 10 meters walking, but not in 2 minutes walking after 10 weeks strength training intervention (Taylor, Dodd, Prasad, & Denisenko, 2006). Difference in duration, intensity, mode and the strength training regime, small sample size or lack of transfer to functional tasks can diverge the training effect (Dalgas, Stenager, & Ingemann-Hansen, 2008).

3 The research question

To my knowledge, an accelerometer has not been used to measure effect of intervention or the differences between two interventions. An accelerometer has shown to be valid in detecting differences between MS patients and healthy controls. From clinical point of view, it is of interest if the accelerometer also detects differences between MS patients who undergo two different interventions since it might give more precise information of trunk movements during walking and the gait quality. In this study, we hypothesize that the treadmill training group would have the best effect on gait variables, simple because it is a task specific training method. The research question is: Does treadmill training improve gait control more than muscle strength training in patients with MS?

4 Methods

4.1 Study design

This was a randomized clinical trial with two parallel groups. The participants were stratified by age and gender after baseline testing. The randomizing was done by an a unit for applied clinical research at Faculty of Medicine, NTNU. The effect size was only calculated for the primary outcome which was the Functional Ambulation Performance (FAP) score in Gaitrite[2]. To expect 10% improvement in FAP score, with a power of .8 and a significance <.05, 13 participants were needed for each group. To take account for drop-outs, it was

decided to try to recruit 15 persons per group. 14 persons were randomized to treadmill training group (TG) and 15 were randomized to strength training group (SG) (Flowchart).

The Norwegian Regional Ethics Committee for Medical Research in the middle part of Norway has approved the study. The participants were given oral and written information, and informed consent was given by all participants before randomization (Appendix 1). They could freely withdraw their participation at any time during the study.

4.2 Participants

Persons with MS over 18 years of age were recruited from the Neurological outpatient department at St. Olav`s Hospital in Trondheim, Norway. The persons were living in or nearby the municipality of Trondheim. The inclusion criteria was (i) any type of MS, (ii) EDSS $\leq$ 6.0, (iii) no relapses or (iv) new medication the last 6 months prior to inclusion, (v) subjective feeling of impaired gait and (vi) sign of pyramidal affection in gait examined by MRI and a neurologist. The exclusion criteria were severe ataxia, severe cognitive affection and injuries, unrelated to the MS disease, that could affect gait. Information on age, type of MS, EDSS and the time of MS debut were registered.

Figure 3. Sensor placement

4.3 Outcomes

Participants walked back and forth a 6.2 meters walkway at three different speed conditions; slow, preferred and fast. Linear trunk acceleration was measured with a tri-dimentional electronic accelerometer. Sensors from Xsens Motion Technologies registered acceleration in anterio-posterior (AP), mediolateral (ML) and in vertical (V) axes using the 3D technology of accelerometry, rate gyro and earth magnetic field. Sensors are piezo-resistant which means that they register the gravity component to correct the effect of inaccurate component to correct the effect of inaccurate positioning and body curvatures. Sensors weight 30 g and the size is 38 x 53 x 21 mm. A six degrees-of-freedom inertial sensors were fastened on an elastic belt on lower back (level L3) and on upper trunk (between scapulae). The belt was placed outside the clothing. This paper only analyzes information from the sensor at lower back (L3). The sensors were connected to a battery operated communication unit which was also fastened on the belt. Communication unit had sampling frequency of 100 Hz. The information was transmitted to a laptop by using Bluetooth technology.

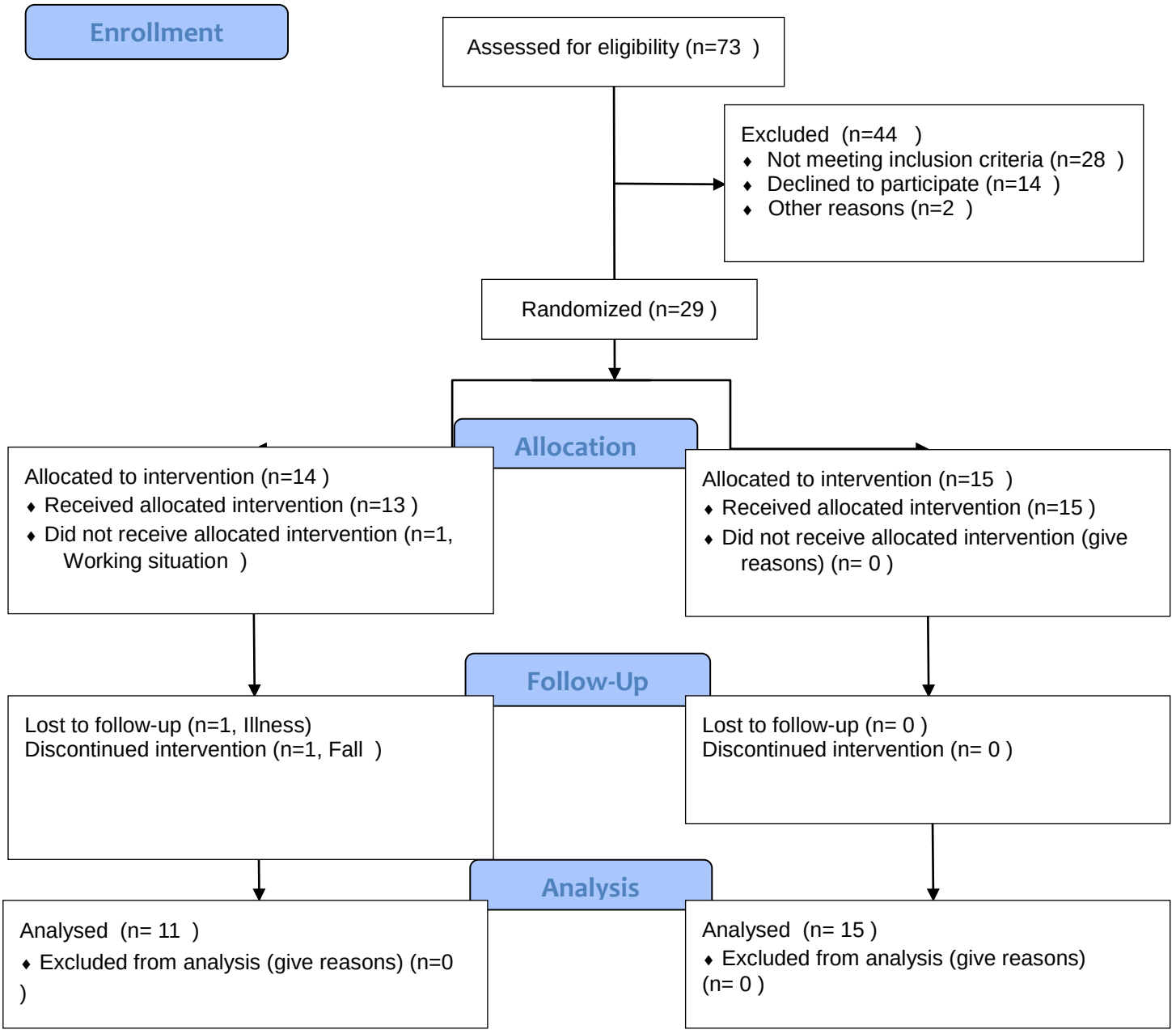
Body weight was measured with a weighing scale and height was measured with a mechanical stadiometer before testing. Working economics was monitored on treadmill using Metamax 2 by Cortex to calculated their maximum heart rate. During intervention, Polar RX300 (polar.com) heart rate monitor was used during treadmill training.

4.4 Test procedure

The participants were tested at 3 different timepoints. Baseline testing was performed twice before randomization with one week in-between the tests. One post-test was proceeded the following week after the intervention ended. Results from baseline 1 are used in this paper.

The height and weight were measured before testing for each participant and the Body Mass Index (BMI) was calculated using formula weight in kg/height in m^2. The participants used stable shoes during testing. Participants walked back and forth in three different velocities. All participants got the same instructions before testing: 1) Walk at your usual speed, 2) Walk at a strolling speed like waiting for a buss and 3)Walk as fast as you safely can.

CONSORT 2010 Flow Diagram



4.5 Test setting

The testing for all participants took place at the neurological department. They used approximately 1,5 hours for the whole procedure including installing the equipment, information, testing and rest. The intervention environment was the physiotherapy department at St. Olav`s Hospital and a private physiotherapy center in Stjørdal for four persons. This location made the transportation to University Hospital unnecessary for them living in or nearby Stjørdal. The physiotherapist in Stjørdal was guided in exercises and informed about the intervention procedure. The groups at St. Olav`s Hospital were lead by to physiotherapists working at the neurological department.

4.6 Intervention

Participants were randomized to SG or TG. Each participant attended an 8 weeks intervention three times weekly for 24 training sessions. Approximately 5 persons attended in one group. The TG used about 30 minutes while SG used approximately 40 minutes on each training session.

4.6.1 The treadmill group (TG)

TG warmed up with two minutes gait on treadmill and chose their preferred speed of the day. Preferred speed was used as a baseline to regulate the intensity of the training that day.

TG walked 3 periods of 7 minutes each with 1)incline walking, 2)focusing on symmetric gait cycle and balance and 3)increased speed. This model was used to avoid fitness training as the focus was on gait control. Support from the railings during gait was allowed if needed. The heart rate was monitored to avoid a longer period with heart rate above 70% of maximum. Participants had a break of 2 minutes between each of the 7 minute periods when they could choose to sit down, stand or walk slowly. Their preferred speed was used to calculate the intensity on increased velocity and incline walking.

The first 7 minutes period on treadmill was inclination increased in accordance with their preferred speed. For example, a person with a preferred speed on 2 to 2.9 km/h walked on 2

% incline while a person walking with 3 to 3.9 km/h increased to 3% inclination and so further. The second period used participants preferred speed and 0% incline. They were verbally guided to focus on their step cycle, especially heel control, weight loading and toe-off, but also knee control if needed. The last period of 7 minutes the velocity was increased in percentage of their preferred speed of the day. During 8 weeks intervention the velocity was gradually increased from 10% to 40%. If a person had a high preferred speed of the day and did not manage 40% higher speed, was this regulated to highest possible speed that the person could manage without risk of falling. Their heart rate was monitored and it was not allowed to run. If their heart rate increased above 70% of maximum, they needed to slow down the gait velocity.

4.6.2 Strength training group (SG)

SG had five exercises, four of them for lower extremities and one for back muscles. All exercises for lower extremities were implemented unilaterally. Recommendation for principles of strength training of American College of Sports Medicine (ACSM)[1] was chosen and the participants were tested for 1 repetition maximum (RM) at first day of exercise. In case of incomplete range of movement (ROM) without resistance, was 1RM measured at best possible ROM. After the RM was unilaterally measured, 80% of RM was used as resistance in 2 series with 6 repetitions. If the person did not manage this, the resistance was regulated down and 5 repetitions was approved. As soon as they managed several than 8 repetitions, the resistance was increased. The minimum increase in resistance was 0.250 kg.

Participants had a physiotherapist (PT) guided warm-up in groups prior to exercises. Some of them chose to use stationary bicycle due to balance problems. Participants were guided in exercises so the risk of injury and incorrect performance was prevented. The participants were monitored for possible overexertion but there was no negative effects. Some of them experienced muscle stiffness after the first training sessions as expected.

The exercises were chosen on the basis of needs of balance, stability and gait control, and by which muscles get weaker due to pyramidal involvement or indirectly as a result of

inactivity. Thereby, the exercises chosen were:

1) Leg press in lying position with 90 degrees hip flexion and horizontal press.

2) Standing hip abductions with low pulley.

3) Calf raises in lying position with leg press device.

4) Dorsal flexion in the ankle with an extended knee in a pulley device while sitting on an aerobic stepper.

5) Participants could choose between a pull-down device or rowing on a pulley for back muscles.

The rest between sets was about 2 minutes. Time between exercises varied individually and also because of some waiting time when a device was taken. Order of exercises was random.

5 Data analysis

The data were collected and processed with MatLab 7.3.0. (R2006b, The Mathworks Inc., Natick, MA) based on a custom-made software, Trask. The acceleration amplitudes in AP, ML and V directions are expressed by root mean square (RMS) values. An unbiased autocorrelation was used to calculate regularity between neighbouring steps and strides. The calculation procedure is described elsewhere (Moe-Nilssen, 1998). Autocorrelation procedure correlates each stride with the next one to see how repeatable the acceleration pattern is (Figure 4). A perfect repeatability will give an autocorrelation coefficient 1 while it gives 0 when there is no repeatability(Moe-Nilssen & Helbostad, 2004). Coefficient 0 means greatest variability during gait (Moe-Nilssen & Helbostad, 2004).

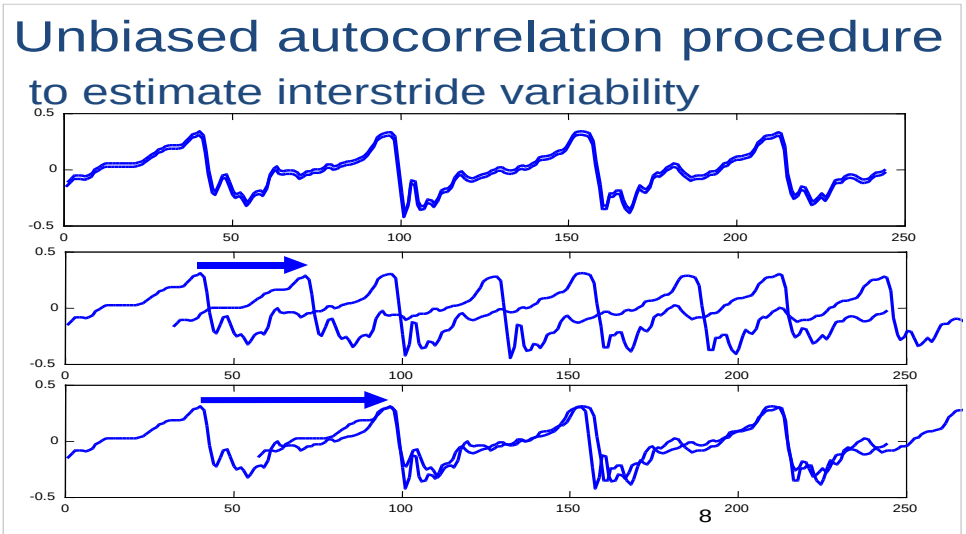


Figure 4. Autocorrelation procedure to correlate each stride with the next one.

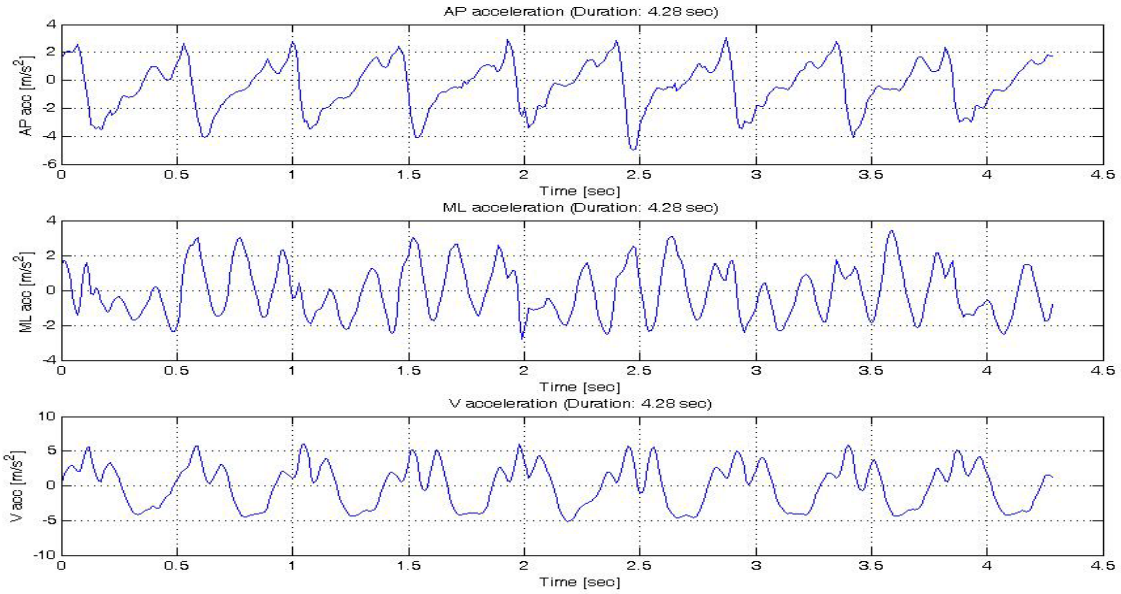


Figure 5. Corrected trunk acceleration signals to a participant during 6.2 m walking in preferred speed. This clearly shows the asymmetry in ML direction compared to figure.

The walking velocity was registered by photo cells, synchronized with the Trask software system, in the beginning and the end of the pathway.

6 Statistical analysis

The data was analyzed with PASW Statistics, SPSS version 18 and19. Sample characteristics were compared between groups at baseline. We analyzed Pearson Chi-Square with Cross-tabs for the nominal values and compared means for the scaled values with an Independent t-test.

A one-way between-groups analysis (Univariate General Linear Model) was conducted to compare the intervention effect between the groups. All gait variables were compared by using the mean values. The mean preferred walks velocity was used to adjust for the velocity in analyzes. As there could be some differences between the groups in baseline, ANCOVA adjusts for the differences in baseline. 95% confidence interval for difference was used and the p-value <.05 was considered as significant change between the groups. Secondary, we performed paired-samples t-test for each groups to see the within group effect of intervention.

The effect size was calculated only for the primary outcome which was the FAP score from Gaitrite, 13 participants in each group was needed to meet the criteria. Thus equally randomizing, because of one dropout after randomizing and two dropouts before the post test, there was 11 person in TG. This thesis has a secondary endpoint and the sample size is probably too small to calculate the effect size in trunk acceleration.

The Intraclass Correlation Coefficient (ICC 1.2) was calculated with Scaled reliability analysis. The test-retest reliability of the acceleration data was determined from between days measures in baseline. On the basis of Fleiss' criteria for clinical acceptability, the relative reliability was determined as high (>0.75) for most of the trunk acceleration variables. Reliability for APIntStrideReg, MLIntStrideReg and ML Asymmetry demonstrates fair to good reliability with values > 0.4 (Henriksen et al., 2004). There is no signs of systematic errors. of Table 1.

Table 1. Between-days ICC at baseline.

Variable	ICC (1.2)	MD
APAcc	.94	0.28
MLAcc	.87	0.47
VAcc RMS	.91	0.67
APIntStrideReg	.69	0.14
MLIntStrideReg	.60	0.25
VIntStrideReg	.77	0.17
AP Asymmetry	.76	0.08
ML Asymmetry	.74	0.19
V Asymmetry	.78	0.11

ICC: Intraclass Correlation Coeffecient; MD: Minimal Difference; APAcc: Anterio-posterior acceleration; MLAcc: Medio-lateral acceleration; Vacc: Vertical acceleration; IntStrideReg: Interstride regularity;

Table 2. Sample characteristics at baseline.

Sample Characteristics		TG (n=11)		SG (n=15)		Differences between groups in baseline P-value
Gender Female (%)		7	(63.6)	10	(66.7)	.873
Age in years (SD)		46.64	(6.15)	49.13	(7.37)	.370
Height, cm (SD)		173.82	(6.53)	170.10	(10.23)	.302
Weight, kg (SD)		84.05	(15.01)	76.48	(22.00)	.335
BMI, kg/m^2 (SD)		27.65	(3.78)	26.18	(6.12)	.490
Type of MS	RRMS (%)	10	(90.9)	9	(60.0)	.103
	SPMS (%)	1	(9.1)	1	(6.7)	
	PPMS (%)			5	(33.3)	
Onset in years (SD)		8,3	(6.44)	6,19	(6.56)	.423
EDSS, 1-6 (SD)		3.09	(1.63)	3,2	(1.39)	.855
Working (%)		6	(54.5)	11	(73.3)	.320

TG: Treadmill group; SG: Strength training group; BMI: Body Mass Index; RRMS: Relapsing-Remitting; SPMS: Secondary Progressive; PPMS: Primary Progressive Multiple Sclerosis; EDSS: Expanded Disability Status Scale; SD: Standard deviation.

Table 3. Baseline differences in gait variables.

Gait variables	**Baseline values**				**Group differences in baseline**
	TG (n=11)		SG (n=15)		
	Mean	SD	Mean	SD	P-value
Velocity Pref (m/s)	1.24	.22	1.09	.20	.395
Velocity Fast (m/s)	1.62	.29	1.51	.37	.097
Cadence (steps/min)	106.22	10.72	103.90	11.81	.612
Steplength (m)	.70	.09	.63	.08	.051
Steptime (s)	.57	.05	.58	.07	.552
APAcc RMS (m/s^2)	1.78	.37	1.49	.28	**.029**
MLAcc RMS (m/s^2)	1.85	.66	1.49	.28	**.019**
VAcc RMS (m/s^2)	2.33	.57	2.06	.59	.251
APIntStrideReg	.82	.11	.80	.11	.675
MLIntStrideReg	.62	.14	.63	.15	.895
VIntStrideReg	.81	.11	.78	.13	.606
AP Asymmetry	.05	.06	.07	.09	.446
ML Asymmetry	.15	.13	.14	.11	.849
V Asymmetry	.03	.07	.06	.11	.508

TG:Treadmill group; SG: Strength training group; Pref: Preferred; RMS: Root Mean Square; APAcc: Anterio-posterior acceleration; MLAcc: Medio-lateral acceleration; Vacc: Vertical acceleration; IntStrideReg: Interstride regularity; SD: Standard deviation.

7 Results

11 persons participated in treadmill group (TG) and 15 persons in the strength training group (SG). TG had 7 and SG had 10 female participants. The average age was 47 years in TG while they were 49 in SG. As the table 2 shows, there was no significant differences in sample characteristics in baseline (Table 2). The average participating rate was high in this study. Participants in TG attended the training approximately 21.4 of 24 times (89%) while participants in SG attended 22.1 (92%) times.

There were significant differences in trunk acceleration in AP (p=.029) and ML (p=.019)

direction at baseline. Also difference in step length was nearly significant (p=.051) (Table 3). The trunk acceleration data shows significant change between the TG and the SG in vertical trunk acceleration (F-ratio=6.031 and p =.022). (Figure 6) There was no significant changes in AP and ML trunk acceleration, interstride regularity or asymmetry between the groups. (Table 4)

Within groups, the TG had a nearly significant decrease in medio-lateral acceleration (p=.064) while SG had a nearly significant decrease in anterio-posterior asymmetry (p=.051). (Table 5)

There was one adverse event as one of the participants in TG fell after one of the training sessions while getting down from the treadmill. The fall resulted in hip fracture.

Figure 6. Showing the difference between groups in vertical trunk acceleration.

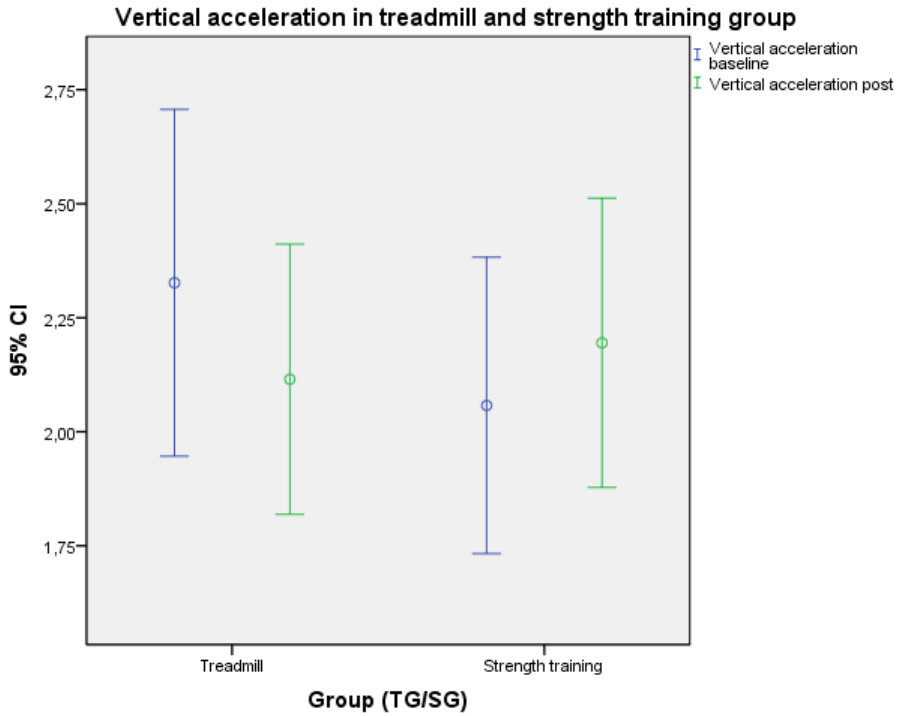


Table 4. Baseline and post test values with the differences between groups in gait variables.

Gait variables	**Baseline values**				**Post values**				**Mean difference between groups**	**95% Confidence Interval for Difference**		**Difference between groups (ANCOVA)**
	TG (n=11)		SG (n=15)		TG (n=11)		SG (n=15)			Group TG - SG		P-value
	Mean	SD	Mean	SD	Mean	SD	Mean	SD		Lower Bound	Upper Bound	
Velocity Pref (m/s)	1.24	.22	1.09	.20	1.18	.17	1.14	.24	-.068	-.192	.056	.267
Velocity Fast (m/s)	1.62	.29	1.51	.37	1.61	.28	1.53	.41	.020	-.146	.186	.805
Cadence (steps/min)	106.22	10.72	103.90	11.81	102.88	8.29	105.39	12.70	-5.162	-11.815	1.490	.122
Steplength (m)	.70	.09	.63	.08	.69	.07	.65	.10	-.009	-.070	.052	.771
Steptime (s)	.57	.05	.58	.07	.59	.05	.58	.08	.023	-.013	.059	.203
APAcc RMS (m/s^2)	1.78	.37	1.49	.28	1.79	.38	1.55	.32	.033	-.215	.281	.785
MLAcc RMS (m/s^2)	1.85	.66	1.49	.28	1.60	.42	1.44	.23	-.107	-.293	.080	.248
VAcc RMS (m/s^2)	2.33	.57	2.06	.59	2.12	.44	2.20	.57	-.352	-.649	-.055	.022
APIntStrideReg	.82	.11	.80	.11	.81	.09	.75	.17	.031	-.089	.152	.596
MLIntStrideReg	.62	.14	.63	.15	.60	.16	.59	.15	.003	-.121	.115	.960
VIntStrideReg	.81	.11	.78	.13	.80	.10	.76	.20	-.014	-.144	.115	.822
AP Asymmetry	.05	.06	.07	.09	.02	.09	.02	.08	.009	-.066	.085	.797
ML Asymmetry	.15	.13	.14	.11	.12	.14	.10	.17	.054	-.070	.179	.373
V Asymmetry	.03	.07	.06	.11	.04	.10	.05	.11	.012	-.062	.087	.734

TG:Treadmill group; SG: Strength training group; Pref: Preferred; RMS: Root Mean Square; APAcc: Anterio-posterior acceleration; MLAcc: Medio-lateral acceleration; Vacc: Vertical acceleration; IntStrideReg: Interstride regularity.

Table 5. Baseline and post values with changes within groups. TG:Treadmill group; SG: Strength training group; Pref: Preferred; RMS: Root Mean Square; APAcc: Anterio-posterior acceleration; MLAcc: Medio-lateral acceleration; Vacc: Vertical acceleration; IntStrideReg: Interstride regularity.

Gait variables	**Baseline values**				**Post values**				**Paired-samples t-test**	
	TG (n=11)		SG (n=15)		TG (n=11)		SG (n=15)		TG	SG
	Mean	SD	Mean	SD	Mean	SD	Mean	SD	P-value	P-value
Velocity Pref (m/s)	1.24	.22	1.09	.20	1.18	.17	1.14	.24	.187	.308
Velocity Fast (m/s)	1.62	.29	1.51	.37	1.61	.28	1.53	.41	.690	.749
Cadence (steps/min)	106.22	10.72	103.90	11.81	102.88	8.29	105.39	12.70	.278	.359
Steplength (m)	.70	.09	.63	.08	.69	.07	.65	.10	.573	.456
Steptime (s)	.57	.05	.58	.07	.59	.05	.58	.08	.281	.425
APAcc RMS (m/s^2)	1.78	.37	1.49	.28	1.79	.38	1.55	.32	.901	.464
MLAcc RMS (m/s^2)	1.85	.66	1.49	.28	1.60	.42	1.44	.23	.064	.178
VAcc RMS (m/s^2)	2.33	.57	2.06	.59	2.12	.44	2.20	.57	.117	.247
APIntStrideReg	.82	.11	.80	.11	.81	.09	.75	.17	.806	.245
MLIntStrideReg	.62	.14	.63	.15	.60	.16	.59	.15	.683	.375
VIntStrideReg	.81	.11	.78	.13	.80	.10	.76	.20	.872	.676
AP Asymmetry	.05	.06	.07	.09	.02	.09	.02	.08	.424	.051
ML Asymmetry	.15	.13	.14	.11	.12	.14	.10	.17	.481	.376
V Asymmetry	.03	.07	.06	.11	.04	.10	.05	.11	.775	.662

8 Discussion

The aim of this study was to see if there was differences in gait variables between two interventions, treadmill training and strength training. We hypothesized that the treadmill group would have more effect of the 8-weeks intervention. Both interventions were well tolerated of the participants. At baseline, the groups had a significant difference in ML and AP trunk accelerations. Additionally, they differed nearly significantly in step length and had tendency to difference in fast velocity.

The main finding, and the only significant change between the groups was in vertical trunk acceleration. In the TG the V trunk acceleration decreased while it increased in the SG. We found no other significant changes in trunk acceleration, variability or repeatability or in spatio-temporal variables between the groups. As secondary findings, we looked at the within group effect on interventions. Treadmill walking had a nearly significant decreased ML trunk acceleration. SG had a nearly significant decreased AP asymmetry. The between-day reliability was calculated for acceleration variables from the two baseline tests. Intraclass Correlation Coefficient show high reliability The reliability between baseline tests seem to be high with ICC .91 in V trunk acceleration.

Intervention studies with the aim to affect gait variables in MS patients greatly vary. Some have shown increased values in gait speed, step length, single support time, swing time and decreased step width and double support. There has been divergent results from earlier studies of effect of strength training on gait variables. Treadmill training has shown to effort both endurance and gait variables(Newman et al., 2007); (Benedetti et al., 2009). Accelerometer based studies have concentrated on investigating if data from an accelerometer can differentiate between MS patients and healthy controls, reliability studies and if measures with accelerometer correlate to balance tests and timed gait tests. To our knowledge, there is no published studies that use accelerometer to measure or compare interventions in persons with MS.

In this study, the only significant difference between the groups was in vertical trunk acceleration. In TG, V trunk acceleration decreased while it increased in SG. In earlier

studies it is shown that increased vertical trunk acceleration is correlated with increased energy consumption ((Bouten, Sauren, Verduin, & Janssen, 1997). Van den Berg et al 2006 found that treadmill training increased gait velocity and showed a trend in lowering muscle fatigue (van den Berg et al., 2006). The effect on VTA could be caused by increased endurance since the participants could walk with up to 70% of O2 max. Earlier studies show that persons with MS can have increased endurance already in training with 55-60% of O2 max (Ponichtera-Mulcare, 1993). This means the TG possibly achieved increased endurance. In persons with MS, it is shown that the energy consumption is increased compared to healthy controls. As many of MS patients experience muscular fatigue, it is desired to normalize the energy spent in mobility tasks like walking. This enables increased physical activity level and possibly enhances the level of participation and improves the quality of life.

Walking on treadmill challenges the neural system and the postural control in many ways. Even though the surface is not challenging in itself, the moving belt has shown to stimulate to symmetric gait pattern in stroke patients. Although the participants were challenged to walk without support, the reduced need to focus on the unevenness of the surface and the possibility to use rails if needed could affect the fear of falling that many people with MS struggle with. There is an increased fall rate in persons with MS, and the fear of falling has shown to affect both gait velocities and the gait pattern (Matsuda et al., 2011). The fact that the environment does not change as in overground walking might give a positive effect in stimulating the vestibular system and giving an effort to balance control.

It is surprising that the spatio-temporal gait variables did not show significant change as several studies have shown significantly increased gait variables. Patients with MS have increased variability in gait parameters compared to healthy controls. At baseline, the groups had a significant difference in ML and AP trunk accelerations. Additionally, they differed nearly significantly in step length and had had also some difference in fast gait velocity. The SG had lower values in all of these variables. Even though ANCOVA measures take account in baseline differences, the differences at baseline might make the distinction during the intervention. For example, muscular fatigue is a common symptom in MS. Physical exhaustion increased V, AP and ML trunk accelerations in older persons during gait

compared to controls (Helbostad et al., 2007). This raises the question whether the relatively high intensive strength training had a tiring effect on muscles in to such an extend that it decreased gait control in SG.

In SG, 5 participants had primary progressive type of MS (PPMS) while TG had none. Even though the EDSS did not diverge, there still can be inequalities in the clinical picture of the participants. Persons with PPMS do more often have bilateral affection in lower limbs. Persons with RRMS usually get immune modulating medication while people with PPMS do not. The course of the disease in PPMS differs from relapsing-remitting type of MS by being continuously in progression. Thereby, the training potential for change might also differ during the intervention.

Even though the change between the groups was the main target in this study, it is interesting to see the effect of intervention within groups as this can help us to understand the differences between groups. Treadmill walking had a nearly significant effect on ML trunk acceleration. ML trunk acceleration is shown to increase with increased gait speed (Helbostad & Moe-Nilssen, 2003). ML acceleration occurs in frontal plane and can be linked with balance control and the hip stability as the gluteus medius muscle has shown to impact stability in pelvic region and lumbar spine most (Liu et al., 2006). Pandy et al found that the same muscles are activated to control ML acceleration as in V acceleration. Also the plantar flexor inverters assist gluteus medius in controlling the balance during stance phase (Pandy, Lin, & Kim, 2010). The SG trained gluteus medius but not the plantar flexor inverters which can have an important role in ML acceleration.

The nearly significant decrease in AP interstride asymmetry in SG does not show the same correlation as in stroke patients. In stroke, the interstride asymmetri increased in slower gait velocities. In this study, gait velocities in SG increased non-significantly. Increased symmetry could be explained by improved muscle strength in lower limbs. A unilateral affection in lower limbs is quite common in persons with MS resulting to asymmetric footfalls during gait. Asymmetric footfalls again influence the trunk movements. Increased asymmetry in stroke patients is suggested to be a result of a compensatory strategy during gait propulsion (Hodt-Billington et al., 2008). Most of the joint movements during gait occur

in AP direction in the sagittal plane. Muscles found to be most active in AP direction during stance and swing phase are the plantar flexors in the ankles and the hip flexors during propulsion. The knee extensors absorb for the pumps. SG trained plantar flexors, knee and hip extensors. Stronger hip extensors promote to longer steps and stimulate the hip flexors. The unilateral strength training removes the possibility for compensation from the stronger leg. Normalizing the muscle strength in the most affected limb could profit an asymmetric gait and increase the interstride symmetry and by that means balance control during walking.

When this is said, SG group still did not change significantly in trunk accelerations. Walking on treadmill challenged the postural stability in TG throughout the whole training session. It is highly task specific training compared to strength training. They were challenged to walk incline, to focus on their gait cycle and balance by walking without rails but still knowing they could get support if needed, and finally to walk in increased velocities during the intervention. SG had exercises in lying and sitting positions not challenging the postural control. Functional strength exercises might have given another result.

The interesting observation in this study, although not significant change, is the direction of change in different variables within groups. While the preferred gait velocity, cadence and trunk acceleration consistently decreased in TG, they consistently increased in SG. The interstride variability did not change at all in TG, but decreased in SG while the interstride symmetry increased in both groups. As mentioned, the other changes were not close to significant, but to get the whole picture, it is an interesting finding to show how differently treadmill walking and strength training might affect gait control. Maybe this picture had been strengthened with a longer intervention time.

This finding also lowers the possibility that the significant and nearly significant results occur by chance. At the same time, this patient group is highly variable in their gait characteristics, which can affect the test results from baseline to post tests, although the reliability between baseline tests was good. Even though the significant differences were few, we interpret that there was some positive effects from both interventions, although the overall effect on gait control was higher in TG. To our knowledge, this is the first intervention study with MS patients examining trunk acceleration with an accelerometer. For

generalizing the results, significant differences are too few and the sample size too small. Still, the results are highly useful in our clinical settings.

Strength of this study were high participating rate and good relative reliability between baseline trunk acceleration measures. Nevertheless, there is some weaknesses too.
We did not have any control group in this study that could have given more precise information of the trunk acceleration measures compared to healthy controls. There was no follow-up after the post test.

In an intervention study, there is always possibilities for improvement. Intervention duration should perhaps been longer to see stronger evidence for change in gait variables. European Multiple Sclerosis Platform[3] recommends longer than 8 weeks interventions to be long enough for significant change. Exercise chosen to strength training were not task specific or functional. In TG the aim was to prevent endurance effect as it is earlier shown the increased endurance has positive effect on gait function. The O2 max limit should have probably been lower to avoid improved fitness effect.

Even if the there was no significant differences in sample characteristics, the groups might have been more homogeneous with only one type of MS as the course of the disease vary between the different types of MS. The participants were not asked to take into account the testing in their everyday life. They were not monitored for their physical activity during the test day so we do not know if they were fatigued before testing. Their stress level, sleep quality and the nutrition might make the difference since the post test was only carried out once.

9 Conclusion

Both treadmill training and strength training were well tolerated of persons with MS. This intervention study showed few changes between the groups after the intervention. The only significant change between the groups was in vertical trunk acceleration. The small sample size and few significant changes make the generalizing difficult, but for our clinical rehabilitation, the study gives an indication of importance of task-specific training in

impaired gait. There is only few studies done with tri-axial accelerometer with MS patients, and, to our knowledge, none of them looking at the intervention effect. Accelerometer appears to be a reliable and easy to use in clinical environment. As studies from earlier show, it can differentiate gait and balance impairment in early course of the MS disease. Tri-axial accelerometer should be considered as a possible evaluation method in rehabilitation of gait control. To get more knowledge of impact of rehabilitation in gait control in MS, there should be further investigation and several studies evaluating trunk accelerations measured with a tri-axial accelerometer.

10 References

1 http://www.acsm.org/docs/current-comments/resistancetrainingandtheoa.pdf

2 http://www.gaitrite.com/Downloads/GAITRite_Measurement_Definitions.pdf

3 http://www.eurims.org/images/stories/documents/Brochures/Recommendations%20on%20MS%20Rehabiltation%20RIMS%20EMSP%202012.pdf

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Appendix 1

Forespørsel om deltakelse i vitenskapelig undersøkelse

Dette er en forespørsel om deltakelse i et forskningsprosjekt hvor vi skal se på trening i forhold til gangfunksjon. Formålet med prosjektet er å finne ut hvilken treningsform, styrketrening eller gangtrening på tredemølle, som er mest effektiv med tanke på å forbedre gangfunksjon ved MS.

Hvem kan delta og hva innebærer deltakelse

Kvinner og menn over 18 år, fra Trondheim og nærliggende kommuner, som har diagnose Multippel Sclerose blir forespurt om å delta i studien. Du må ha gangfunksjon og greie å gå minst 100 meter i strekk. Nyere forskning viser at både styrketrening og gange på tredemølle har gunstig effekt på gangfunksjon hos pasienter med MS, men vi vet ikke hvilken treningsform som er mest effektiv for å bedre eller vedlikeholde gangfunksjonen.
Dersom du ønsker å delta, må du ha mulighet til å komme på St.Olav og delta på trening her 3 ganger i uka i 8 uker. Treningstimen vil vare ca 45 minutter.

Tester og undersøkelser

Vi kommer til å undersøke gangfunksjonen din ved at du går på en matte, og balanse ved hjelp av en balanseplate som du står på. I tillegg vil vi teste utholdenheten din samt styrke av lårmuskelen. Du vil bli bedt om å vurdere både gangfunksjon og egen helse gjennom et spørreskjema.
Til sammen vil det ta ca en og en halv time å gjennomføre disse testene og det vil bli lagt inn pauser underveis. De vil bli gjennomført to ganger før treningsperioden igangsettes og like etter at den er avsluttet.

Fordeler og risiko/ubehag

Fordelen med å delta i en treningsstudie er at du vil komme i bedre form og forhåpentligvis bli motivert til videre trening i etterkant. Du vil også kunne oppleve at noen av undersøkelsene gir deg nyttig informasjon.

Ubehag i form av muskelstølhet kan forekomme, og muskelstrekk og overtråkk kan en risikere ved fysisk aktivitet. Det forekommer at personer med MS kan oppleve økt trettbarhet etter trening. Dette vil vi overvåke nøye. Undersøkelsene du skal gjennom brukes rutinemessig til diagnostikk i helsevesenet og de har svært lite potensial for å gi skadelige eller ubehagelige bivirkninger.

Frivillighet og samtykke

Deltakelse i prosjektet er frivillig. Alle deltakere i prosjektet har rett til å trekke seg fra prosjektet når de måtte ønske uten å måtte oppgi årsak, det får heller ingen konsekvenser for videre oppfølging og behandling. Deltakere er dekket av Pasientskadeerstatningsordningen.
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 resultater og opplysninger, med mindre opplysningene allerede er inngått i analyser eller brukt i vitenskapelige publikasjoner.

Etisk og faglig vurdering

Prosjektet er vurdert av Regional komité for medisinsk forskningsetikk, Region Sør-Øst, og komiteen har godkjent at prosjektet gjennomføres.

Randomisering

Som deltaker i denne studien, er det tilfeldig hvilken behandling du får (styrketrening eller gange på tredemølle). En datamaskin avgjør ved ”loddtrekning” (randomisering) hvilken behandling du skal ha. Opplysninger om initialer, kjønn og alder, og hvilken studie du deltar i legges inn før det trekkes hvilken treningsform du skal delta i. En person ved Enhet for anvendt klinisk forskning ved NTNU har ansvaret trekkingen. Alle opplysningene om deg avidentifiseres før de overføres på e-post til prosjektkontakt. Du får et tilfeldig nummer i databasen, og bare prosjektkontakten kjenner koblingen mellom nummeret i databasen og din identitet.

Ansvarlige

Prosjektleder er spesialfysioterapeut Siri Brændvik og medisinsk ansvarlig er nevrolog Harald Olav Hovdal ved St.Olavs Hospital. Kontaktpersoner er fysioterapeutene Teija Koret og Karen Schei. Prosjektmedarbeiderne har taushetsplikt i henhold til Forvaltningsloven § 13 og Helsepersonelloven § 21. Alle data behandles konfidensielt og lagres i avidentifisert form i en database slik at deltakerne kun er registrert med et løpenummer. Undersøkelsesresultater samt navneliste som knytter løpenummer opp mot navn oppbevares forskriftsmessig. Av kontrollhensyn blir grunnlagsdata oppbevart forsvarlig nedlåst fram til 31.12.2019. Deretter vil data bli slettet. Det er Siri Brændvik som er ansvarlig for datamaterialet i denne perioden. Instanser som kan tenkes å kontrollere grunnlagsmaterialet er for eksempel forskningsansvarlige, Uredelighetsutvalget for forskning og Helsetilsynet.

Hvis du ønsker å delta i undersøkelsen, ber vi om at du fyller ut samtykkeerklæringa på neste side. Ta gjerne kontakt hvis du har spørsmål.

Vennlig hilsen

Teija Koret
Fysioterapeut
Nevrologisk avdeling
St.Olavs Hospital
tlf 72575756

Siri merete Brændvik
Spesialfysioterapeut
Klinisk Service
St.Olavs Hospital
tlf 72573830

Samtykkeerklæring

Tredemølle eller styrketrening?

Jeg har mottatt skriftlig og muntlig informasjon om prosjektet og har hatt anledning til å stille spørsmål.
Jeg samtykker i å delta i prosjektet.

Sted/dato Underskrift

_____

_____

Jeg bekrefter å ha gitt informasjon om studien

_____
(Signert, rolle i studien, dato)

Appendix 2
Testskjema MS-prosjekt

ID-nr

Testnr./dato

Kjønn

Alder

Høyde

Vekt

MS-klassifisering (atakkvis el. sekundær progressiv)

EDSS skår

Komorbiditet

Evt.medisiner

Yrkesaktiv

Hvis ja, yrke

Kommentarer

1. Test statisk balanse – Good Balance

Selvvalgt komfortabel utgangsposisjon på plattform – parallelle ben. Armene festes på hoften

Avstand H-V (distanse senter hæl)

☐

A) 20sek åpne øyne ☐

B) 20 sek lukkede øyne ☐

C) 20 sek balansepute åpne øyne ☐

D) 20 sek balansepute lukkede øyne ☐

Gangfunksjon/dynamisk balanse – GaitRite/TRASK

Bruk av to sensorer – øvre og nedre truncus
Alle gangforsøk starter minst to meter utenfor matta.

Gange frem og tilbake på matte i tre hastigheter. Gjennomføres to ganger med 5min mellomrom!

Tilvenningsforsøk: "Gå fram og tilbake i vanlig tempo"

1. **”Gå fram og tilbake i vanlig tempo"** ☐
2. **”Gå fram og tilbake i rusletempo"** ☐
3. **"Gå fram og tilbake så fort som du trygt kan gå"** ☐

Pause!

”Gå fram og tilbake i vanlig tempo" ☐

”Gå fram og tilbake i rusletempo" ☐

"Gå fram og tilbake så fort som du trygt kan gå" ☐

Sensornummer:

Ekstensjonsstyrke i kne - Biodex
Isometrisk ekstensjon på tre vinkler; 30, 45 og 60º.

Kontraksjonsperiode 3 sek.

Instruksjon: ”**Ta i så mye du greier så raskt som mulig**”

Pause mellom hver kontraksjon: 30sek.

Pause ved hver vinkelendring: 1min

Begge ben testes. Begynne med ve ben.

Appendix 3

Id nr:	

Benpress

	dato
1 RM pre	
1 RM post	

	Belastning kg		> 6 reps	
	H	**V**	**H**	**V**
1. tr.økt	/		/	
2. tr.økt	/		/	
3. tr.økt	/		/	
4. tr.økt	/		/	
5. tr.økt	/		/	
6. tr.økt	/		/	
7. tr.økt	/		/	
8. tr.økt	/		/	
9. tr.økt	/		/	
10. tr.økt	/		/	
11. tr.økt	/		/	
12. tr.økt	/		/	
13. tr.økt	/		/	
14. tr.økt	/		/	
15. tr.økt	/		/	
16. tr.økt	/		/	
17. tr.økt	/		/	
18. tr.økt	/		/	
19. tr.økt	/		/	
20. tr.økt	/		/	
21. tr.økt	/		/	
22. tr.økt	/		/	
23. tr.økt	/		/	
24. tr.økt	/		/	

Kommentar:

Plantarfl.

	dato
1 RM pre	
1 RM post	

	Belastning kg		> 6 reps	
	H	**V**	**H**	**V**
1. tr.økt	/		/	
2. tr.økt	/		/	
3. tr.økt	/		/	
4. tr.økt	/		/	
5. tr.økt	/		/	
6. tr.økt	/		/	
7. tr.økt	/		/	
8. tr.økt	/		/	
9. tr.økt	/		/	
10. tr.økt	/		/	
11. tr.økt	/		/	
12. tr.økt	/		/	
13. tr.økt	/		/	
14. tr.økt	/		/	
15. tr.økt	/		/	
16. tr.økt	/		/	
17. tr.økt	/		/	
18. tr.økt	/		/	
19. tr.økt	/		/	
20. tr.økt	/		/	
21. tr.økt	/		/	
22. tr.økt	/		/	
23. tr.økt	/		/	
24. tr.økt	/		/	

Kommentar:

Hofteabd

	dato
1 RM pre	
1 RM post	

	Belastning kg		> 6 reps	
	H	**V**	**H**	**V**
1. tr.økt	/		/	
2. tr.økt	/		/	
3. tr.økt	/		/	
4. tr.økt	/		/	
5. tr.økt	/		/	
6. tr.økt	/		/	
7. tr.økt	/		/	
8. tr.økt	/		/	
9. tr.økt	/		/	
10. tr.økt	/		/	
11. tr.økt	/		/	
12. tr.økt	/		/	
13. tr.økt	/		/	
14. tr.økt	/		/	
15. tr.økt	/		/	
16. tr.økt	/		/	
17. tr.økt	/		/	
18. tr.økt	/		/	
19. tr.økt	/		/	
20. tr.økt	/		/	
21. tr.økt	/		/	
22. tr.økt	/		/	
23. tr.økt	/		/	
24. tr.økt	/		/	

Kommentar:

Dorsalfl.

	dato
1 RM pre	
1 RM post	

	Belastning kg	> 6 reps
	H / V	**H / V**
1. tr.økt	/	/
2. tr.økt	/	/
3. tr.økt	/	/
4. tr.økt	/	/
5. tr.økt	/	/
6. tr.økt	/	/
7. tr.økt	/	/
8. tr.økt	/	/
9. tr.økt	/	/
10. tr.økt	/	/
11. tr.økt	/	/
12. tr.økt	/	/
13. tr.økt	/	/
14. tr.økt	/	/
15. tr.økt	/	/
16. tr.økt	/	/
17. tr.økt	/	/
18. tr.økt	/	/
19. tr.økt	/	/
20. tr.økt	/	/
21. tr.økt	/	/
22. tr.økt	/	/
23. tr.økt	/	/
24. tr.økt	/	/

Kommentar:

Rygg

	dato
1 RM pre	
1 RM post	

	Belastning kg	> 6 reps
1. tr.økt		
2. tr.økt		
3. tr.økt		
4. tr.økt		
5. tr.økt		
6. tr.økt		
7. tr.økt		
8. tr.økt		
9. tr.økt		
10. tr.økt		
11. tr.økt		
12. tr.økt		
13. tr.økt		
14. tr.økt		
15. tr.økt		
16. tr.økt		
17. tr.økt		
18. tr.økt		
19. tr.økt		
20. tr.økt		
21. tr.økt		
22. tr.økt		
23. tr.økt		
24. tr.økt		

Kommentar:

Appendix 4

										3	, km/h
										4	, km/h
										5	, km/h
	Bolk1		Bolk 2		Bolk 3					**6**	, km/h
										7	, km/h
	Foretr. hastighet		Gangmønster		Øke hastighet					**8**	, km/h
	↓		↓		↓					**9**	, km/h
					Tr. 1-3	Tr. 4-10	Tr. 11-18	Tr. 19-24		**10**	, km/h
	Helning %		Foretrukket		Hastighet	Hastighet	Hastighet	Hastighet		**11**	, km/h
			hastighet km/h		økt 10 %	økt 20 %	økt 30%	økt 40 %		**12**	, km/h
	6		6		6,6	7,2	7,8	8,4		**13**	, km/h
	5		5,5		6,1	6,6	7,2	7,7		**14**	, km/h
Finne	5	aktiv/passiv	5	aktiv/passiv	5,5	6	6,5	7		**15**	, km/h
foretrukket	4	pause	4,5	pause	5,0	5,4	5,9	6,3		**16**	, km/h
ganghastighet	4		4		4,4	4,8	5,2	5,6		**17**	, km/h
	3		3,5		3,9	4,2	4,6	4,9		**18**	, km/h
	3		3		3,3	3,6	3,9	4,2		**19**	, km/h
	2		2,5		2,8	3	3,3	3,5		**20**	, km/h
	2		2		2,2	2,4	2,6	2,8		**21**	, km/h
	1		1,5		1,7	1,8	2,0	2,1		**22**	, km/h
	1		1		1,1	1,2	1,3	1,4		**23**	, km/h
										24	, km/h
2 min	7 min	2 min	7 min	2 min	7 min						

Treningstid 27 min **Hjertefrekv <**

Appedix 5

Kurtzke Expanded Disability Status Scale (EDSS)

.

0.0 - Normal neurological exam (all grade 0 in all Functional System (FS) scores*).

.

1.0 - No disability, minimal signs in one FS* (i.e., grade 1).

.

1.5 - No disability, minimal signs in more than one FS* (more than 1 FS grade 1).

.

2.0 - Minimal disability in one FS (one FS grade 2, others 0 or 1).

.

2.5 - Minimal disability in two FS (two FS grade 2, others 0 or 1).

.

3.0 - Moderate disability in one FS (one FS grade 3, others 0 or 1) or mild disability in three or four FS (three or four FS grade 2, others 0 or 1) though fully ambulatory.

.

3.5 - Fully ambulatory but with moderate disability in one FS (one grade 3) and one or two FS grade 2; or two FS grade 3 (others 0 or 1) or five grade 2 (others 0 or 1).

.

4.0 - Fully ambulatory without aid, self-sufficient, up and about some 12 hours a day despite relatively severe disability consisting of one FS grade 4 (others 0 or 1), or combination of lesser grades exceeding limits of previous steps; able to walk without aid or rest some 500 meters.

.

4.5 - Fully ambulatory without aid, up and about much of the day, able to work a full day, may otherwise have some limitation of full activity or require minimal assistance; characterized by relatively severe disability usually consisting of one FS grade 4 (others or 1) or combinations of lesser grades exceeding limits of previous steps; able to walk without aid or rest some 300 meters.

.

5.0 - Ambulatory without aid or rest for about 200 meters; disability severe enough to impair full daily activities (e.g., to work a full day without special provisions); (Usual FS equivalents are one grade 5 alone, others 0 or 1; or combinations of lesser grades usually exceeding specifications for step 4.0).

.

5.5 - Ambulatory without aid for about 100 meters; disability severe enough to preclude full daily activities; (Usual FS equivalents are one grade 5 alone, others 0 or 1; or combination of lesser grades usually exceeding those for step 4.0).

.

6.0 - Intermittent or unilateral constant assistance (cane, crutch, brace) required to walk about 100 meters with or without resting; (Usual FS equivalents are combinations with more than two FS grade 3+).

.
6.5 - Constant bilateral assistance (canes, crutches, braces) required to walk about 20 meters without resting; (Usual FS equivalents are combinations with more than two FS grade 3+).
.
7.0 - Unable to walk beyond approximately 5 meters even with aid, essentially restricted to wheelchair; wheels self in standard wheelchair and transfers alone; up and about in wheelchair some 12 hours a day; (Usual FS equivalents are combinations with more than one FS grade 4+; very rarely pyramidal grade 5 alone).
.
7.5 - Unable to take more than a few steps; restricted to wheelchair; may need aid in transfer; wheels self but cannot carry on in standard wheelchair a full day; May require motorized wheelchair; (Usual FS equivalents are combinations with more than one FS grade 4+).
.
8.0 - Essentially restricted to bed or chair or perambulated in wheelchair, but may be out of bed itself much of the day; retains many self-care functions; generally has effective use of arms; (Usual FS equivalents are combinations, generally grade 4+ in several systems).
.
8.5 - Essentially restricted to bed much of day; has some effective use of arm(s); retains some self-care functions; (Usual FS equivalents are combinations, generally 4+ in several systems).
.
9.0 - Helpless bed patient; can communicate and eat; (Usual FS equivalents are combinations, mostly grade 4+).
.
9.5 - Totally helpless bed patient; unable to communicate effectively or eat/swallow; (Usual FS equivalents are combinations, almost all grade 4+).
.
10.0 - Death due to MS.
*Excludes cerebral function grade 1.

Note 1: EDSS steps 1.0 to 4.5 refer to patients who are fully ambulatory and the precise step number is defined by the Functional System score(s). EDSS steps 5.0 to 9.5 are defined by the impairment to ambulation and usual equivalents in Functional Systems scores are provided.

Note 2: EDSS should not change by 1.0 step unless there is a change in the same direction of at least one step in at least one FS.

Sources: Kurtzke JF. Rating neurologic impairment in multiple sclerosis: an expanded disability status scale (EDSS). Neurology. 1983 Nov;33(11):1444-52.

Haber A, LaRocca NG. eds. Minimal Record of Disability for multiple sclerosis. New York: National Multiple Sclerosis Society; 1985.