Faculty of Health Sciences
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The ATLET study: Can subjects with long-standing motor incomplete spinal cord injury learn to walk?

A randomized clinical trial

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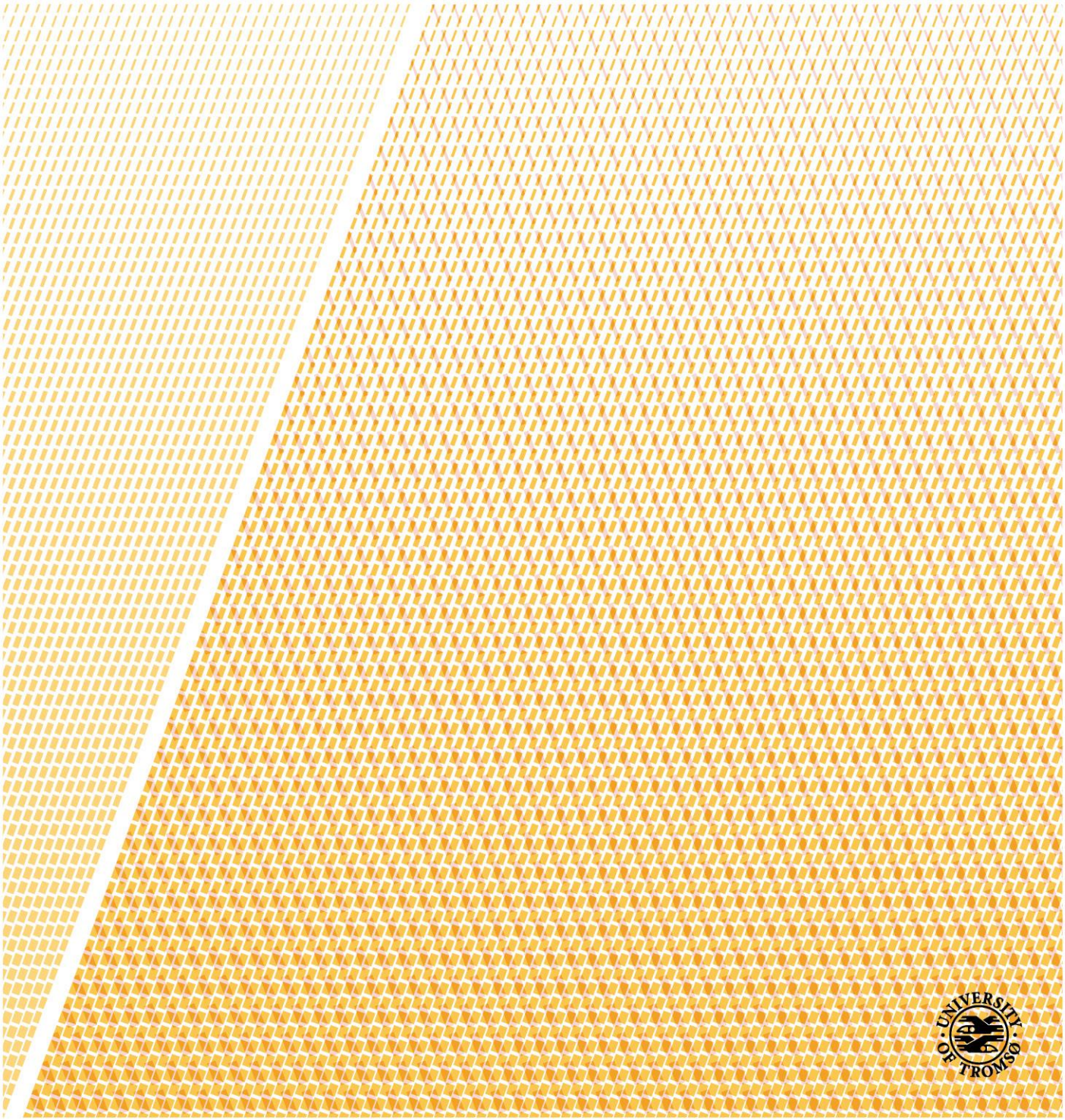
A dissertation for the degree of Philosophiae Doctor – Month Year



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List of abbreviations

AIS	ASIA Impairment Scale
AIS C-D	ASIA Impairment Scale grade C-D
ASIA	American Spinal Injury Association
BBS	Berg's Balance Scale
BMI	Body Mass Index
BWS	Body-Weight Support
BWSLT	Body-Weight Supported Locomotor Training
BREQ	The Behavioural Regulation in Exercise Questionnaire
EBSE	Exercise Barrier Self-Efficacy
HRQOL	Health-Related Quality Of Life
ICF	The International Classification of Function, Disability and Health
IPAQ-SF	The International Physical Activity Questionnaire - Short Form
ISNCSCI	The International Standards for Neurological Classification of Spinal Cord Injury
LEMS	Lower Extremity Motor Score
MCID	Minimal Clinically Important Difference
MCS	Mental Component Score
MFR	Modified Functional Reach
n	Numbers / sample size
n.s.	Not significant
PEDro	The Physical therapy Evidence Database
PCS	Physical Component Score
RCT	Randomized Clinical Trial
SCI	Spinal Cord Injury
SDT	Self-Determination Theory
SF-36	36-Item Short-Form health status survey
10MWT	10 Meter Walk Test
6MWT	6 Minute Walk Test
VO_{2max}	Maximal oxygen uptake
QoL	Quality of Life

Summary of thesis

Body-weight supported locomotor training (BWSLT) is used to improve walking function in persons with motor incomplete Spinal Cord Injuries (SCI). BWSLT facilitates activation of the neuromuscular system below the lesion, with the goal of retraining the nervous system to recover specific motor tasks related to mobility, posture, standing and walking. Both manually- and robot-assisted programs have been utilized, but they are costly and have not been sufficiently validated through randomized controlled trials (RCT) for use among subjects with chronic (≥1 year post-injury) incomplete SCI and poor walking function.

The aim of this thesis was to recruit 30 subjects with poor walking function and long-standing (≥2 years post-injury) motor incomplete SCI, American Spinal Injury Association Impairment Scale (ASIA) grade C and D, to two simultaneously, but independent, single-blinded RCTs using manually and robot-assisted BWSLT, respectively. Outcomes were changes in physical function, health-related quality of life (HRQOL) and psychological factors. Intervention consisted of 60 days of BWSLT, in-patient and manually assisted in study 1 (n=20) and outpatient and robot-assisted in study 2 (n=24), each with separate control groups receiving low-intensity usual care.

Unfortunately, both studies were underpowered due to inability to recruit the planned 30 participants to each study. We were unable to re-establish walking function in both of the two studies, but there was a statistically significant increase in lower extremity muscle strength (LEMS) in both intervention groups compared to their controls. Modest, but non-significant improvements in walking speed and truncus control/balance were also found. Merged data from both studies shows high baseline scores for both HRQOL, autonomous motivation, physical activity and expectation to the interventions and no noticeable change in these after completion of the intervention. The fact that even baseline scores were high, raises the question of whether these subjects already at baseline were high performers, and therefore had exhausted their potential for improvements, reaching a “ceiling” effect before study start.

In conclusion, we can neither refute nor confirm the efficacy of BWSLT in these subjects. Although both manually and robot-assisted approach may have benefits, there is a need to carefully consider what type of patients should be candidates for these costly training options. We found minimal effects among these SCI persons with poor baseline walking ability and late training start. This does not exclude the possibility that such training could be more useful in others, i.e. subjects with subacute SCI with some baseline walking function.

Papers in the thesis

Paper I — Piira A, Lannem AM, Sørensen M, Glott T, Knutsen R, Jørgensen L, Gjesdal K, Hjeltnes N. & Knutsen SF. Manually assisted body-weight supported locomotor training does not re-establish walking in non-walking subjects with chronic incomplete spinal cord injury: a randomized clinical trial. Journal of Rehabilitation Medicine, 2019; 51: 113-119.

Paper II — Piira A, Lannem AM, Sørensen M, Glott T, Knutsen R, Jørgensen L, Gjesdal K, Hjeltnes N & Knutsen SF. Robot-assisted locomotor training did not improve walking function in patients with chronic incomplete spinal cord injury: a randomized clinical trial. Short communication. Journal of Rehabilitation Medicine, 2019; 51: 385-389.

Paper III — Piira A, Lannem AM, Gjesdal K, Glott T, Knutsen R, Jørgensen L, Hjeltnes N, Knutsen SF & Sørensen M. Quality of life and psychological outcomes of body-weight supported locomotor training in spinal cord injured persons with long-standing incomplete lesions. Spinal Cord, 2019 Dec 17. doi: 10.1038/s41393-019-0401-2. (Epub ahead of print)

1 Introduction / background

A spinal cord injury (SCI) usually has devastating consequences for the subject, with dramatic changes of functions and quality of life. To regain walking and related motor functions, such as balance and mobility, are extremely important for the person with SCI (1, 2). Loss of walking function and ability to stand upright restricts a person's mobility, autonomy and severely affects the quality of life (QoL) (3). The focus of this thesis is to describe the rationale, the study aims and objectives, as well as the research design, methods and results of two long-lasting randomized clinical trials among subjects with long-standing (≥2 years post-injury time) incomplete SCI. Both studies assessed the effects of body-weight supported locomotor training (BWSLT), with one utilizing manual assistance and the other using a robot.

1.1 International Classification of Function, Disability and Health (ICF)

Since evaluation of motor function is the central theme in this thesis, we use the International Classification of Function, Disability and Health (ICF) to classify outcome measurements and set our results in context (4). The purpose of the ICF is to provide a standard language and framework for the description of health and health-related conditions (Fig. 1) (4). In this thesis, we limit the use of ICF for body structure/function, activity and participation domains that have also been used in clinical and research settings. Based on the suggested use of ICF in SCI research, we have classified our outcome measures to the following ICF domains: 1) Neurological impairment/measure (the International Standards for Neurological Classification of Spinal Cord Injury ISNCSCI) and physiological measures are part of the "Body structure and functions" domain outcome measure, 2) "Activity" domain outcome measures are related to functional capacity (walking and balance assessments and physical activity), and 3) the "Participation" domain is patient-reported quality of life (4-6). We also refer to a contextual factor "Personal factors" which includes the individual's personal characteristics such age, gender, coping styles, behaviour, experiences (psychological assessments) etc. (4, 5).

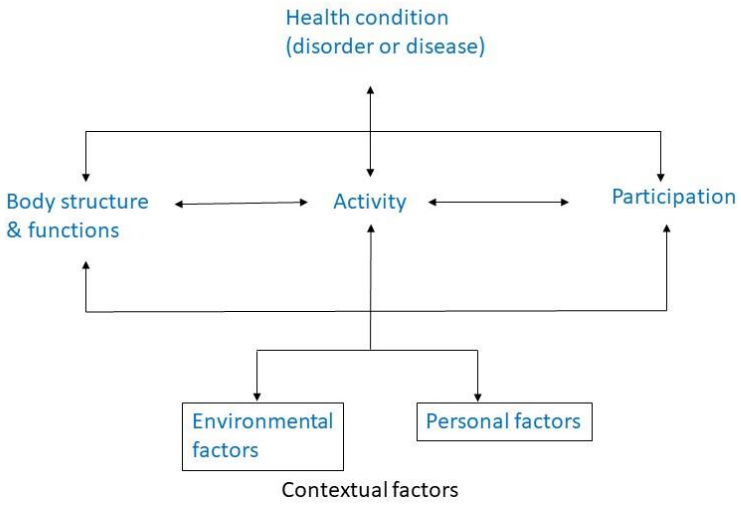

Figure 1 Illustration of the International Classification of Function, Disability and Health (4)

1.2 Spinal Cord Injury (SCI)

A SCI represents an injury to any part of the spinal cord or nerves within the spinal canal, traumatic (motor vehicle accidents, falls etc.) as well as atraumatic (spondylosis causing compression, vascular issues, spinal tumours, inflammation affecting the neural tissues). A SCI produces sensory and/or motor function loss below the level of injury, and the degree of loss depends on the level and extent of the lesion (7). Terms related to SCI are paraplegia and tetraplegia. In paraplegia, the injury level can be either in the thoracic, lumbar or sacral segments of the spine, and impairments of sensory and motor function can affect the trunk, pelvic organs and lower limbs (7). In tetraplegia, cervical segment functions are impaired, manifested in upper and lower limbs, trunk and pelvic organs. The traditional method for classification of level and extend of SCI is the International Standards for Neurological Classification of Spinal Cord Injury (ISNCSCI) (7). This classification system assesses sensory and motor function, including 28 dermatomes, by using pinprick and light touch sensation and manual muscle test: scores of 0-5 to assess five key muscles in the upper limbs and five in the lower limbs. The American Spinal Injury Association (ASIA) Impairment Scale (ASIA impairment Scale [AIS]) classifies the degree of neurological impairment (Table 1). Complete injury is defined as AIS A, with no remaining sensory and motor functions in

the lowest sacral segments, incomplete injuries are defined as AIS B, C, & D, and AIS E describes normal sensory and motor functions (7).

Table 1 Classification of the degree of the neurological impairment based on The American Spinal Injury Association Impairment Scale (ASIA impairment Scale [AIS]) (7)

AIS A - Complete	No sensory or motor function is preserved in the sacral (S) segments S4-5.
AIS B – Incomplete	Sensory, but not motor function is preserved below the neurological level including sacral segments S4-5.
AIS C - Incomplete	Motor function is preserved below the neurological level and, and more than half of the key muscles below the neurological level have a muscle grade <3 (Grades 0-2). (3= Movement against gravity)
AIS D - Incomplete	Motor function is preserved below the neurological level, and at least half of the key muscles below the neurological level have muscle grade ≥3.
AIS E - Incomplete	Sensory and motor functions are normal.

There is a lack of precise data for the proportional distribution of incomplete and complete spinal cord injuries. A recent study from Victoria in Australia shows 58 % incomplete vs 42% complete SCI (8). Van Asbeck and co-workers report 51% incomplete and 49% complete SCI among a Dutch population (9). Among the Finnish population, Ahoniemi et al report a slightly higher proportion of incomplete injuries, with 67% for the tetraplegia being incomplete and 33% complete, and 53% of the paraplegias being incomplete and 47% complete (10). Recent data from Norway shows a greater proportion with traumatic motor incomplete injuries classified as AIS C and D (58%), a smaller proportion (33%) with motor complete injuries AIS A and B, and 9% lacked AIS classification (11). Similarly, among the atraumatic Norwegian SCI population there was also a higher proportion (58%) of motor incomplete injuries (AIS D) (12).

A review from 2010 from van den Berg et al reports that the proportion of SCI paraplegic varies between 19-68%, and between 32-75% for tetraplegic (13). Among the Norwegian traumatic SCI population, the proportion of paraplegia was somewhat smaller (42%) than the proportion of tetraplegia (48%) and 10% was unknown or not applicable (11). Opposite trends were observed among the atraumatic Norwegian SCI population, where 69% had paraplegia and 22 % tetraplegia (12).

Neurological or functional spontaneous recovery occurs mainly within the first three months post-injury, but recovery has been observed up to one year, and even longer after the injury (14-16). The degree of recovery after incomplete injuries is greater than that observed in complete injuries (16). For instance, during the first post-injury year >80% of individuals with AIS C converted to AIS D (16). Individuals with AIS A have poor prognosis for improvement, however, they can experience conversion of AIS grade to a lesser degree even after several years. It has been reported that 5.6 % of individuals with AIS A classification one year after SCI, still converted to an incomplete injury after 5 years, with 3.5% converting to AIS B and approximately 1% to either AIS C or D (14).

In this thesis the focus will be on incomplete SCI AIS C and D, both from traumatic and atraumatic injuries.

1.3 Epidemiology of SCI

There are great variations in the incidence of SCI between countries (17). The worldwide incidence has been estimated to 23 per million persons per year (17). In Western Europe the incidence is 16 per million persons per year (17), and the prevalence of individuals with SCI varies widely from 223 to 775 per million persons (18). Men have higher risk of all forms of SCI than women, and for traumatic SCI, the sex ratios are about three time higher for males, whereas for atraumatic SCI the sex ratios are closer to unity (8-10, 12, 19). In Norway, the incidence of traumatic SCI is approximately 12 per million persons per year (11), and the prevalence is estimated to 365 per million persons (20), or a total of 1,825 subjects living with traumatic SCI. Many (22-28%) SCIs occur after traumatic accidents among young adults (15-29 years) and 25-51% occur among adults in the middle of their productive life (30-59 years) with another peak of new cases (approx. 14-30%) among people over 60 years that mainly results from falls (9, 11, 13, 19).

Data from Norway shows that the age group 60-74 years have higher incidence (27.8 per million person-years) compared to the other age groups. For example, age group 15-29 years has an incidence of 15.4 per million persons per year, and in age group 45-59 years the incidence is 14.7 per million persons per year, compared to the overall incidence of 12 per million persons per year; however, the mean age is 47 years at the time of injury (11). Common causes of traumatic SCI are motor vehicle accidents, falls and accidents in sports and leisure time activities (13). In Norway, the most common cause is falls (approx. 50%), followed by sports (21%) and transport/ motor vehicle accidents (18%) (11).

The reported incidence of atraumatic SCI is lower, and often associated with age-related conditions that affect the spinal cord, and thus can be misdiagnosed (13). According to Grassner et al, leading causes of atraumatic SCI are inflammatory /autoimmune diseases (22.6%), infection (26.9%), vascular disorders (18.3%), motor neuron diseases (12.9%), disorder in the spinal column (8.6%) and other (10.8%) (21). A study from Australia estimated the crude incidence for atraumatic SCI to 22.6 per million (22). In Norway, the incidence for atraumatic SCI is lower 7.7–10.4 per million person years (12), and there is no certainty of prevalence, since atraumatic cases may be treated outside the SCI units and escape registration. It seems that atraumatic SCI incidence increases due to advancing age (13).

In general, the SCI population has increased mortality and reduced longevity compared to the normal population (23). The most common causes of death among the SCI population are septicaemia, pneumonia/ influenza, cardiovascular diseases (ischemic heart disease), urinary tract diseases, respiratory complications, cancer and suicide (20, 23-25). Mortality is related to the severity of the injury; tetraplegics and persons with complete injuries have elevated risk compared to paraplegics and those with incomplete injuries (23). Due to improved care of SCI, survival after the first year post-injury has improved greatly over the last decades. The first year survival varies between the WHO regions: 86.5 % (95% CI 75.3, 93.1) in the Americas, 95.6 % (95 % CI 81.0-99.1) in Europe compared to 7.0 % (95% CI 1.5 – 27.4) in Western Pacific (23). The numbers from the Americas and Europe are similar to that found in the Norwegian SCI population, although there were two time periods with lower survival rates: in 1972-1981 and 1992-2001 (20).

The standardized mortality rate is reported to be high (1.9) in a Norwegian chronic SCI population, especially among women 4.9 (95% CI 3.0-7.5), versus men 1.8 (95% CI 1.5-2.2) (20, 24). Overall, comparison of incidence, prevalence and mortality of SCI worldwide is difficult due to lack of standardized methods for obtaining accurate and comparable data. This is especially true for information on the epidemiology of atraumatic SCI (13, 23).

1.4 Quality of life after SCI

The World Health Organization has defined quality of life (QoL) as “The individual’s perception of their position in life in the context of the culture and value system in which they live and in relation to goals, expectations, standards and concerns” (26). QoL has become an important outcome in rehabilitation of the SCI population although it is a complex measure due to various definitions and measurements (27). Health-related QoL (HRQOL) is a

narrower term than QoL, and it can be defined as an individual's or a group's perceived physical and mental health over time (28). According to Post and Noreau (29), QoL can be seen as a superordinate construct that includes both health-related QoL and well-being, and it can be closely related to the ICF model among SCI population (29). In general, subjects with SCI experience lower level QoL than the normal population (29, 30). The literature suggests that individuals with incomplete SCI who exercise regularly are more content with life than the same population who do not exercise regularly (31).

Other psychological components such as expectations regarding the outcome of the treatment, perceptions of control and mastery (self-efficacy = belief in one's ability to achieve goals) and motivation for the training, may influence both the outcome of physical training as well as the feeling of well-being (32-34). In line with social-cognitive theory, positive outcome expectations and higher self-efficacy have been found to positively influence effort spent in pursuit of goals, increasing the likelihood of obtaining results also in the physical exercise domain (33). Self-determination theory (SDT) is a theoretical model for exploring motivation in several life domains, also within the exercise setting (35). According to SDT, there are different forms of motivation that characterize qualitatively different ways of behavior regulation. The more internally regulated the motivation is, the more robust it is (35).

Research among subjects with SCI on motivation for physical activity are scarce. However, in addition to autonomous motivation, health benefits and other gains are important for the motivation for physical activity for persons with disabilities in general (36). Overall, there is some evidence of a positive relationship between physical activity and well-being among subjects with SCI (37), but effects of diverse training forms on HRQOL are scarce and inconclusive (36, 38).

Few studies have assessed the role of such psychological factors as to how they influence the outcomes and individual experiences of the training in a Body-weight supported locomotor training program (BWSLT). Hence, knowing that psychological factors influence, and are being influenced by, experiences and behaviour, our aim was to investigate if BWSLT improves HRQOL and psychological outcomes (such as outcome expectations, exercise barrier self-efficacy and motivation) compared to usual care. Our study population consists of subjects with long-standing (≥2 years post-injury time) incomplete SCI with severely reduced physical function such as walking function, lower extremity muscle strength or balance.

1.5 Recovery of walking function after SCI

In the past decades, people have experienced long-term survival after SCI thanks to improved acute and chronic medical care and functional integration into the community. Most of the motor function recovery happens within the first six months (14), but improvement in motor strength may continue during the second year, but to a lesser degree (14). The degree of recovery depends on level of the injury, the completeness of the injury and the remaining motor strength.

In the past, rehabilitation after SCI mainly focused on strengthening muscles above the lesion to compensate for the weak or paralyzed muscles below the injury level (39). Focus has been on the compensatory strategies rather than on strategies that could restore function below the level of the lesion. However, over the last decades, we have seen a transition towards studying more activity-based interventions where focus is on recovery. This is done by providing activation of the neuromuscular system below the level of the injury with the goal of retraining the individual to recover function of a specific motor task, for example to improve walking function (3, 40-44).

1.6 Body-weight supported locomotor training and SCI

BWSLT is defined as a physiology-based approach to retrain walking after neurologic injury that capitalizes on the basic mechanisms of the spinal cord to generate stepping for the purpose of walking. This approach can apply to subjects with neurological impairments such as stroke and SCI (40, 45, 46). The BWSLT term has also been used synonymously with Treadmill therapy, Laufband therapy etc. (40, 42, 44, 47).

Three decades ago, knowledge about the effect of BWSLT was based on experiences from studies on animal with SCI (48). These studies showed for instance, that cats with a complete surgical transection of their spinal cord, could regain walking function on a treadmill, suggesting a great potential for a spinal cord circuit that could facilitate walking without involving the brain. (49-51). Increasing evidence showed the efficacy of exercise training in animal models of SCI, but it was still uncertain if BWSLT would transfer to over-ground walking (52, 53). Among the human population, this training method has now become established, but its efficacy has not been sufficiently confirmed by randomized controlled trials (54).

1.6.1 Uncontrolled human studies

The encouraging results from a clinical non-randomized study more than 20 years ago (Wernig et al (42, 43)), resulted in greater interest in conducting BWSLT studies. Thus, a few years later, the first robot-assisted BWSLT study was published (44). In the early 1990s, human studies of intensive locomotor training in incomplete SCI patients reported improvements that were maintained over long time periods (44, 55). Harkema et al, in a study of 197 patients with incomplete SCI demonstrated improved walking and balance after BWSLT (mean 47 training sessions) (45). Similar, BWSLT studies by Hicks et al, and Wirz et al among subjects with incomplete SCI, showed improved walking, particularly in those with initial poor function (47, 56). Other studies reported that good treatment results were achieved even when training started several years after the SCI (44, 55). And the improvements were maintained for months after completed BWSLT (44, 56, 57), but this depended on the subjects' continued training and physical activity (47, 57). A regular BWSLT program led to increased muscle volume, improved voluntary muscle activation and stability in joints in the lower extremities (56, 58, 59). In addition, BWSLT was associated with decreased spasticity, improved bowel function and cardiovascular fitness in subjects with SCI (57, 60, 61). Data on the effects of BWSLT on HRQOL and psychological wellbeing are sparse and it is unclear, whether this training results in better HRQOL among the SCI population (3, 47, 62).

1.6.2 Randomized human controlled clinical trials

Currently neither BWSLT with manual, nor with robot-assistance, have been demonstrated to be more effective in improving walking speed and distance walked than the same amount of conventional gait training in subjects with SCI (54). However, BWSLT of any kind, makes it possible to have more repetitions and seems well tolerated with respect to safety and acceptability.

In order to compare BWSLT trials in this review, we selected studies, which used similar training methods as in our studies. The well-known Physical Therapy Evidence Database (PEDro) was used and this rates RCTs, reviews and guidelines in physical therapy (63, 64). The PEDro scale, an 11-item rating scale, has shown good reliability with intraclass correlation coefficient of 0.68, indicating a robust relation between two variables, and high validity with correlation 0.99 indicating that it truly measures what it is designed to measure (63, 65). High quality studies receives scores 7-10, scores 4-6 indicate moderate quality and low quality are given scores <3 (63). The author (AMP) also reviewed and assessed those

trials that were not included in the database (66-68). Tables 2 and 3 show the quality rating of each study.

RCTs on BWSLT in early stage (<1 year) after SCI

As far as we know, eleven RCTs have been conducted among SCI subjects with <1 year post-injury time (69-79) (Table 2). These vary in length from 4 (77) to 16 weeks (71), and also in the number of study subjects: between 14 (69) and 146 (70). Moreover, some included only subjects without walking function at baseline (69, 70, 73, 75, 76), whereas others included only study subjects that were walkers (71, 72, 74, 78). In addition, the control groups were different. We used a "usual care" control group, whereas another study used a control group similar to ours, but it had higher frequency of physical therapy (5 times per week compared to our 1-3 times per week) (69). Eight other trials used control groups with specific over ground gait training that ranged from visually guided walking over obstacles (72) to walking with BWS (74, 79) or without BWS (70, 71, 75-77). One study had a control group that received passive lower limbs training (78).

The BWSLT interventions varied between manual assistance (69, 71-74), robot-assisted (74-79), and one study that had an addition of electrical stimulation (69). Three of the studies (69, 74, 77) did not use blinded assessors, as was done in our studies. Overall, the effect of BWSLT in these studies was moderate (69, 71, 75-77). Some trials report improvements in endurance (72, 75, 76) or in lower extremity strength (75, 76) while other were unable to detect any effect of BWSLT (70, 73-75).

The largest RCT so far, by Dobkin et al (70), failed to detect difference in effect between BWSLT and conventional training, and they concluded that there were no differences between the groups in any of the assessed outcomes. One possible reason for this lack of effect could be that subjects were included rather early (8 weeks after injury), and with such a short interval since the injury, spontaneous recovery frequently occurs, contributing to the lack of statistically significant differences. Senthilvelkumar et al (73) found no difference in effect between the groups in lower extremity strength, nor in walking function. Hornby et al (74) found better muscle strength in lower limbs and higher functional levels in all groups, but no significant difference between the groups. Lucareli et al (71) concluded that BWSLT is more effective than traditional physical therapy in improving spatio-temporal and kinematic walking parameters. Yang et al (72) concluded that manually assisted BWSLT is an effective method to improve over ground walking (endurance). Shin et al (77) reported improved walking function favoring the intervention group. Alcobendas-Maestro et al (75) concluded

that BWSLT improved walking function compared to the over-ground training group. Similar results of improvement in endurance and lower limb muscle strength, were also reported by Esclarin-Ruz et al (76). A recent RCT by Cheung et al (78) reported improvement in functional levels, gait symmetry and aerobic capacity compared to the lower limb training group and they concluded that BWSLT may improve physical fitness. Wirz et al (79) studied an acute SCI population post-injury time 1-2 months, and concluded that longer BWSLT sessions (50 min) have a beneficial effect on walking function compared to those who had 50% shorter training time.

Overall, it seems that many of the RCTs in the subacute stage included subjects with poor or no walking function at baseline (69, 70, 73, 74, 77, 79), or they had a high proportion (1/2 and 1/3) of subjects who were unable to perform baseline walking tests (75, 76). Only three studies required that all subjects were able to walk (71, 72, 78). Taken together, despite the methodological differences, there is agreement that gait training in the subacute phase improves over ground walking.

Only Dobkin et al (70) included a quantitative assessment of HRQOL among their subacute SCI study population. However, as far as we know, these results have not been published. A few RCTs have included psychological outcomes such as depression (72) and perception of pain (74-76), but motivation has not been included. Comparison of these trials is therefore difficult due to methodological differences.

Table 2 Overview of randomized body-weight supported locomotor training trials in spinal cord injury <1 year post-injury

Study / Quality	**Country**	**Design**	**Subjects**	**Intervention**	**Outcome measures**	**Results**
Cheung 2019[78] High quality PEDro=8	China	RCT	n=16 Post injury time: 6-24 months AIS grade: B,C&D Inclusion: Subjects are able to walk and stand in tilt-table >30 min. Number of subjects not completing the study: 0	**I:** Robot BWSLT with EMG feedback 30 min 3 days/wk, 8 wks **C:** Passive lower limbs training 30 min 3 days/wk, 8 wks	*Speed:* gait analysis *Muscle strength:* LEMS L-force *Spasticity:* MAS *Functional level:* SCIM-Mobility, WISCI *Other:* $VO_{2,}$ Peak expiratory flow	*Speed:* I-group: +0.9 cm/s C-group: +4.2 m/s Gait symmetry: I-group: +0.1 units C-group: 0 *LEMS:* I-group: +1 units C-group: +0.6 units L-force: I-group:+38.6 units C-group: + 0.5 units *WISCI II:* I-group +1.7 units C-group: +0.1 units *SCIM:* I-group: +4.6 units C-group: +0.2 units

						Between groups differences in functional levels, gait symmetry, aerobic capacity and respiratory function, favoring the I-group.
Wirz 2017[79] Moderate quality PEDro=6	Switzerland	RCT	n=21 Post injury time: 1-1.5 months AIS grade: B&C Inclusion: Subjects have limited walking ability Number of subjects not completing the study: 3	**I:** Robot BWSLT >50 min 3-5 days/wk, 8 wks **C:** Robot BWSLT <25 min 3-5 days/wk, 8 wks	*Spasticity:* MAS, PENN *Functional level:* SCIM, WISCI *Other:* GICS	Spasticity: No between groups differences *SCIM-L:* I-group: + 19 units C-group: + 5 units Between groups difference favoring the I-group. GICS: No between groups difference
Esclarin-Ruz 2014 [76] High	Spain	RCT	n=88 Post injury time: 3-6 months AIS grade: C&D Stratified on upper and lower motor neuron injuries	**I:** Robot BWSLT 60 min 5 d/wk, 8 wks **C:** OGT 60 min	*Speed:* 10MWT *Endurance:* 6MWT	Speed: I-group: +0.1 m/s C-group: +0.2 m/s *Endurance:* I-group: + 70 m

quality PEDro=8			Inclusion: Subjects can stand with external support, but unable to walk. Number of subjects not completing the study: 5	5 days/wk, 8 wks	*Muscle strength:* LEMS *Spasticity:* MAS *Pain:* VAS *Functional level:* FIM-L, WISCI	C-group: + 39 m *LEMS:* I-group: +7 units C-group: +4 units Between groups difference in endurance ($p<0.05$) and in LEMS ($p<0.05$), favoring the I-group.
Shin 2014[77] Moderate quality PEDro=5	South Korea	RCT	n=60 Post injury time: <6 months AIS grade: D Inclusion: No specified walking function Number of subjects not completing the study: 7	**I:** Robot BWSLT 40 min 3 days/wk, 4 wks **C:** OGT 60 min 5 days/wk, 4 wks Both: conventional PT 30 min 2 days/wk, 4 wks	*Muscle strength:* LEMS *Functional level:* SCIM III, WISCI II, AMI	*LEMS:* I group: +6 units (sign) C-group: +4 units (sign) *SCIM III:* I group: + 6 units (sign.) C-group: +3 (sign.) *WISCI II:* I-group +8 units (sign.) C-group: +5 units (sign.) Only WISCI II had sign difference between groups ($p<0.01$), favoring I-group.

Alcobendas -Maestro 2012[75] High quality PEDro=8	Spain	RCT Open	n=80 Post injury time: <6 months AIS grade: C&D Inclusion: Subjects can stand with external support but unable to walk. Number of subjects not completing the study: 5	**I:** Robot BWSLT 60 min 5 days/wk, 8 wks **C:** OGT 60 min 5 days/wk, 8 wks	*Speed:* 10MWT *Endurance:* 6MWT *Muscle strength:* LEMS *Spasticity:* MAS *Pain:* VAS *Functional level:* FIM-L, WISCI II	*Speed:* I-group*:* +0.1 m/s C-group: 0 m/s *Endurance:* I-group: + 59 m C-group: + 9 m *LEMS:* I-group: +7 units C-group: + 5 units *Functional levels:* WISCI II I-group: +12 units C-group: + 7 units *FIM-L:* I-group: + 6 units C-group: + 3 units. Between groups difference in endurance ($p<0.05$), LEMS ($p<0.05$) and functional levels ($p<0.05$), favoring the I-group.

Hornby 2005[74] Low Quality PEDro=3	USA	RCT	n=35 Post injury time: <6 months AIS grade: B, C and D Inclusion: Physical assistance from at least one physical therapist to walk Number of subjects not completing the study: 5	**I1:** Robot BWSLT 30 min 3 d/wk, 8 wks **I2:** manual BWSLT 30 min 3 d/wk, 8 wks **I3:** OGT with body-weight support 30 min 3 d/wk, 8 wks	*Speed:* 10MWT *Endurance:* 6MWT *Muscle strength:* LEMS *Balance:* TUG *Spasticity:* MAS *Pain:* VAS *Functional level:* FIM-L, WISCI II *Other:* EMG, VO_2	All groups improved LEMS and functional levels, but no difference observed between the groups.
Senthilvelkumar 2015[73] High	India	RCT	n=16 Post injury time: <6 months AIS grade: C & D	**I**: Manual BWSLT 30 min 5 d/wk. 8 wks	*Muscle strength:* LEMS	*LEMS:* I-group: +9 units C-group: +10 units *WISCI:* significant

quality PEDro=7			Inclusion: ability to sit independently 2 hours and stand 1 hour with a standing frame. Number of subjects not completing the study: 2	**C:** OGT with body-weight support 30 min 5 d/wk, 8 wks	*Functional level:* WISCI II	+ 10 units in both groups. No between the groups differences was observed.
Yang 2014[72] Moderate quality PEDro=6	Canada	RCT Cross over	n=22 Post injury time: ≥7 months AIS grade: not given, only incomplete SCI Inclusion: Ability to walk at least 5 m with or without walking aid and / or braces Number of subjects not completing the study: 2	**I:** Manual BWSLT 60 min 5/wk x 8 wks **C:** OGT with visually guided walking over obstacles 60 min 5/wk x 8 wks	*Speed:* 10MWT *Endurance:* 6MWT *Muscle strength:* Manual muscle strength test *Functional level:* SCI-FAP, WISCI II *Other:* Depression and ABC scales	*Speed:* I-group: +0.07 m/s (sign) C-group: + 0.04 m/s (sign) *Endurance:* I-group: +30 m (sign) C-group: +10 m (sign) Depression reduced, balance confidence and functional ambulation improved in both groups ($p<0.05$). One between the groups difference: I-group walked 3 times longer than C-group ($p<0.05$).

Lucareli 2011[71] Moderate quality PEDro=6	Brazil	RCT	n=30 Post injury time: <11 months AIS grade: C & D Inclusion: All subjects have be able to walk Number of subjects not completing the study: 6	**I:** Manual BWSLT 30 min 2 d/wk, 16 wks **C:** OGT 30 min 2 d/wk, 16 wks	*Gait analysis:* velocity, distance and spatiotemporal characteristics *Spasticity:* MAS	*Speed:* I-group: +0.4 m/s (sign) C-group: +0.2 m/s (ns) *Endurance:* I-group: + 11 m (sign) C-group: + 2 m (ns) Between group differences in angular kinematic ($p<0.001$) favoring the I-group.
Dobkin 2006 [70] High quality PEDro=7	USA	RCT	n=146 Post injury time: <6 months AIS grade: B, C and D Inclusion: Unable to walk over ground without at least moderate assistance. Number of subjects not completing the study: 29	**I:** Manual BWSLT 60 min 5 d/wk, 12 wks **C**: OGT 60 min 5 d/wk, 12 wks	*Speed:* 15MWT *Endurance:* 6MWT *Muscle strength:* LEMS *Balance:* BBS *Spasticity:* MAS	In both groups, some subjects without walking function at baseline regained walking speed (1.1 m/s), endurance, lower extremity muscle strength, balance and functional levels. No between group

					Functional level: FIM-L, WISCI II *QoL:* SF-54	differences for any of the outcomes.
Postans 2004 [69] Moderate quality PEDro=4	Scotland	RCT Cross over	n=14 Post injury time: <5 months AIS grade: C & D Inclusion: Unable to walk or significant walking impairment. Number of subjects not complete the study: 2	**I:** Partial BWSLT with functional electric stimulation ≤60 min 5 d/wk, 4 wks followed by conventional PT 4 weeks **C:** Conventional PT 4 wks follow by partial BWSLT with functional electric stimulation	*Gait analysis:* speed, spatiotemporal characteristics *Endurance:* 6MWT *Muscle strength:* manual muscle strength test *Spasticity:* MAS Passive range of motion	*Endurance:* I-group: + 64 m (n.s.) C-group: + 38 m (sign) *Speed*: + 0.2 m/s in both groups (n.s). (data from treadmill)

Methodological quality of studies by using the PEDro rating scale: High quality when studies were rated 7-10, moderate quality when rated 4-6 and low quality <3 score (63). AMP reviewed and assessed those trials that were not included in the database. Abbreviations: n: number of

subjects; BWSLT: Body-Weight Supported Locomotor Training; EMG: Electromyography; I: Intervention group; C: Control group; LEMS: Lower Extremity Motor Score; MAS: Modified Ashworth Scale; SCIM: Spinal Cord Independence Measure; WISCI II: Walking Index for Spinal Cord Injury version II; VO_2: Oxygen uptake; PENN: The Modified Penn Spasm Frequency Scale; GICS: The Global Impression of Change Scale; OGT: Over Ground Training; 10MWT: 10 Meter Walk Test; ; 6MWT: 6 Minute Walk Test; VAS: Visual Analog Scale; FIM-L: Functional Independence Measure –Locomotor item; PT: Physical Therapy; AMI: Ambulatory Motor Index; SCI-FAP: Spinal Cord Injury – Functional Ambulation Profile; ABC scale: The Activities-specific Balance Confidence Scale; 15MWT: 15 Meter Walk Test; BBS: Berg's Balance Scale; QoL; Quality of Life; SF-54; Short Form 54; TUG: Timed Up and Go test;

RCTs on BWSLT in chronic stage (> 1 year) after SCI

To our knowledge, a total of 14 RCTs have been conducted among SCI subjects with > 1 year post-injury time (66-68, 80-91), see Table 3. These vary in length from 4 weeks (66-68, 82, 83) to 12-16 weeks (84, 87, 90, 91), and also in the number of study subjects: from 7 (88) to 83 (66). Also, some included only subjects without walking function at baseline (67, 80-82, 85-88), whereas others included only study subjects who were walkers (66, 83, 89, 91). Also, their control groups were quite different. We had a "usual care" control group similar to four other studies (66-68, 82), whereas others (85, 86) used control groups that had specific over ground gait training or other types of pre-specified training (80, 81, 83, 84, 87-91).

The BWSLT interventions varied between manual assistance (80, 84-89), robot-assisted (66-68, 80-82, 85, 90, 91) and those who had an addition of electrical stimulation (84, 85, 87). While both of our studies varied guidance force or manual assistance given, based on the function of the subject, Field-Fote et al (85) used 100% guidance force throughout the intervention (robot-assisted training group). The assessment measures also differed between the studies, making direct comparisons challenging. Also, while we used blinded assessors for our evaluations, some studies (68, 80, 81, 83, 87, 88) had assessors who were unblinded with regards to group allocation, and some studies did not mention whether assessment was blinded or not (66, 82, 85). This could have influenced the effect estimates.

The effect of BWSLT was moderate, and only Alexeeva et al (86), Field-Fote et al (85), Niu et al (68), Varqui et al (67), Brazg et al (89) and Wu et al (80) reported improvement in actual walking measures, while Duffel et al (66) concluded that only minor improvements in walking in the intervention group compared to the inactive control group. Lam et al (91) showed improvement in skilled walking after BWSLT with a resistance training component. Both Kapadia et al (87) and Hitziq et al reported "improvement in mobility" from the same study in two separate papers (84, 87), while Mirbagheri et al (82) concluded that BWSLT can reduce neuromuscular abnormalities associated with spasticity, and Gorman et al (81) reported improvement in cardiovascular fitness. The more recent study by Gorman et al (90) did not find difference in cardiovascular fitness when comparing BWSLT to aquatic therapy. Brazg et al (89) also found improved aerobic capacity after high intensity compared to low intensity BWSLT. The study by Labrueyre et al found no effect of BWSLT compared to strength training (83). Adams & Hicks (88) concluded that there was no change in muscle tone but somewhat better effect in the management of spasticity.

Overall, it seems that many of the RCTs in late stage included subjects with poor or no walking function at baseline (81, 85, 86). Four studies had subjects with walking function (80,

83, 89, 91). Mean post-injury time varied between 4–10 years in ten studies (66-68, 80, 82-84, 86-91). Gorman et al (81) and Field-Fote et al (85) did not report mean post-injury times in their papers.

Overall, in spite of various findings on improvement in endurance, muscle strength, spasticity, aerobic capacity /cardiac fitness and mobility, it seems reasonable to conclude that the effect of BWSLT in subjects with chronic SCI is small with respect to improvement in walking function. There is no clear indication that robot-assisted BWSLT has better effects than the manually assisted BWSLT.

Only four RCTs reported HRQOL outcomes in their studies of chronic SCI population measured with quantitative methods (80, 84, 86, 88). Alexeeva et al (86) reported improved HRQOL including satisfaction with their function and well-being, irrespective of training method. Wu et al (80) found that the HRQOL did not improve despite of BWSLT method. Adams & Hicks (88) concluded that BWSLT has positive effects on HRQOL compared to a different training method. Hitzig et al (84) assessed HRQOL and community participation as their main outcomes and did not find effects. Comparison between these studies is difficult due to their use of different or only parts of standardized questionnaires, differences in study subjects, training methods etc.

Table 3 Overview of randomized body-weight supported locomotor training trials in spinal cord injury >1 year post-injury

Study and Quality	**Country**	**Design**	**Subjects**	**Intervention**	**Outcome measures**	**Results**
Gorman 2019[90] High quality PEDro=7	USA	RCT	n=37 Post injury time: >12 months AIS grade: C&D Inclusion: Able to hold up-right posture min 30 min Number of subjects not completing the study: 4	**I:** Robot BWSLT 40-45 min 3/wk x 12 wks **C:** Aquatic therapy 45 min 3/wk x 12 wks	*Cardiovascular fitness*: peak VO_2 measured with arm ergometer and robotic treadmill	Cardiovascular fitness: I-group: -0.7% (n.s.) C-group:+8.1% (n.s.) No between the groups difference in change in peak VO_2. Although testing on robotic treadmill improved 14% across I-group.
Wu 2018[80] Moderate quality PEDro=6	USA	RCT	n=16 Post injury time: >12 months AIS grade: C&D Inclusion: Lower extremities range of motion within functional limits for walking.	**I:** Robot BWSLT with facilitation of weight shift 45 min 3/wk x 6 wks	*Speed:* 10 m walk on instrumented mat *Endurance:* 6MWT *Balance:* BBS, ABC Scale	*Speed:* I-group: +0.1 m/s (sign.) C-group: 0 (ns) No between the groups difference. *Endurance:* I-group 1: +36.8 m (sign.) C-group 2: +6.9 m/s (ns)

			Number of subjects not completing the study: 2	**C:** Manual BWSLT without facilitation of weight shift 45 min 3/wk x 6 wks	*Muscle strength*: LEMS *Spasticity:* MAS *Functional level*: WISCI II *Quality of Life:* SF-36 (MCS & PCS)	Between the groups difference favors I-group ($p<0.03$). *BBS:* I-group 1: -0.3 units (ns) C-group 2: +1.0 units (ns) *ABC:* I-group 1: +5.8 units (ns) C-group 2: +2.4 units (ns) No between the groups differences. *Muscle strength:* I-group 1: +0.2 units (ns) C-group 2: -0.2 units (ns) No between the groups differences. *Spasticity:* I-group 1: -0.3 units (ns) C-group 2: +1.0 units (ns) No between the groups difference.

						Quality of Life: PCS: I-group 1: +0.5 units (ns) C-group: -0.4 units (ns) MCS: I-group 1: -1.6 units (ns) C-group: +0.8 units (ns) No between the groups difference.
Gorman 2016[81] Moderate quality PEDro=4	USA	RCT	n=18 Post injury time: >12 months AIS grade: C & D Inclusion: Able to hold up-right posture min 30 min Number of subjects not completing the study: 4	**I:** Robot BWSLT 20-45 min 3/wk x 12 wks **C:** Home stretching 20-25 min 3/wk x 12 wks	*Cardiovascular fitness*: peak VO_2 *Other:* DXA evaluation *Muscle strength*: LEMS	Cardiovascular fitness: I-group: +12.3% (sign.) C-group:+3.9% (ns) Between the groups difference in change in peak VO_2 ($p<0.002$).
Lam 2015[91] 2015	Canada	RCT	n=15 Post injury time: >12 months AIS grade: C & D	**I:** Robot BWSLT with resistance 45 min	*Speed:* 10MWT *Endurance:* 6MWT	Improvements in walking speed +0.1 m/s and endurance +19.6 m across

High quality PEDro=8			Inclusion: Ability to walk on a treadmill without assistance Number of subjects not completing the study: 2	3/wk x 12 wks **C:** Robot BWSLT with conventional set up 45 min 3/wk x 12 wk	*Other:* SCI-FAP	all subjects but no between- group differences. Skilled walking had sign. between the group change favoring the I-group
Mirbagheri 2015[82] Moderate quality PEDro=4	USA	RCT	n=46 Post injury time: Chronic AIS grade: C & D Inclusion: Ability walk or lower limbs range of motion within functional limits for walking. Number of subjects not completing the study: not reported	**I:** Robot BWSLT 60 min 3/wk x 4 wks **C:** No intervention	*Ankle stiffness*: Intrinsic stiffness Reflex stiffness	I-group: reduction in ankle stiffness (sign.) C-group: ns.
Duffel 2015[66]	USA	RCT	n=83 Post injury time: >12 months	**I1**: Robot BWSLT <45 min	*Speed:* 10MWT	Minor improvements in walking speed and

Moderate quality PEDro=4 Rated by AMP			AIS grade: C & D Inclusion: Ability walk and lower limbs range of motion within functional limits for walking. Number of subjects not completing the study: not reported	3/wk x 4 wks **I2**: Anti-spasticity medication **C**: No intervention	*Endurance:* 6MWT *Balance:* TUG *Spasticity:* MAS *Functional level*: WISCI II	endurance in the I-groups with no between the groups differences.
Labruyere 2014[83] Moderate quality PEDro=6	Switzerland	RCT Cross over	n=9 Post injury time: >12 months AIS grade: C & D Inclusion: Ability to walk with at most, moderate assistance Number of subjects not completing the study: 0	**I:** Robot BWSLT 45 min 4/wk x 4 wks **C:** Strengt training 45 min 4/wk x 4 wks	*Walking speed:* 10MWT *Endurance:* 6MWT FET *Gait symmetry* *Muscle strength*: LEMS, UEMS *Balance:* BBS, sway *Spasticity:* MAS	*Walking speed:* Between the groups difference was observed in maximal walking speed that improved significantly ($p<0.04$) favoring C-group. *Other:* Post training pain reduction was observed in both groups but the between the groups

					Functional level: SCIM, WISCI II *Other:* FES, VAS pain, PCI	difference favored the C-group (p<0.01).
Varoqui 2014[67] Moderate Quality PEDro=6 Rated by AMP	USA	RCT	n=15 Post injury time: >12 months AIS grade: C and D Inclusion: Ability to take at least one step independently Number of subjects not completing the study: not reported	**I:** Robot BWSLT 60 min 3/wk x 4 wks **C:** No intervention	*Speed:* 10MWT *Endurance:* 6MWT *Balance:* TUG *Spasticity:* MAS *Muscle strength:* MVC Ankle kinematic	*Speed:* I-group: +0.08 m/s (sign.) C-group: n.s. *Balance:* I-group: +6.3 sec (sign.) C-group: n.s. *Muscle strength:* I-group: improved strength in ankle muscles (sign.) and ankle kinematic (sign.) C-group: n.s.
Niu 2014[68] Moderate quality	USA	RCT	n=40 Post injury time: >12 months AIS grade: B,C and D	**I:** Robot BWSLT <60 min 3/wk x 4 wks **C:** No intervention	*Speed:* 10MWT *Endurance:* 6MWT *Balance:* TUG *Spasticity:* MAS	*Speed:* I-group: +0.13 m/s (sign.) for high functioning group C-group: ns.

PEDro=5 Rated by AMP			Inclusion: Spastic hypertonia in lower extremities Number of subjects not completing the study: 0		*Muscle strength:* MVC	*Balance:* I-group: -1.6 sec (sign.) for low functioning group C-group: ns. *Muscle strength:* Can predict walking capacity classification (sign.)
Brazg 2017[89] Moderate quality PEDro=6	USA	RCT Crossover	n=17 Post injury time: >12 months AIS grade: C and D Inclusion: walking speed <1.0 m/s without physical assistance but with assistive devices Number of subjects not completing the study: 2	**I:** Manual BWSLT with maximal heart rate 70-85% 60 min 3-5/wk x 4-6 wks **C:** Manual BWSLT with maximal heart rate 50-65% 60 min 3-5/wk x 4-6 wks	*Speed:* Treadmill speed and gait mat *Endurance:* 6MWT *Muscle strength:* LEMS *Balance:* BBS *Other:* VO_{2peak} VO_{2macth} $VO_{2peak-match}$ O_{2cost}	*Speed:* Treadmill speed: I-group: 0.2 m/s (sign.) C-group: 0 m/s (n.s.) *Endurance:* I-group:+27 m (n.s.) C-group:+14m (n.s.) *Muscle strength:* I-group: -1 units (n.s.) C-group: +1 units (n.s.) *Balance:* I-group: +2 units (n.s.) C-group: +1 units (n.s.) *Other:*

				4 weeks wash-out period		$VO_{2\ peak\text{-}match}$: I-group:-3 ml/kg/min (sign.) C-group:-1 ml/kg/min (sign.)
Kapadia* 2014[87] Moderate quality PEDro=5	Canada	RCT	n=34 Post injury time: >12 months AIS grade: C & D Inclusion: non-walkers and those who used walking aids or had walking speed <0.5m/s Number of subjects not completing the study: 7	**I:** Manual BWSLT with functional electrical stimulation 45 min 3/wk x 16 wks **C:** Aerobic/ resistance training 45 min 3/wk x 16 wks	*Speed:* 10MWT *Endurance:* 6MWT *Balance:* TUG *Spasticity:* MAS *Biomechanics:* Pendulum test *Functional level:* SCIM FIM ADS WMS	*Speed:* I-group: +0.1 m/s (sign.) C-group: +0.1 m/s (sign.) No between the groups differences *Endurance:* I-group: +29.2 m (sign.) C-group:+51.5 m (sign.) No between the groups differences *Balance:* I-group: -10.6 sec (sign.) C-group: -12.1 sec (sign.) No between the groups differences

						Spasticity, biomechanics and functional level: SCIMT – mobility was only between the groups difference favoring the I-group (p<0.003)
Hitzig* 2013[84] Moderate quality PEDro=5	Canada	RCT	n=34 Post injury time: >12 months AIS grade :C & D Inclusion: no specific to related to walking Number of subjects not completing the study: 7	**I:** Manual BWSLT with functional electrical stimulation 45 min 3/wk x 16 wks **C:** Aerobic/ resistance training 45 min 3/wk x 16 wks	*Functional level:* SCIM - mobility *Quality of Life:* SWLS *Participation:* IADL CHART RNL	*Functional level:* I-group: +4.1 units (sign) C-group: -1.7 units (n.s*)* between the groups difference favoring the I-group (p<0.003).
Adams 2011[88] Moderate quality	Canada	RCT Cross-over	n=7 Post injury time: >12 months AIS grade: A, B & C Inclusion: wheelchair as primary mode of mobility	**I:** Manual BWSLT 45 min 3/wk x 4 wks **C:** Tilt-table standing 45 min	*Spasticity:* MAS and other spasticity assessments *Quality of Life:* QLI SCI *Functional level:*	*Spasticity:* Overall no change in muscle tone. *Quality of Life:* Effect size 0.5 in QoL favoring BWSLT.

PEDro=5			Number of subjects not completing the study: 0	3/wk x 4 wks 4 weeks wash-out period	FIM – motor score	
Field-Fote 2011[85] Moderate quality PEDro=6	USA	RCT	n=74 Post injury time: >12 months AIS grade: C & D Inclusion: Ability to take at least one step with one leg and ability to rise to standing position with moderate assistance from one person. Number of subjects not completing the study: 10	**I1:** Manual BWSLT 60 min 5 d/wk, 12 wks **I2:** BWSLT with functional electric stimulation 60 min 5 d/wk, 12wks **I3:** OGT with functional electric stimulation 60 min 5 d/wk, 12 wks **I4:** Robot BWSLT 60 min 5 d/wk, 12 wks	*Speed:* 10MWT *Endurance:* 2MWT *Muscle strength:* LEMS	*Speed:* I-group 1: +0.1 m/s (sign.) I-group 2: +0.1 m/s (sign.) I-group 3: +0.1 m/s (sign.) I-group 4: 0 m/s (n.s.) No between the groups differences. *Endurance:* I-group 1: +0.8 m (n.s.) I-group 2: +3.8 m (sign) I-group 3: +14.2 m (sign) I-group 4: +1.2 m (n.s.)

						Between the group difference: Favoring I-group 3 ($p \leq 0.01$). *Muscle strength:* I-group 1: +1.6 units (sign) I-group 2: +1.6 units (sign) I-group 3: +1.4 units (sign) I-group 4: +1.3 units (sign) No between the groups differences.
Alexeeva 2011[86] High quality PEDro=7	USA	RCT	n=35 Post injury time: >12 months AIS grade: C & D Inclusion: voluntary movement at least one leg, ability to rise to standing	**I1:** Manual BWSLT 60 min 3 d/wk, 13 wks **I2:** OGT with body-weight support 60 min 3 d/wk, 13 wks	*Speed:* 10MWT *Balance:* Tinetti scale *Muscle strength:* MMT /LEMS *Spasticity:* MAS	*Speed:* I-group 1: +0.2 m/s (sign.) I-group 2: +0.1 m/s (sign.) I-group 3: +0.1 m/s (sign.)

			position with (at most) moderate assistance and independently move at least one leg. Number of subjects not completing the study: 5	**I3:** Conventional PT 60 min 3 d/wk, 13 wks	*Functional level:* FIM-L *Cardiovascular fitness*: VO_{peak2} *Quality of Life:* Subset of SAWS, SF-36	*Balance:* I-group 1: +0.6 units (n.s.) I-group 2: +1.4 units (sign.) I-group 3: +2.8 units (sign.) Between the group difference: Favoring I-groups 2&3 ($p<0.01$). *Muscle strength (MMT):* I-group 1: +6.6 units (sign.) I-group 2: +3.8 units (sign.) I-group 3: +5.5 units (sign.) No between the groups differences *Cardiovascular fitness:* No effect

						Quality of Life: 80% reported improved satisfaction with abilities and well-being across the groups ($p<0.05$).

Methodological quality of studies by using the PEDro rating scale: High quality when studies were rated 7-10, moderate quality when rated 4-6 and low quality <3 score (63). AMP reviewed and assessed those trials that were not included in the database. * Abbreviations: n: number of subjects; BWSLT: Body-Weight Supported Locomotor Training; I: Intervention group; C: Control group; VO_2: Oxygen uptake; 10MWT: 10 Meter Walk Test; 6MWT: 6 Minute Walk Test; BBS: Berg's Balance Scale; ABC Scale: The Activities-specific Balance Confidence Scale; LEMS: Lower Extremity Motor Score; MAS: Modified Ashworth Scale; WISCI II: Walking Index for Spinal Cord Injury version II; SF-36: Short Form 36; MCS: Mental Component Score; PCS: Physical Component Score; DXA: Bone densitometry; SCI-FAP: Spinal Cord Injury-Functional Ambulation Profile; TUG: Timed Up and Go test; FET: Figure Eight Test; UEMS: Upper Extremity Motor Score; SCIM: Spinal Cord Independence Measure; FES: Falls Efficacy Scale; VAS: Visual Analog Scale; PCI: Physiological Cost Index; MVC: Maximal Voluntary Contraction; FIM: Functional Independence Measure; ADS: Assistive Device Score; WMS: Walking Mobility Scale; SWLS: Satisfaction With Life Scale; IADL; Lawton Instrumental Activities of Living; CHART: Craig Handicap and Assessment Reporting Technique; RNL: Reintegration to Normal Living; QLI SCI: Quality of Life Index spinal cord injury; OGT: Over Ground Training; 2MWT: 2 Minute Walk Test; MMT: Manuel Muscle Test; SAWS: Satisfaction with Abilities and Wellbeing Scale.

Choices for gait training in SCI

In BWSLT the subjects wear a harness and are suspended in a body-weight support system, and either receive manual assistance or use a robotic device for the actual gait training. *BWSLT with manual assistance* requires great and expensive human resources (Fig.2). Each training session needs a team of 2–5 persons to assist movements of hips and lower limbs. This approach allows specific adjustments during the gait cycle, and permits step-by-step adjustments that may improve the training effects. The sessions require heavy, long-lasting work for the therapists involved. Their skills may vary, and this may cause problems during training sessions and limit the training effects as it is difficult to maintain standardization of the training staff. In an attempt to avoid these challenges, robotic devices have been developed to move the lower limbs in a more standardized way. One difference between the two BWSLT methods is that the robots less sensitive in capturing any movement from the subject and thus do not adequately reduce assistance given, as needed, to the same degree as is done in the manual BWSLT approach. Robot-assisted BWSLT (Fig. 3) moves lower limbs through the entire gait cycle, whereas manual facilitation of movements can adjust the assistance given to specific and/or weak part of the gait cycle. Thus, subjects may perform better with manual assistance on a treadmill, without the possibility to lean solely on gait orthosis.

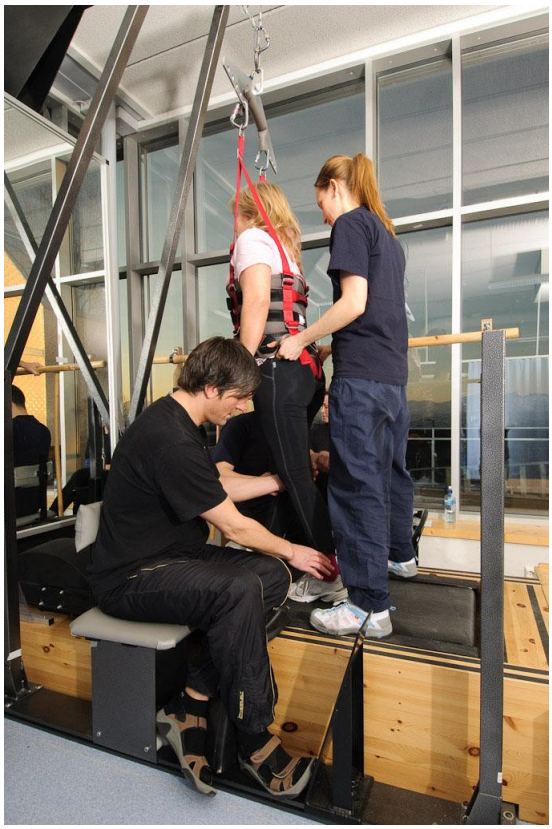

Figure 2 A set up for manual assisted body-weight supported locomotor training. Picture is provided by North Norway Rehabilitation Center and the ATLET study.

There are several types of robotic devices used to recover walking function. The Lokomat (Hocoma, Zurich, Switzerland) uses a system where subjects have body-weight support while walking on a treadmill, and motorized braces move subjects' lower limbs through the trajectories (Fig. 3) (44, 56). A stepping machine-like Gait Trainer (RehaStim, Berlin, Germany), G-EO that utilizes walking movements in a fixed track (Reha technology AG, Olten Switzerland) and Kineassists (HDT Global, Fredricksburg, VA, USA) which uses body-weight support around the pelvis, and the treadmill which reacts to subjects' initiation of the movement. In addition, robotic exoskeletons for over ground walking have been developed. However, these devices require better balance, upper limb strength / function and postural control to walk, unlike treadmill-based BWSLT systems were subjects can rely on the body-weight support system to stand and walk.

During BWSLT with a robot (Lokomat), the subjects' feet and hips are fastened to motorized orthoses, and during stepping on a treadmill, the subjects will receive feedback on a screen, indicating the degree of effort they exert. Computer software controlled motors, matched with the speed of the treadmill, move the subjects' lower limbs through trajectories that imitate normal physiological walking patterns. Each training session requires only one therapist, and

longer bouts of training are feasible. However, the equipment is expensive. Detailed descriptions exist for both manually assisted and robot-assisted BWSLT (40, 42, 43, 46, 56).

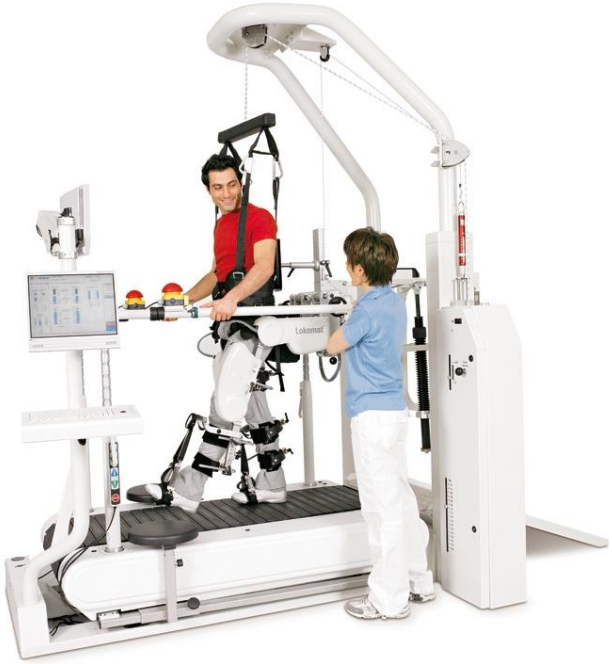

Figure 3 A set up for robot-assisted body-weight supported locomotor training. Picture is provided by HOCOMA.

Most trials on BWSLT have had a duration of 4-16 weeks, with a training frequency of 2-5 times per week and sessions duration from 30-60 minutes (54). So far, few randomized clinical trials have directly compared robot and manually assisted BWSLT (54). Collaboration within the Norwegian rehabilitation environment made it possible to conduct a randomized controlled clinical trial to investigate the independent effect of the two approaches.

Experiences from a pilot feasibility study

We conducted a pilot study before starting our RCTs. Eight inpatients with stable, incomplete traumatic SCI (mean age 50 years, mean time since injury 3.7 years, and using a wheelchair) were enrolled. They underwent on average 55 days of manual assisted BWSLT (written informed consent, approval from the Regional Ethical Committee (REK NORD 37/2009)). Five of eight subjects had some walking function at baseline, and experienced a statistically significant improvement in their walking function. Those with injury more than one year prior to training, showed the greatest improvement in motor function. The remaining three subjects showed no significant improvement in gait, although, they reported generally reduced spasticity, improved postural control, and better voluntary control of the lower extremity muscles. In addition, those who were unable to walk, reported increased sensibility and

sweating function in their lower extremities, and finally, they required less manual assistance on the treadmill.

Unresolved questions for the thesis

There are indications that early gait training in motor incomplete SCI, irrespective of training method, generally improves over ground walking (54). Subjects with chronic incomplete SCI (>1 year post-injury) also improve over ground walking after participation in a systematic gait-training program. However, several questions remain with regards to understanding which method of gait training is most useful, and which subjects will benefit the most from gait training. For instance, it is not clear whether subjects with more severe physical function deficit benefit from the training. Comparison between manually assisted and robot-assisted locomotor training has been difficult due to difference in intensity of training, duration and evaluation instruments (54, 92). Thus, there is no clear evidence favoring manual or robotic training for improving locomotor function in subjects with incomplete SCI (54). The only psychological aspects that have been included in the studies reviewed are well-being and psychological welfare (84, 86, 88). Other psychological variables such as expectations regarding the outcome of the treatment, perceptions of control and mastery (barrier exercise self-efficacy) and motivation for the training may both influence the functional outcome of physical training, as well as the HRQOL(33, 34).

2 The aims of the thesis

The aims of this thesis were to:

1. Evaluate the effects of body-weight supported locomotor training with manual assistance compared to a control group receiving low-intensity usual care, in subjects with long-standing motor incomplete spinal cord injuries and poor baseline walking function. (Paper I)

2. Evaluate the effects of body-weight supported locomotor training with robot-assistance compared to a control group receiving low-intensity usual care, in subjects with long-standing motor incomplete spinal cord injuries and poor baseline walking function. (Paper II)

3. Evaluate effects on health-related quality of life and psychological outcomes after participation in body-weight supported locomotor training programs compared to a control group receiving low-intensity usual care in subjects with long-standing motor incomplete spinal cord injuries and poor baseline physical function. (Paper III)

3 Material and methods

3.1 Study design in the ATLET study

The same study design was used for the two RCTs in this thesis. We chose a single-blinded, controlled randomized efficacy clinical trial design for the two independent RCTs that were conducted in parallel during the same time period. The two studies had similar assessments, both recruited subjects with incomplete SCI, and subjects were selected for one or the other study based on their place of residence. Study 1 (Paper I): "Manually assisted body-weight supported locomotor training does not re-establish walking in non-walking subjects with chronic incomplete spinal cord injury: a randomized clinical trial" was conducted in an in-patient setting (Tromsø), and included subjects from all of Norway, except those living in the Oslo area, who were included in Study 2 (Paper II): "Robot-assisted locomotor training did not improve walking function in patients with chronic incomplete spinal cord injury: a randomized clinical trial" in outpatient setting. In paper III, we merged data from Study 1 and Study 2 to assess change in HRQOL and psychological variables, with BWSLT outcomes. Figure 4 shows subject flow through recruitment, assessment, intervention and follow-up in the three papers. Collaboration with the various Norwegian rehabilitation environments led to the start of this ATLET study (Avlastet Trening hos Lamme etter Traume); two RCTs to investigate two intensive BWSLT rehabilitation approaches.

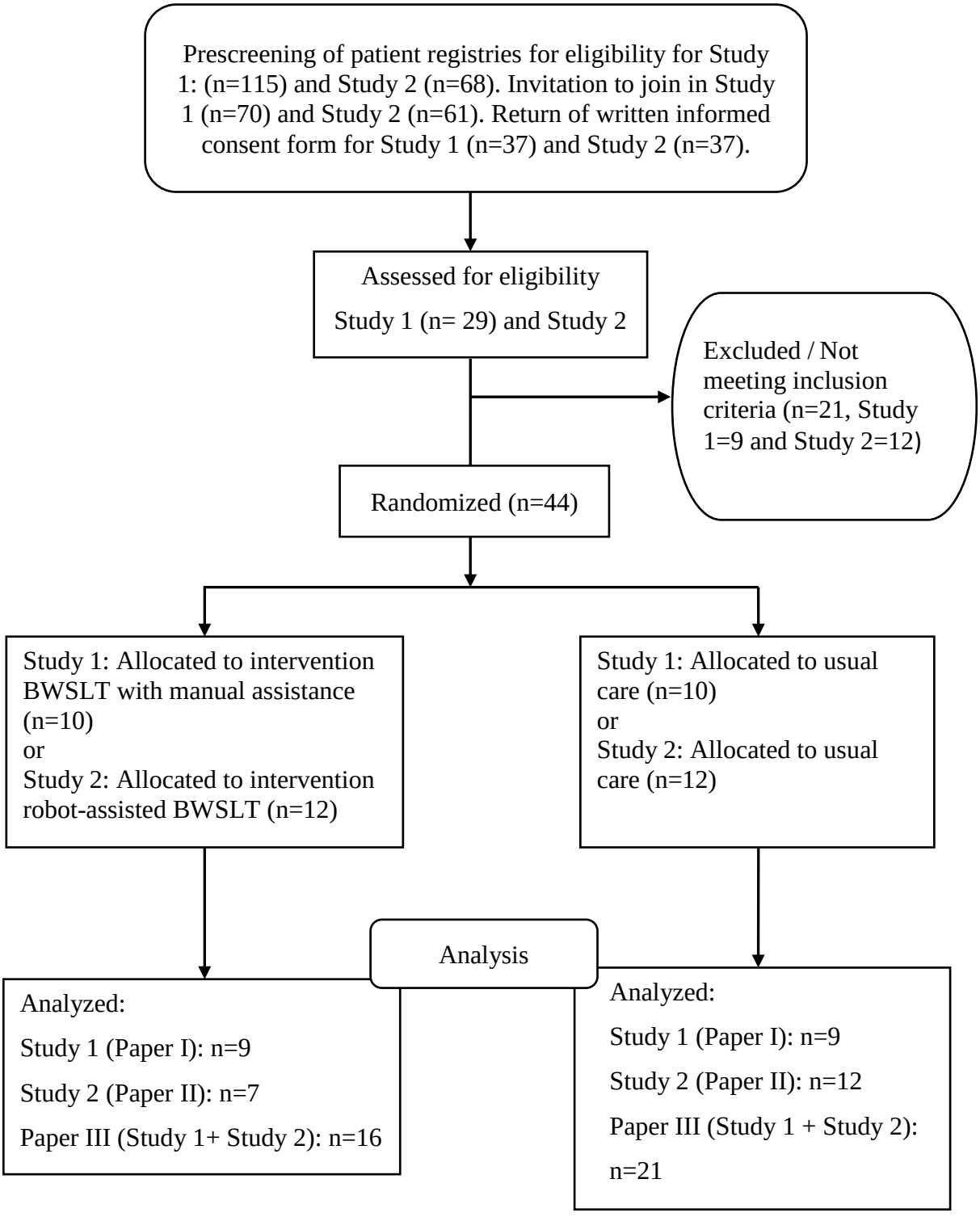

Figure 4: Flow chart of study subjects inclusion in the research papers I, II and III

In Study 1 study subjects were recruited nationwide in Norway through
1) the three SCI units in Nesodden (Oslo), Bergen and Trondheim and
2) advertisements in the magazines for SCI patients and traffic injured patient organizations. In Study 2, subjects were recruited through the Sunnaas rehabilitation Hospital [Nesodden, Oslo], as well as the advertisements using patient organizations that were the same as in Study 1. Recruitment occurred simultaneously for both studies from 2008 through 2017. The original plan was to enrol a total of 60 subjects (30 in each of the two studies).

Inclusion and exclusion criteria for these two studies are listed in Table 4 and were the same for both studies with one exception. To be considered for the robot-assisted BWSLT study 2, the subjects must live within driving distance from the training site in Oslo (≤70 km). Due to the poor recruitment, we increased the age limit of subjects to 70 years and increased the maximal travel distance to the robot intervention site from 30 km to 70 km in Study 2. All subjects in both studies were advised not to change use of spasm reducing medication during the intervention period.

All the pre- and post-intervention assessments were conducted single blinded at Sunnaas rehabilitation Hospital. Pre-assessments were conducted 2-4 weeks prior to start of the intervention/control period, and post-assessments were made 2-4 weeks after completing the intervention or the control period. Subjects in the control groups were offered participation in the same BWSLT program after completing the study. After baseline assessments, subjects in both studies were randomized by the sealed envelope method in blocks of ten, either to intervention or to the control group. The randomization was carried out by the project coordinator in Tromsø.

Table 4 Inclusion and exclusion criteria in The ATLET study.

Study population at the Study 1 and Study 2: Subjects with motor incomplete SCI	**Inclusion criteria:** 1) 18-70 years 2) ASIA Impairment Scale grade C and D (AIS C-D) 3) Post-injury time ≥2 years 4) ≤30 BMI 5) Wheelchair dependent in daily life 6) Cognitively unaffected and motivated for training 7) Study 2: ≤70 km travel distance to the robot intervention site **Exclusion criteria:** 1) Spasticity and contractures which might inhibit training 2) Known osteoporosis in the spine and/ or joints 3) Physical limitations for using the robotic device 4) Pregnancy 5) Participation in other intensive training programs 6) Other medical conditions which may interfere with the training 7) Previous knee- or hip replacement 8) Study 2: travel distance to the robot intervention site to >70 km and physical limitations to use the robotic device.

We used the following equipment in our studies: Study 1: treadmill with body-weight support system (Vigor Equipment, Inc., Stevensville, MI, USA) and Study 2: robotic device was used (Lokomat, version 4, HOCOMA, Zurich, Switzerland).

Organizational structure in the ATLET study

The study had a steering committee that included representatives from the two rehabilitation institutions involved, the Universities of Oslo and Tromsø, and the Norwegian School of Sports Sciences and patient organization representatives (Table 5). Both studies received partial funding from the Norwegian Health Directorate, The Regional Health Authorities and Norwegian Health and Rehabilitation funds. The collaborators work and involvement were funded by internal funds to the respective institutions. Gjensidige insurance company sponsored the LOKOMAT robot through an unrestricted grant.

Table 5 Organizational structure in The ATLET study

The ATLET study collaborators and steering group (2008-2019)	
Collaborators name	**Role**
Department of Health and Care Sciences, Faculty of Health Sciences, University of Tromsø, The Arctic University of Norway	Project coordination and management, co-supervision of PhD candidate
Sunnaas Rehabilitation Hospital, Nesodden Sunnaas Outpatient clinic, Oslo	Pre- and post-assessments, advisory function and co-supervision of PhD candidate Study 2: Intervention site
North Norway Rehabilitation Center, Tromsø	Study 1: Intervention site, advisory function and co-supervision of PhD candidate
Department of Coaching and Psychology, Norwegian School of Sport Sciences, Oslo	Development of the psychological assessments, advisory function
Institute of Clinical Medicine, University of Oslo, Oslo	Advisory function
National Association of the Spinal Cord Injured	Advisory function
National Association of the Traffic Injured	Advisory function

3.2 Interventions

Study 1: Body-weight supported locomotor training with manual assistance

The intervention started 2-4 weeks after randomization. The study protocol for BWSLT included 60 days divided into 3 periods, each of 4 weeks of training, with a total 1.5 hours of intensive gait training daily for 5 days per week during 6 months. Intervention included:

1) BWSLT with manual assistance
2) body-weight supported strength exercises for lower extremities 1-2 times per day and
3) soft tissue mobilization/ stretching – before/ after each training session.

In addition, over ground training was incorporated in the training protocol, to transfer learned skills from treadmill to the community environment. The duration of each training session and the progression was determined by the subjects' daily condition. A team of 3-5 therapists was needed to facilitate the movements in the lower limbs and pelvis with a minimum of 20 min of walking daily depending on subjects' function/ fitness. Subjects also received home

exercises for use after each completed 4-weeks training period. These exercises followed the same principles as the general BWSLT, to transfer learned skills from treadmill to community environment in a safe manner and with use of appropriate assistive devices such as walker, crutches with or without use of braces, using standing frame etc. depending on subject's functional level. Subjects with no ability to stand independently could for instance use standing frame/table to load the lower extremities.

Study 2: Body-weight supported locomotor training with robot-assistance

As for Study 1, the outpatient intervention group in Study 2 received 60 robot-assisted BWSLT sessions over 6 months, 3 times per week. Each session lasted for 60 min on treadmill, with total time 1.5 hours inclusive preparation for training. Subject's lower limbs and hips were strapped to the exoskeleton, and during walking on the treadmill, subject received visual feedback on his/her own contribution to the movements. Body-weight support, speed and guidance force were adjusted to the subjects daily condition, and these training parameters were used to guide the progression in the sessions. The training session was supervised and controlled by one therapist. Duration and progression of the training session depended of the same factors as in the Study 1. Similarly, subjects in this study also received soft tissue mobilization/ stretching of lower limbs as preparation for training, and were prescribed home exercises after finished training sessions, similar to those in Study 1.

Control groups in Study 1 and Study 2

There were independent control groups in each of the two studies. The control groups in both studies received the low-intensity usual care treatment/ training with their local physical therapists, since this is common practice in the chronic stage of SCI. To ensure compliance, subjects daily recorded their daily activities in a diary. They recorded the length of all physical activities, the kind of activity and the number of daily training sessions. They also counted other physical activities that occurred during everyday life, for example doing home exercises, swimming or driving a manual wheelchair. Subjects submitted their diaries once a month, and received follow-up-calls from the project coordinator. Unfortunately, collection of the diaries was incomplete since some of the subjects were non-compliant in returning them to the project coordinator. At the end of the control period, control subjects in both studies were invited to receive the same BWSLT as the intervention group had received, and 62% of them accepted this post-intervention training.

3.3 Evaluation and outcome measures in ICF framework

The selected evaluations and assessments in our study reflects the ICF framework: Body structure and functions for neurological evaluation, activity for functional evaluation and participation for Quality of life (4). The evaluation and assessments were identical in Study 1 and Study 2. Prior to randomization subjects underwent evaluation within one month before the active study period. Likewise, post-evaluation took place 2-4 weeks after completing 60 days of training. The evaluators (physicians and physical therapists) were blinded to the patients' group allocation in both studies, and they were not involved in providing the interventions. Our primary outcome was complete or partial recovery of walking function and secondary outcomes were change in physical function (walking speed, endurance, lower limb muscle strength, balance and aerobic capacity). Additionally, HRQOL and psychological outcomes were assessed in both studies. Table 6 provides an overview of our assessments in both Study 1 and Study 2, with reference to papers of the thesis where they were used.

Table 6 Overview of outcome measures collected in the ATLET study (both for Study 1 and Study 2) and reported in the papers I, II and III

Variables	Paper I	Paper II	Paper III
Sociodemographic variables (Personal factors)			
Age at time of intervention (in years)	X	X	X
Year of injury (and time since injury)	X	X	X
Gender	X	X	X
Need of home health care (nurse or personal assistant)	X	X	X
Education, work, marital status etc.	X	X	X
Use of assisted devices for primary ambulation	X	X	
Neurological impairment and physiological evaluation (Body structure and functions): pre and post test			
ASIA classification inclusive LEMS	X	X	X
Peak VO_2 max ml/kg/min (arm ergometer)	X		X
Functional evaluation (Activity): pre and post test			
Walking assessments (10MWT, 6MWT)	X	X	X
Balance assessments (BBS, MFR)	X	X	X
Health-related quality of life (Participation), psychological factors (Personal factors) and physical activity (Activity): Self-administrated Questionnaires- pre and post test			
HRQOL (SF-36) (Participation)			X
IPAQ-SF (Physical activity)			X
EBSE (Personal factors)			X
BREQ - motivation (Personal factors)			X
Outcome expectations (Personal factors)			X

Abbreviations: LEMS: Lower Extremity Motor Score; 10MWT: 10 Meter Walk Test; 6MWT: 6 Minute Walk Test; BBS: Berg's Balance Scale; MFR: Modified Functional Reach test; VO2: Oxygen uptake; SF-36: Short Form 36; HRQOL: Health-Related Quality of Life; IPAQ-SF: The International Physical Activity Questionnaire Short Form; EBSE: Exercise barrier self-efficacy; BREQ: The Behavioral Regulation in Exercise Questionnaire.

3.3.1 Neurological impairment and physiological evaluation (Body structure and functions)

In the context of the ICF classification "body structure and functions" subcategory neurological impairment, our subjects' injury level and severity of the injury were assessed by the American Spinal Injury Associations' (ASIA) and ASIA Impairment Scale (AIS) (7), as recommended for RCTs in SCI populations (15). Lower extremity motor score (LEMS), a subscale in the ASIA classification, measures motor recovery and reflects the level of the impairment and neurological recovery (7). LEMS assessed muscle strength and was determined by experienced physicians. The scores vary from 0-5 for each of five key muscles of the right and left lower limbs, with a maximum score of 50 for both lower extremities (7, 93). LEMS has been shown to be a reliable and valid test (94-97). It correlates well with outcome measures of walking function: correlation coefficient with walking speed -0.5 ($p<0.04$), endurance/ distance walked 0.5 ($p<0.01$) and level of walking function 0.5 ($p<0.02$) (98).

Maximal oxygen uptake is the amount of oxygen used during maximal exercise in activities that require use of large muscle groups in upper or lower extremities or both, and is commonly used to measure aerobic capacity (99, 100). An arm crank ergometer was used to assess aerobic capacity (Lode Angio, Groningen, the Netherlands). It was a stepwise, graded exercise test until exhaustion. During the tests, VO_2 (l/min and ml/kg/min), carbon dioxide production (VCO_2; l/min), respiratory exchange ratio, and pulmonary ventilation (VE; l/min) are continuously measured by a computerized standard open-circuit technique breath-by-breath spirometer (Vmax 220 Sensormedics Corporation, USA). These results are reported in Paper 1 only.

3.3.2 Functional evaluation (Activity)

In the context of the ICF classification activity, we measured motor function with different assessments. Walking function was assessed by using the 10-meter walk test (10MWT) for walking speed and the 6-minute walk test (6MWT) for endurance/ distance walked (98, 101, 102). In the 10MWT, subjects were asked to walk 10 m as fast as possible with a dynamic start (103). It was completed twice, and the mean of the two time periods was used for analysis. In 6MWT, subjects attempted to cover maximal distance in an over ground gait during six minutes, and it was measured as meters. In both tests, subjects were allowed to use walking aids and braces that they normally used to ambulate/ walk. Both tests were performed in the same corridor with a walking course of 30 m length. Both tests are described as valid

and reliable in SCI populations (101, 103). The 10MWT has shown high degree of agreement among raters (inter/intra reliability, 0.98), for flying start and a similar finding of 0.98 for inter/intra reliability is also reported for the 6MWT among the chronic SCI population (103).

Berg's balance scale (BBS) was used to assess dynamic balance (104). BBS is a valid and reliable measure that commonly is used on the SCI population (104-106). It is a scale with 14 items (scores 0-4 per item, and maximal score 56) for assessment of a subject's ability to maintain a challenging position and transitions, with higher scores indicating better balance. The Modified functional reach test (MFR) assessed postural control in subjects with or without the ability to independently stand upright. Subjects were in a sitting position with their shoulders flexed to 90 degrees, and were then asked to lean forward as far as possible and come back to the upright sitting position without using their hands for support. Measures were recorded from the ulnar styloid process, since tetraplegic subjects usually are unable to make a fist (107). It distinguishes between tetraplegia and paraplegia (107). MFR is also a reliable test for subjects with SCI (107), and concurrent validity (the degree to which results from one test agree with results from other different tests) has been shown to be good among stroke subjects (108).

3.3.3 Health-related quality of life (Participation) and psychological assessments (Personal factors)

In the context of the ICF classification participation and personal factors, we assessed quality of life and other psychological aspects among study subjects. HRQOL and psychological outcome evaluation was done prior to randomization using self-administered questionnaires, and again at post-evaluation. We collected data about demographic characteristics and used standardized questionnaires to assess HRQOL, physical activity, self-efficacy and motivation (33, 34). All these assessments forms have been used previously in subjects with SCI and disabilities. We merged data from Study 1 and Study 2, and results are presented in Paper III.

HRQOL was measured by the 36-Item Short-Form Health Status Survey (SF-36), (version 1.2 chronic) (30, 109). This questionnaire has been widely used and validated, and provides reliable assessments of eight health-related components from limitation of physical functioning due to health problems to questions on general mental health (109, 110). These eight subscales can be merged into a physical component score (PCS) and a mental component score (MCS). These scores are reported in Paper III. Higher scores indicate better perception of physical and mental HRQOL.

The other outcomes were assessment of physical activity, exercise barrier self-efficacy, and motivation for physical activity. The International Physical Activity Questionnaire short version (IPAQ-SF) is a valid and reliable tool to collect information about physical activity during the last seven days, and it assesses time spent on various activities such as walking/ wheeling, sitting, etc. (111). Scoring and reporting was managed according to the guidelines to IPAQ-SF (available at: https://sites.google.com/site/theipaq/home). IPAQ has been used also in the Norwegian SCI population as well as with other disabilities (36, 112)

Exercise barrier self-efficacy (EBSE), refers to the belief in own ability to exercise in spite of barriers. Higher self-efficacy positively influences effort spent in pursuit of goals and the likelihood of obtaining results (33). This was assessed with 14-items, each rated on a scale of 1-7 (113). The Behavioral Regulation in Exercise Questionnaire (BREQ), with 14- items, each with a scale of 1-7, assessed motivation regulation (114). Type of motivation is measured along a continuum from external, identified, introjected and intrinsic motivation. We merged these subscales and reported motivation as autonomously regulated (intrinsic and introjected) and controlled motivation (external and identified) (35, 114). Higher scores showed greater agreement with the autonomously or controlled forms of motivation and EBSE scores. These psychological questionnaires are well tested and validated (114-116).

Outcomes expectations were assessed by asking the subjects to note three expectations that they believed would be gained from the training. Additionally, they were asked to rate each expectation on a visual analogue scale from 0-100 with respect to how well they thought they were able to meet the expectations (117, 118).

3.4 Statistical analysis, sample size and power

The data were analysed with the versions 23.0.and 25.0 of IBM SPSS for Windows (IBM SPSS, Armonk, New York) for all three papers. Table 7 gives an overview of the statistical methods used in papers I, II and III. Descriptive statistics were used to characterize the study subjects in Paper I, Paper II and Paper III, where the data from Study 1 and Study 2 were merged. In all three papers, we used parametric independent samples t-test or Pearson's Chi-square test or Fisher's exact test to assess baseline characteristics and differences between the intervention and the control group. Non-parametric tests were used where the data did not meet the normality assumption. To compare pre- and post-assessment within each group, non-parametric tests as well parametric paired sample t-test were used to assess change in the pre-assessment values (pre-to post-assessments) within each group in Paper I and II. Independent

samples t-test was used for between group analyses (two-tailed test with significance level $p<0.05$) in all three papers. In addition, in Paper I, due to small sample size, the intervention and control groups had some imbalance at baseline, and we therefore used linear regression to assess differences in change in physical function between the intervention group and control group, adjusting for age, gender and use of anti-spastic medication, as these potentially could be related to treatment effect. In Paper II, due to small sample size, we reported the effect size as mean change and range (not SD), since this better reflected the characteristics of the distribution.

Because the baseline characteristics were similar in the two studies, we decided that for paper III, we would combine the data from the two independent studies, and thus increase the total number of subjects in each group. This gave power to report on HRQOL and psychological outcomes. In Paper III the main analysis compared mean changes from baseline to final evaluation at the end of the 60 training days, in the combined intervention groups vs the combined control groups (merged data from Study 1 and Study 2). Student's t-test for independent samples (two-tailed test with significance level $p<0.05$) was used for the majority of analyses. However, data that were not normally distributed, were analysed using the Mann Whitney test. Chi-square test/Fisher Exact test was used for categorical variables. In addition, we assessed clinical importance, and we used the minimal clinically important difference (MCID) with the analytic distribution-based approach. A result of an outcome measure, a 0.5 standard deviation (SD) improvement of the baseline value is considered the threshold for a MCID in HRQOL and chronic conditions (119). We calculated MCID for HRQOL and psychological variables.

Table 7 An overview of the statistical methods used in the papers I, II and III.

Methods	**Paper I**	**Paper II**	**Paper III**
Descriptive statistics			
Frequency (n), percent (%)	X	X	X
Median, range	X	X	X
Mean SD or range	X	X	X
Statistical methods			
Independent samples t-test	X		X
Mann-Whitney test	X	X	X
Chi-square test	X	X	X
Fisher's exact test	X	X	X
Paired samples t-test or Wilcoxon signed rank test	X	X	
Linear regression	X		
Distribution-based approach for minimal clinically important difference			X

Power and Sample Size – With power of 0.80 and an alpha of 0.05 we estimated that 30 subjects (15 in each intervention and control group) were necessary in each of the two studies. These estimations were based on expected difference between intervention- and control group obtained from published literature and findings from our unpublished pilot study (56, 70, 120).

4 Results

The ATLET study became a much longer-lasting RCT than anticipated. Enrolment started in August 2008 and the first interventions in March 2009. Our study was originally scheduled to be completed by 2012, but lasted until 2018. Recruitment was much more challenging than expected, and we were not able to reach the planned 30 subjects per study. In autumn 2018 the steering committee therefore decided that, due to lack of potential participants, the study must stop further recruitment. Figure 4 shows the flow chart of study subjects.

Baseline characteristics

The baseline characteristics of the study subjects in each of the three papers are presented in Table 8, and include subjects that dropped out (Paper I, II, III) and one subject who was excluded from the final analysis of Study 2 (Paper II). For the total sample of subjects (n=44), mean age was 48 years (SD 15), with mean post-injury time 12 years (SD 15), while the corresponding medians were 5 (min 2 – max 54) and 5 (min 2 – max 48) years, respectively in the intervention and the control group. Age, gender and post-injury time distribution were slightly different between Study 1 and Study 2. In Study 1, 15 of 20 subjects were men, compared to12 of 22 in Study 2. Subjects in Study 2 had slightly longer time since injury than in Study 1. However, there was no statistically significant difference in baseline characteristics between Study 1 and Study 2, and therefore it seemed reasonable to merge data from these two studies for the HRQOL and psychological outcomes paper (Paper III).

Table 8 Baseline characteristics of the study subjects in the ATLET study

Variables	Study 1: Manually assisted BWSLT (n=20) (Paper I)		Study 2: Robot-assisted BWSLT (n=24) (Paper II)		Merged total sample from the Study I and Study II (n=44) (Paper III)	
	Intervention (n=10)	Control (n=10)	Intervention (n=12)	Control (n=12)	Intervention (n=22)	Control (n=22)
Age, mean (SD), years	46 (14)	54 (13)	45 (16)	46 (15)	45 (15)	50 (15)
Men, n (%)	6 (60)	9 (90)	7 (58)	5 (42)	13 (59)	14 (64)
Post-injury time, mean (SD), years	9 (10)	6 (6)	14 (19)	15 (18)	12 (15)	11 (15)
Post-injury time, median, (min-max), years	5 (2-33)	3 (2-22)	4 (2-54)	7 (2-48)	5 (2-54)	5 (2-48)
Traumatic SCI, n (%)	4 (40)	6 (60)	10 (83)	6 (50)	14 (64)	12 (55)
AIS D, n (%)	7 (70)	7 (70)	9 (75)	6 (50)	16 (73)	14 (64)
Injury level, n (%):						
Cervical	3 (30)	5 (50)	5 (42)	6 (50)	8 (36)	11 (50)
Thoracic	4 (40)	4 (40)	4 (33)	6 (50)	8 (36)	10 (45)
Lumbar	3 (30)	1 (10)	3 (25)	0 (0)	6 (27)	1 (5)
Primary ambulation in wheelchair, n (%)	8 (80)	8 (80)	11 (92)	12 (100)	19 (86)	20 (91)
LEMS, mean (SD)	26.9 (13.0)	28.3 (12.6)	26.8 (7.4)	27.1 (11.9)	26.9 (10.1)	27.7 (11.8)

Characteristics of the dropouts

There were 6 subjects who dropped out for personal reasons, and 1 was excluded due to non-compliance. The characteristics of the dropouts are listed in Table 9. They had high expectations to improve their physical function, similar to those who completed the interventions (Paper III). One subject in Study 2 (Paper II and III) was excluded from the final analysis due to noncompliance with the study protocol, which stated that subjects must complete a minimum of 30 days of training in order to be included in the final study population. This female subject, 21 years old with 3 years of post-injury time, was classified as AIS D, had a thoracic lesion and used a wheelchair as primary method for mobility/ ambulation. The information for this subject is not included in Table 9.

Table 9 Baseline characteristics of the study subjects that dropped out from the ATLET study

	Study 1		Study 2		TOTAL dropouts
	I-group (n=1)	C-group (n=1)	I-group (n=4)	C-group (n=0)	6
Age in years, mean (min-max)	51	69	34 (20-58)	0	43 (20-69)
Men, n	0	1	3	0	4
Woman, n	1	0	1	0	2
Post-injury time, mean (min-max), years	4	9	6 (2-16)	0	6 (2-16)
Injury level:					
Cervical	0	1	1	0	2
Thoracic	1	0	0	0	1
Lumbar	0	0	3	0	3
Traumatic SCI, n	0	1	4	0	5 of 6
AIS D, n	1	1	2	0	4
AIS C, n	0	0	2	0	2
Week of dropout:					
<2 of 26 total wks	1	0	2	0	3
13-18 of 26 total wks	0	1	2	0	3
Primary ambulation in wheelchair, n	1	0	4	0	5 of 6
LEMS, mean (min-max)	42	43	23 (18-30)	0	29 (18-43)

4.1 Summary of results in Paper I

The aim of Paper 1 was to evaluate the effects on physical function of BWSLT with manual assistance compared to usual care, in subjects with chronic incomplete SCI and severely reduced walking function. Twenty subjects were randomly assigned, either to the manually assisted BWSLT that included training 5 days per week during three in-patient stays each of 4-weeks. The outpatient control group received low-intensive usual care. The primary outcomes were strength in lower extremity and walking function, and secondary outcome was balance.

We were unable to recruit sufficient number of study subjects, and the final study group consisted of only 66% of the target sample size (n=30). Thus, the study suffered from inadequate statistical power. The intervention group experienced marginally significant improvement in lower extremity strength (2.1 points, SD 2.8, p=0.05) and non-significant improvement in Modified Functional Reach (MFR) (+0.8cm, SD 15.4, n.s.) from baseline to post test. MFR decreased in the control group (-5.8 cm, SD 6.9, p=0.04). There was no significant difference in change between the intervention and the control group in regards to strength, balance, walking speed or distance walked.

We concluded that 60 days of BWSLT with manual assistance was well tolerated, with statistically non-significant improvements in strength in lower extremity muscles and walking speed when compared to the control group. Among the four subjects who were unable to walk at baseline, no measureable functional improvement in gait was observed, neither in the intervention group nor in the control group. We conclude that our results are inconclusive with respect to our aims.

4.2 Summary of results in Paper II

The aim of the Paper II was to assess effects of robot-assisted BWSLT in an outpatient setting, compared to low-intensity usual care in individuals with chronic incomplete spinal cord injury that had occurred a minimum of two years earlier. Twenty-four subjects were assigned randomly, either to the intervention group that received robot-assisted BWSLT three days per week over 6 months, or to the control group that received usual care. We found that the intervention group showed improvement in muscle strength in the lower limbs and in balance, but walking speed or endurance did not change. The only significant between-group difference was in postural control.

We concluded that 60 days of BWSLT with robot-assistance was well tolerated. Since we were unable to reach the target number of study subjects, (only 63% of the target was recruited), our study was underpowered with non-significant results, and was thus inconclusive. Robot-assisted BWSLT may have some benefits, but the robotic device is costly, and training effects are limited when the subject's baseline physical function is poor and the training starts late after incomplete SCI.

4.3 Summary of results in Paper III

The aim of Paper III was to assess effects on health-related quality of life and psychological outcomes after participation in manually and robot-assisted BWSLT programs in subjects with long-standing SCI and poor physical function at baseline. In order to increase power for this analysis, which was low due to the recruitment problems, we chose to merge the data from the two independent parallel-randomized controlled trials to achieve a total sample size of 44 subjects. Subjects in the combined intervention group (n=16) received 60 days of BWSLT, 3-5 times per week and 60-90 minutes per day/session. The combined control group (n=21) received usual low-intensity care. Prior to randomization and again after the study period, subjects completed a set of standardized questionnaires that assessed HRQOL and psychological factors.

As far as we know, our study is one of the first RCTs that has explored psychological outcomes after BWSLT. We found that study subjects had high self-efficacy, related to ability to exercise in spite of barriers; and they reported strong autonomous motivation at baseline. In addition, at baseline they were physically active and optimistic, expecting improvement of their physical function as a result of participating in the study. We found that neither physical nor mental HRQOL improved during the study period, and there was only a small or no change in physical function. We therefore suggest that questions on individuals' satisfaction should be included in future studies aimed at supporting and improving the psychological welfare and functioning of the chronic SCI population. We cannot exclude the possibility that some unmeasured favourable effects could have occurred, although undetected by our assessment tools. We conclude that our RCT demonstrates that BWSLT in subjects with long-standing incomplete spinal cord injury and poor baseline physical function, does not improve physical outcomes or self-reported HRQOL. Our results cannot, however, be generalized to other settings or to those who have better walking function or shorter time since SCI.

5 Discussion

In subjects with long-standing motor incomplete spinal cord injuries and poor baseline walking function, the ATLET study failed to show an effect on muscle strength or walking function, of BWSLT when compared to low intensity usual care when such training started many years post-injury. This was the case both for manual assisted and robot-assisted BWSLT. The lack of effect was true also for physical function and HRQOL. Due to recruitment problems, we were unable to achieve sufficient power, and therefore we cannot approve or confirm any beneficial effect of the training methods, as our results were non-significant and inconclusive. This is discussed further under limitations.

Rehabilitation of individuals with spinal cord injuries is demanding and expensive, and patients' and therapists' enthusiasm over new methods and devices need to be validated by scientific methods before they are adopted as treatments of choice. One challenge is to use assessment tools that can identify those who will most likely benefit from intensive BWSLT (121). In this discussion, we will focus on the methodological choices, the challenges encountered and the results. Our experience illustrates the complexity and challenges, but also the feasibility of such clinical research.

Prerequisites for our study was that health care is free in Norway, that the three primary rehabilitation centres for SCI in Norway all contributed to patient recruitment, and that the ATLET study was supported financially both by the government and non-governmental institutions. This study was initiated by two patient organizations, and their involvement has been important. The study protocol was influenced by the demographics of the Norwegian population. In Norway, people live scattered, and for many, inpatient training has been the only available option for BWSLT. The effect of an in-patient approach was evaluated in Study 1. For those who lived in a densely populated area, outpatient robot-assisted BWSLT was offered, and this was considered less demanding for both subjects and staff. This approach was tested in Study 2. Our study therefore was not a head-to-head comparison of manual versus robot-assisted BWSLT, but rather an evaluation of the feasibility and efficacy of each of the two approaches of training compared to low-intensity usual care. The source of study subjects was thus geographically different, as were the training schedules. However, the demographic and disability characteristics of the study subjects in the two studies were very similar.

Selection of study subjects

The selection of study subjects was based on previous training studies and recommendations on how to conduct clinical trials among subjects with chronic SCI. Early gait training for subjects with incomplete SCI has been shown to improve over ground walking (54). Training should probably start as early as possible to obtain maximal benefit, but then spontaneous recovery of function is frequent, and that would confound the picture and require an unobtainable, much larger study group (15). SCI may be considered stable 12 to 18 months after injury (14). To avoid interference from spontaneous improvement, which would reduce the power to detect differences in the treatment effects, our study included only subjects whose injury occurred at least two years prior to enrolment (15). With this design, fewer study subjects were needed, making the study feasible. Since there was no evidence that subjects with a complete SCI can improve gait, they were not included (70). We included subjects 18–70 years old, similar to most previous studies (70, 75, 86). Older subjects were not included in the study due to aging, natural decline in physical function and proneness to other health-related problems. Elderly subjects with SCI may also have more problems in transferring an improvement in motor score into functional improvement (122-124). At the time of our study start, there was uncertainty as to whether subjects with poor physical function and lack of independent walking would benefit from BWSLT, even if classified as AIS C and D (40, 56, 70, 125). However, there was evidence that subjects in these categories with some physical function, were well-suited candidates who often were able to attain independent walking (with or without assisting devices) over ground after BWSLT (40, 56, 75, 85).

In generally chronic SCI has defined as post-injury time ≥1 year. However, our study subjects had been living with chronic SCI for a mean post-injury time of 12 years (range 2-54 years), longer than any other RCT of BWSLT among SCI subjects, and therefore we considered them as long-standing SCI (≥2 years post-injury time), since spontaneous improvement in physical function weakens after the first year. In this thesis, long-standing SCI is defined as ≥2 years post-injury time.

We can only speculate on what our results would have been if we had chosen to include only subjects with post-injury time of 1-2 years. Possibly, they would have been different. Perhaps the time since injury among our study subjects was too long, and the physiological or anatomical changes that make motor recovery therefore was more difficult.

Also, since the start of our study, the Neuromuscular Recovery Scale (NRS) has been found to be a better predictor of change in physical performance (121) than the AIS

classification used in the present study (126). If the NRS had been available when we planned our RCT, we might have been able to design better selection criteria for our study subjects, possibly resulting in clearer results.

Recruitment of the study subjects

The chosen recruitment strategy was based on information that was available in 2008, on incidence and type of SCI in Norway. Two recent reports show that every year more than 100 persons with new spinal cord injury receive rehabilitation in Norway (11, 12). However, at the time of planning the present RCTs, we lacked information on the proportion of incomplete SCI as the National Spinal Cord Injury Registry has only been in operation since 2011. The registry report shows that the proportion of atraumatic injuries is 39% compared to 61% for traumatic SCIs (11). Similarly, the incidence of traumatic SCI has increased by a total of 18 new cases during the 5 years from 2012 to 2016 and for atraumatic SCI, the number of new cases has declined by 12 cases in the same time period. The numbers may be somewhat inaccurate since some atraumatic cases may have been treated in other places than the spinal care units (12). Additionally, 49.1% of the incident SCI cases are incomplete SCI classified as AIS D, including both traumatic and atraumatic injuries. Unfortunately, information for specific proportion among those with AIS C is not given (11), but for instance an annual registry report from 2017 shows that among 119 subjects, 75 % were classified as AIS C and D (127). Unfortunately, our recruitment plan was therefore based on an overestimation of the number of eligible subjects. Thus, recruitment was much more challenging than anticipated, and we never reached our goal despite intensive recruitment strategies and a significant extension of the recruitment period. Due to the 2-year post-injury requirement, some of the eligible subjects seemed to already have adapted so well to their situation that they were unwilling to invest significant time and efforts on a study with an uncertain outcome.

Two members of the steering committee represented relevant SCI patient organizations, and we used advertisements through their members' magazines. Members from the steering committee and project workers regularly attended the annual meetings of the patient organizations, where we presented the study and invited subjects to join. In addition, the three national SCI units gave a helping hand with recruitment over many years. Thus, despite vigorous efforts by the steering committee, recruitment was slow, causing severe delays. Originally, the study was expected to finish in 2012, but this turned out not to be the case. We finally terminated the two studies when our pool of eligible subjects was empty, and the last recruited subjects to Study 2 had completed their intervention in the fall of 2018.

Training intensity and duration

The training methods selected and training intensity and duration used in our studies, were based on earlier BWSLT studies on SCI. This level of training was evaluated to be a tolerable amount of training for individuals with SCI both in the in- and outpatient settings.
The manual BWSLT is physically very demanding for the therapists, as it requires manual guiding of the legs and pelvis during the training session. To reduce the ergonomic burden, robotic devices have been developed to move the subjects' legs. Some clinical trials have investigated the use of robotic devices in locomotor training with varying results (56, 75, 76, 80, 81).

The two intervention types in our study were not directly comparable, even though an appropriate design (a three-arm study) might have been useful. Since the start of our study, others have pointed out the benefits of doing multiarm randomized trials (128). However, given the low number of SCI per year, even in the most heavily populated area of Oslo where the robot was located, we had an insufficient patient population for a 3-arm RCT. Thus, we chose to conduct the robot study (Study 2) in an outpatient setting in Oslo and use an inpatient setting utilizing SCI subjects from the rest of Norway at the only available site, in Tromsø in Northern Norway (Study 1). Most studies on BWSLT have a duration of four to 16 weeks, and include training 2-5 times per week with 30-60 minutes sessions (54). Our studies were similar, with the robot-assisted outpatient clinic organizing BWSLT three times a week with 60 minutes of walking each time, and this was evenly distributed over six months for a total of 60 sessions. This close-to-home outpatient regiment interferes to a lesser degree with other daily activities (work, studies etc.) than daily inpatient training sessions. To maintain motivation we limited the entire training period to six months, as we believed that loss of motivation could become a problem if the interventions continued for longer periods. The inpatient setting in Study 1, however, allowed and required a more intensive training approach (3x4 weeks for a total of 60 training days, and 2 training sessions per day). Because of these differences, training effects of the two intervention types were compared to controls with low-intensity usual care, each control group recruited from the corresponding source population. Direct comparison of the outcomes from the two intervention groups must therefore be done with caution.

There is uncertainty as to whether there is a dose-response outcome in relation to different forms of locomotor training among chronic SCI population (92). There are indications that over ground training increases endurance and results in greater distance walked than the other methods of gait training. Also, Sandler et al (92) suggest that in relation

to outcomes such as walking speed and endurance/distance walked, subjects' engagement in the activity during gait-training irrespective of gait training method, is more important than time spent on the training. This is also pointed out by Behrman et al (121).

Training intensity in BWSLT can include a variety of elements such as duration and frequency of the training session, walking speed, number of steps taken, monitoring of heart rate and rating of perceived exertion etc. Unfortunately, we did not monitor heart rate during the training, nor did we register number of steps during the training sessions to assess intensity. In our studies, intensity was defined by duration and frequency of the sessions. Behrman et al argue that, in order to improve functional change in a activity-based plasticity, the intensity of the locomotor training defined by number of training sessions should be greater than 60 sessions, there should be daily sessions and the length of sessions should be ≥ 1.5 hours (121). This was also a goal in our study 1. Furthermore, Behrman et al state that the degree of improvement is dependent on spinal cord networks maintaining the appropriate central state excitability (increased activity) for the walking task (121). Field-Fote et al agree that the number of steps taken during training session is a critical component to induce motor and physiological improvements (129). Thus, lack of step counts in our study could be a limitation.

Methods of assessment in the ICF context

The outcome assessment methods selected were guided by the ICF framework, and are widely used in clinical trials on subjects with SCI as well as in other neurological populations. The methods were chosen based on their reliability and validity, their administrative ease and low costs. Gait analysis would have been ideal, but was not affordable, and further, such data are difficult to analyse statistically.

Muscle strength (*Body structure and functions)* has often been used to measure recovery of motor function after SCI, and is good because it can be assessed both for those with and without walking function (14). Lower extremity motor score (LEMS) is a widely used assessment, however, there is limited or mixed evidence that BWSLT improves the strength of muscles in the lower limbs. Esclarin-Ruz et al compared robot-assisted BWSLT with over ground training in subjects with subacute SCI, and found significant improvement in LEMS favoring robot-assisted BWSLT (76). However, no effect was seen in those with chronic SCI (130). On the other hand, no difference was found when manually assisted BWSLT was compared with over ground training among subjects with chronic SCI (85, 86). A change of >3 points in LEMS seems to be needed in order to improve walking function (131). However, this measure can have limits in responsiveness in scores over 3, and also a

ceiling effect among those who have good walking function (6). In our study, we found improvements in LEMS (average of 3.6 points) in both intervention groups, but this change did not lead to improved walking function. One reason for the lack of improved walking function could be that subjects had none or very poor walking function at baseline. The ability to walk in a community setting requires a LEMS score ≥30 (132) and our subjects were below this threshold at the final assessment with values of 29.0 in the manual BWSLT group, but somewhat higher and above this threshold (33.8) in the robot assisted BWSLT group.

Maximal oxygen uptake VO_{2max} (*Body structure and functions)* is commonly used to measure aerobic capacity. VO_{2peak} values (tested with arm crank cycling) for subjects with tetraplegia ranges between 0.8 - 1.0 l/min^{-1} and for subjects with paraplegia 1.1-2.3 l/min^{-1} (99). Three BWSLT studies from Brazg (89), Hornby (74) and Gorman (81) have shown positive effects of BWSLT on aerobic capacity. Alexeeva et al (86) reported null finding similar to our results in Paper I, despite high intensity of the BWSLT. The test methods, however, have been different with arm crank cycling being used in some studies (81, 86) vs. treadmill in others (74, 81, 89). Gorman et al (81) found that aerobic capacity improved when tested using treadmill test, but not in arm crank cycling test. This can be explained by improved lower limb muscle strength. Unfortunately, we were unable to test all subjects with arm crack cycling due to occasional problems with equipment in the test laboratory or ability to perform arm crack test due to subjects' poor arm function. We tested with an arm crank cycling due to poor baseline walking function among our study subjects in spite of the fact that our interventions were focused on lower limbs and truncus. In future studies, we believe that other VO_{2peak} test methods that are more suitable for subjects with poor baseline walking function should be utilized. Based on our limited number of tested subjects, there is no clear evidence that BWSLT is sufficient to improve aerobic capacity.

Walking speed and distance walked (Activity). Assessment of walking speed with 10MWT and endurance / distance walked with 6MWT are well-established outcome measures in SCI research (98, 103). There is a lack of consensus on how to define a meaningful walking speed for daily living (6). However, the following recommendations have been suggested to discriminate between the functional walking categories after SCI. The following speeds are needed 1) a minimum speed of 0.2 ±0.1 m/s to be able to walk indoors, 2) >0.4 ±0.1 m/s for assisted walking outdoors and 3) >0.7 ±0.1 m/s for independent walking outdoors (133). Based on the categories above, it seems that 84% of the subjects in our study were in the category "assisted walkers", but 16% (6/37) were subjects who were unable to walk at baseline, and did not regain walking function during the study period. Similarly, there

are varying opinions as to what is a meaningful change in distance walked / endurance as measured by the 6-minute walk test (6MWT), ranging from 46 m (134) in the study by Lam to 31 m, as noted by Mehrholz (54). Our study subjects were unable to reach these recommended changes in distance walked. Mehrholz and co-workers suggests that an improvement in distance walked of more than 31 m is necessary to justify the use of this costly training method (54). In our study, only four subjects among the 13 total in the intervention groups combined, who had some baseline walking function, had changes of 31 m or more. Therefore, the intervention subjects in our two studies did not reach this mean threshold suggested by Mehrholz et al. Similarly, our study subjects were unable to reach the recommended change in walking speed 0.13 m/s (134). Only six of the total intervention group of 14 with some baseline walking function, had a change of 0.1 m/s or more, and thus, again, we did not reach the threshold suggested by Lam et al (134).

In general, 10MWT and 6MWT are easy to use and sensitive in detecting changes, but they do not assess quality of walking. Thus, these tests may be less suitable for subjects with poor baseline walking function where external help is required to advance the legs during stepping. There is a need for assessments that will detect changes also among those with poor walking function (6). It is possible that other tools, such as the Timed up and go (TUG) test may be better suited for such studies. It is a more complex test than 10MWT and 6MWT, and consists of different elements such as sitting down – standing up, walking and turning with additional elements for maintenance of balance, and will therefore better reflect daily life activities. On the other hand, there might be a disadvantage in using the TUG, since it includes different and complex tasks in the same test, possibly reducing sensitivity of the test (135). In order to obtain more accurate information about a subject's function, it might be beneficial to assess these complex tasks separately (135). Van Hedel (2008) suggests, for instance, to use the 10MWT to assess walking speed, another test for sitting up and down, independently assess strength and ability to transfer, test for turning around 360 degree (such as subtest in BBS), and finally assess dynamic balance (135). Such an approach may be more time-consuming than the 10MWT and 6MWT since it requires that subjects need to stand up without assistance from the sitting position, and it can take several minutes before he/she is able to continue testing of gait. Due to time constraints because all tests had to be completed in 1-2 days, we chose not to use the TUG test, as we already had many physical tests. Also, it was important to avoid overloading the study subjects with testing extending more than 1-2 days.

Balance (Activity). Even though Berg balance scale (BBS) does not directly measure walking function, it assesses the ability to stand upright as well as maintain balance, both prerequisites for walking. This assessment is probably more suitable for subjects with poor walking function, such as in our study, since it has been found to have a ceiling effect among subjects with AIS D who are able to walk outside (106, 136). Therefore, two more recent assessments (The Mini-BESTest and the Community Balance and Mobility Scale) may be more suitable to assess subjects with better walking function (136, 137). The Modified Function Reach (MFR) test is a simple useful test to assess truncus stability among non-walkers (107). But for those subjects with limited or no walking function, there is also a need for other assessments that are more sensitive to changes. Abou and colleagues (138) have criticised MFR for having limited validity since it has been unable to show correlation with another SCI related mobility test (the Spinal Cord Independence Measure III) (139). It is possible that the bending forward movement is not sufficient alone to measure sitting balance nor ADL function (138, 139). Therefore, Abou et al (138) proposed the use of three newer assessments as alternatives to MFR: 1) the Sitting Balance Measure, 2) the Trunk Control Test and 3) the Set of Assessment Tools when evaluating sitting balance in the clinical setting. These tests have good measurement property scores, are easy to use and administer, and they are appropriate for all types of SCI (138). These assessments were unavailable at the time we designed our studies in 2008.

Health-related quality of life (Participation) and psychological outcomes (Personal factors). HRQOL measures have become an important concept in treatment of SCI. There is a variety of different assessments available, such as the WHO Quality of life questionnaire and the Life satisfaction questionnaire (29), but we used SF-36 due to familiarity with this instrument, and because this test is frequently used in the SCI population (30). SF-36 has some flaws due to emphasis on walking among SCI population (29) and it has been criticized for interpretation and reporting the aggregated scores PCS and MCS (140). But we found that in terms of HRQOL assessments, our study sample was similar to the Norwegian long-standing SCI population (30), confirmed by newer Norwegian norm data from Garret et al in 2017, that also reports PCS ad MCS (110). To date and to our knowledge, six HRQOL-studies (4 RCTs and 2 observational studies) have been conducted in conjunction with BWSLT (47, 62, 80, 84, 86, 88). However, these have varying quality due to methodological issues such as weak study designs, use of different outcome measures or use of only parts of the standardized questionnaires (47, 86). This makes comparison between the studies difficult (3). We believe our results may contribute to reducing the gap of knowledge regarding

changes in HRQOL among the long-standing SCI population after participation in long-term intervention, even when there is no significant improvement in the physical outcome measures.

The six HRQOL studies (both randomized and non-randomized) associated with BWSLT are summarized below with comments as to how they are different from the present study.

1. The most recent non-blinded RCT by Wu et al, with 16 chronic SCI subjects with >1 year post-injury time, compared BWSLT with manual assistance to robot-assisted BWSLT that focused on weight shift, and found that HRQOL did not improve in any of two groups (80). This result was similar to our finding in Paper III, but differs from our study in that the control group had a specific activity-based intervention regime, and also had unblinded assessors and a shorter intervention period.
2. A RCT by Hitzig et al with 34 chronic SCI and post-injury time >1 year, assessed QoL and community participation as their main outcomes (84). A variety of outcome measures was used. The results showed no improvement expect in mobility, favoring the intervention group. This study is different from our study (Paper III) in that the BWSLT was augmented by functional electrical stimulation and their control group received aerobic and resistance training, had lower intensity of the training, and the QoL assessment was different.
3. Adams & Hicks conducted a small RCT with cross-over design in seven subjects with chronic SCI, and compared BWSLT to tilt-table standing (88). The intervention lasted 3x4 weeks separated by a 4-week washout period. The authors concluded that both approaches may be beneficial for reducing spasticity, but that BWSLT also has positive effects on QoL. This study differs from ours in their cross-over design, a control group with specified active intervention, inclusion of subjects with AIS A & B, a shorter intervention period and no gait assessments. QoL was assessed with the Quality of life index for spinal cord injury version III.
4. A RCT by Alexeeva et al with 35 chronic SCI subjects and post injury time >1 year, used HRQOL as their outcome (86). They reported improved health-related quality of life including satisfaction with their function and well-being after completing 39 training sessions, irrespective of training method; *i)* body-weight supported fixed track over ground training, *ii)* manually assisted BWSLT or *iii)* comprehensive physical therapy. This study was different from ours (Paper III) in that it compared several types of interventions, had fewer training sessions, and only used parts of a standardized QoL and wellbeing questionnaire. In addition, the QoL assessment

incorporated two subsets from the two standardized questionnaires (the SF-36 and the Satisfaction with abilities and wellbeing scale SAWS) which were not used in our study.

5. An observational study from 2005 by Hicks et al (47) showed that long-term BWSLT has an effect on QoL and wellbeing among 14 subjects with chronic SCI. The study showed improvement in walking function and satisfaction with life and physical function correlated with improvements in walking function. The study used a different or only part of the standardized QoL assessments, different from the ones we used in Paper III. Further, walking function was assessed on a treadmill with no formal testing of over ground walking.
6. In a small observational study with three subjects motor incomplete SCI and post injury time was more than 4 years, Effing et al. (62) concluded that BWSLT had positive effects on training parameters and functional health status but not on QoL measures. This study differs from our study in that it was an observational case-series study with only 3 participants compared to our larger RCT. In addition, they used a different QoL assessment (Schedule for the Evaluation of Individual Quality of Life).

Only three of these studies (47, 86, 88) found improvements in QoL after BWSLT. As with our study, it is possible that subjects who agree to join studies on BWSLT are a select group of highly motivated individuals who are more likely to take responsibility for their own rehabilitation and health-related outcomes (36, 141). Based on the objective instruments used in our study, the subjects were strongly autonomously motivated with high expectations. They were already involved in many physical activities, and had achieved more than one would normally expect. We expected that a possible improvement in autonomous motivation, or a shift from controlled towards more autonomous motivation would be observed. This could be due to the possibilities for more satisfaction of the needs for autonomy, competence and relatedness through the intervention, by their the decision to participate and stay in the program. We would also expect a growing sense of competence during the mastery and completion of the activities, as well as experiencing positive physical results.

We found, however, that the changes in HRQOL and psychological outcomes were small; the changes in the physical and mental HRQOL as well as the physical activity (IPAQ), autonomous motivation and importance of benefits gained, did not exceed the thresholds for the Minimal Clinical Important Difference (MCID). However, the differences in change between the intervention and control group exceeded the MCID for exercise barrier self-efficacy, controlled motivation and meeting the outcome expectations.

Some may criticize that our post-assessment was conducted weeks after the end of the intervention. For administrative reasons we chose to conduct the post-tests 2-4 weeks after completing the intervention. Testing earlier than 2 weeks post intervention would have been challenging due to logistical issues such as coordinating beds for the study subjects, securing that the testing team and labs were available, transport arrangements for study subjects who lived outside of the Oslo area and thus needed to travel across Norway to Sunnaas etc. Possibly, subjects might need some time to recover physically from the participation in the intensive and long-lasting training, or, on the other side, training effects might fade rapidly after end of the program. A valuable and clinically relevant training effect should, however, not vanish immediately after resumption of usual care; if so, the intensive training would not be worth the effort and costs. Therefore, in our opinion, our chosen timing is both more realistic, and may be even better than immediate testing. Many of the other published BWSLT studies (66-68, 70, 72, 80, 84-87) state that post evaluations were conducted after the end of the intervention period, but they did not specify how many days or weeks it took to conduct the post assessments. Only one study stated that they conducted post assessments within 24-48 hours after finishing the intervention (88).

Study Strengths

In general, the major benefit of RCT design is the possibility to do direct investigation of a cause-effect relationship with minimal bias and confounding factors. The pre-requisite is that the study sample is sufficiently large in relation to the expected outcomes. The strength of our study lies in the RCT design that included a predefined study sample and randomization as well as blinded assessment both at pre- and post-intervention evaluation. Our two studies were completely independent, with separate control groups as well. All of our study subjects were recruited well beyond the time when spontaneous improvement can be expected, and the randomization was conducted after baseline evaluation. Finally, our study used experienced and blinded evaluators the same 2 physicians and 2 physical therapists throughout all years of the study.

Study Limitations

There are several limitations to our study. First, our studies recruited subjects with long-standing SCI with an average length of 12 years post-injury. Thus, the results are not applicable to early stages of rehabilitation, where benefits may be greater. Due to the challenging recruitment, the study lasted much longer than anticipated, which resulted in several changes in study staff over the 9 years. This has probably introduced significant variability and lower level of standardization in the manually assisted approach, thus

attenuating the results. Similarly, it was necessary to change the venue for the robot two times during the study. These changes also included training of new staff to supervise the training at the new sites, again reducing standardization and ultimately potentially attenuating our outcomes.

Another limitation of this study is the fact that we did not do block randomization based on baseline use of antispasmodic medication, AIS category and walking function. Thus, we have significant baseline variations in these factors within the groups, and this could have influenced our results. We cannot exclude the possibility that more intensive and focused training would give better results, or that a longer total training period would have resulted in improved walking function. However, our choice of study size was based both upon earlier studies of BWSLT as well as results from our pilot study. Since all our study subjects had incomplete SCI, our results cannot be generalized to persons with complete SCI.

All subjects were motivated to exercise. That may have become a problem in the control group as we know that some control subjects increased their activity level during the control period. Some subjects may have been disappointed that they were allocated to the control group, and have changed their exercise behaviour during the study, unrecognized by the project coordinator.

In order to obtain maximum utilization of neuroplasticity and change in walking function, the subject needs to be mentally engaged in the activity (92, 142). Our study started at a time when there was great focus on many repetitions and less on the quality of the steps. Thus, we do not have an assessment of the degree of mental engagement each study subject was putting into each gait training session. Lack of this focus may have contributed to our null findings, as newer research has found that this to be a crucial factor for obtaining neuroplastic changes (142-144).

6 Methodological considerations

Several administrative challenges occurred in The ATLET study, causing delays. For financial reasons, the Lokomat gait-training robot in Study 2 was moved twice within the Oslo area, and each time required months of training of new staff. Another issue was occasional problems with transport logistics from home to the outpatient-training site in Study 2.

We chose the randomized parallel, examiner-blinded controlled design for this clinical trial. A crossover design would have been unsuitable because of carry-over effects from training in the first sequence, to an ensuing control period. Since the recruitment was challenging, we considered modifying our design in order to complete the study within a reasonable timeframe. One such option would be to offer the intervention to those who had completed the control period, and thus deviate from the blinded outcome assessment. However, we decided against that option, as it would have been in conflict with the approved RCT design.

In an ideal world, we should have followed the subjects and conducted reassessments after 6 months. However, due to lack of funding, this was not possible. Our funding only allowed for simple outcome measure assessments that were easy to use in a clinical setting. Use of formal gait analysis would possibly have given more insight into any changes in gait pattern in subjects with incomplete SCI.

At the time of designing our studies, we had calculated a sample size, based on our pilot study and the literature that was large enough to detect clinically important changes in physical function with adequate statistical power. We had expected to find improvements after the interventions for both physical function and HRQOL. Due to the unexpected challenges encountered in recruitment, the steering group finally made the decision to terminate the studies without reaching the predetermined subject numbers. This probably has contributed to our null findings.

For the HRQOL assessment, we decided to merge data from the Study 1 and Study 2 due to the low number of subjects and insufficient power. Our justification for merging data in Paper III was based on the fact that our RCTs were independent, but the training intensity and duration were similar. Also, the evaluations before and after intervention used identical objective and well-established assessment methods. Furthermore, there were no statistically significant differences between the groups in baseline HRQOL, psychological, physical

activity or expectation variables after merging the data. Nor were there such differences in the outcomes. Thus merging the data seemed defensible.

Due to the nature of RCTs, intention to treat analysis is recommended. However, non-compliance to study protocols and missing outcomes are major problems. We included only subjects who were protocol compliant, as the aim of our study was to be an exploratory and efficacy study rather than a study of effectiveness.

We were surprised by the seeming paradox between the objective results and the subjects' personal satisfaction with the study (Paper III). Our impression was that the majority of the subjects were pleased to participate in the BWSLT, and this is in contrast to both the null findings in physical function (Paper I and II) and the HRQOL (Paper III) results. Unfortunately, we did not do a formal assessment of subjects' satisfaction with study participation, but we recommend that this should be done in future RCTs of subjects with SCI.

Based on our findings, and in spite of some of the challenges encountered in this study, we feel that there is a need to carefully consider what types of patients with SCI who will profit from BWSLT. Since the intervention is expensive, both for the manual assistance and for the robot-assisted approach, such evaluation is warranted. Although our study groups were smaller than intended, the lack of clear beneficial trends suggests that also among larger groups of patients with chronic SCI and with more uniform characteristics at baseline, even if positive effects were shown, the cost-benefit yield is uncertain. However, this does not exclude the possibility that such training can be more useful in other patients, i.e. subjects with SCI in the subacute or less chronic stage, and those with some baseline walking function.

Bias risk in the ATLET study

Internal validity determines how well a trial can exclude alternative explanation for its findings. In RCTs, bias is known as systematic errors, meaning deviations that are not a consequence of intervention alone. Bias can occur in multiple ways, such as selection effects, uncontrolled prognostic factors, procedural flaws and use of improper statistical methods, and from perceptual error, attitudes and beliefs. The strength of the RCT design is that a solid randomization procedure will eliminate some effects of factors that might interfere with the outcomes (145, 146). As far as we can see, there are no obvious biases in our study. However, as mentioned earlier, there are several limitations that could contribute to our null findings, including standardization challenges of staff, large variation in baseline factors of study subjects combined with low number of subjects. There is some indication that large variation in baseline characteristics within the groups influenced the findings as the multivariable

adjusted models in Paper I did modify the results, especially for 10MWT and 6MWT. However, whether these changes would be statistically significant in a larger group with more uniform baseline characteristics, is uncertain.

Selection bias. Selection bias can occur at the time of inclusion of the study subjects or randomization procedure. Information of approaching randomization may influence subjects' decision regarding inclusion. In the ATLET study, assessment of subject's eligibility as well as obtaining consent was obtained before the allocation to avoid selection bias. The randomization procedure was carried out independently, outside of the Sunnaas Rehabilitation Hospital where the evaluations took place, thus further ensuring an unbiased sample. However, the fact that we restricted participation to those who were 2 or more years post-SCI injury, may have resulted in a select group of the most motivated subjects volunteering for the study. Thus, it is possible that a ceiling effect might have occurred in the study. We found that, already at baseline, our study subjects were highly autonomously motivated and physically active and this may have influenced /contributed to a lack of effect in outcomes.

Information bias can arise due to measurement errors or misclassification of outcomes measured in RTCs. Improper design of the measure, faults in the test protocol, inadequately conducted protocol or improper assessment tools can cause errors in measurement (146). In the ATLET study, we used identical standardized outcome measures in all groups when assessing subjects' physical function and the same set of questionnaires to assess HRQOL and psychological outcomes. Also, the evaluators were standardized and were the same throughout the study. Thus, we do not believe we have any significant information bias in this study.

Attrition bias. We had a dropout rate of 13 % (2 of 20 subjects) from Study 1 and 17% (4 of 24) in Study 2. Subjects dropped out due to issues unrelated to the studies. Therefore, we think this may have had only a small impact, if any, on our results in Paper I, where there was one dropout in each of the intervention and control group. However, for the robot-assisted BWSLT (Paper II), the risk of bias may have greater since all the dropouts were in the intervention group and they were somewhat younger (average 34 years ranging from 20-58 years) compared to 55 years in the remaining subjects of the intervention group. The younger age, would most likely have been a benefit with respect to improvement of their physical function. On the other hand, their LEMS was lower than in the remaining intervention group and 2 of them had a poorer AIS classification which would have been a disadvantage. Thus, this could have wiped out any beneficial effect of younger age. Overall, we therefore believe that these dropouts have only had a minor effect on outcomes. Our

dropout rate was lower than 20%, which is considered as the cut-off level for potential bias and threat to validity (147, 148). However, in addition to these dropouts, one subject, also in the robot-assisted BWSLT (Study 2 – Paper II), was excluded from the final analysis due to non-compliance with the training protocol (only completed 20 of 60 training sessions). Including this subject among the dropouts gives an attrition rate of 21%, barely taking us over the threshold for potential attrition bias.

Incomplete outcome data. We were unable to report aerobic capacity (VO_{2max}) in paper II due to poor data quality since several subjects had an incomplete pre- and post-registration of this variable, sometimes due to problems with the measuring device or unavailability of staff. However, we present this data in Paper III in spite of many missing values.

Reporting bias can occur because trials with null findings tend not to be published as frequently as those with findings. This can typically be a problem in meta-analyses. To minimize this bias, RCTs are required to publish their design and planned outcomes prior to start of the trial, as we have done. Report bias, also occurs when authors are selective in what results they report (149). For instance, in RCTs they may be less likely to mention negative results, and instead focus only on significant positive results. Thus, the reader is left with the impression that the overall treatment effects are better than what they would look like if all results were presented. A major focus of our study has been to make a complete report, to contribute to a critical discussion of the use of time-consuming, labour-intensive and expensive interventions in research and clinics.

Performance bias can occur for instance if the subjects change their behaviour during the trial. In our study, we observed that some of the subjects in the control group increased their physical activity level or possibly also their training intensity (Paper I) despite specific instructions to continue “as usual” during the control period. Thus, these changes in the control group, a performance bias or Hawthorne effect (150), could have contributed to our null findings.

Since confounding in RCTs can twist the relationship between the exposure of interest and outcome, researchers try to control confounding to provide valid measures of the treatment effects (151). This can be prevented with randomization or masking, and also, to some degree by block randomization if there are several strong factors that are known to be related to the outcome (151).

External validity describes whether the findings also apply to similar or different populations. As pointed out earlier, we cannot generalize our results to subjects with

incomplete SCI since our study lacked power due to low number of recruited study subjects and since our study population was a very select group of incomplete SCI injured persons (long time since injury, very poor walking function with high physical activity at baseline). Perhaps our results can only be generalized to those SCI subjects who are eager to exercise. On the other hand, our recruitment was nationwide and our study population seems to a have similar characteristics as the most recent Norwegian Spinal Cord Injury registry (NorSCIR) with respect to proportion of men (61 %) (27 of 44 in combined study) and mean age of 49 years (SD=14) (11). A moderate proportion 32% (14 of 44) of subjects had poor function classified with AIS C.

HRQOL assessment was also similar to the previous study of long-standing SCI subjects by Lidal et al (30), and also in relation to the newer Norwegian norm data for this age category (40-59 years) (110). Therefore, we think that our study may be representative for the Norwegian SCI population in terms of physical function and HRQOL. Unfortunately, we do not have any reference point with regards to motivation.

7 Ethical considerations

The Regional committee of Ethics (REK) in North Norway approved the ATLET study (P REK NORD 69/2008 and 2009/634-5). All study subjects gave their written informed consent before evaluation and randomization. Our study was registered on the United States National Institutes of Health Clinical Trials Registry, ClinicalTrials.gov identifier #NCT00854555, and the study was conducted in accordance with the Declaration of Helsinki.

All subjects received full evaluation of his/her function before the study started, and were given advice for training at the time of the final evaluations at Sunnaas Rehabilitation Hospital. As a thank you for their effort, subjects in the control group were offered the BWSLT after finishing their control period.

8 Conclusion & implication / future perspectives

Despite our null findings, we think some lessons can be learned from the ATLET study:

1. Few individuals with long-standing SCI are willing to participate in an intensive long-lasting training program. As a consequence this results in a selection of strongly autonomously motivated individuals.
2. Late onset training of long-standing SCI subjects with poor baseline function, results in only minor improvements in physical function and no change in HRQOL. Therefore, large study groups may be needed to obtain statistically significant results.
3. Our experience from an appropriately designed study, as we think is the case here, might be useful for researchers planning similar studies, not the least with regard to the challenges of recruitment.

The clinical importance of our findings are debateable. Our study showed small changes in HRQOL and physical function among persons with SCI who already had both relatively high HRQOL and high level of physical activity at baseline. It would be interesting to know what effects BWSLT could have on HRQOL, EBSE, type of motivation, psychosocial/environmental factors and physical function among physically inactive, less autonomously motivated individuals with SCI in a less chronic stage. Previous experience of extensive exercise among subjects with long-standing SCI should be considered before starting intervention/ training. This will make it easier to avoid including subjects in exercise studies who have already used significant resources to improve their physical function and thus may have already reached a ceiling in what is possible to achieve.

Quel de Oliveira et al (3) have argued that activity-based interventions, when applied to lower limbs in a chronic SCI population, do not have effects on motor function nor on QoL, and therefore use of these interventions should be carefully considered because of high cost and labour-intensive rehabilitation. Even though we found an effect of BWSLT on LEMS, our overall findings are small. Thus, our study findings can partly support Quel de Oliveira's argument. However, even a small improvement in walking function, strength in lower limbs and balance may be important to an individual who struggles to cope with the daily life activities. Also, some subjects report general wellbeing, improved bowl & bladder function and increased sensitivity as a result of BWSLT and these may be important for general health (57, 152, 153). Therefore, the overall decision as to whether to advice use of BWSLT on such patients should be carefully considered.

Since we started our study, there has been further development in Activity-based therapies (including body-weight supported locomotor training) such as epidural stimulation of spinal cord to create a central state of excitably and improve function. Also, there is better understanding of how locomotor training, when applied in the presence of a sufficient level of supraspinal influence, possibly drives both the central state of excitability and task-specific retraining (121).

We propose that rehabilitation teams that offer BWSLT constantly keep up on the development in SCI research and incorporate additional elements that might be useful in helping subjects with SCI to improve function, participation and HRQOL. Thus, the final message from this dissertation is that emphasis should be on the right use of BWSLT with the right patient groups.

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Paper I

Paper II

Paper III

Appendix

Paper I

Piira A, Lannem AM, Sørensen M, Glott T, Knutsen R, Jørgensen L, Gjesdal K, Hjeltnes N. & Knutsen SF. **Manually assisted body-weight supported locomotor training does not re-establish walking in non-walking subjects with chronic incomplete spinal cord injury: a randomized clinical trial**. Journal of Rehabilitation Medicine, 2019; 51: 113-119.

J Rehabil Med 2019; 51: 113–119

ORIGINAL REPORT

MANUALLY ASSISTED BODY-WEIGHT SUPPORTED LOCOMOTOR TRAINING DOES NOT RE-ESTABLISH WALKING IN NON-WALKING SUBJECTS WITH CHRONIC INCOMPLETE SPINAL CORD INJURY: A RANDOMIZED CLINICAL TRIAL

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Objective: **To assess the effects of manually assisted body-weight supported locomotor training in subjects with chronic incomplete spinal cord injury.**

Design: **Randomized controlled clinical trial.**

Subjects: **Twenty subjects with American Spinal Injury Association Impairment Scale grades C or D and >2 years post-injury.**

Methods: **Random allocation to 60 days of body-weight supported locomotor training, or usual care, which might include over-ground walking. Walking function, lower extremity muscle strength and balance were blindly evaluated pre-/post-intervention.**

Results: **A small, non-significant improvement in walking function was observed (0.1 m/s (95% confidence interval (95% CI) −0.2, 0.4)), but subjects without baseline gait function, did not re-establish walking. The effect on lower extremity muscle strength was 2.7 points (95% CI −1.4, 6.8). No difference was observed in balance measures.**

Conclusion: **Subjects with chronic incomplete spinal cord injury without baseline walking function were unable to re-establish gait with manually assisted body-weight supported locomotor training. A modest, non-significant, improvement was found in strength and walking speed. However, due to study recruitment problems, an effect size that was smaller than anticipated, and large functional heterogeneity among study subjects, the effect of late-onset body-weight supported locomotor training is not clear. Future studies should include larger numbers of subjects with less functional loss and greater functional homogeneity. Intensive training should probably start earlier post-injury.**

Key words: spinal cord injury; locomotor training; body-weight support; treadmill.

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LAY ABSTRACT

This randomized clinical trial assesses the effects of manually assisted body-weight supported treadmill training in patients with chronic functionally incomplete spinal cord injury acquired >2 years earlier. Due to recruitment challenges, it was only possible to recruit two-thirds of the planned number of study participants. The intervention group received gait training 5 days per week over 12 weeks, and the control group received usual care with their local physical therapist. Subjects with no baseline gait function did not regain walking ability. Compared with the control group, the intervention group showed modest improvements in walking speed, lower extremity strength, and body control. However, all between-group differences were non-significant. Because the target number of study participants was not reached, the study was underpowered and non-significant, and thus the findings are inconclusive. It does, however, seem that this training method has benefits, but it is labour-intensive and requires large amounts of human resources.

Body-weight supported locomotor training (BWSLT) has been used to retrain walking function after spinal cord injury (SCI) after experimental SCI in animals (1) and in uncontrolled human clinical studies (2–8). Both older (2, 3) and more recent studies (4–8) have reported encouraging results. Locomotor gait training increased muscle volume (7), improved activation of muscles in the lower limbs (9), increased ankle stability (10), and was associated with decreased spasticity (11). There is also some evidence that BWSLT improves subjects' wellbeing and quality of life (6), and the benefits seem to be sustained (12). A 2017 review concluded that, so far, locomotor training has not proven more effective in restoring walking speed and distance walked than the same amount of conventional gait training in patients with SCI (13).

Spontaneous improvement in SCI can occur up to 2 years post-injury (14), blurring the effects of training in studies in the early post-injury phase. Such an effect attenuation may explain the null findings of a large multicentre randomized controlled trial (RCT) (n=146) with subjects enrolled 8 weeks after injury (15). On the other hand, early intervention may be

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more effective than a later start. In spite of methodological differences, there seems to be consensus that early gait training in motor incomplete SCI improves over-ground walking independently of the training method (15). This also seems to hold true for patients with chronic incomplete SCI (> 1 year post-injury) (7).

Uncertainty exists, however, as to whether patients with incomplete SCI with more severe functional deficit also benefit from such training, because patients without walking function before training are frequently unable to walk independently after intervention (5, 6, 13).

The aim of the present study was to evaluate the effects on physical function of BWSLT with manual assistance compared with usual care, in subjects with chronic incomplete SCI (2+ years post-injury) and severely reduced or no gait function, classified by the American Spinal Injury Association (ASIA) Impairment Scale (AIS) as grade C–D (16).

METHODS

A single-blinded RCT was conducted in collaboration with the 3 Norwegian SCI rehabilitation units in order to investigate the effect of BWSLT with manual assistance in subjects with incomplete SCI who lived outside the Norwegian capital Oslo (where another study was recruiting SCI subjects). Fig. 1 shows patient flow through recruitment, assessment, intervention and follow-up.

Training protocol

Subjects in the control group received usual care from their local physical therapist. Physical therapy sessions varied in frequency and, for some, included merely passive movement of the joints in the lower extremities and stretching, whereas more than 50% of subjects also had some sessions with over-ground gait training and independent training in the gym. Their daily activities and training were recorded in a diary that was submitted monthly, and subjects received follow-up telephone calls and were advised not to change their training programme/leisure-time physical activities during the study.

A treadmill with body-weight support system (Vigor Equipment, Inc., Stevensville, MI, USA) was used for 60 days training, with 2 daily sessions of BWSLT with manual assistance for a total of 90 min per day, 5 days per week during 3 periods, each of 4 weeks. The duration of each training session depended on each subject's endurance, ability to maintain correct movements in the lower extremities and ability to maintain normal walking rhythm. The aim was to reduce the body-weight support to < 40% and/or increase walking speed towards normal (3–5 km/h). Lower-limb braces or orthoses were not allowed during BWSLT, and there was minimal use of handrails for support. A mirror placed in front of the subject provided visual feedback during training. Each training session involved a team of 3–5 persons to facilitate movements of the pelvis and legs. Subjects received soft-tissue mobilization/stretching before and after each session to prepare for training and reduce spasticity. BWSLT also included over-ground training. The subjects were given home exercises for use between the training periods, selected to improve carry-over of learned skills from treadmill to the community environment. Data from each training session were recorded in an Excel file.

Recruitment and consent

Subjects were recruited from the 3 SCI units in Norway through advertisements in national magazines for persons with SCI. The Regional Committee of Ethics (REK) in North Norway approved the study (P REK NORD 69/2008) (ClinicalTrials.gov identifier #NCT00854555). All potential study subjects gave their written informed consent before final evaluation for inclusion. The inclusion criteria were age 18–70 years and motor incomplete SCI classified as AIS C–D, with a minimum of 2 years since injury. Subjects should primarily be wheelchair dependent with or without some walking ability, have body mass index (BMI) < 30, be cognitively unaffected and motivated for locomotor training. Exclusion criteria included spasticity and contractures that inhibited locomotor training, known osteoporosis in the lower limbs, pregnancy, participation in other intensive training programmes, medical conditions that might interfere with the training protocol, and previous knee or hip replacement. Subjects were encouraged not to change their anti-spasticity medication during the study period.

Setting

Assessments before and after the intervention or control period were conducted single blindly at Sunnaas Rehabilitation Hospital outside Oslo. The in-patient intervention site was North-Norway Rehabilitation Center, Tromsø.

Randomization was concealed. Allocation to intervention (I) or control (C) groups was performed by the sealed envelope method, in blocks of 10. The project coordinator prepared the sealed envelopes and a staff member, who was not involved with the study, selected an envelope for each subject and informed the project coordinator on the allocation.

Outcome measures

Evaluation and testing were carried out prior to randomization, within the last month before start of the intervention/control period. Post-evaluation took place 2–4 weeks after the final intervention/control week. The assessors (physicians and physical therapists) were blinded to each subject's group allocation.

All primary outcome measures used are common in neurological and SCI rehabilitation: (*i*) change in over-ground walking speed; (*ii*) distance walked with use of necessary walking aids; and (*iii*) lower extremity motor score (LEMS), a subscale in the ASIA classification that assesses muscle strength. The score range is 0–5 for each of 5 key muscles (hip flexors, knee extensors, ankle dorsi-flexors, long toe extensors and ankle plantar flexors) of each leg, with maximum score of 50 (16).

Walking speed was assessed with the 10-m walk test (10MWT), where subjects are asked to walk 10 m as fast as possible with a flying start (17). The mean time of 2 tests was recorded. Endurance was measured by the 6-min walk test (6MWT), where the distance walked within 6 min is measured (17).

Secondary outcomes were change in balance and aerobic capacity. Berg's balance scale (BBS) was used for dynamic balance test, and the Modified Functional Reach test (MFR) for postural control. The quality of performance on each of the 14 tests is recorded using a 4-point scale (maximum score 56 points) (18, 19). Higher scores indicate better balance. The MFR assesses postural control in the sitting position in subjects

without independent standing ability (20). Aerobic capacity was tested on an arm crank ergometer (Lode Angio, Groningen, the Netherlands) and breath-by-breath spirometer (Vmax 220 Sensormedics Corp., USA): stepwise, graded exercise until exhaustion. Maximal oxygen uptake (VO_{2max}) (l/min) was recorded by a computerized standard open-circuit technique breath-by-breath spirometer.

Statistical analysis

Sample size. It was estimated that 30 subjects (15 subjects in each group) were required to obtain a statistical power of 0.80 with alpha error 0.05 for primary outcomes. The calculations were based on the expected differences between intervention and control groups obtained from primarily our own pilot study (unpublished) and, to a lesser degree, on published literature (15, 21). The expected training improvements, e.g. differences in change between the intervention and control groups, were 0.5 m/s (SD 0.6) in 10MWT, 55 m (SD 40) in 6MWT, and 15 points (SD 7) in BBS.

The main analysis compared mean or median changes from baseline to final evaluation. Comparison of baseline values between the 2 groups was done using χ^2 test/Fisher exact test for categorical variables and independent samples *t*-test (2-tailed test with significance level $p<0.05$). For non-normally distributed data, the Mann–Whitney test was used. Paired samples *t*-test or Wilcoxon signed-rank test was used to analyse change within groups. The difference in change between the 2 groups was assessed using linear regression. The data was analysed with the 23rd version of SPSS for Windows (IBM SPSS, Armonk, NY, USA). Because of low numbers, the intervention and control groups were imbalanced on several parameters at baseline. Therefore, multivariable analyses adjusting for *a priori* selected variables potentially related to treatment effect were also carried out (Table SI[1]).

RESULTS

As shown in Fig. 1, only 20 of the planned 30 study subjects were recruited within a reasonable timeframe. Based on search of the medical records from the 3 SCI units in Norway, 115 potential participants were identified based on injury type, time of injury, functional level and age. In addition, some subjects contacted project workers directly as a result of information they had obtained from advertisement campaigns. These subjects were pre-screened for eligibility through a phone call. A total of 70 subjects who met the inclusion criteria, were invited to join the study and, of these, 37 returned the written consent form. Eight of the 37 did not attend the clinical pre-screening, leaving 29 subjects who completed the full screening procedure at Sunnaas Hospital. However, nine subjects did not meet the inclusion criteria and thus 20 subjects were randomized

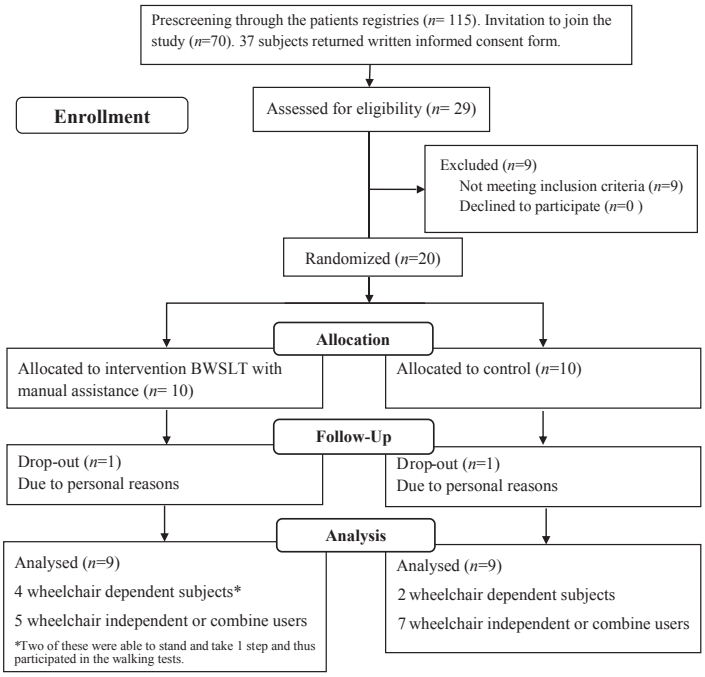

Fig. 1. CONSORT (Consolidated Standards of Reporting Trials) flow diagram of participants.

Two subjects, one from each group, dropped out for personal reasons after 1 and 18 weeks, respectively. Thus, 9 subjects from each group were available for post-analyses.

The training intervention was well tolerated with no adverse events, and there were only minor side-effects, such as superficial abrasions, which did not interfere with the regular training programme. Baseline data on the study subjects are shown in Table I. Some differences and potential imbalances in baseline levels of outcome variables are seen between the groups in strength, distance covered, walking speed, balance and aerobic capacity (Table II). Detailed BWSLT data were recorded daily for each person in the intervention group, and are summarized in Tables III and IV.

In each group, 2 subjects with AIS grade C (22%) were unable to walk at baseline, and did not gain independent walking post-intervention. Thus, only 7 subjects in each group, those with some ambulatory function at baseline, were available for post-intervention testing of walking speed (10MWT) and distance covered (6MWT). Fig. S1[1] shows individual changes in walking speed (10MWT) and distance covered (6MWT) in each group.

Both groups walked faster (10MWT) at post-test. However, the difference between the 2 groups was small (0.1 m/s (95% CI –0.2, 0.4)), and not statistically significant.

Endurance (distance walked), as measured by the 6MWT, improved approximately the same amount in both groups; the standard deviations were very large

[1]http://www.medicaljournals.se/jrm/content/?doi=10.2340/16501977-2508

Table I. Baseline demographics of study subjects according to intervention or control group

Variables	Intervention group (n=10)	Control group (n=10)
Sex, n (% males)	6 (60)	9 (90)
Age, years, mean (SD)	46 (14)	54 (13)
Post-injury time in years, median (range)*	5 (2–33)	3 (2–22)
Traumatic injury, n (%)	4 (40)	6 (60)
Injury level, n (%)		
Cervical	3 (30)	5 (50)
Thoracic	4 (40)	4 (40)
Lumbar	3 (30)	1 (10)
ASIA classification, n (%)		
AIS C	3 (30)	3 (30)
AIS D	7 (70)	7 (70)
Marital status, n (%)		
Married	3 (30)	4 (40)
Other	7 (70)	6 (60)
Smoker, n (%)	1 (10)	1 (10)
Education, n (%)		
<7 years	1 (10)	0
Elementary school	0	2 (20)
High school	6 (60)	4 (40)
University	3 (30)	4 (40)
At work, yes, n (%)	5 (50)	2 (20)
Use of antispasmodics, n (%)	6 (60)	2 (20)
BMI (kg/cm^2), mean (SD)	25.7 (5.1)	25.2 (2.5)
Ambulation ability, n (%)		
Wheelchair dependent	5 (50)	2 (20)
Wheelchair independent	3 (30)	2 (20)
Combined user	2 (20)	6 (60)
Use of assistance/day, n (%)		
None	6 (60)	8 (80)
>2 h	3 (30)	1 (10)
3–5 h	0	1 (10)
>6 h	1 (10)	0

BMI: body mass index; SD: standard deviation; ASIA: American Spinal Injury Association; AIS: American Spinal Injury Association Impairment Scale.

Table II. Outcome measures at baseline

Variables	Intervention group (n=10) Mean (SD)	Control group (n=10) Mean (SD)
10MWT, m/s	0.5 (0.5) n=8	0.5 (0.3) n=8
6MWT, m	226 (151) n=7	165 (98) n=7
LEMS	26.9 (13.0)	28.3 (12.6)
BBS, mean (SD)	32 (19)	29.3 (18.2)
MFR, cm	40 (7)	42 (12)
VO_{2max}, l/min	1.4 (0.5)	1.5 (0.4) n=8

SD: standard deviation; BMI: body mass index; LEMS: lower extremity motor score; 6MWT: 6-min walk test; 10 MWT: 10-m walk test; WISCI: Walking Index for Spinal Cord Injury; BBS: Berg's Balance Scale; MFR: Modified Functional Reach test; VO_{2max}: maximal oxygen uptake.

and there was no significant difference between the groups (–4.3 m (95% CI –52.7, 44.1)) (Table V). One subject was unable to walk due to pain in his lower limb, thus we were only able to repeat the 6MWT in 6 subjects in the control group.

Baseline range in LEMS was similar in the 2 groups, 6 to 46 and 8 to 40 points in the intervention and control groups, respectively. In the intervention group, LEMS increased by a mean of 2.1 points (SD 2.8, p=0.05), whereas there was little change in the control group (mean change –0.6 (SD 5.1), p=0.75).

Table III. Body-weight supported locomotor training data from the intervention group, n=9

Characteristics	Mean (SD)	Min–Max
Number of days[a]	56 (4)	50–60
Days from 1st to last training session	154 (20)	137–189
Distance stepped per training day, m[b]	1,202 (420)	741–1,746
Effective stepping time on treadmill, min/day	36 (12)	21–54
Used bodyweight support, kg[c]	24.4 (5.0)	9.1–30.6
Used stepping speed on treadmill, km/h	2.0 (0.3)	1.4–2.3
Used stepping speed on treadmill, m/s	0.6 (0.1)	0.4–0.6

[a]Major public holidays prohibited completing 60 training sessions or participants travel arrangements from the rehabilitation facility to home. [b]Total of 2 training sessions up to 90 min on treadmill. [c]Mean kg of all training sessions through stays 1 and 3. SD: standard deviation.

Table IV. Mean change in walking distance and walking speed on the treadmill from first to last training session

	Mean diff (95% CI)	p-value
Distance walked per training session, m	301 (–43, 644)	0.08
Speed, km/h	0.9 (0.5, 1.3)	0.001

95% CI: 95% confidence interval.

The difference in mean changes between the groups was 2.7 (95% CI –1.4, 6.8, p=0.19) (Table V).

As part of the statistical plan, a few a priori variables were selected for possible adjustment in the final analyses. Because of the small numbers, the intervention and control groups were imbalanced with respect to baseline levels of some of these *a priori* selected variables. Adjustment by multivariable linear regression did not change the main results (Table SI[1]).

Other outcomes

Changes in balance, as measured by BBS and MFR, are shown in Table V. There was no significant difference in change between the groups for either outcome, –1.2 points 95% CI (–4.3, 1.9), p=0.42 and 6.6 cm (–5.4, 18.5), p=0.26, respectively, for BBS and MFR (Table V). There was no significant change in VO_2 measurement in any group, nor in the difference between them ((0.0 l/min, 95% CI (–0.2, 0.3), p=0.87)) (Table V). However, for the VO_2 test there were small numbers

Table V. Changes in walking speed and walking distance, strength, balance, aerobic capacity, from baseline to evaluation 2–4 weeks post-intervention/control period

Variables	Intervention group (n=9) Mean (SD)	p-value	Control group (n=9) Mean (SD)	p-value	Difference in mean change between the groups (95% CI)*	p-value
10MWT	0.2 (0.3)[a]	0.14	0.1 (0.2)[a]	0.23	0.1 (–0.2, 0.4)	0.43
6MWT	25.4 (40.9)[a]	0.15	29.6 (38.2)[b]	0.12	–4.3 (–52.7, 44.1)	0.85
LEMS	2.1 (2.8)	0.05	–0.6 (5.1)	0.75	2.7 (–1.4, 6.8)	0.19
BBS	0.0 (2.6)	1.00	1.2 (3.9)	0.33	–1.2 (–4.3, 1.9)	0.42
MFR, cm	0.8 (15.4)	0.88	–5.8 (6.9)	0.04	6.6 (–5.4, 18.5)	0.26
VO_{2max} l min^{-1}	–0.1 (0.2)[a]	0.37	–0.1 (0.2)[c]	0.18	0.0 (–0.2, 0.3)	0.87

[a]n=7, [b]n=6, [c]n=8, *Change in intervention group – change in control group.
10MWT: 10-m walk test; 6MWT: 6-min walk test; LEMS: lower extremity motor score; BBS: Berg's Balance Scale; MFR: Modified Functional Reach test; VO_{2max}: maximal oxygen uptake; SD: standard deviation; 95% CI; 95% confidence interval.

of subjects, since 2 subjects missed the baseline testing, and 3 were unable to perform the post-test due to technical problems.

DISCUSSION

To the best of our knowledge, the present study is the first RCT to include only subjects with longstanding incomplete SCI (AIS C and D), >2 years post-injury, i.e. when spontaneous improvement is no longer expected. In addition, the study included a control group that received usual treatment. The treatment effects were modest, and not statistically significant.

Are the present results poor compared with previous studies?

There are a number of previous RCT training studies in SCI (13). However, they merely compare various training forms without a control group receiving the non-intensive training that is usual at this stage post-injury. In the present context, these studies must therefore be regarded as observational, presenting the sum of spontaneous improvements and true training effects. Only one non-randomized study from 1995 has a control groups similar to ours (3). The positive results of this study sparked interest in conducting training studies, but the findings have not been replicated. A large observational multicentre study recruited 146 patients early after SCI (8 weeks post-injury). The patients were unable to walk, or needed assistance to ambulate (15). Similar to our study, authors report measured, but not statistically significant, improvement in walking speed. A meta-analysis of the effects of training is inconclusive (13), but methodological issues complicate comparison of the studies. In general, uncontrolled studies achieve better results, probably due to spontaneous recovery, assessors' bias etc. (2–6).

The majority of subjects in the current study had some walking function at baseline, and both their walking distance and speed increased or were maintained in the intervention group. However, the improvements were modest. The small improvement in walking speed (0.1 m/s) may, however, be clinically relevant (15, 22), but this is uncertain, since a walking speed of at least 0.44 m/s is required for community walking (7, 22, 23). A minimum of 46 m (22) or 31 m (13) increase in the 6MWT is considered clinically meaningful, but the improvement in both of the groups in the current study was smaller.

In line with this research, most previous studies report small effects. Some found increased walking speed of magnitude similar to the current study (0.2 m/s increase for the intervention group) (4, 5, 7, 13), 2 studies report greater (6, 24), and 2 somewhat poorer improvement (8, 21). On average, our subjects improved distance walked/endurance by 25 m, comparable to the findings of 2 other studies (8, 21). Two studies have reported better results among those with post-injury time from 8 weeks to <3 years (5, 15) and one reports poorer improvement (24).

Similar to 3 observational studies (5, 6, 21), subjects in the current study who were unable to establish walking function, had poorer baseline neurological status (5, 6, 21) and balance (5) than the rest of the group. On the other hand, and in line with previous findings (5, 6, 21), subjects in the current study with the weakest walking function tended to make the largest percentage improvement.

Lower extremity muscle strength can predict walking function in subjects with SCI, and scores of 30 or more are common in subjects with functional/community walking ability, whereas scores <20 are associated with poor walking ability (7, 25, 26). LEMS improved 2.7 points more in the intervention group than among controls (not significant). Several studies have shown that BWSLT improves lower limb strength in subjects with SCI (3, 7, 8, 15, 21). Two studies (4, 21) report improvement of similar size as in the present study, whereas another study (7) found as much as 9.1 points improvement in LEMS in the BWSLT group vs 2.9 points reduction in the physical therapy group, possibly due to early onset of training and better baseline function. In contrast to our study, others have found that those with higher baseline LEMS experience most improvement in walking speed (7, 25, 26). An improvement of >6 points in LEMS may be needed to detect a significant clinical change. It is thus questionable whether the present small, borderline significant improvement in LEMS contributes to subjects' walking ability. However, it is possible that BWSLT can improve postural stability in standing and sitting positions, through increased muscle strength and coordination. The clinical importance of the current findings seems to be modest, but even a small improvement may be important to an individual who struggles to cope with activities of daily living (5, 13).

Was the function too poor at baseline?

We chose to study subjects with poor baseline walking function since data on their training effects are scarce. Previous studies included no, or only a few, subjects who were unable to stand or to move at least 1 step (4, 7, 15). In the large observational study the majority of non-responding subjects were among those with poor baseline function (5). However, in addition, a large proportion (13 of 19 AIS D and 15 of 50 AIS C) who were unable to ambulate at baseline, had regained some

walking function at the final evaluation (5). Thus, poor baseline function does not preclude benefit, but training is perhaps most useful for those who can already walk a little (4, 5, 7, 8).

Was the onset of training too late?

In 3 trials with early enrolment (≥7 months, 9–11 months or 1+ years post-injury) walking ability improved significantly (7, 8, 24). Yang et al., studying 22 participants with post-injury time ≥7 months, found significant 27-m improvement in distance walked in the BWSLT group (focus on endurance training), similar to our findings, compared with 10 m in controls (precision training) (8). Harkema et al. report the greatest improvements among those recruited ≤1–3 years post-injury, compared with later onset of training, whereas training initiated >3 years post-injury, resulted in less functional improvement (5). Findings among the group with longest post-injury time were similar to our results. Several of our subjects were included even later than this. Interestingly, some have also reported good results with training starting several years after SCI (21). BWSLT should possibly start earlier, but then spontaneous recovery of function is frequent, and a much larger study is required to account for large variations (27).

Improvements in secondary outcomes

Balance control scores were below 45 at baseline, indicating poor balance (18), and did not improve. Some (3, 5, 21), but not all BWSLT studies (7), show improved balance. Falls and fall-related injuries are well-known complications after SCI (28), and improvement gained in truncus stability and balance after BWLT could contribute to the prevention of such events.

In spite of the training, there was no improvement in maximal oxygen uptake. Alexeeva et al. (7) reported similar findings. The negative findings are, however, not surprising because testing was done with arm crank cycling, while training was directed at legs and trunk.

Could our training programme be non-optimal?

The present training protocol was conventional. We doubt whether patients would tolerate more intense or longer training, and this was also limited by available resources. Furthermore, recently no correlation was found between training dose and outcome in various gait training protocols (29). However, increasing the amount of over-ground training could be considered (4, 15, 24).

Study strengths, weaknesses and limitations

This study has several strengths. The single-centre study design reduces method variation, and the single-blind design reduces evaluation bias. Post-injury time ≥2 years reduces spontaneous improvement, allowing a lower number of study subjects. The main weakness is the slow rate of patient recruitment, which forced us to close the study when only two-thirds of the target patient number was reached. *Post-hoc* analysis revealed that, assuming better balanced groups, we would need a study size between 76 and 208 participants to detect significant improvements. Thus, the study was statistically underpowered, resulting in unbalanced groups at baseline (Table I), and a low probability of detecting modest improvements. The number of eligible and willing subjects was overestimated. Due to our 2-year post-injury requirement, some subjects had adapted well, and were reluctant to invest time, travelling and efforts on a project with an uncertain outcome. Another limitation is that we relied on usual care for the control group. At least 2 control subjects increased their training during the trial, attenuating the effect size of the intervention. Also, the majority of the control group had over-ground gait training as part of their regular physical therapy. Despite the limitations of the present study, our experience illustrates the complexity of conducting such clinical research.

Conclusion

BWSLT with manual assistance was well tolerated, and led to statistically non-significant improvements in walking and lower extremity muscle strength. The present results neither prove nor disprove the efficacy of this training, but suggest that the benefit is, at the best, modest in patients with poor function long after injury. Future research should include a higher number of participants and use block randomization based on function.

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The authors have no conflicts of interest to declare.

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Paper II

Piira A, Lannem AM, Sørensen M, Glott T, Knutsen R, Jørgensen L, Gjesdal K, Hjeltnes N & Knutsen SF. **Robot-assisted locomotor training did not improve walking function in patients with chronic incomplete spinal cord injury: a randomized clinical trial. Short communication**. Journal of Rehabilitation Medicine, 2019; 51: 385-389.

J Rehabil Med 2019; 51: 385–389

SHORT COMMUNICATION

ROBOT-ASSISTED LOCOMOTOR TRAINING DID NOT IMPROVE WALKING FUNCTION IN PATIENTS WITH CHRONIC INCOMPLETE SPINAL CORD INJURY: A RANDOMIZED CLINICAL TRIAL

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Objective: **To assess the effects of robot-assisted locomotor training in patients with chronic incomplete spinal cord injury.**

Design: **Randomized single-blind controlled clinical trial.**

Setting: **The intervention site was an outpatient clinic, and pre- and post-evaluations were performed in a rehabilitation hospital.**

Patients: **A total of 24 subjects with American Spinal Injury Association Impairment Scale grades C or D, > 2 years post-injury.**

Interventions: **Subjects were randomized to 60 days of robot-assisted locomotor training, or to usual care.**

Methods: **Walking function, lower extremity muscle strength and balance were assessed single-blinded pre- and post-intervention.**

Results: **After a 9-year recruitment period, only 24 of the planned 30 subjects had been enrolled (mean time since injury 17 (standard deviation (SD) 20) years for all subjects). Walking function, lower extremity muscle strength and balance improved modestly in both groups, with no statistically significant group difference in walking function or muscle strength, whereas postural control declined significantly in the intervention group, compared with controls ($p = 0.03$).**

Conclusion: **Late-onset robot-assisted locomotor training did not re-establish independent walking function. A modest, but non-significant, effect was seen on muscle strength and balance. However, significant between-group differences were found only in postural control in the control group.**

Key words: spinal cord injury; robot-assisted locomotor training; gait; treadmill.

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LAY ABSTRACT

This randomized clinical trial assesses the effects of robot-assisted treadmill training in persons with chronic incomplete spinal cord injury acquired > 2 years earlier. Due to recruitment challenges, it was possible to recruit only 63% of the planned number of participants. The intervention group received gait training 3 days per week for a period of 6 months and the control group received usual care with their local physical therapist. The intervention group showed improvements in lower extremity strength and balance, but no change in walking function. Significant between-group difference was found only in postural control, favouring the control group. Because the target number of study participants was not reached, the study was underpowered and non-significant, and thus the findings are inconclusive. This training method may have benefits, but the robotic device is expensive and training effects are limited when the person's baseline function is poor and the training starts late in incomplete spinal cord injury.

Various locomotor training methods have been used in attempts to recover walking function after spinal cord injury (SCI). Older (1, 2) and more recent studies (3–7) have reported promising results by using robotics to recover gait. A review from 2017 concluded that robot-assisted locomotor training (RALT) had effects similar to other types of body-weight-supported locomotor training, and to the same amount of conventional training or physical therapy (8), in re-establishing walking independence and endurance/distance walked.

A number of randomized controlled trials (RCTs) using robotic walking therapy have been conducted with varying types of control groups, degree of injury, time since injury, site of the lesion, and varying number and length of the training sessions (3–7, 9–11). These and other factors, such as use of anti-spastic medication, all seem to influence the outcome.

Several RCTs have compared different intensive training forms in subjects with chronic or subacute SCI. However, these studies control groups did not receive "usual care". Rather, the control groups received other interventions, such as over-ground gait training with or without functional electrostimulation (4, 11), conven-

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tional physical therapy (3), or body-weight-supported locomotor training with manual assistance (11).

Spontaneous improvement after SCI can occur up to 2 years post-injury (12), and, as expected, uncontrolled studies of training in the early phase after injury show more recovery of walking function than when training starts later. Regardless of methodological differences in the studies, there seems to be consensus that early gait training in motor incomplete SCI improves walking function irrespective of the training method (8).

Subjects with incomplete SCI with more severe functional deficit also seem to benefit from RALT. However patients without walking function before training are also frequently unable to walk independently after intervention (1, 11, 13).

There are little data available regarding late-onset training in subjects severely affected by SCI. We recently published a controlled study on manually assisted weight-supported locomotor training in subjects with chronic incomplete SCI (2+ years post-injury), with severely reduced or no walking function (13). The rationale for the present robot-assisted RCT was to investigate whether a less personnel-demanding robot-assisted training programme would have similar treatment effects as the manually assisted approach in comparison with control groups receiving usual care. The 2 studies are parallel in design, outcome assessment and time, but the participants, training site and staff are different.

METHODS

Recruitment and consent

Compared with our previous study (13), which recruited subjects nationally, subjects in this study were eligible if they lived within 70 km of the training site. Recruitment occurred either from Sunnaas Rehabilitation Hospital or through advertisements in magazines for persons with SCI. Written informed consent was obtained prior to inclusion. The study was approved by the Regional Committee of Ethics (REK) in North Norway (P REK NORD 69/2008 and 2009/634-5) and ClinicalTrials.gov identifier #NCT00854555.

Inclusion criteria included age 18–70 years, motor incomplete SCI classified as American Spinal Injury Association (ASIA) Impairment Scale (AIS) C or D at least 2 years post-injury. Subjects should be mainly wheelchair-dependent with or without some walking function, have a body mass index (BMI) $\leq$30, and be cognitively unaffected. Exclusion criteria were conditions that might prevent or conflict with locomotor training (13) or physical limitations for using the robotic device.

Setting

Evaluation and testing were completed within 30 days before randomization, and post-evaluation within 14–30 days after completion of the intervention/control period. Examiners were not involved in the training. Subjects were randomized to either intervention (I) or control group (C) using concealment by sealed envelopes. The outpatient intervention site was located in the Oslo area. Assessments were conducted single blindly at Sunnaas Rehabilitation Hospital. Subjects were instructed to not change their anti-spasticity medication during the study period.

Training protocol

Intervention subjects received 60 days of RALT, with 3 training sessions per week over a period of 6 months. The Lokomat® gait training robot (version 4.0) (HOCOMA, Zürich, Switzerland) was used. Each session included preparation (stretching, fitting harness, etc.) for approximately 20–30 min, stepping on a treadmill 20–60 min with body-weight support <40% of the subject's initial weight, and, finally, a few minutes of overground walking and/or exercises on the treadmill if time permitted. Subjects' feet and hips were secured to motorized braces and, during the treadmill walking, the subjects received continuous feedback on their contribution to the movements. Computer-controlled motors, synchronized with the speed of the treadmill, moved the subjects' legs through trajectories that imitate physiological gait patterns. One therapist managed the training session. Progression in the training programme was defined as a reduction in body-weight support, adjusted guidance force and/or an increase in walking speed.

Similar to the control group of our manually assisted RCT (13), control subjects received low-intensity usual care from their local physical therapist, usually 1–5 times per week. Their daily activities and training were recorded in a diary that was submitted once a month. To secure compliance, control subjects received regular follow-up telephone calls.

The primary outcome was full or partial recovery of walking function, and there were several secondary outcomes: walking speed and endurance were assessed using the 10-m walk test (10MWT) and 6-min walk test (6MWT). Lower extremity motor score (LEMS), a subscale of ASIA classification, was used to evaluate strength in the lower limbs. Dynamic balance and postural control were assessed by Berg's Balance Scale (BBS) and the Modified Functional Reach test (MFR), respectively. All tests have been described in detail elsewhere (13).

Power and statistical analysis

Sample size. Based on our unpublished pilot data and literature (1, 13), it was estimated that 30 subjects (15 in each group) were needed to obtain a statistical power of 0.80 with alpha error 0.05 for the outcomes walking speed, endurance and balance.

The main statistical analysis compared mean or median changes from baseline to final evaluation. The 2 groups were compared at baseline using χ^2 test/Fisher exact for categorical variables and independent sample *t*-test (2-tailed, significance level $p < 0.05$) for continuous variables. For non-normally distributed data, Mann–Whitney test was used. Paired samples *t*-test or Wilcoxon signed-rank test were used to analyse changes within groups. Difference in change between the 2 groups was assessed using Mann–Whitney test. Effect size was calculated using correlation coefficient, *r*, to determine the magnitude of the treatment effects. All analyses were performed using the 23rd version of SPSS for Windows (IBM SPSS, Armonk, New York, USA).

RESULTS

It was not possible to recruit the predetermined number of subjects within a reasonable time. After 9 years, only 24 of the planned 30 subjects had been randomized. Four subjects had an early dropout from the intervention group, and 1 was non-compliant (completed only one-third of sessions). Thus, the study population included only 7 intervention and 12 control subjects. There was no significant group difference at baseline, although the intervention group was older (mean 9 years), had a larger proportion traumatic SCIs, and had less walking function at baseline (Table I).

The intervention was well tolerated with no adverse events, except for minor issues such as small leg abrasions. In the control group, no change in the frequency of physical therapy sessions was noted. The intervention subjects had a mean of 59 days (standard deviation SD 2 days) of RALT, and sessions lasted 48 min (SD 8 min). The mean distance walked was 2,271 m (SD 465 m), and the mean body-weight support was 40% (SD 21%), with a guidance force of 82% (SD 8%) per training session.

Table I. Baseline demographics of the final sample of subjects according to the Intervention or Control group with robot-assisted locomotor training

Variables	Intervention group *n* = 7	Control group *n* = 12
Sex, *n* (% males)	4 (57)	5 (42)
Age, years, mean (SD)	55 (8)	46 (15)
Post-injury time, years,		
Mean (SD)	21 (23)	15 (18)
Median (range)	8 (2–54)	7 (2–48)
Traumatic injury, *n* (%)	6 (86)	6 (50)
Injury level, *n* (%)		
Cervical	4 (57)	6 (50)
Thoracic	3 (43)	6 (50)
Lumbar	0 (0)	0 (0)
ASIA classification, *n* (%)		
AIS C	1 (14)	5 (42)
AIS D	6 (86)	7 (58)
Marital status, *n* (%)		
Married	3 (43)	4 (33)
Other	9 (57)	8 (67)
Smoker, *n* (%)	2 (29)	5 (42)
Education, *n* (%)		
< 7 years	0 (0)	0
Elementary school	1 (14)	0 (0)
High school	2 (29)	3 (25)
College	2 (29)	2 (17)
University	2 (29)	7 (58)
At work, yes, *n* (%)	2 (29)	4 (33)
Use of antispasmodics, *n* (%)	3 (43)	5 (42)
BMI (kg/cm^2), mean (SD)	25.9 (3.8)	25.0 (5.4)
Walking function, *n* (%)		
Wheelchair dependent with some or without walking function	6 (86)	12 (100)
Wheelchair independent – walking function with assistive device	1 (14)	0 (0)

SD: standard deviation; BMI: body mass index.

Recovery of walking function. This goal was not achieved in any subject.

Walking speed and endurance. Despite randomization, the groups differed in several respects. All subjects in the intervention group had some walking function, whereas 3 subjects in the control group were unable to walk. Also, the controls with some baseline walking function had twice the walking speed and endurance compared with the I-group. Both groups improved or maintained their walking speed (10MWT) at post-test. However, the group difference in improvement was small and not statistically significant. Mean endurance (distance walked), as measured by the 6MWT, improved more in the control group (23.1 vs 6.6 m, not significant) than the intervention group (Table II).

Lower extremity motor score. In the intervention group, LEMS increased by 5.4 points, vs 0.2 in controls (Table II).

Balance. Changes measured by BBS, were minimal, but there was a statistically significant group difference in postural control (MFR), which declined 8.6 cm more in the intervention compared with the control group (Table II).

DISCUSSION

This study is among the first RCTs to include only subjects with chronic incomplete SCI (AIS C and D) >2 years post-injury, when spontaneous recovery is no longer expected. Furthermore, the study includes a control group that received low-intensity usual care. The effects of RALT were small and not statistically significant. Similar to previous studies, RALT was well tolerated and safe with no serious injuries reported (8).

Effects on walking

Our results confirm those of previous studies: Field-Fote and co-workers reported non-significant improvements in walking parameters both for RALT and other interventions, except over-ground training, in a group with baseline gait function similar to our study (11), as did Duffell et al. (7) and Niu et al. in their non-blinded RCTs (5). However, the latter study demonstrated significant improvements in walking speed and endurance in the higher functioning group, and Varoqui et al. reported 0.08 m/s improvement in their I-group, against no effects in controls (6).

Effect on lower extremity muscle strength

LEMS scores >30 are common in subjects with functional walking, whereas scores <20 are associated

Table II. Changes in walking speed and walking distance, strength, and balance from baseline to evaluation 2–4 weeks post-intervention/control period

	Intervention group ($n = 7$)			Control group ($n = 12$)			Difference in mean change between the groups** I vs C group			
Variables	Baseline (range)	Mean change (range)	*p*-value	Baseline (range)	Mean change (range)	*p*-value		Z	*p*-value	r
10MWT	0.3 (0.1–0.7)	0 (–0.1–0.1)	0.80	0.6 (0.1–1.0)	0.1 (–0.1–0.6)*	0.44	–0.1	–0.58	0.61	–0.15
6MWT	82.3 (25.0–214.5)	6.6 (–14.0–34.0)	0.25	170.4 (63.0–390.0)	23.1 (–45.0–43.0)*	0.59	–16.5	–0.27	0.84	–0.07
LEMS	28.4 (14.0–38.0)	5.4 (–1.0–19.0)	0.03	27.2 (9.0–47.0)	0.2 (–11.0–7.0)	0.69	5.2	–1.40	0.17	0.32
BBS	18.3 (5.0–37.0)	4.3 (0–10.0)	0.03	19.8 (4.0–48.0)	3.2 (–1.0–9.0)	0.04	1.1	–0.77	0.48	0.18
MFR, cm	47.0 (42.0–55.0)	–11.0 (–19.0–0)	0.03	43.0 (20.0–55.0)	–2.4 (–14.0–8.0)	0.28	–8.6	–2.17	0.03	–0.50

*$n = 9$; **(Intervention – Control)
10MWT: 10-m walk test; 6MWT: 6-min walk test; LEMS: lower extremity motor score; BBS: Berg's balance scale; MFR: Modified Functional Reach test. Non-parametric test used. r: effect size; r = 0.10 small effect; r = 0.30 medium effect; r = 0.50 large effect.

with poor walking function at baseline (9, 14). Our baseline scores were mostly intermediate, and improved after RALT, similar to previous findings (3, 4). Those with higher baseline LEMS, seem to gain most improvement in walking speed (11).

Balance

There were poor baseline balance scores with significant improvement (4.3 points) in the intervention group compared with controls (3.2 points). However, postural control declined, possibly due to training-related stiffness. In comparison, balance assessed with the Timed-Up-and-Go test, also improved in 3 small RALT studies (1, 5, 6). RALT may improve truncus stability, and even a small improvement here may be important to a person with poor function in daily life (8, 9).

Late-onset robot-assisted locomotor training

A recent meta-analysis (8) concludes that gait training in subjects with injury < 1 year ago (2–4) have better effects on walking function than studies, such as the present and others (1, 5–9, 13), conducted years after injury. In addition, LEMS improves most in subjects with subacute SCI (3, 4), whereas among subjects with chronic SCI, only minor improvements are found (1, 11). Cheung et al. (8) argue that neuroplasticity is more efficient in the acute stage, and repetitive functional gait training improves muscle activation and facilitates learning of new walking patterns to a larger degree at this stage.

Baseline function may be important

It was decided to include subjects with poor baseline walking function since data on their training effects are more limited. Mirbagheri et al. (10) found that subjects with more baseline neuromuscular disturbances were more likely to have reduced spasticity after RALT. Based on studies so far, including meta-analyses (8), the effects of RALT on walking function remain inconclusive, and it is still unclear whether subjects with chronic SCI without baseline gait function are able to regain functional walking (5, 10, 11). However, even among non-walkers, there appear to be some benefits of gait training, such as improved VO_2 and neuromuscular control (9, 10).

Strengths, weaknesses and limitations

The present study has several strengths: most important is the usual care control group. A single centre reduces method variation, and single-blind design diminishes evaluation bias. Post-injury time > 2 years reduces spontaneous improvement, allowing a lower number of subjects.

The main limitations are the slow recruitment and the drop-out subjects. Thus, the study was statistically underpowered with a low likelihood of detecting modest improvements, albeit, large enough to demonstrate no major gains. The number of eligible subjects was overestimated. Due to the 2-year post-injury inclusion requirement, some subjects were well-established in their life with a disability, and reluctant to invest the time and effort required. The low number of subjects recruited resulted in unbalanced baseline characteristics (Table I). For instance, the C-group had a baseline walking function twice that of the I-group, which may have attenuated potential positive effects, as could the fact that the usual care (C-group) had over-ground gait training in some cases. More intense or longer training would hardly be tolerated, and furthermore, no relation was previously found between training dose and outcome in various gait training protocols (15). Our experience exemplifies the complexity of this type of clinical research.

Conclusion

In conclusion, the primary goal of re-establishing walking function was not achieved, and between-group differences in secondary outcomes were not observed, except the unexpected decline in postural control favouring the control group. Small, non-significant improvements in lower extremity strength and ba-

lance were found, but not in walking function. As the study was underpowered, it cannot be excluded that RALT may have some, although modest, effects on this subject group. The fact that both manual (13) and the present robot-assisted RCT gave such small gains among subjects with chronic incomplete SCI, suggests that the treatment effects are limited and cost-benefit low when baseline function is poor and training starts late in subjects with incomplete SCI.

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The authors have no conflicts of interests declare.

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Paper III

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ARTICLE

Quality of life and psychological outcomes of body-weight supported locomotor training in spinal cord injured persons with long-standing incomplete lesions

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Abstract

Study design Health-related quality of life (HRQOL) data from two parallel independent single-blinded controlled randomized studies of manual (Study 1) and robotic (Study 2) locomotor training were combined (ClinicalTrials.gov #NCT00854555).

Objective To assess effects of body-weight supported locomotor training (BWSLT) programs on HRQOL in persons with long-standing motor incomplete spinal cord injury and poor walking function.

Settings Two inpatient rehabilitation facilities and one outpatient clinic in Norway.

Methods Data were merged into intervention (locomotor training 60 days) or control group ("usual care"). Participants completed questionnaires before randomization and 2–4 weeks after the study period, including demographic characteristics, HRQOL (36-Item Short-Form Health Status Survey, SF-36), physical activity (The International Physical Activity Questionnaire Short Form, IPAQ-SF), exercise barrier self-efficacy (EBSE), and motivation for training (Behavioral Regulation in Exercise Questionnaire, BREQ). Physical outcomes i.e., Lower extremity motor score (LEMS) was assessed. The main outcome was change in HRQOL. Secondary outcomes included changes in IPAQ-SF, EBSE, BREQ, and physical outcomes.

Results We recruited 37 of 60 predetermined participants. They were autonomously motivated with high baseline physical activity. BWSLT with manual or robot assistance did not improve HRQOL, though LEMS increased in the BWSLT group compared with control group.

Conclusions The study was underpowered due to recruitment problems. The training programs seem to benefit LEMS, but not other physical outcomes, and had minimal effects on HRQOL, EBSE, and motivation. Autonomous motivation and high physical activity prior to the study possibly limited the attainable outcome benefits, in addition to limitations due to poor baseline physical function.

Introduction

In the last decades, body-weight supported locomotor training (BWSLT) has been promoted as a rehabilitation tool for persons with incomplete spinal cord injury (SCI) [1]. An early report [2] and more recent studies [3–8] show that BWSLT improves walking function for persons with

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SCI in subacute (<1 year post injury) and chronic (≥1 year post injury) phases. Also, health-related quality of life (HRQOL) [5, 6, 9] and perceived physical function seem to improve [8–10] in the chronic phase, but so far, HRQOL-studies following BWSLT are relatively few [5–10]. Table 1 provides an overview of BWSLT studies that have assessed HRQOL and well-being among SCI populations with postinjury time >1 year. A recent review and meta-analysis of activity-based interventions among SCI populations included three BWSLT randomized controlled trials (RCTs) that assessed HRQOL [11]. The authors conclude that such intervention had no effect on HRQOL compared with none or conventional physical therapy.

Although the main goal of BWSLT is to improve walking function, there may be secondary psychological benefits from the experience of standing and walking [9]. In addition, there are several psychosocial factors at work in an intervention, such as psychological needs satisfaction or social support from instructors. Few studies have assessed the role of psychosocial factors in relation to how they influence the outcomes and individual experiences of a BWSLT program. Knowing that psychosocial factors influence, and are influenced by a totality of experiences and behavior, the present study tests the hypothesis that compared with controls, a BWSLT intervention improves HRQOL and psychological outcomes such as exercise barrier self-efficacy (EBSE) and quality of motivation in participants with long-standing (+2 years post injury) incomplete SCI with severely reduced physical function (walking function, lower limb muscle strength or balance).

Methods

Design

We combined data from our two independent single-blinded randomized controlled RCTs [12, 13], study 1 with manually assisted BWSLT and study 2 with robot assistance. The studies follow the CONSORT 2010 guidelines, were approved by the Regional Ethics Committee in North Norway (P REK NORD 69/2008 and 2009/634–5) and registered in ClinicalTrials.gov (#NCT00854555).

Recruitment

Briefly, participants were recruited nationwide through the Norwegian SCI units and cooperation with patient organizations. For logistical reasons, participants from the entire country, except the Oslo area, were enrolled to the inpatient study in Tromsø (Study 1), whereas those living within driving distance from Oslo were enrolled as outpatients (Study 2). Written informed consent was obtained prior to inclusion.

Participants

The study included adults (18–70 years) with motor incomplete SCI classified as American Spinal Injury Association (ASIA) Impairment Scale grade C or D (AIS C-D) [14], with postinjury time +2 years and body mass index <30 kg/m^2. Participants were primarily wheelchair dependent, cognitively unaffected and motivated for BWSLT (Supplementary Fig. 1) and instructed to continue their usual dose of antispasmodic medication and physical activity level throughout the study.

Setting

Pre- and post-intervention evaluations were conducted single-blinded by the same physical therapists and physicians at Sunnaas Rehabilitation Hospital, Norway.

Randomization

In both studies, participants were randomized in blocks of ten by the sealed envelope method.

Training protocol

Intervention consisted of 60 training days of BWSLT, either with manual or robotic assistance 60–90 min per day, 3–5 days per week over 6 months [12, 13]. Participants were suspended in a body-weight support system with treadmills (Vigor Equipment, Inc., Stevensville, MI, USA) (Study 1) or the Lokomat® gait training robot (HOCOMA AG, Zürich, Switzerland, version 4) (Study 2). A physical therapist supervised three to five staff members (Study 1) or controlled the robotic device (Study 2).

Control group

The C-group received usual care, typically one-on-one, by their local physical therapists 1–3 times per week (range 0–5). Telephone follow-up secured compliance [12, 13]. After the study period, control participants were offered the BWSLT.

Outcome measures

Prior to randomization, baseline evaluation occurred within 1 month before and post evaluation 2–4 weeks after the study period. Assessors were blinded to participants' group allocation.

Physical outcome variables included lower extremity motor score (LEMS), 10-meter walk test, 6-min walk test and Berg balance scale, modified functional reach, and aerobic capacity (VO_2) [12, 13] (Table 2). Self-administered

Table 1 Overview of randomized and non-randomized body-weight supported locomotor training studies that have assessed health-related quality of life.

Author	Study design	Intervention	Early/late SCI, years	*N*	Control group	Physical assessment and results	QoL assessment and results	Bias risk[a]					
								A	B	C	D	E	F
Hicks et al. [9]	Non-RCT	Manually assisted BWSLT 60 min 3/week for 15 weeks	>1	14	No	Assessment: Walking function was tested on a treadmill. Results: Reduction in use of BWS. Increased walking speed and distance walked. Positive association between satisfaction in life and in physical function with improved in walking function.	Assessments: subjective well-being that includes QoL: 1.CES-D 2. SF-36: general health 3. SWLS 4. IADL Results: No effect on CES-D, SF-36 nor IADL. Significant improvement in SWLS.	+	+	+	+	−	−
Effing et al. [10]	Non-RCT	Manually assisted BWSLT 30 min 5/week for 12 weeks	>1	3	No	Assessments: BBS, TUG test, WCS, and COMP Results: Minor improvements in WCS. No comparison between the three individuals.	Assessment: SEIQoL Results: small and inconclusive in QoL	+	+	+	+	−	−
Adams and Hicks [6]	RCT cross-over	Manually assisted BWSLT or Standing in a tilt table 30 min 3× week for 4 weeks (4 weeks washout period)	>1	7	Yes	Assessments: MAS and Spinal cord assessment tool for spinal reflexes Result: Overall no change in muscle tone. No between group difference.	Assessment: QLI Results: Effect size 0.5 in QoL favoring BWSLT	−	+	+	+	−	−
Alexeeva et al. [5]	RCT	Manually assisted BWSLT or BWSLT in fixed track or conventional physical therapy 60 min 3/week for 13 weeks	>1	35	Yes	Assessments:10MWT, Tinetti scale, VO_2, and LEMS Results: walking speed improved in all three groups, balance improved in conventional and fixed tract training groups, increased LEMS in all three groups. No between group difference in change.	SF-36 subscales for general and mental health and vitality. SAWS subscales. Results: SAWS improvement in all groups No change in SF-36 QoL. Trend positive association between SAWS and balance (ns). Changes in walking speed was not consistent with SAWS scores (ns). No between group difference.	−	−	+	−	−	−
Hitzig et al. [8]	RCT	Manually assisted BWSLT and electrical stimulation assistance or Aerobic and resistance training 45 min 3/week for 16 weeks	>1	27	Yes	Assessments: SCIM for Mobility Results: Between group difference improvement in mobility score favoring intervention group.	Assessment: SWLS Results: No between group difference in changes. No changes within the groups.	−	−	+	−	+	−
Wu et al. [7]	RCT	Manually assisted BWSLT without facilitation of weight shift or Robot-assisted BWSLT with facilitation of weight shift. 45 min 3/week for 6 weeks	>1	16	Yes	Assessments: 6MWT, WISCI, LEMS, BBS, TUG, ABC Scale, and MAS. Results: Improved walking function during BWSLT. Between groups difference only in endurance (6MWT) favoring BWSLT with robotic assistance group.	Assessment:SF-36 PCS and MCS Results: No between group difference in change in QoL.	−	−	+	+	−	−

N number of participants, *BWSLT* Body-Weight Supported Locomotor Training, *BWS* Body-Weight Support, *CES-D* Center for Epidemiological Studies Depression scale, *SF-36* Short Form 36, *SWLS* Satisfaction with Life Scale, *IADL* Instrumental Activities of Daily Living, *SEIQoL* Schedule for the Evaluation of Individual Quality of Life, *WCS* Walking Capability Scale, *COMP* Canadian Occupational Performance Measure, *BBS* Berg Balance Scale, *TUG* Timed Up and Go test, *MAS* Modified Ashworth Scale, *QLI* Quality of Life Index for SCI, *10MWT* 10-meter walk test, *LEMS* Lower Extremity Motor Score, VO_2 oxygen uptake, *SAWS* Satisfaction with Abilities and Well-being Scale, *SCIM* Spinal Cord Independence Measure, *ABC* Activities-Specific Balance Confidence Scale, *6MWT* 6-minute walk test, *PCS* Physical Component Summary, *MCS* Mental Component Summary

[a]The risk of bias refers to A: Random allocation (selection bias); B: Allocation concealment (selection bias); C: Participant or staff blinding (performance bias); D: Assessor blinding (detection bias); E: Incomplete outcome data (attrition bias); F: Selective reporting (reporting bias). High risk is indicated as "+", low risk as "–" and Unclear risk as "?". Reference: The Cochrane Collaboration. The Cochrane Handbook for Systematic Reviews of Interventions Version 5.1.0 [updated in March 2011] The Cochrane Collaboration, 2011

Table 2 Baseline characteristics of the participants included in the study.

Variables	Intervention group ($n = 16$)	Control group ($n = 21$)
Sex, males, (n %)	10 (63)	13 (62)
Age (years), mean (SD), Median (range)	50 (13) 53 (20–69)	49 (14) 52 (22–69)
Post injury time in years, mean (SD)	14.6 (17.2)	11.1 (15.0)
Traumatic injury, n (%)	10 (63)	11 (52)
Injury level, n (%)		
Cervical, n (%)	7 (44)	10 (48)
C1–C4	2	2
C5–C8	5	8
Thoracic, n (%)	6 (38)	10 (48)
T1–4	2	4
T5–8	1	1
T9–12	3	5
Lumbar, n (%)	3 (19)	1 (4)
L1	1	0
L2 or lower	2	1
ASIA classification, n (%)		
AIS C	4 (25)	8 (38)
AIS D	12 (75)	13 (62)
Education, n (%)		
<7 years	1 (6)	0
Elementary school	1 (6)	2 (9.5)
High school	7 (44)	6 (29)
College	2 (13)	2 (9.5)
University	5 (31)	11 (52)
At work, yes, n (%)	7 (44)	6 (29)
Use of assistance per days, n (%)		
None	10 (62)	14 (67)
>2 h	3 (19)	4 (19)
3–5 h	0	1 (5)
>6 h	3 (19)	2 (9)
Smokers, n (%)	3 (19)	6 (29)
SF-36		
PCS, mean (SD)	57.1 (19.5)	53.9 (16.4)
MCS, mean (SD)	77.1 (14.9)	72.7 (16.0)
IPAQ, weekly MET minutes, mean (SD)	5210 (5070)[a]	3601 (2667)[e]
Exercise barrier self-efficacy, mean (SD)	6.1 (0.9)[c]	6.2 (0.8)
Autonomous motivation, mean (SD) (range)	6.0 (0.6)[c] (5.0-6.8)	5.5 (1.1) (3.0-7.0)
Controlled motivation, mean (SD) (range)	2.2 (1.1)[c] (1.0-4.4)	2.7 (1.1) (1.0-5.4)
Importance of the benefits, mean (SD)	5.7 (0.8)[b]	5.6 (0.7)[f]
Meet the outcome expectation (0–100), mean (SD)	79.9 (24.4)[c]	86.6 (22.8)
LEMS, mean (SD)	26.6 (10.6)	27.0 (11.5)
6MWT, mean (SD)	160.1 (137.4)[a]	159.2 (112.5)[c]
10MWT, mean (SD)	0.5 (0.4)[b]	0.5 (0.4)[d]
BBS, mean (SD)	26.1 (18.2)	22.9 (17.3)
MFR, mean (SD)	42.8 (7.4)	43.6 (11.1)
VO_{2max} l/min, mean (SD)	1.5 (0.5)[g]	1.5 (0.4)[d]

Noncategoric values are expressed as mean (SD). Categoric variables are expressed as n (%)

SD standard deviation, *ASIA* American Spinal Injury Association Impairment scale, *IPAQ* International Physical Activity Questionnaire with weekly MET minutes, *SF-36* Short Form 36, *PCS* Physical Component Summary, *MCS* Mental Component Summary, *10MWT* 10-meter walk test, *6MWT* 6-minute walk test, *LEMS* Lower extremity motor score, *BBS* Berg Balance Scale, *MFR* The Modified Functional Reach test, VO_{2max} maximal oxygen uptake

[a] $n = 13$

[b] $n = 14$

[c] $n = 15$

[d] $n = 16$

[e] $n = 18$

[f] $n = 20$

[g] $n = 12$

questionnaires were completed at baseline and post evaluation, and included demographic characteristics, a standardized questionnaire on HRQOL [15, 16] and well-tested, validated questionnaire on physical activity [17], EBSE and motivation for the training [18, 19]. Participants' expectations to the BWSLT and how important these were regarded, were registered. All outcome measures have previously been used in disabled persons [20–23].

The primary outcome was change in HRQOL measured by the 36-Item Short-Form Health Status Survey (SF-36, version 1.2 chronic) [15, 23]. This generic questionnaire includes eight health-related components, from limitation of physical functioning due to health problems to questions on general mental health [15, 16]. Two aggregated component scores were used: (1) Physical component score (PCS) and (2) Mental component score (MCS) with higher score indicating better perception of HRQOL on a scale of 0–100.

Secondary outcomes were changes in (1) Self-reported physical activity, (2) Self-efficacy related to confidence in ability to exercise in spite of barriers, (3) Type of motivation, and (4) Participants' expectations of the results and their importance.

The International Physical Activity Questionnaire short form (IPAQ-SF) gathers information about physical activity from the last 7 days and has shown good or acceptable reliability and validity [17]. Time spent walking/wheeling, engagement in moderate activity, vigorous-intensity activities, time spent sitting, and total physical activity (MET-min/week) were recorded according to IPAQ guidelines (https://sites.google.com/site/theipaq/home) [24].

EBSE was assessed with 14 items rated on a 1–7 scale [18]. We used the Behavioral Regulation in Exercise Questionnaire with 14 items rated on a 1–7 scale, describing the type of motivation on a continuum from external, identified, introjected and intrinsic motivation [19]. These subscales were merged and reported as autonomously regulated (intrinsic and introjected), and controlled motivation (external and identified). According to Self-determination theory, the autonomous types of motivation are the more robust forms [19]. Outcome expectations were assessed by asking the participants to note expectations they believed to gain from the BWSLT and rate how well they thought they were able to meet the expectations, on a scale of 0–100 [19]. Physical outcome measures are described in detail elsewhere [12, 13].

Statistical analysis

Sample size estimation was based on data from our pilot study and the literature. For each study, 30 participants (15 in interventions and 15 in controls) were required to obtain statistical power of 0.80 with alpha error 0.05 for the primary outcome, walking function [12, 13]. HRQOL and the psychological outcomes were not used in sample size calculation, since the primary aims of the original studies was on changes in physical outcomes.

For the present analyses, we merged data from studies 1 and 2 after confirming that baseline characteristics and interventional changes in physical outcomes were similar. Baseline comparisons between the merged intervention (I) and C-groups were done using Chi-square test/Fisher Exact test and Independent samples t-test, as appropriate. Differences in between-group changes were compared by independent samples *t*-test or non-parametric Mann-Whitney test (non-normal distribution). Significance levels were all two-sided $p < 0.05$. IBM SPSS for Windows statistical software was used (version 25, IBM SPSS, Armonk, New York). We estimated the minimal clinical important difference (MCID) by the analytic (distribution-based) approach, and considered 0.5 standard deviation (SD) of baseline value as threshold for MCID [25].

Results

We were able to recruit only 44 of the 60 predetermined participants. Six participants dropped out from the intervention, and one was excluded (attended only 20/60 training sessions) resulting in 16 participants in the I-group and 21 in the C-group (Supplementary Fig. 1). At enrollment, participants had poor physical function but they were physically active, motivated and were confident of the positive consequences of the planned training (Table 2). Twenty-four of the 37 participants were wheelchair-dependent for ambulation.

The I-group had 58 days (SD 3) of BWSLT, and effective walking during each training session averaged 42 min (SD 10) with mean walking distance 1737 m (SD 443) and mean body-weight support 40% and 33%, respectively, for the robot-assisted and the manually assisted.

At study start, 15/16 in the intervention and 18/21 in the C-group had expectations of improvement in physical outcomes, especially walking function (Table 3), but at the final evaluation, expectations had declined in both groups, most among the controls (Table 4). The mean difference between the groups in "meeting the outcome expectation" variable exceeded the MCID value of 11.8 by 11.9 units (Table 5).

Table 3 Participants' self-reported expectation of the results from the BWSLT at the time of baseline testing.

Intervention group ($n = 16$)	Control group ($n = 21$)
Expectation:	Expectation:
Physical improvement:	Physical improvement:
To improve walking function or standing ($n = 7$)	To improve walking function or standing ($n = 8$)
To improve function level ($n = 2$)	To improve physical fitness ($n = 6$)
To improve endurance ($n = 2$)	To overall improve range of motion ($n = 1$)
To improve strength ($n = 2$)	To get stronger ($n = 3$)
To reduce spasticity ($n = 1$)	Other improvements:
To softer ankle joints ($n = 1$)	To be able focus only on training ($n = 1$)
Other improvements:	Find an alternative training method ($n = 1$)
To increase confidence and motivation ($n = 1$)	No belief of improvement in own function ($n = 1$)

Table 4 Changes in health-related quality of life, self-perception in exercise and physical activity, from baseline to evaluation 2–4 weeks post intervention/control period. Final analytic sample.

Variables	Intervention group ($n = 16$) Mean change (SD)	Control group ($n = 21$) Mean change (SD)	Difference in mean change between the groups (CI 95%)
SF-36 PCS	−1.2 (13.4)[c]	0.6 (17.0)	−1.8 (−12.6 to 8.9)
SF-36 MCS	0.2 (19.4)[c]	1.7 (8.8)	−1.5 (−11.2 to 8.2)
IPAQ – weekly MET min	227 (4897)[a]	−647 (3224)[e]	874 (−2446 to 4195)
Exercise barrier self-efficacy	−0.7 (1.4)[c]	−1.5 (2.2)	0.8 (−0.5 to 2.1)
Autonomous motivation	0.0 (0.7)[c]	0.0 (1.0)	−0.1 (−0.7 to 0.5)
Controlled motivation	0.7 (1.1)[c]	0.0 (1.2)[f]	0.7 (−0.1 to 1.5)
Importance of the benefits	−0.4 (1.1)[b]	−0.2(0.4)[e]	−0.2 (−0.8 to 0.4)
Meet the outcome expectation (0–100)	−13.6 (39.1)	−37.3 (30.4)	23.7 (−1.3 to 48.7)
LEMS	3.6 (5.0)	−0.1 (5.0)	3.7 (0.3 to 7.1)
6MWT	15.5 (32.6)[a]	25.7 (58.2)[c]	−10.2 (−47.7 to 27.3)
10MWT	0.1 (0.3)[b]	0.1 (0.3)	0.0 (−0.2 to 0.2)
BBS	1.9 (3.7)	2.3 (3.8)	−0.4 (−3.0 to 2.0)
MFR	−1.8 (21.7)	−3.9 (7.4)	2.1 (−8.3 to 12.2)
VO_{2max} l/min	−0.1 (0.3)[g]	−0.1 (0.2)[c]	0.0 (−0.2 to 0.2)

Noncategoric values are expressed as mean ± standard deviation

SD standard deviation, *IPAQ* Physical Activity Questionnaire with weekly MET minutes, *SF-36* Short Form 36, *PCS* Physical Component Summary, *MCS* Mental Component Summary, *10MWT* 10-meter walk test, *6MWT* 6 min walk test, *LEMS* Lower Extremity Motor Score, *BBS* Berg Balance Scale, *MFR* the modified functional reach test, VO_{2max} maximal oxygen uptake

[a] $n = 13$

[b] $n = 14$

[c] $n = 15$

[d] $n = 16$

[e] $n = 18$

[f] $n = 20$

[g] $n = 10$

Table 5 Minimal clinically important difference (MCID) for an outcome measure 0.5 standard deviation (SD) improvement considered as the threshold for being clinically important.

Variable	Baseline SD (X1 + X2)/2 = y MCID (0.5 SD of Y)	(Δ1–Δ2) Mean diff in change between the groups	Exceeded MCID Yes + /No −
PCS	9.0	−1.8	–
MCS	7.7	−1.5	–
IPAQ	1919	874	–
Exercise barrier self-efficacy	0.4	0.8	+
Autonomous motivation	0.4	0.1	–
Controlled motivation	0.6	0.7	+
Importance of the benefits	0.4	−0.2	–
Meet the outcome expectation (0-100)	11.8	23.7	+

SF-36 Short Form 36, *PCS* Physical Component Summary, *MCS* Mental Component Summary, *IPAQ* International Physical Activity Questionnaire with weekly MET minutes

Quality of life

Baseline PCS and MCS were similar in the I- and C-group, with minor and nonsignificant changes (Table 4) and none of the mean differences between the groups exceeded the MCID values (Table 5).

EBSE and other measurements

The I-group reported higher physical activity level at baseline (5210 METs/week vs 3601 in the C-group) (Table 2), and differences were slightly greater at follow-up (Table 4), but the between group change was smaller than

MCID (Table 5). EBSE was high in both groups at baseline, and declined in both, especially in the controls −1.5 compared with −0.7 in the I-group (Table 4) and the between-group difference was twice the MCID value (Table 5). The between-group difference in change in controlled form of motivation was greater than the MCID threshold (Table 5) and the change in the I-group was larger than the C-group (Table 4). However, the between-groups difference in autonomous motivation was below the MCID threshold (Table 5). Both groups had high baseline scores on expected importance of benefits from BWSLT, but changes from baseline to follow-up were small, similar and difference was below the MCID value (Table 5).

Physical outcomes

Among the physical outcomes, only LEMS showed significant improvement. A MCID >3 units has been reported as required for improving walking function [26], and we found a between-group difference of 3.6 units, favoring the I-group (Table 4). Threshold values were not exceeded for walking speed, endurance or balance [27–29].

Discussion

To our knowledge, this is the first RCT assessing the effect of a BWSLT intervention on HRQOL and psychological outcomes in relation to changes in physical functions among persons with long-standing incomplete SCI. Compared with usual care, intensive BWSLT did not improve physical outcomes or HRQOL. However, some of the changes in psychological outcomes including EBSE, controlled form of motivation and meeting the outcome expectations, may be of clinical importance.

For this research, we merged data from our two independent RCTs that were virtually identical in design, duration, intensity, evaluation, and outcomes, but where methods of assisted BWSLT differed. The primary purpose of the two RCTs was to assess the effect of BWSLT on walking [12, 13] and whether the interventions influenced HRQOL and psychological factors such as social and mental functioning. For these latter outcomes, we used standardized generic self-administered questionnaires [15, 18, 19, 23] suitable for the SCI population, despite shortcomings with mobility, reporting and interpretation of PCS and MCS [20, 23].

In general there is a positive association between physical activity and well-being among the SCI populations [11], but HRQOL effect studies of different training methods are scarce and inconclusive [11, 20]. This also applies to studies using BWSLT [5–10]. Mean postinjury time varied between 5 and 10 years in four RCTs [5–8], hence our study is the one with the longest time (mean time 13 years) from injury to start of intervention.

We consider the term well-being and mental HRQOL closely related, and focus on the mental dimension of the SF-36. The changes in the two HRQOL assessments (PCS and MCS) and psychological outcomes were small and the physical activity (IPAQ, autonomous motivation and importance of benefits gained) did not exceed the thresholds for the MCID. However, the difference in change between the I- and C-group exceeded the MCID for EBSE, controlled motivation and meeting the outcome expectations. Some BWSLT studies [5, 8, 9] report beneficial effects both on well-being and quality of life. Different HRQOL measures (Quality of Life index, Satisfaction with Life scale, Schedule for the Evaluation of Individual Quality of Life) [6, 8, 10], or only parts of the standardized questionnaires (SF-36) have previously been used [5, 9], making it difficult to compare the results.

EBSE and participants' expectations

We chose to study psychological components since they may influence the outcome of physical training, and vice versa. Expectations regarding outcome, perceptions of control and mastery and type of motivation for the training [18, 19] may all be important. We were, however, unable to demonstrate improvement in psychological outcomes, possibly because our participants were strongly motivated at baseline. EBSE is a persons' confidence in own capability to keep exercising in spite of barriers [18]. Persons with high EBSE use sufficient efforts that often lead to success, whereas those with low EBSE are likely to stop their efforts early and thus fail [18]. EBSE has not been investigated in the earlier BWSLT studies [5–10]. However, a study of home-based upper-body training found a positive association between improved physical outcome and exercise self-efficacy, a more task oriented form for self-efficacy [20]. In the present study, EBSE scores fell for both groups, and more so for the controls. This may be an effect of low statistical power, as one would expect the scores to be lower among participants in the intervention group, due to the lack of substantial improvements in physical outcomes. In hindsight, we underestimated the fact that the demands of the intervention would result in a selection of individuals with an initial robust EBSE, and therefore it was not realistic to expect an increase in barrier self-efficacy post intervention. Participants' expectations of improving their walking function were high, maybe unrealistic, considering their poor baseline function and long-standing incomplete SCI. Overall, 33 of the 37 (89%) reported that their main expectation was to improve physical outcome. This is in line with reports from a previous study showing that the priority among persons with SCI recovering from an injury

(irrespective of severity, age and time of injury) was to improve walking function [30]. The lowering of expectations found in our study is most likely due to the limited training results.

We anticipated improvement in physical outcomes followed by improved HRQOL, but this was not evident. Even though the participants had invested time, completed the study and experienced a positive training environment with some effects on LEMS, there was still no clear effect on HRQOL. Nor did disappointment with the results seem to lower HRQOL. Hicks et al. [9] in 12 month observational BWSLT study ($n = 14$), found improvements in both walking function and mental HRQOL among persons with incomplete SCI with mean postinjury time of 8 years. Satisfaction in life and in physical outcomes correlated with improvements in walking function. Alexeeva et al. [5] compared BWSLT with manual assistance when needed, BWSLT in a fixed track and conventional therapy in a RCT of 35 persons with incomplete SCI grade AIS C and D (postinjury time 7 years). Although walking speed, LEMS and Satisfaction with abilities of well-being Scale (SAWS) improved significantly in all three groups, no clear benefit was between any of the groups. A positive association was found between Mental HRQOL (SAWS) and change in balance, but not with walking speed, but again, there was no difference between the groups. On the other hand, some studies show discordant changes in physical outcomes and HRQOL. A RCT compared exercise (control) with BWSLT with functional electrostimulation, and the latter group had improvement on a mobility scale, but not in mental HRQOL [8]. Wu et al compared manual and robot-assisted BWSLT in a RCT: both groups improved walking function during training, but there was no association with HRQOL measures as assessed with SF-36 [7]. Thus, based on our findings and the literature, the association of the physical outcomes of BWSLT with HRQOL and psychological factors remains inconclusive.

Are the participants representative of the long-standing SCI population in Norway?

We think that they are, with respect to HRQOL [23]. Interestingly, their PCS and MCS scores are similar to the general Norwegian population [16], confirming data from a previous training study [20]. The participants reported being physically very active, well above the weekly 3000 MET minutes, which is the threshold value for a high physical activity level in the general population [24]. We anticipated that participation in the study would be attractive to persons with long-standing incomplete SCI, since opportunities for intensive rehabilitation are rather limited. Few individuals, however, were willing to participate in the intensive long-lasting training programs, in spite of extensive recruitment efforts through advertisements, patient organizations' meetings, conferences etc. Their return to a regular life with established assistance, equipment, school or work, and a stabilized social life may have reduced motivation for intensive training and resulted in selection of individuals with high scores on a strong and robust form of motivation for training and exercise.

Strengths and limitations

The main strengths of our study include the randomized design, the blinded evaluation of outcomes by the same team and a homogenous patient group with respect to time since injury. Thus, we have avoided the overly optimistic results reported in previous uncontrolled studies. The main limitation is that we were unable to recruit the planned number of participants, resulting in a statistically underpowered study with less balanced intervention and control groups. However, a few more participants would hardly have changed the mainly negative outcomes.

The intense training program many years after SCI resulted in selection of well-trained participants, with very high self-reported baseline physical activity and high scores on EBSE as well as on autonomous motivation, and a strong belief that they should gain important benefits from the training. Hence, we cannot exclude the possibility that our participants already had reached the best function they could obtain within the limits given by their injury. Their strong autonomous motivation and positive attitudes could thus contribute to a "ceiling effect" both for physical and mental function. Even though the C-group was instructed to continue their usual training programs, we cannot exclude the possibility that some also increased their training during the study, thus contributing to the null findings in physical outcomes.

Some effects, such as increased lower extremity muscle strength, could potentially facilitate future alternative training (such as cardiotraining), and in the end, improve a person's HRQOL. Others may think evaluation immediately after intervention would increase the chance of detecting improvement, which may be true. However, our intensive training program was limited in time, and participants were expected to continue their regular conventional training afterwards. If the improvement gained should decline or vanish within 2–4 weeks after return to ordinary life, the training program would not be worth the efforts and costs. Finally, the intensity of the treatment was different between the groups, mainly due to the lack of funding to develop a standardized and more intensive training for the C-group. Low intensity treatment is the common practice

among individuals with long-standing SCI in Norway, and therefore we chose this approach.

At the time we designed the RCT, no psychological instruments were validated for use among SCI populations. SF-36 and IPAQ emphasize walking function, which is not relevant for wheelchair-dependents. We were able to use a modified IPAQ version that included activities performed by wheelchair users [21]. We did not formally measure participant satisfaction. However, our general impression was that they were grateful for the training, and felt it had been a good experience, even if their goal of better walking was not achieved. Appreciation of the therapists' enthusiasm and the care provided (a Hawthorne effect) is likely, as well as other psychosocial/environmental factors present in the BWSLT setting. The role of these in eliciting changes should probably also have been better assessed.

What can be learned from this study?

Late onset training of individuals with long-standing SCI and poor baseline function resulted in only minor improvements in physical outcomes and small or no changes in HRQOL. Admittedly, the study was underpowered, but we find it unlikely that a larger number of participants would have changed the outcome significantly. Few individuals with long-standing SCI were willing to participate in an intensive long-lasting training program, and this resulted in a selection of autonomously motivated, well-trained individuals who possibly already had reached their ceiling for improvement. When training studies are compared, it may be important to consider participants' baseline motivation and training status/exercise habits.

The clinical importance of our findings is debatable. The results argue neither for, nor against late onset intensive BWSLT in long-standing SCI, but we believe future studies should preferably be done among persons with somewhat better baseline function, and at an earlier postinjury stage. It would be interesting to see what effects a BWSLT intervention would have on walking ability, HRQOL, EBSE, type of motivation, psychosocial/environmental factors and physical outcomes among physically inactive, less autonomously motivated persons with SCI.

In conclusion, this RCT demonstrates that BWSLT among poorly functioning individuals with long-standing SCI, improves neither physical outcomes nor HRQOL. The present results cannot be extrapolated to other settings, such as training early after injury, or to those who have regained or have some remaining walking function. In this study, training started long after the SCI resulting in selection of autonomously motivated participants who already had trained intensively, and thus may have had a very small potential for further improvement.

Data Archiving

The datasets analyzed during the current study are not publicly available due to Norwegian laws and regulations.

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Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

Ethical statement We ensured that this research was conducted with high ethical standards.

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Appendix

Approval

Study 1 and Study 2: Approval from the Regional Ethics Committee in North Norway

Information letters with consent forms

Study 1 and Study 2: Invitation to participate in the ATLET study

Study 1: Information letter with consent form

Study 2: Information letter with consent form

Outcome assessments

Questionnaires

Physical outcome measures

BWSLT protocols

Study 1 and registration form of training session

Study 2 and registration form of training session

Training diary registration sheet

Approval

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Deres ref.: Vår ref.: 200802136-9/MGA006/400 Dato: 01.07.2008

P REK NORD 69/2008 ATLET (AVLASTET TRENING HOS LAMME ETTER TRAUME) STUDIEN. KAN PERSONER MED MOTORISK INKOMPLETT RYGGMARGSSKADE LÆRE Å GÅ? - PROSJEKTET GODKJENNES

Vi viser til prosjektleders brev av 11.06.2008 vedlagt reviderte informasjonsskriv og prosjektbeskrivelse.

Prosjektleders tilbakemelding på komiteens merknader til prosjektet i møte 15.05.2008 tas til etterretning.

Etter fullmakt har komiteens leder fattet slikt
Vedtak: prosjektet godkjennes.

Det forutsettes at prosjektet er godkjent av andre aktuelle instanser før det settes i gang.
Det forutsettes at prosjektet forelegges komiteen på nytt, dersom det under gjennomføringen skjer komplikasjoner eller endringer i de forutsetninger komiteen har basert sin avgjørelse på.
Komiteen ber om å få melding dersom prosjektet ikke blir sluttført.

Komiteens vedtak kan påklages av en part eller annen med rettslig klageinteresse i saken jf. fvl. §28. Klagefristen er tre uker fra det tidspunkt underretning om vedtaket er kommet fram til vedkommende part, jf. fvl. § 29. Klageinstans er Den nasjonale forskningsetiske komité for medisin og helsefag, men en eventuell klage skal rettes til Regional komité for medisinsk og helsefaglig forskningsetikk, Nord Norge. Det følger av fvl. § 18 at en part har rett til å gjøre seg kjent med sakens dokumenter, med mindre annet følger av de unntak loven oppstiller i §§ 18 og 19. For nærmere informasjon om klageadgang og partsinnsynsrett se nettadressen http://www.etikkom.no/REK/klage

Vennlig hilsen

May Britt Rossvoll
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Information letters with consent forms

Study 1 and study 2: Invitation to participate in the ATLET study

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E-post: anu.piira@kurbadet.no

Tromsø, 00.00.2008

Vi vil gjerne spørre deg om du vil delta i en forskningsstudie for å finne ut mer om nytten av tredemølletrening med vektavlastende sele. Denne henvendelsen er sendt ut fra Sunnaas sykehus sitt ryggmargsskaderegister.

ATLET-studien er en forskningsstudie for å finne ut om intensiv gangtrening på tredemølle kan bedre gangfunksjonen hos ryggmargsskadde. Vi ønsker å få med deltagere som har motorisk inkomplett ryggmargsskade, dvs ikke er fullstendig lamme i bena. Fordi deltakerne ikke kan gå alene, skjer treningen med avlastet kroppsvekt, dvs at en heises opp i en klatresele under gåtreningen. Dette er et unikt samarbeidsprosjekt mellom ulike instanser i Helse-Norge. Studien vil vare fra høsten 2008 til 2011, med ½ års trening for hver deltager. Studiedeltagerne blir testet ved Sunnaas sykehus før og etter trening, og selv treningen vil foregå enten på Friskvernklinikken i Asker eller Rehabiliteringssenteret Nord-Norges Kurbad i Tromsø.

Om du er interessert i å høre mer om studien, vil vi gjerne ringe til deg. Send svarslipp i vedlagte frankerte svarkonvolutt.

Hvis du etter telefonsamtalen fortsatt er interessert og oppfyller kravene til å delta, sender vi deg utfyllende skriftlig informasjon og formell forespørsel om deltagelse i ATLET-studien sammen med samtykkeskjema. Når du har lest nøye gjennom informasjonen og tatt god betenkingstid, kan du bestemme om du vil delta i studien.

Dersom det er noe du lurer på, kan du gjerne kontakte prosjektkoordinator Anu M. Piira tlf. 77 66 88 03 eller mobil 952 299 39, eller sende e-post til anu.piira@kurbadet.no

Med vennlig hilsen,

Nils Hjeltnes	Raymond Knutsen	Anu M. Piira
Sjeflege	Leder for	Prosjektkoordinator
Sunnaas Sykehus HF	ATLET styringsgruppe	ATLET studien

SVARSLIPP

Sett inn kryss, fyll ut navn og telefonnummer, og klokkeslett som passer best for deg å ta imot en telefonsamtale.

Jeg vil gjerne vite mer om deltagelse i ATLET studien ☐

Navn:
_____

Ring til meg telefonnummer:
_____

Klokkeslett som passer best for meg for telefon samtale:
_____

Study 1: Information letter with consent form

Forespørsel om deltakelse i forskningsprosjektet

"Kan personer med motorisk inkomplett ryggmargsskade lære å gå?"

Bakgrunn og hensikt
Dette er et spørsmål til deg om å delta i en forskningsstudie for å finne ut om intensiv gangtrening med vektavlastning i tredemølle kan bedre gangfunksjonen hos ryggmargsskadde. Vi ønsker å få deltagere som har motorisk inkomplett ryggmargsskade. Forskningsstudien er et samarbeidsprosjekt mellom Rehabiliteringssenteret Nord-Norges Kurbad (RNNK), Sunnaas sykehus, Norges idrettshøgskole, Friskvernklinikken i Asker og Universitet i Tromsø (UiT). Prosjektet ledes av ATLET styringsgruppen, og koordinator er doktorgradstipendiat, fysioterapeut MPH Anu M. Piira, RNNK. Dersom treningseffekten er vesentlig større enn med vanlig trening, vil vi prøve å få denne intense behandlingen allment tilgjengelig for ryggmargsskadde.

Hva innebærer studien?
I alt 30 personer vil delta i studien. Inntakskravene er alder 18 - 65 år, motorisk inkomplett ryggmargsskade og nedsatt gangfunksjon. Se vedlegg A for detaljer. Deltakernes motoriske funksjon testes først på Sunnaas sykehus, de besvarer noen spørreskjemaer og det tas noen vanlige blodprøver. Deretter fordeles deltakerne ved loddtrekking til en treningsgruppe og en kontrollgruppe som følger sitt vanlige opplegg. Treningen vil foregå over 3 - 4 perioder på 3 - 4 uker hver, som innlagt pasient ved RNNK i Tromsø. Du vil få sykemelding for den perioden du er på RNNK dersom du er i arbeid. Det er intens trening: 2 treningsøkter alle hverdager. Hvis du etter loddtrekking blir plassert i kontrollgruppen, vil du senere få det samme tilbud som treningsgruppen dersom det viser seg at treningsopplegget har klar effekt og under forutsetning av at Helse Norge vil betale for slik trening. Etter ½ år vil alle på ny bli vurdert på Sunnaas sykehus.

Mulige fordeler og ulemper
Deltagere som får intens gangtrening, vil mest sannsynlig forbedre sin gangfunksjon og kroppsstabilitet i løpet av treningen. Alle deltagerne vil få en grundig testing av sin funksjon og råd om videre trening. Deltagerne i kontrollgruppen kan regne med å få tilbud om intensiv gangtrening senere hvis studien viser at det er til stor nytte. Ulempene ved treningen er at det kreves stor innsats og tar mye tid. I pilotprosjektet med 6 personer rapporterte noen økt spastisitet og tretthet etter treningsøktene, og noen fikk gnagsår på legg eller ankel.

Hva skjer med prøvene og informasjonen om deg?
Informasjonen som registreres og prøvene som er tatt, skal kun brukes slik som beskrevet i hensikten med studien, og blir behandlet uten navn, fødselsnummer eller andre persondata. En kode knytter deg til dine opplysninger og prøver gjennom en navneliste. Det er kun autorisert personell knyttet til studien som har adgang til navnelisten, og som kan finne tilbake til deg. Navnelisten slettes senest 31.12.2025. Når dataene fra studien skal analyseres og publiseres, vil alle personidentifiserbare data være fjernet. Det vil ikke være mulig å identifisere deg i resultatene av studien når disse publiseres.

Frivillig deltakelse
Det er frivillig å delta i studien. 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 ønsker å delta, undertegner du samtykkeerklæringen på siste side. Om du nå sier ja til å delta, kan du senere trekke tilbake ditt samtykke uten at det påvirker din øvrige behandling. Dersom du senere ønsker å trekke deg eller har spørsmål til studien, kan du kontakte Fysioterapeut, MPH Anu M. Piira, RNNK, på telefon 77 66 88 03 eller mobil: 952 29939.

Ytterligere informasjon om studien finnes i *Kapittel A* – *utdypende forklaring om hva studien innebærer.*
Ytterligere informasjon om biobank, personvern og dine rettigheter finnes i Kapittel B – *Personvern, Biobank, økonomi og forsikring.* **Samtykkeerklæring følger etter kapittel B**

Kapittel A- utdypende forklaring om hva studien innebærer

Kriterier for deltagelse
Inntakskravene er alder 18 - 65 år og motorisk inkomplett ryggmargsskade med nedsatt gangfunksjon. Det må være gått minst 2 år siden skadetidspunktet, og deltaker må være ferdig rehabilitert og tilpasset rullestol. Deltaker må også være motivert for trening og kunne følge instruksjoner. Vekten må heller ikke være for tung (kroppsmasseindeks, KMI, under 30).
Man passer ikke til å delta hvis det ikke er noen muskelaktivitet i den lamme delen av kroppen, eller det er spasmer, kontrakturer, smerter eller annen sykdom som vanskeliggjør trening (vurderes individuelt) eller som krever kontinuerlig spasmedempende medisin. En kan heller ikke samtidig delta i andre intense treningsopplegg. Kvinner som er eller kan bli gravide, kan ikke delta. For seksuelt aktive kvinner i fruktbar alder regnes P-pille, pessar med sæddrepende krem eller bruk av kondom som tilstrekkelig beskyttelse.

Bakgrunnsinformasjon for studien
Nyere forskning viser at sentralnervesystemet har langt større evne til tilpasning enn man tidligere trodde. Forsøk på dyr har vist at de kan gjenlære motoriske ferdigheter som er tapt som følge av skade. Noen få studier er gjort på personer med ryggmargsskade og nedsatt gangfunksjon, og de viser at det kan være stort potensial for bedring dersom man gir intens gangtrening. RNNK har gjort et pilotprosjekt med intens gangtrening med avlastning på 6 pasienter med inkomplette tverrsnittslesjoner. Resultatene har vært lovende. Behandlingseffekten er imidlertid ikke vitenskapelig godt dokumentert, og det er behov for en kontrollert studie der ryggmargsskadde ved loddtrekking fordeles til en gruppe som får vektavlastet trening på tredemølle og en annen, tradisjonelt behandlet kontrollgruppe.

Alternative prosedyrer eller behandling pasienten får dersom personen velger ikke å delta i studien
Hvis du ikke vil delta på studien, så vil dette ikke få konsekvenser for din videre behandling. Du vil få samme behandlingstilbud som før i din hjemkommune.

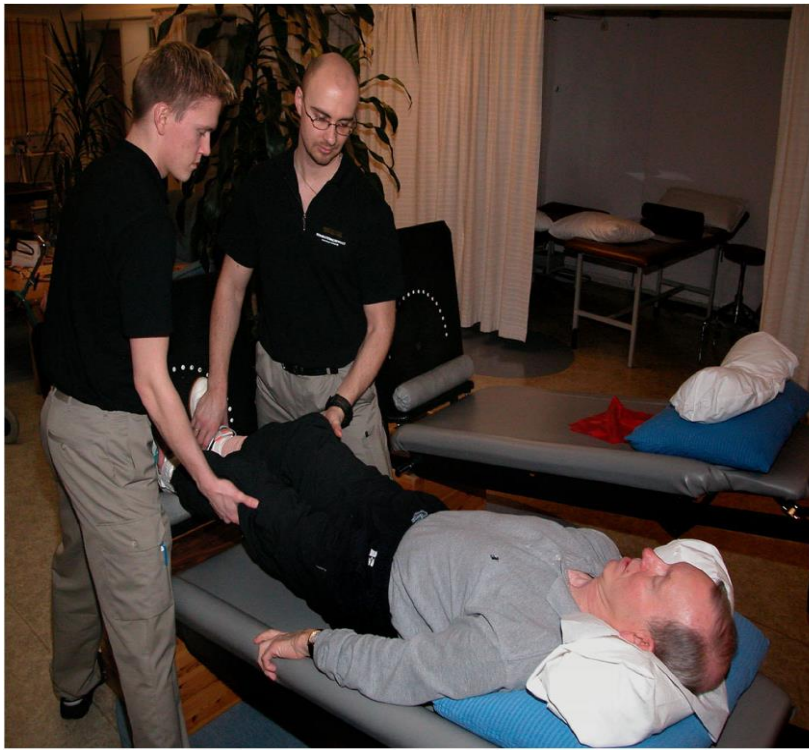
Undersøkelser, blodprøver og annet deltageren må gjennom
Testing gjøres før loddtrekking og evt. treningsstart og 6 måneder senere (ca ett år fra prosjektstart). Vurderingen vil foregå under et to-dagers opphold på Sunnaas sykehus. Det vil bli gjort standardiserte tester av motorisk funksjon, som benyttes for ryggmargsskadde personer. Deltakerne skal besvare spørreskjemaer med tanke på egne observasjoner av evt. endring i motorisk funksjon og ferdigheter, og egen opplevelse av deltagelse i forskningsstudien.
Under oppholdet vil det bli tatt noen vanlige blodprøver (ca 100 ml blod til sammen). Noen av disse vil bli frosset ned for senere analyse. Du vil også bli spurt om å gi prøve til evt. arvestoffanalyse. Om dette vil det bli gitt separat informasjon, og det kreves egen samtykkeerklæring. Det går an å delta i studien uten å måtte gi prøve til genanalyse.

Treningen vil foregå over 3 - 4 perioder på 3 - 4 uker hver, som innlagt pasient ved RNNK i Tromsø. Du vil få sykmelding for den perioden du er på RNNK dersom du er i arbeid. Det er intens trening: 2 treningsøkter alle hverdager.

Treningsøktene består av
1. Gange på tredemølle med hjelp av 4-5 terapeuter/instruktører som leder føttene og støtter bekkenet under treningen. Under treningen vil deltageren henge i en sele slik at en del av kroppsvekten blir tatt av. Derved kan trening av god gangfunksjon skje uten at deltageren samtidig må belaste med hele sin kroppsvekt. Dette gir økt effektivitet under gangen, og minsker risikoen for tretthet og belastningsskader.
2. Knebøy på VigørGym. Deltageren ligger på et skråttstilt brett som glir på skinner. Ved å bøye og strekke i hofter og knær, får man god trening for de muskler som er nødvendige og viktige for gang- og ståfunksjon.

3. Tøyninger og massasje før/etter tredemøllegange. Dette vil minske tendensen til spasmer.

Bilde: oppsett for intensiv gangtrening i tredemølle med robot. Vi har personens tillatelse å bruke bildene.



Tidsskjema – hva skjer og når skjer det?

1. 1-2 dagers vurderingsopphold på Sunnaas sykehus før studiestart.
2. loddtrekning for plassering i trenings – eller kontrollgruppe.
3. Innkalling til treningsopphold ved RNNK skjer ca 1 måned etter vurderingsoppholdet. Treningen vil foregå over 3 - 4 perioder på 3 - 4 uker hver slik at det blir sammenlagt 12 ukers trening.
4. Sluttevaluering (både intervensjons- og kontrollgruppen) foregår 2-4 uker etter avsluttet 12 ukers intens trening, og igjen 6 mnd etter avsluttet trening.
5. Det vil ta ca et år for den enkelte deltager å bli ferdig med studien.

Mulige fordeler- Deltagere som får intens gangtrening, vil mest sannsynlig kunne se forbedring av sin gangfunksjon og kroppsstabilitet i løpet av treningen. Deltagere som er med i studien, vil få en grundig testing av sin funksjon i løpet av prosjektet og kunne få råd om videre trening.

Mulige bivirkninger- Se punkt nedenfor om ubehag/ulemper ved å delta.

Ubehag/ulemper ved å delta- Ulempene ved treningen er at det kreves stor innsats og tar mye tid. I pilotprosjektet med 6 personer rapporterte noen økt spastisitet og tretthet etter treningsøktene, og noen fikk gnagsår på legg eller ankel.
Deltagerne i kontrollgruppen kan regne med å få tilbud om intensiv gangtrening senere hvis denne studien viser at det er til stor nytte.

Studiedeltagerens ansvar - Studiedeltager kan ikke samtidig delta i andre intense treningsopplegg. Dette gjelder både trenings- og kontrollgruppen. Behandling i løpet av "hvileperiodene" må avtales med og godkjennes av koordinator. Deltagere må informere koordinator snarest hvis det er noe som hindrer deltagelse i trening/studie. Fravær i en treningsøkt meldes til treningsansvarlig fysioterapeut ved RNNK.

Prosjektlederens ansvar for deltagere- Prosjektleder har delegert ansvar for koordinator. Koordinatoren vil sørge for at deltageren blir opplyst så rask som mulig dersom det kommer ny informasjon som kan påvirke deltagerens villighet til å delta i studien. Koordinatoren vil opplyse deltageren snarest om mulige beslutninger/situasjoner som gjør at deres deltagelse i studien kan bli avsluttet tidligere enn planlagt.

Kompensasjon og dekning av utgifter til deltagere- Deltager vil ikke få ekstra kompensasjon for deltagelse i studien. Deltageren får sykmelding når trening foregår ved RNNK i Tromsø. Man benytter trygdesystemet for å kompensere for tapte inntekter. Det forutsettes at helseforetakene dekker reise- og behandlingskostnader for den enkelte deltager.

Kapittel B - Personvern, biobank, økonomi og forsikring

Personvern
Opplysninger som registreres om deg er din egen oppfatning av helse, livskvalitet og skade, og det gjøres funksjonsundersøkelse. Blodprøver blir tatt som del av studien, og andre opplysninger som er relatert til ryggmargskaden hentes fra din journal på Sunnaas sykehus. Alle opplysningene og prøvene som tas vil bli behandlet uten navn og fødselsnummer eller andre direkte gjenkjennelige opplysninger. En kode knytter deg til dine opplysninger og prøver gjennom en navneliste. Det er kun autorisert personell knyttet til studien som har adgang til navnelisten, og som kan finne tilbake til deg. Navnelisten slettes senest 31.12.2025. Når dataene fra studien skal analyseres og publiseres, vil alle personidentifiserbare data være fjernet. Det vil ikke være mulig å identifisere deg i resultatene av studien når disse publiseres.

Sunnaas sykehus HF ved administrerende direktør er databehandlingsansvarlig.

Biobank
Blodprøvene som blir tatt og informasjonen utledet av dette materialet vil bli lagret i en forskningsbiobank ved Sunnaas sykehus HF. Hvis du sier ja til å delta i studien, gir du også samtykke til at det biologiske materialet og analyseresultater inngår i biobanken. Sjeflege Nils Hjeltnes ved Sunnaas sykehus HF er ansvarlig for biobanken. Biobanken planlegges å vare til 2025. Etter dette vil materiale og opplysninger bli ødelagt etter interne retningslinjer.

Utlevering av opplysninger til andre – Det blir ikke levert ut opplysninger til andre instanser i inn- eller utland. Data som kan identifiseres deg vil bli utlevert til Sunnaas sykehus. Dette er nødvendig for å oppfylle formålet med studien.

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 prøver og opplysninger, med mindre opplysningene allerede er inngått i analyser eller brukt i vitenskapelige publikasjoner.

Økonomi og rolle
Prosjektansvarlig og andre medarbeidere har ingen økonomisk vinning knyttet til prosjektet.
Studien er finansiert gjennom forskningsmidler fra Stiftelsen Helse og rehabilitering og studien har fått startstøtte fra helsedirektoratet. Sunnaas sykehus HF eier biobanken. Gjennomføring av denne studien forutsetter at helseforetakene vil betale reise- og oppholdsutgifter til den enkelte deltager.

Forsikring
Alle deltagerne er forsikret mot ev. studierelaterte skader.

Informasjon om utfallet av studien
Resultatene av denne studien vil bekjentgjøres i medlemsblad for Landsforening for trafikkskadde, i Patetra samt i anerkjente internasjonale vitenskapelige tidsskrifter. Det vil også sendes informasjon til alle deltagerne i studien. Studien er beregnet å være ferdig i 2011.

Samtykke til deltakelse i studien

Jeg er villig til å delta i studien

(Signert av prosjektdeltaker, dato)

Stedfortredende samtykke når berettiget, enten i tillegg til personen selv eller istedenfor

(Signert av nærstående, dato)

Jeg bekrefter å ha gitt informasjon om studien

(Signert, rolle i studien, dato)

Study 2: Information letter with consent form

Forespørsel om deltakelse i forskningsprosjektet

"Kan personer med motorisk inkomplett ryggmargsskade lære å gå?"

Bakgrunn og hensikt
Dette er et spørsmål til deg om å delta i en forskningsstudie for å finne ut om intensiv gangtrening med vektavlastning i tredemølle kan bedre gangfunksjonen hos ryggmargsskadde. Vi ønsker å få deltagere som har motorisk inkomplett ryggmargsskade. Forskningsstudien er et samarbeidsprosjekt mellom Rehabiliteringssenteret Nord-Norges Kurbad (RNNK), Sunnaas sykehus, Norges idrettshøgskole, Friskvernklinikken i Asker (FVK) og Universitet i Tromsø (UiT). Prosjektet ledes av ATLET styringsgruppen, og koordinator er doktorgradstipendiat, fysioterapeut MPH Anu M. Piira, RNNK. Dersom treningseffekten er vesentlig større enn med vanlig trening, vil vi prøve å få denne intense behandlingen allment tilgjengelig for ryggmargsskadde.

Hva innebærer studien?
I alt 30 personer vil delta i studien. Inntakskravene er alder 18 - 65 år, motorisk inkomplett ryggmargsskade og nedsatt gangfunksjon. Se vedlegg A for detaljer. Deltakernes motoriske funksjon testes først på Sunnaas sykehus, de besvarer noen spørreskjemaer og det tas noen vanlige blodprøver. Deretter fordeles deltakerne ved loddtrekking til en treningsgruppe og en kontrollgruppe som følger sitt vanlige opplegg. Treningen vil foregå 3-5 ganger per uke over 24-40 uker, som poliklinisk pasient ved Friskvernklinikken i Asker. Hvis du etter loddtrekking blir plassert i kontrollgruppen, vil du senere få det samme tilbud som treningsgruppen dersom det viser seg at treningsopplegget har klar effekt og under forutsetning av at Helse Norge vil betale for slik trening. Etter 6-9 mndr. vil alle på ny bli vurdert på Sunnaas sykehus.

Mulige fordeler og ulemper
Deltagere som får intens gangtrening, vil mest sannsynlig forbedre sin gangfunksjon og kroppsstabilitet i løpet av treningen. Alle deltagerne vil få en grundig testing av sin funksjon og råd om videre trening. Deltagerne i kontrollgruppen kan regne med å få tilbud om intensiv gangtrening senere hvis studien viser at det er til stor nytte. Ulempene ved treningen er at det kreves stor innsats og tar mye tid. I pilotprosjektet med 6 personer rapporterte noen økt spastisitet og tretthet etter treningsøktene, og noen fikk gnagsår på legg eller ankel.

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Ytterligere informasjon om studien finnes i *Kapittel A* – *utdypende forklaring om hva studien innebærer.*
Ytterligere informasjon om biobank, personvern og dine rettigheter finnes i Kapittel B – *Personvern, Biobank, økonomi og forsikring.* **Samtykkeerklæring følger etter kapittel B.**

Kapittel A- utdypende forklaring om hva studien innebærer

Kriterier for deltagelse
Inntakskravene er alder 18 - 65 år og motorisk inkomplett ryggmargsskade med nedsatt gangfunksjon. Det må være gått minst 2 år siden skadetidspunktet, og deltaker må være ferdig rehabilitert og tilpasset rullestol. Deltaker må også være motivert for trening og kunne følge instruksjoner. Vekten må heller ikke være for tung (kroppsmasseindeks, KMI, under 30).
Man passer ikke til å delta hvis det ikke er noen muskelaktivitet i den lamme delen av kroppen, eller det er spasmer, kontrakturer, smerter eller annen sykdom som vanskeliggjør trening (vurderes individuelt) eller som krever kontinuerlig spasmedempende medisin. En kan heller ikke samtidig delta i andre intense treningsopplegg. Kvinner som er eller kan bli gravide, kan ikke delta. For seksuelt aktive kvinner i fruktbar alder regnes P-pille, pessar med sæddrepende krem eller bruk av kondom som tilstrekkelig beskyttelse.

Bakgrunnsinformasjon for studien
Nyere forskning viser at sentralnervesystemet har langt større evne til tilpasning enn man tidligere trodde. Forsøk på dyr har vist at de kan gjenlære motoriske ferdigheter som er tapt som følge av skade. Noen få studier er gjort på personer med ryggmargsskade og nedsatt gangfunksjon, og de viser at det kan være stort potensial for bedring dersom man gir intens gangtrening. RNNK har gjort et pilotprosjekt med intens gangtrening med avlastning på 6 pasienter med inkomplette tverrsnittslesjoner. Resultatene har vært lovende. Behandlingseffekten er imidlertid ikke vitenskapelig godt dokumentert, og det er behov for en kontrollert studie der ryggmargsskadde ved loddtrekking fordeles til en gruppe som får vektavlastet trening på tredemølle og en annen, tradisjonelt behandlet kontrollgruppe.

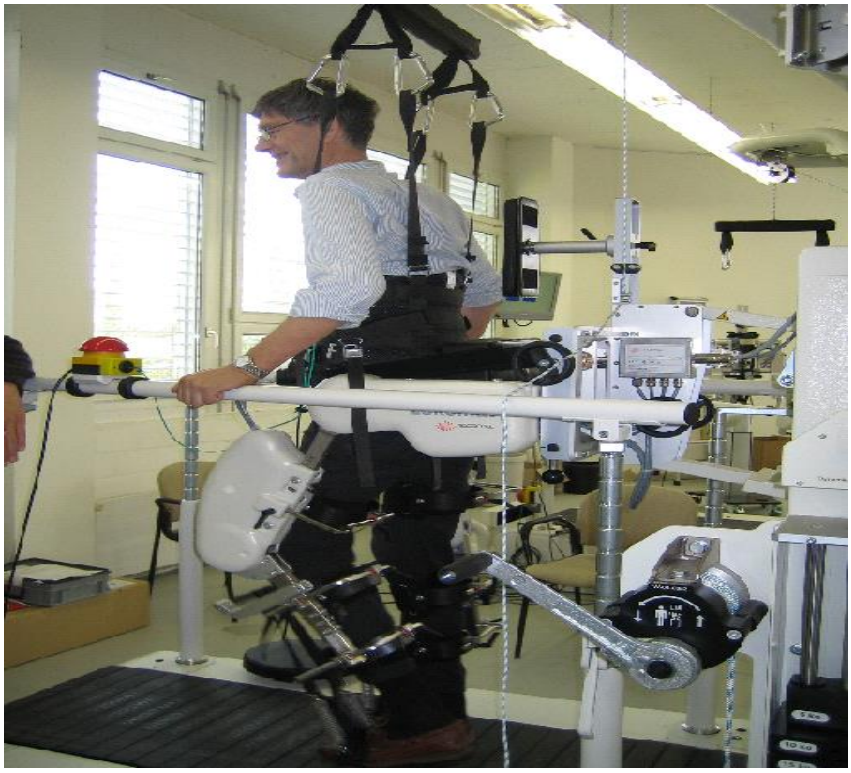
Alternative prosedyrer eller behandling pasienten får dersom personen velger å ikke delta i studien
Hvis du ikke vil delta på studien, så vil dette ikke få konsekvenser for din videre behandling. Du vil få samme behandlingstilbud som før i din hjemkommune.

Undersøkelser, blodprøver og annet deltageren må gjennom
Testing gjøres før loddtrekking og evt. treningsstart og 6 måneder senere (ca ett år fra prosjektstart). Vurderingen vil foregå under et to-dagers opphold på Sunnaas sykehus. Det vil bli gjort standardiserte tester av motorisk funksjon, som benyttes for ryggmargsskadde personer. Deltakerne skal besvare spørreskjemaer med tanke på egne observasjoner av evt. endring i motorisk funksjon og ferdigheter, og egen opplevelse av deltagelse i forskningsstudien.
Under oppholdet vil det bli tatt noen vanlige blodprøver (ca 100 ml blod til sammen). Noen av disse vil bli frosset ned for senere analyse. Du vil også bli spurt om å gi prøve til evt. arvestoffanalyse. Om dette vil det bli gitt separat informasjon, og det kreves egen samtykkeerklæring. Det går an å delta i studien uten å måtte gi prøve til genanalyse.

Treningen vil foregå på 24-40 uker, som poliklinisk pasient ved Friskvernklikken i Asker. Dette innebærer 1 treningsøkt 3 -5 ganger i uke. En treningsøkt varer ca 1,5 timer. Treningsøktene består av

1. Gange på tredemølle med hjelp av robot som leder føttene og støtter bekkenet under treningen. Fysioterapeut styrer treningen. Under treningen vil deltageren henge i sele for å avlaste kroppsvekten og ben og hofter spennes fast i motordrevne skinner. Derved kan trening av god gangfunksjon skje uten at deltageren samtidig må belaste med hele sin kroppsvekt. Under gange på tredemølle gir utstyret tilbakemelding om hvor mye egeninnsats man bidrar med. Dette gir økt effektivitet under gangen, og minsker risikoen for tretthet og belastningsskader.
2. Tøyninger og massasje før/etter tredemøllegange. Dette vil minske tendensen til spasmer.

Bilde: oppsett for intensiv gangtrening i tredemølle med robot. Vi har personens tillatelse å bruke bildet.



Tidsskjema – hva skjer og når skjer det?

1. 1-2 dagers vurderingsopphold på Sunnaas sykehus før studiestart.
2. loddtrekning for plassering i trenings – eller kontrollgruppe.
3. Innkalling til trening skjer ca 1 måned etter vurderingsoppholdet. Treningen vil foregå over 24 - 40 uker avhengig av hvor mange treningsøkter det er per uke slik at det sammenlagt blir 120 treningsøkter.
4. Sluttevaluering (både intervensjons- og kontrollgruppen) foregår 6 mnd etter avsluttet trening
5. Det vil ta ca et år for den enkelte deltager å bli ferdig med studien.

Mulige fordeler- Deltagere som får intens gangtrening, vil mest sannsynlig kunne se forbedring av sin gangfunksjon og kroppsstabilitet i løpet av treningen. Deltagere som er med i studien, vil få en grundig testing av sin funksjon i løpet av prosjektet og kunne få råd om videre trening.

Mulige bivirkninger- Se punkt nedenfor om ubehag/ulemper ved å delta.

Ubehag/ulemper ved å delta- Ulempene ved treningen er at det kreves stor innsats og tar mye tid. I pilotprosjektet med 6 personer rapporterte noen økt spastisitet og tretthet etter treningsøktene, og noen fikk gnagsår på legg eller ankel. Deltagerne i kontrollgruppen kan regne med å få tilbud om intensiv gangtrening senere hvis denne studien viser at det er til stor nytte.

Studiedeltagerens ansvar- Studiedeltager kan ikke samtidig delta i andre intense treningsopplegg. Dette gjelder både trenings- og kontrollgruppen. Behandling i løpet av "hvileperiodene" må avtales med og godkjennes av prosjektkoordinator. Deltagere må informere prosjektleder snarest hvis det er noe som hindrer deltagelse i trening/studie. Fravær i en treningsøkt meldes til treningsansvarlig fysioterapeut ved FVK.

Prosjektlederens ansvar for deltagere- Prosjektleder har delegert ansvar for koordinator. Koordinatoren vil sørge for at deltageren blir opplyst så rask som mulig dersom det kommer ny informasjon som kan påvirke deltagerens villighet til å delta i studien. Koordinatoren vil opplyse deltageren snarest om mulige beslutninger/situasjoner som gjør at deres deltagelse i studien kan bli avsluttet tidligere enn planlagt.

Kompensasjon og dekning av utgifter til deltagere- Deltager vil ikke få ekstra kompensasjon for deltagelse i studien. Deltageren får sykmelding ved behov når poliklinisk trening foregår i Asker. Man benytter trygdesystemet for å kompensere for tapte inntekter. Det forutsettes at helseforetakene dekker reise- og behandlingskostnader for den enkelte deltager.

Kapittel B - Personvern, biobank, økonomi og forsikring

Personvern
Opplysninger som registreres om deg er din egen oppfatning av helse, livskvalitet og skade, og det gjøres funksjonsundersøkelse. Blodprøver blir tatt som del av studien og andre opplysninger som er relatert til ryggmargskaden hentes fra din journal på Sunnaas sykehus. Alle opplysningene og prøvene som tas vil bli behandlet uten navn og fødselsnummer eller andre direkte gjenkjennelige opplysninger. En kode knytter deg til dine opplysninger og prøver gjennom en navneliste. Det er kun autorisert personell knyttet til studien som har adgang til navnelisten, og som kan finne tilbake til deg. Navnelisten slettes senest 31.12.2025. Når dataene fra studien skal analyseres og publiseres, vil alle personidentifiserbare data være fjernet. Det vil ikke være mulig å identifisere deg i resultatene av studien når disse publiseres.

Sunnaas sykehus HF ved administrerende direktør er databehandlingsansvarlig.

Biobank
Blodprøvene som blir tatt og informasjonen utledet av dette materialet vil bli lagret i en forskningsbiobank ved Sunnaas sykehus HF. Hvis du sier ja til å delta i studien, gir du også samtykke til at det biologiske materialet og analyseresultater inngår i biobanken. Sjeflege Nils Hjeltnes ved Sunnaas sykehus HF er ansvarlig for biobanken. Biobanken planlegges å vare til 2025. Etter dette vil materiale og opplysninger bli ødelagt etter interne retningslinjer.

Utlevering av opplysninger til andre – Det blir ikke levert ut opplysninger til andre instanser i inn- eller utland. Data som kan identifiseres deg vil bli utlevert til Sunnaas sykehus. Dette er nødvendig for å oppfylle formålet med studien.

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 prøver og opplysninger, med mindre opplysningene allerede er inngått i analyser eller brukt i vitenskapelige publikasjoner.

Økonomi og rolle
Prosjektansvarlig og andre medarbeidere har ingen økonomisk vinning knyttet til prosjektet.
Studien er finansiert gjennom forskningsmidler fra Stiftelsen Helse og rehabilitering og studien har fått startstøtte fra helsedirektoratet. Sunnaas sykehus HF eier biobanken. Gjennomføring av denne studien forutsetter at helseforetakene vil betale reise- og oppholdsutgifter til den enkelte deltager.

Forsikring - Alle deltagerne er forsikret mot ev. studierelaterte skader.

Informasjon om utfallet av studien
Resultatene av denne studien vil bekjentgjøres i medlemsblad for Landsforening for trafikkskadde, i Patetra samt i anerkjente internasjonale vitenskapelige tidsskrifter. Det vil også sendes informasjon til alle deltagerne i studien. Studien er beregnet å være ferdig i 2011.

Samtykke til deltakelse i studien

Jeg er villig til å delta i studien

(Signert av prosjektdeltaker, dato)

Stedfortredende samtykke når berettiget, enten i tillegg til personen selv eller istedenfor

(Signert av nærstående, dato)

Jeg bekrefter å ha gitt informasjon om studien

(Signert, rolle i studien, dato)

Outcome assessments

Questionnaires

Skjema nro:_____

Dato for utfylling:_____

Background information - OPPLYSNINGSSKJEMA

ATLET studien - ”Kan personer med motorisk inkomplett ryggmargsskade lære å gå?”

Noen opplysninger om deg. Kryss av alternativ som passer for deg eller skriv inn svar:

1. □ Kvinne □ Mann

2. Alder:_____ år

3. Hvor høy er du?_____cm Hvor mye veier du?_____kg

4. Røyker du? □ Ja □ Nei

Hvis ja, angi antall av sigaretter per dag: _____

5. Sivil status:

1. □ Gift 2. □ Skilt 3. □ Samboer 4. □ enke/enkemann 5. □ Enslig

6. Familie. Bor du sammen med noen? □ Ja □ Nei

Hvis ja:

Ektefelle/samboer	□ Ja	□ Nei
Andre personer, 18 år og eldre	□ Ja, antall___	□ Nei
Personer under 18 år	□ Ja, antall___	□ Nei

7. Hvor mange års skolegang og utdannelse har du?

1. □ Mindre enn ≤7 år grunnskole
2. □ Grunnskole 8-10 år
3. □ Realskole, middelskole, yrkesskole, 1-2 årig videregående skole
4. □ Ex. Artium eller liknende
5. □ Høgskole/universitet, antall år_____

8. Arbeids-/trygdesituasjon. Jeg er for tiden:

1. □ I arbeid □ Fulltid □ Deltid→ Hvor mange timer/uke? ___timer/uke
2. □ Student
3. □ Sykemeldt □ Full tid □ Delvis → Hvor mange prosent? _____%
4. □ Uforetrygt □ Helt (100%) □ Delvis→ Hvor mange prosent? _____%
5. □ Arbeidsløs
6. □ Annet _____

9. Hvis du jobber, har du skiftarbeid, nattarbeid eller vakter? □ Ja □ Nei

10. Hvis du er i lønnet eller ulønnet arbeid, hvordan vil du beskrive ditt arbeid? (sett bare ett kryss)

1. □ For det meste stillesittende arbeid (f.eks. skrivebordsarbeid, montering)
2. □ Arbeid som krever at du går mye (f.eks. ekspeditørarb., lett industriarb., undervisning)
3. □ Arbeid hvor du går og løfter mye (f.eks. postbud, pleier, bygningsarb.)
4. □ Tungt kroppsarbeid (f.eks. skogsarb., tungt jordbruksarb., tungt bygningsarb.)

11. Når fikk du din ryggmargskade? Skriv skadetidspunkt, (dato-mnd-år): _____

12. I hvilket nivå er skaden ditt? _____

13. I hvilken alder ble du skadet? _____ år

14. Ble du skadet i trafikk- eller fallulykke? □ Ja □ Nei

15. Ble du skadet på grunn av en annen sykdom □ Ja □ Nei

16. Hvor mange *timer per dag* har du hjemmehjelp eller personlig assistent?

1. □ Ingen
2. □ ≤2 timer
3. □ 3-5 timer
4. □ 6-9 timer
5. □ 10 timer eller mer

17. Hvor mange *dager per uke* har du hjemmehjelp eller personlig assistent?

1. □ Ingen
2. □ 1-2 dager
3. □ 3-4 dager
4. □ 5 – 6 dager
5. □ alle dager

18. Hvilken medisiner bruker du for tida?

1. □ Smertestillende	2. □ Spastisitetdempende
3. □ Muskelavslappende	4. □ Beroliggende
5. □ Sovemedisin	6. □ Antidepressiva
7. □ Andre	8. □ Ingen

19. Hvis du bruker spastistetsdempende medisin, vær vennlig å angi navn og dose?

Navn_____Dose: styrke: antall ganger per dag:_____

_____

20. Har du noen av følgende sykdommene?

1. Beinskjørhet	□ Ja	□ Nei
2. Hjerte- karsykdom	□ Ja	□ Nei
3. Diabetes	□ Ja	□ Nei
4. Høy blodtrykk	□ Ja	□ Nei

21. Har du fått innsatt hofte- eller kneprotese? □ Ja □ Nei

I spørsmal 22 og 23, skal du tenke på om du jevnlig har smerter i en kroppsdel. Disse kan variere etter om du er i hvile eller i aktivitet. I forhold til disse smertene:

22. Hvor mye *smerter* har du når du er *i aktivitetet* (feks. når du går, står osv.)? (Skala fra 0 til 10, 0 vil si ingen smerter og 10 er uutholdelige smerter.)

□	□	□	□	□	□	□	□	□	□	□
0	1	2	3	4	5	6	7	8	9	10
Ingen smerte										Uutholdelig smerte

23. Hvor mye *smerter* har du *i hvile*? (Skala fra 0 til 10, 0 vil si ingen smerter og 10 er uutholdelige smerter.)

□	□	□	□	□	□	□	□	□	□	□
0	1	2	3	4	5	6	7	8	9	10
Ingen smerte										Uutholdelig smerte

24. Hvilket hjelpemiddel benytter du mest for å forflytte deg?

1. □ Rullestol
2. □ Gåstol
3. □ Rullator
4. □ Krykker uten skinne(r)
5. □ Krykker med skinne(r)
6. □ Annet, spesifiser:_____

25. Hvor ofte har du fysioterapi?

1. □ Har ikke fysioterapi
2. □ 1 gang i uken
3. □ 2-3 ganger i uken
4. □ 4– 5 ganger i uken
5. □ mer enn 5 ganger i uken

26. Egentrening utenom fysioterapi. Hvor ofte trener du per uke ?

1. □ Trener ikke i hele tatt
2. □ Sjeldnere enn 1 ganger i uken
3. □ 1 gang i uken
4. □ 2-3 ganger i uken
5. □ 4 – 5 ganger i uken
6. □ mer enn 5 ganger i uken

27. Hvor lenge trener du hver gang (i minutter)?

1. □ trener ikke
2. □ mindre enn 15 min
3. □ 16 – 30 min
4. □ 31 – 45 min
5. □ 46 – 60 min
6. □ Over 60 min

28. Hva slags trening driver du med?

1. □ Bassengtrening
2. □ Ergometersykling
3. □ Styrketrening
4. □ Kondisjonstrening
5. □ Turgåing
6. □ Ridning
7. □ Balansetrening
8. □ Annet, spesifiser_____

29. Har du tidligere prøve å gå i tredemølle med assistanse? □ Ja □ Nei

30. Er du for tiden med i en annen studie/program hvor du får intensiv trening?

□ Ja □ Nei

Short-Form Health Status Survey (SF-36), (version 1.2 chronic)

SF-36 SPØRRESKJEMA OM HELSE

INSTRUKSJON: Dette spørreskjemaet handler om hvordan du ser på din egen helse. Disse opplysningene vil hjelpe oss til å få vite hvordan du har det og hvordan du er i stand til å utføre dine daglige gjøremål.

Hvert spørsmål skal besvares ved å sette en ring rundt det tallet som passer best for deg. Hvis du er usikker på hva du skal svare, vennligst svar så godt du kan.

1. Stort sett, vil du si at din helse er: *(sett ring rundt ett tall)*

Utmerket……	1
Meget god……..	2
God……. ……..	3
Nokså god…….	4
Dårlig…….	5

2. Sammenlignet med for ett år siden, hvordan vil du si at din helse stort sett er nå?

(sett ring rundt ett tall)

Mye bedre nå enn for ett år siden…….	1
Litt bedre enn for ett år siden……	2
Omtrent den samme som for ett år siden…….	3
Litt dårligere nå enn for ett år siden……	4
Mye dårligere enn for ett år siden……	5

3. De neste spørsmålene handler om aktiviteter som du kanskje utfører i løpet av en vanlig dag. Er din helse slik at den begrenser deg i utførelsen av disse aktivitetene nå. Hvis ja, hvor mye?

(sett ring rundt ett tall på hver linje)

AKTIVITETER	**Ja, begrenser meg mye**	**Ja, begrenser meg litt**	**Nei, begrenser meg ikke i det hele tatt**
a. Anstrengende aktiviteter som å løpe, løfte tunge gjenstander, delta i anstrengende idrett	1	2	3
b. Moderate aktiviteter som å flytte et bord, støvsuge, gå en tur eller drive med hagearbeid	1	2	3
c. Løfte eller bære en handlekurv	1	2	3
d. Gå opp trappen i flere etasjer	1	2	3
e. Gå opp trappen en etasje	1	2	3
f. Bøye deg eller sitte på huk	1	2	3
g. Gå mer enn to kilometer	1	2	3
h. Gå noen hundre meter	1	2	3
i. Gå hundre meter	1	2	3
j. Vaske deg eller kle på deg	1	2	3

4. I løpet av de siste 4 ukene, har du hatt noen av de følgende problemer i ditt arbeid eller i andre av dine daglige gjøremål på grunn av din fysiske helse?

(sett ring rundt ett tall på hver linje)

	JA	**NEI**
a. Du har måttet **redusere tiden** du har brukt på arbeid eller på andre gjøremål	1	2
b. Du har **utrettet mindre** enn du har ønsket	1	2
c. Du har vært hindret i å utføre **visse typer** arbeid eller gjøremål	1	2
d. Du har hatt **problemer** med å gjennomføre arbeidet eller andre gjøremål (f.eks. fordi det krevde ekstra anstrengelser)	1	2

5. I løpet av de siste 4 ukene, har du hatt noen av de følgende problemer i ditt arbeid eller i andre av dine daglige gjøremål på grunn av følelsesmessige problemer (som f.eks. å være deprimert eller engstelig)

(sett ring rundt ett tall på hver linje)

	JA	**NEI**
a. Du har måttet **redusere tiden** du har brukt på arbeid eller andre gjøremål	1	2
b. Du har **utretter mindre** enn du hadde ønsket	1	2
c. Du har utført arbeidet eller andre gjøremål mindre **grundig** enn vanlig	1	2

6. I løpet av de siste 4 ukene, i hvilken grad har din fysiske helse eller følelsesmessige problemer hatt innvirkning på din vanlige sosiale omgang med familie, venner, naboer eller foreninger?

(sett ring rundt ett tall)

Ikke i det hele tatt…… 1

Litt……... 2

En del…….. 3

Mye……. 4

Svært mye…… 5

7. Hvor sterke kroppslig smerter har du hatt i løpet av de siste 4 ukene?

(sett ring rundt ett tall)

Ingen…… 1

Meget svake…… 2

Svake…… 3

Moderate……. 4

Sterke…….. 5

Meget sterke…… 6

8. I løpet av de siste 4 ukene, hvor mye har smerter påvirket ditt vanlige arbeid (gjelder både arbeid utenfor hjemmet og husarbeid)?

(sett ring rundt ett tall)

Ikke i det hele tatt…… 1

Litt……... 2

En del…….. 3

Mye…… 4

Svært mye…… 5

9. De neste spørsmålene handler om hvordan du har følt deg og hvordan du har hatt det de siste 4 ukene. For hvert spørsmål, vennligst velg det svaralternativet som best beskriver hvordan du har hatt det. Hvor ofte i løpet av de siste 4 ukene har du:

(sett ring rundt ett tall på hver linje)

	Hele tiden	**Nesten hele tiden**	**Mye av tiden**	**En del av tiden**	**Litt av tiden**	**Ikke i det hele tatt**
a. Følt deg full av tiltakslyst?	1	2	3	4	5	6
b. Følt deg veldig nervøs?	1	2	3	4	5	6
c. Vært så langt nede at ingenting har kunnet muntre deg opp?	1	2	3	4	5	6
d. Følt deg rolig og harmonisk?	1	2	3	4	5	6
e. Hatt mye overskudd?	1	2	3	4	5	6
f. Følt deg nedfor og trist?	1	2	3	4	5	6
g. Følt deg sliten?	1	2	3	4	5	6
h. Følt deg glad?	1	2	3	4	5	6
i. Følt deg trett?	1	2	3	4	5	6

10. I løpet av de siste 4 ukene, hvor mye av tiden har din fysiske helse eller følelsesmessige problemer påvirket din sosiale omgang (som det å besøke venner, slektninger osv.)?

(sett ring rundt ett tall)

Hele tiden……. 1

Nesten hele tiden……. 2

En del av tiden……. 3

Litt av tiden……. 4

Ikke i det hele tatt…… 5

11. Hvor RIKTIG eller GAL er hver av de følgende påstander for deg?

(sett ring rundt ett tall på hver linje)

	Helt riktig	**Delvis riktig**	**Vet ikke**	**Delvis gal**	**Helt gal**
a. Det virker som om jeg blir syk litt lettere enn andre	1	2	3	4	5
b. Jeg er like frisk som de fleste jeg kjenner	1	2	3	4	5
c. Jeg tror at helsen min vil forverres	1	2	3	4	5
d. Jeg har utmerket helse	1	2	3	4	5

The International Physical Activity Questionnaire short version (IPAQ-SF) –

I det følgende spørsmålet bruker vi disse definisjonene om fysisk aktivitet:

Meget anstrengende er fysisk aktivitet som får deg til å puste mye mer enn vanlig
Middels anstrengende er fysisk aktivitet som får deg til å puste litt mer enn vanlig.

2.1.a Hvor mange dager i løpet av de siste 7 dager har du drevet med *meget anstrengende* fysiske aktiviteter som tunge løft, gravearbeid, aerobics, sykle fort eller rulle fort med rullestol. Tenk bare på aktiviteter som varte minst 10 minutter i ett strekk.

……. Dager pr. uke …..Ingen. Gå til spørsmål 2.2.a

2.1.b. På en vanlig dag hvor du utførte *meget anstrengende* fysiske aktiviteter, hvor lang tid brukte du da på dette?

…..Timer ….. Minutter

2.2.a Tenk bare på aktiviteter som varte minst 10 minutter i ett strekk. Hvor mange dager i løpet av de siste 7 dager har du drevet med *middels anstrengende* fysiske aktiviteter som bære lette ting, sykle eller rulle med rullestol i moderat tempo.

……. Dager pr. uke …..Ingen. Gå til spørsmål 2.3.a

2.2.b. På en vanlig dag hvor du utførte middels anstrengende fysiske aktiviteter, hvor lang tid brukte du da på dette?

…..Timer ….. Minutter

2.3.a Hvor mange dager i løpet av de siste 7 dager gikk eller rullet du med rullestol minst 10 min i strekk for å komme deg fra et sted til et annet? Dette inkluderer gang/rulling på jobb og hjemme, til buss, eller gang/rulling som du gjør på tur eller som trening.

……. Dager pr. uke …..Ingen. Gå til spørsmål 2.4

2.3.b. På en vanlig dag hvor du gikk eller rullet for å komme deg fra et sted til et annet, hvor lang tid brukte du da på dette?

…..Timer ….. Minutter

2.4 Dette spørsmålet omfatter all tid du tilbringer i ro (sittende) på jobb, hjemme, på kurs på fritiden. Det kan være tiden du sitter ved et arbeidsbord, hos venner, mens du leser eller sitter eller ligger for å se på TV.

I løpet av de siste 7 dager, hvor lang tid brukte du totalt på å sitte på en vanlig hverdag?

…..Timer ….. Minutter

The Behavioral Regulation in Exercise Questionnaire BREQ -
Motivasjon for fysisk trening generelt – utenom prosjektperioden

Det er mange ulike grunner til at folk driver med regelmessig fysisk trening. Vær vennlig å indikere hvordan utsagnene under stemmer med dine grunner for å trene.

Skalaen er:

1	2	3	4	5	6	7
Ikke i det hele tatt			delvis sant			Svært sant

Jeg forsøker å trene regelmessig:

1.	Fordi jeg ville føle negativt om meg selv hvis jeg ikke gjorde det.	1	2	3	4	5	6	7
2.	Fordi andre ville bli sinte på meg om jeg ikke gjorde det	1	2	3	4	5	6	7
3.	Fordi jeg liker å trene	1	2	3	4	5	6	7
4.	Fordi jeg føle meg mislykket hvis jeg ikke gjorde det	1	2	3	4	5	6	7
5.	Fordi jeg føler det er den beste måten å hjelpe meg selv på	1	2	3	4	5	6	7
6.	Fordi jeg føler at jeg ikke har noe valg i forhold til å trene, andre får meg til å gjøre det.	1	2	3	4	5	6	7
7.	Fordi det er en utfordring å nå mine mål	1	2	3	4	5	6	7
8.	Fordi jeg tror trening får meg til å føle meg bedre.	1	2	3	4	5	6	7
9.	Fordi det er moro	1	2	3	4	5	6	7
10.	Fordi jeg bekymrer meg for å få problemer med andre om jeg ikke gjorde det.	1	2	3	4	5	6	7
11.	Fordi det føles viktig for meg personlig å få nå det målet	1	2	3	4	5	6	7
12.	Fordi jeg føler meg skyldig om jeg ikke trener regelmessig	1	2	3	4	5	6	7
13.	Fordi jeg ønsker at andre skal se at jeg gjør det jeg er blitt bedt om å gjøre	1	2	3	4	5	6	7
14.	Fordi det å føle meg sunnere er en viktig verdi for meg.	1	2	3	4	5	6	7

Exercise barrier self-efficacy (EBSE)- Forhold til fysisk trening i prosjektet –

Jeg er sikker på at jeg kan gjennomføre den planlagte treningen selv om:

		Ikke sikker i det hele tatt			kanskje			veldig sikker
		1	**2**	**3**	**4**	**5**	**6**	**7**
4.1	Jeg er trett	☐	☐	☐	☐	☐	☐	☐
4.2	Jeg føler meg nedtrykt	☐	☐	☐	☐	☐	☐	☐
4.3	Jeg har bekymringer	☐	☐	☐	☐	☐	☐	☐
4.4	Jeg er sint på grunn av noe	☐	☐	☐	☐	☐	☐	☐
4.5	Jeg føler meg stresset	☐	☐	☐	☐	☐	☐	☐
4.6	Jeg har venner på besøk	☐	☐	☐	☐	☐	☐	☐
4.7	Andre vil at jeg skal bli med på en annen aktivitet	☐	☐	☐	☐	☐	☐	☐
4.8	Familien min/partneren min tar mye av tiden min	☐	☐	☐	☐	☐	☐	☐
4.9	Jeg ikke finner noen å trene sammen med	☐	☐	☐	☐	☐	☐	☐
4.10	Været er dårlig	☐	☐	☐	☐	☐	☐	☐
4.11	Jeg fremdeles har mye arbeid å gjøre	☐	☐	☐	☐	☐	☐	☐
4.12	Det er et interessant program på TV	☐	☐	☐	☐	☐	☐	☐
4.13	Jeg har smerter	☐	☐	☐	☐	☐	☐	☐
4.14	Aktiviteten er vanskelig tilgjengelig for meg	☐	☐	☐	☐	☐	☐	☐

Outcome expectations - Nevn 3 konkrete resultater som du forventer å få ut av treningen i dette prosjektet.

1 ……

……

2 ……

……

3 ……

……

Hvor sikker er du på å oppnå resultat 1 på en skala fra 0-100%

0 100

Svært Usikker Svært sikker

Hvor sikker er du på å oppnå resultat 2 på en skala fra 0-100%

0 100

Svært Usikker Svært sikker

Hvor sikker er du på å oppnå resultat 3 på en skala fra 0-100%

0 100

Svært Usikker Svært sikker

Psychological centrality - **Hvordan vurderer du disse mulige konsekvensene av å gjennomføre treningen i prosjektet?. <u>Sett kryss</u> i den ruta som samsvarer med i hvilken grad du mener konsekvensen er viktig.**

	Uviktig						Svært viktig
	1	**2**	**3**	**4**	**5**	**6**	**7**
Å komme i bedre fysisk form er for meg……	☐	☐	☐	☐	☐	☐	☐
Å få mer overskudd er for meg……	☐	☐	☐	☐	☐	☐	☐
Å få løst opp spenninger og stress i kroppen er for meg……	☐	☐	☐	☐	☐	☐	☐
Å komme i bedre humør er for meg…	☐	☐	☐	☐	☐	☐	☐
Å gå ned i vekt er for meg……	☐	☐	☐	☐	☐	☐	☐
Å få bedre helse er for meg……	☐	☐	☐	☐	☐	☐	☐
Å få mindre tid til andre ting som følge av fysisk aktivitet er for meg……	☐	☐	☐	☐	☐	☐	☐
At trening / mosjon koster innsats er for meg……	☐	☐	☐	☐	☐	☐	☐
Risikoen for å pådra meg skader som følge av fysisk aktivitet er for meg……	☐	☐	☐	☐	☐	☐	☐
Å forbedre min fysiske funksjon vesentlig er for meg……	☐	☐	☐	☐	☐	☐	☐

ATLET SCALES TRANSLATED IN ENGLISH

Motivation for physical activity in general (BREQ)

There are several reasons for people g to exercise regularly. Please use the scale below to indicate to which degree the statements below are in accordance with your reasons to be physically active.

The scale is:

1	2	3	4	5	6	7
not		partly				Very
at all		true				true

I try to exercise regularly because:

1.	I would feel negatively about myself if I did not.	1 2 3 4 5 6 7
2.	others would be angry with me if I did not	1 2 3 4 5 6 7
3.	Because I like exercising	1 2 3 4 5 6 7
4.	I would feel like a failure if I did not	1 2 3 4 5 6 7
5.	I feel that it is the best way I can help myself	1 2 3 4 5 6 7
6.	people would think I am a weak person if I did not	1 2 3 4 5 6 7
7.	I feel I do not have any choice as to exercising, others make me do it.	1 2 3 4 5 6 7
8.	it is a challenge to reach my goals	1 2 3 4 5 6 7
9.	I believe exercise makes me feel better.	1 2 3 4 5 6 7
10.	it is fun	1 2 3 4 5 6 7
11.	I worry about getting problems with others	1 2 3 4 5 6 7

If I did not.

12. it feels important for me personally to reach that goal 1 2 3 4 5 6 7

13. I feel guilty if I do not exercise regularly 1 2 3 4 5 6 7

14. I wish others to see that I do 1 2 3 4 5 6 7
What I have been told to do

15. it is interesting to see my own progress 1 2 3 4 5 6 7

16. to feel more healthy is an important value to me. 1 2 3 4 5 6 7

Exercise barrier self-efficacy

I am certain that I can carry out the planned exercise even if :

		Not at all sure			maybe			Absolutely sure
		1	**2**	**3**	**4**	**5**	**6**	**7**
1	I am tired	☐	☐	☐	☐	☐	☐	☐
2	I feel depressed	☐	☐	☐	☐	☐	☐	☐
3	I have worries	☐	☐	☐	☐	☐	☐	☐
4	I am angry for something	☐	☐	☐	☐	☐	☐	☐
5	I feel stressed out	☐	☐	☐	☐	☐	☐	☐
6	I have friends visiting	☐	☐	☐	☐	☐	☐	☐
7	Others want me to take part in another activity	☐	☐	☐	☐	☐	☐	☐

8	My family/my partner take up a lot of my time	☐	☐	☐	☐	☐	☐	☐
9	I cannot find somebody to exercise with	☐	☐	☐	☐	☐	☐	☐
10	The weather is bad	☐	☐	☐	☐	☐	☐	☐
11	I still have much work to do	☐	☐	☐	☐	☐	☐	☐
12	There is an interesting program on TV	☐	☐	☐	☐	☐	☐	☐
13	I am in pain	☐	☐	☐	☐	☐	☐	☐
14	The activity is not easily accessible for me	☐	☐	☐	☐	☐	☐	☐

OUTCOME EXPECTATIONS

List 3 concrete results that you expect to get out of the training in this project:

1 ……

……

2 ……

……

3 ……

……

How sure are you to obtain the result nr. 1 on a scale from 0-100%

0 100

_____

Very Very

unsure sure

How sure are you to obtain the result nr. 2 on a scale from 0-100%

0 100

_____

Very Very

unsure sure

How sure are you to obtain the result nr. 3 on a scale from 0-100%

0 100

_____

Very Very

unsure sure

Psychological centrality

How do you evaluate these possible consequences of carrying out the physical training in the project?. Mark with a cross in the square that corresponds with how important you think the consequence is.

	Unimportant						Very important
	1	**2**	**3**	**4**	**5**	**6**	**7**
To get more fit is to me ……	☐	☐	☐	☐	☐	☐	☐
To get more energy is to me……	☐	☐	☐	☐	☐	☐	☐
To loosen up tension and stress In the body is to me……	☐	☐	☐	☐	☐	☐	☐
To get in a better mood is for me …	☐	☐	☐	☐	☐	☐	☐
To reduce weight is for me……	☐	☐	☐	☐	☐	☐	☐
To get better health is to me……	☐	☐	☐	☐	☐	☐	☐
To get less time for other things Is to me	☐	☐	☐	☐	☐	☐	☐
That training/exercise demands effort is to me……	☐	☐	☐	☐	☐	☐	☐
The risk to get injured during physical activity is to me……	☐	☐	☐	☐	☐	☐	☐
To improve my physical function considerably is to me……	☐	☐	☐	☐	☐	☐	☐

Outcome assessments

Physical outcome measures

Patient Name _____

Examiner Name _____ Date/Time of Exam_____

STANDARD NEUROLOGICAL CLASSIFICATION OF SPINAL CORD INJURY

ASIA American Spinal Injury Association

ISCOS

MOTOR

KEY MUSCLES
(scoring on reverse side)

	R	L	
C5	☐	☐	Elbow flexors
C6	☐	☐	Wrist extensors
C7	☐	☐	Elbow extensors
C8	☐	☐	Finger flexors (distal phalanx of middle finger)
T1	☐	☐	Finger abductors (little finger)

UPPER LIMB TOTAL (MAXIMUM) ☐ + ☐ = ☐ (25) (25) (50)

Comments:

L2	☐	☐	Hip flexors
L3	☐	☐	Knee extensors
L4	☐	☐	Ankle dorsiflexors
L5	☐	☐	Long toe extensors
S1	☐	☐	Ankle plantar flexors

Voluntary anal contraction (Yes/No) ☐

LOWER LIMB TOTAL (MAXIMUM) ☐ + ☐ = ☐ (25) (25) (50)

SENSORY

KEY SENSORY POINTS

0 = absent
1 = impaired
2 = normal
NT = not testable

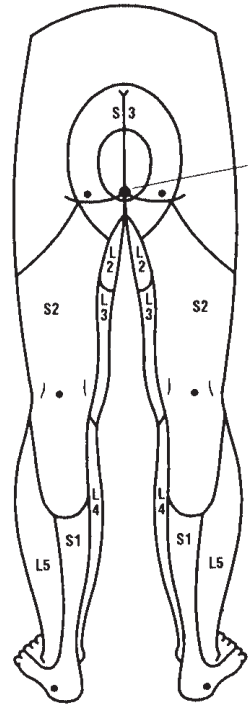
	LIGHT TOUCH R	LIGHT TOUCH L	PIN PRICK R	PIN PRICK L
C2				
C3				
C4				
C5				
C6				
C7				
C8				
T1				
T2				
T3				
T4				
T5				
T6				
T7				
T8				
T9				
T10				
T11				
T12				
L1				
L2				
L3				
L4				
L5				
S1				
S2				
S3				
S4-5				

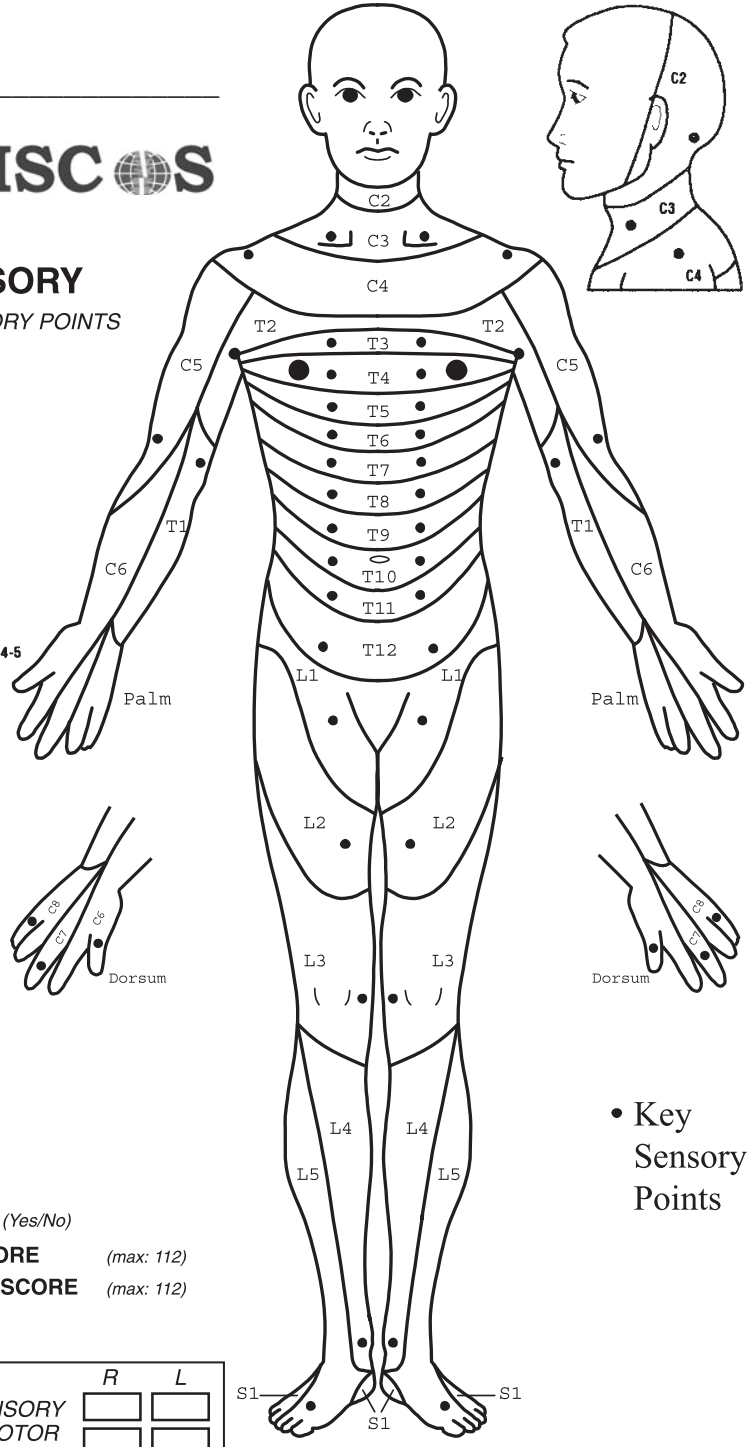
TOTALS (MAXIMUM) ☐ (56) + ☐ (56) = ☐ (56) ☐ (56)

☐ Any anal sensation (Yes/No)

☐ + ☐ = ☐ **PIN PRICK SCORE** (max: 112)

= ☐ **LIGHT TOUCH SCORE** (max: 112)





• Key Sensory Points

NEUROLOGICAL LEVEL		R	L	COMPLETE OR INCOMPLETE?	ZONE OF PARTIAL PRESERVATION		R	L
The most caudal segment with normal function	SENSORY	☐	☐	Incomplete = Any sensory or motor function in S4-S5 ☐	Caudal extent of partially innervated segments	SENSORY	☐	☐
	MOTOR	☐	☐	ASIA IMPAIRMENT SCALE ☐		MOTOR	☐	☐

REV 03/06

MUSCLE GRADING

0 total paralysis

1 palpable or visible contraction

2 active movement, full range of motion, gravity eliminated

3 active movement, full range of motion, against gravity

4 active movement, full range of motion, against gravity and provides some resistance

5 active movement, full range of motion, against gravity and provides normal resistance

5* muscle able to exert, in examiner's judgement, sufficient resistance to be considered normal if identifiable inhibiting factors were not present

NT not testable. Patient unable to reliably exert effort or muscle unavailable for testing due to factors such as immobilization, pain on effort or contracture.

ASIA IMPAIRMENT SCALE

☐ **A = Complete**: No motor or sensory function is preserved in the sacral segments S4-S5.

☐ **B = Incomplete:** Sensory but not motor function is preserved below the neurological level and includes the sacral segments S4-S5.

☐ **C = Incomplete:** Motor function is preserved below the neurological level, and more than half of key muscles below the neurological level have a muscle grade less than 3.

☐ **D = Incomplete:** Motor function is preserved below the neurological level, and at least half of key muscles below the neurological level have a muscle grade of 3 or more.

☐ **E = Normal:** Motor and sensory function are normal.

CLINICAL SYNDROMES (OPTIONAL)

☐ Central Cord
☐ Brown-Sequard
☐ Anterior Cord
☐ Conus Medullaris
☐ Cauda Equina

STEPS IN CLASSIFICATION

The following order is recommended in determining the classification of individuals with SCI.

1. Determine sensory levels for right and left sides.
2. Determine motor levels for right and left sides.
   Note: in regions where there is no myotome to test, the motor level is presumed to be the same as the sensory level.
3. Determine the single neurological level.
   This is the lowest segment where motor and sensory function is normal on both sides, and is the most cephalad of the sensory and motor levels determined in steps 1 and 2.
4. Determine whether the injury is Complete or Incomplete (sacral sparing).
   If voluntary anal contraction = **No** *AND all S4-5 sensory scores* = **0** *AND any anal sensation* = **No**, *then injury is COMPLETE. Otherwise injury is incomplete.*
5. Determine ASIA Impairment Scale (AIS) Grade:

Is injury <u>Complete</u>? If **YES**, AIS=A Record ZPP (For ZPP record lowest dermatome or myotome on each side with some (non-zero score) preservation)

NO ↓

Is injury motor <u>incomplete</u>? If **NO**, AIS=B (Yes=voluntary anal contraction OR motor function more than three levels below the motor level on a given side.)

YES ↓

Are <u>at least</u> half of the key muscles below the (single) <u>neurological</u> level graded 3 or better?

NO ↓ AIS=C

YES ↓ AIS=D

If sensation and motor function is normal in all segments, AIS=E
Note: AIS E is used in follow up testing when an individual with a documented SCI has recovered normal function. If at initial testing no deficits are found, the individual is neurologically intact; the ASIA Impairment Scale does not apply.

ATLET studien – 10 meters gangtest vår 2009

The 10-meter walk test (10MWT) - 10-meter gangtest - Utføres av fysioterapeut fra SSH. Plass: En 30 meter lang korridor. En meters markering. Utstyr: stopperklokke, målband og tape. Utførelse: Pasienten står 2 meter bak startstreken. Når pasientens første fot passer startstrek startes klokken (flying start). Be pasienten å gå 10 m så fort men trygt som det er mulig med det ganghjelpemiddel han/hun bruker primært. Start- kommando er "klar, ferdig gå, "og stopp kommando er "stopp". Tester teller antall av steg og stopper klokken når pasienten har passert 10 meter. Testes 2 ganger og gjennomsnitt tiden regnes ut.

---

10 meters gangtest med flying start

Initialer tester: _____ IDnummer: _____

Testdato: _____ Klokkeslett: _____

Brukt hjelpemidler:_____

	Tid i min og sek	Skritt	Kommentar
Forsøk1			
Forsøk 2			
Gjennomsnitt			

Pasienten trenger tilsyn □ assistanse fra 1 person □ assistanse fra 2 person □

The 6-minute walk test (6MWT) - 6 minutters gangtest - Utføres av fysioterapeut fra SSH. Plass: En lang korridor 30 meter ved Sunnaas. En meters markering. Utførelse: Pasienten står 2 meter bak startstreken. Når pasientens første fot passer startstrek startes klokken (flying start). Pasienten går så fort som det er trygt og langt han/hun kan på 6 minutter med den ganghjelpemiddel han/hun bruker primært. Når 6 minutter har gått be pasienten å stoppe og sett en tape rett bak hæl og antall meter regnes ut. Ved 30 meters snu pasienten bes å trø på teip – snu og gå videre. Testen utføres 1 gang.
En fysioterapeut tar tid og instruerer pasienten. Hun gir også beskjed hvor lang tid det har gått og hvor mye tid er igjen 1 minutts intervall. Den andre fysioterapeuten/testeren passer på sikkerheten av pasienten. Helst ikke støtte, hvis må støtte så skriv opp hvor mye man støttet pasienten. Pasienten skal ha skjorta i bukse så at fysioterapeuten har mulighet å gripe inn hvis pasienten mister balanse.

Pasient kan testes ved sluttesting 2. gang hvis pasienten har klart å redusere bruk av hjelpemidler når han/hun går.

---

6 min gangtest

Testdato: _____ Klokkeslett: _____

Initialer tester: _____ IDnummer: _____

Brukt hjelpemidler:_____

	Tid i min og sek	meter	Kommentar
Forsøk			

Pasienten trenger tilsyn □ assistanse fra 1 person □ assistanse fra 2 person □

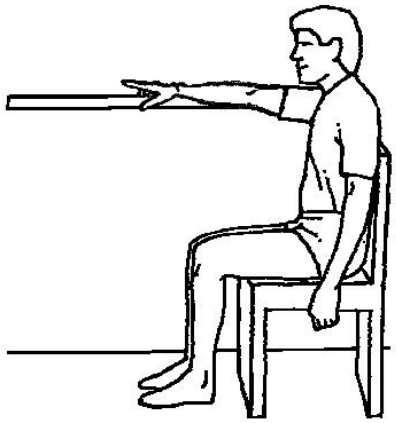
The Modified Functional Reach (MFR) - Modifisert Functional Reach

Utstyr:

- Benyttes teststasjon på fys.avd. ved Sunnaas
- Stol med fast, polstret sete og ryggstøtte (helst ca 80°)

Målingen:

1. Pasienten i sittende, hviler mot ryggstøtte. Staven er festet til veggen i høyde med pasientens acromion.
2. Pasienten flekterer 90° i skulder. Testansvarlig merker av startpunktet ved å bruke proc. styloideus ulnae som referansepunkt.
3. Instruksjon til pasient: ”Strekk deg så langt frem som du kan, med hånden langsmed staven. Det er ikke lov å berøre staven. Den andre armen skal ikke brukes som støtte, eller som hjelp til å komme tilbake til utgangsstillingen”.
4. Mens pasienten lener seg maksimalt fremover merkes sluttpunktet for testen med proc. styloideus ulnae som referansepunkt.
5. Pasienten returnerer så til ryggstøtten uten personhjelp, uten bruk av armer på lår og uten støtte av stolen. Dersom pasienten trenger hjelp/støtte scores testen som 0 cm.
6. Pasienten får to prøveforsøk før han/hun utfører tre tellende forsøk.
7. Avstanden mellom avmerket startpunkt og sluttpunkt føres på skjema i antall centimeter (cm) underveis.



ID/Navn:			Fødselsdato:				
1. Testdato:	Scoring:	cm	Scoring:	cm	Scoring:		cm

Bergs Balanseskala: Skåringsskjema

Testpersonens navn/fødselsdato og år:

Dato/signatur					
1. Sittende til stående					
2. Stående uten støtte					
3. Sittende uten støtte					
4. Stående til sittende					
5. Fra en stol til en annen					
6. Stående med lukkede øyne					
7. Stående med føttene inntil hverandre					
8. Strekke seg fremover med utstrakt arm					
9. Ta opp noe fra gulvet					
10. Vri seg og titte bakover					
11. Vende seg 360 grader					
12. Sette en og en fot vekselvis på et trappetrinn					
13. Stå med en fot fremfor den andre					
14. Stå på ett ben					
Poengsum					

Oversatt til norsk av Astrid Bergland, Jorunn L. Helbostad og Torunn Askim i 2004. Oversatt tilbake til engelsk av Sherry Heckler

Bergs balanseskala

Instruksjon: Vis og forklar for den som skal testes (testpersonen eller bare personen), hver oppgave som hun/han skal utføre. Kun det første forsøket gis poeng. Det er derfor veldig viktig at testpersonen fra starten av får all informasjon som trengs, slik at hun/ han forstår hva som skal gjøres. Gi informasjonen på en naturlig måte og bruk malen nedenfor som utgangspunkt. Føy eksempelvis til "Vil du være så snill å..." eller " I neste oppgave skal du..."

Poengsetting: I mange av oppgavene skal testpersonen opprettholde en gitt stilling en viss tid. Du gir gradvis lavere poengsum dersom tids- og avstandskriteriene ikke oppfylles, f.eks. testpersonen krever tilsyn, støtter seg eller behøver hjelp av en person. Med tilsyn menes at du må være forberedt på å gi støtte på grunn av risiko for at testpersonen kan miste balansen. Med støtte og hjelp menes fysisk kontakt mellom testpersonen og en stødig gjenstand eller en person.

Testpersonen velger selv hvilket ben hun/han vil stå på eller hvordan hun/ han vil strekke seg fremover. Det innebærer for eksempel at testpersonen i punkt åtte får null poeng hvis hun/han strekker seg for langt fram og mister balansen. Testpersonens bedømming av egen kapasitet påvirker her oppgaveløsningen og derved poengskåren. Om du er i tvil om hvilken poengskåre som best svarer til det testpersonen klarer, skal du alltid velge **det laveste alternativet**. Det innebærer at testpersonen i det minste klarer denne poengskåren. Ved gjentatte testinger er det svært viktig at du ikke ser på tidligere skåringer, da dette kan påvirke poenggivningen din.

Utstyr: For å bedømme resultatene trengs:

- en stoppeklokke eller en klokke med sekundviser.
- en lineal eller et annet mål som markerer en nullposisjon samt markerer avstandene 5, 12 og 25 cm
- sko eller tøffel
- stol i standardhøyde med armlene
- stol i standardhøyde uten armlene, eller en seng i standardhøyde
- trappetrinn eller en skammel med tilsvarende høyde som et trappetrinn (standard høyde)

Oversatt til norsk av Astrid Bergland, Jorunn L. Helbostad og Torunn Askim i 2004. Oversatt tilbake til engelsk av Sherry Heckler

1 SITTENDE TIL STÅENDE

INSTRUKSJON: ***Reis deg opp. Forsøk å ikke bruke hendene som støtte.*** *(For å få 2 poeng kan pasienten gjøre flere enn ett forsøk på oppgaven)*

( ) 4 Kan reise seg opp uten å bruke hendene og finner selv balansen
( ) 3 Kan reise seg opp på egen hånd med hjelp av hendene
( ) 2 Kan reise seg opp med hjelp av hendene etter flere forsøk
( ) 1 Trenger minimal hjelp av en person for å reise seg opp eller for å finne balansen
( ) 0 Trenger middels eller maksimal hjelp av en eller flere personer for å reise seg opp

2 STÅ UTEN STØTTE

INSTRUKSJON: ***Stå i 2 minutter uten støtte.*** *(For å få 1 poeng får pasienten flere enn et forsøk på denne oppgaven)*

( ) 4 Kan stå stødig i 2 minutter
( ) 3 Kan stå i 2 minutter med tilsyn
( ) 2 Kan stå i 30 sekunder uten støtte
( ) 1 Trenger flere forsøk for å stå i 30 sekunder uten støtte
( ) 0 Kan ikke stå i 30 sekunder uten støtte

Dersom pasienten kan stå i 2 minutter uten støtte; Gi full skåre for oppgave 3 "sitte uten ryggstøtte", og fortsett med oppgave 4

3 SITTE UTEN RYGGSTØTTE MED FØTTENE PÅ GOLVET ELLER PÅ EN SKAMMEL

INSTRUKSJON: ***Sitt med armene i kors i 2 minutter.*** *(Hvis pasienten ikke forstår at han/hun ikke skal lene seg mot ryggstøtten bør oppgaven utføres uten ryggstøtte, for eksempel på sengen eller sengekanten)*

( ) 4 Kan sitte trygt og sikkert i 2 minutter
( ) 3 Kan sitte i 2 minutter med tilsyn
( ) 2 Kan sitte i 30 sekunder
( ) 1 Kan sitte i 10 sekunder
( ) 0 Kan ikke sitte i 10 sekunder uten støtte

4 STÅENDE TIL SITTENDE

INSTRUKSJON: ***Sett deg ned***

( ) 4 Setter seg på en trygg måte med minimal hjelp av hendene
( ) 3 Kontrollerer det å sette seg ved hjelp av hendene
( ) 2 Bruker baksiden av bena mot stolen for å kontrollere det å sette seg
( ) 1 Setter seg selvstendig men ukontrollert
( ) 0 Trenger hjelp av en person for å sette seg

Oversatt til norsk av Astrid Bergland, Jorunn L. Helbostad og Torunn Askim i 2004. Oversatt tilbake til engelsk av Sherry Heckler

5 FRA SITTENDE PÅ EN STOL MED ARMLENE TIL EN ANNEN STOL UTEN ARMLEN OG VICE VERSA

(Undersøkeren plasserer en stol med armlen i 90 graders vinkel mot en stol uten armlen eller en seng) ***INSTRUKSJON: Flytt deg fra stolen med armlene til stolen uten armlene/sengen. Bruk hendene så lite som mulig. Flytt deg så tilbake fra stolen uten armlene/sengen til stolen med armlene****. (Hvis pasienten ikke greier å flytte seg begge veier kan undersøkeren flytte stolen etter den første overflyttingen. Det viktige er at overflyttingen skjer fra en stol med armlene og fra en stol uten armlene/seng)*

( ) 4 Kan forflytte seg på en trygg måte med minimal hjelp av hendene
( ) 3 Kan forflytte seg på en trygg måte med mye hjelp av hendene
( ) 2 Kan forflytte seg ved hjelp av muntlige ledetråder og/eller tilsyn
( ) 1 Trenger hjelp av en person
( ) 0 Trenger hjelp av to personer (for å støtte eller veilede for å være trygg)

6 STÅ UTEN STØTTE MED LUKKEDE ØYNE

INSTRUKSJON: Lukk øynene og stå stille i 10 sekunder

( ) 4 Kan stå sikkert i 10 sekunder
( ) 3 Kan stå i 10 sekunder med tilsyn
( ) 2 Kan stå i 3 sekunder
( ) 1 Står stille, men må åpne øynene i løpet av 3 sekunder
( ) 0 Trenger hjelp for ikke å falle

7 STÅ UTEN STØTTE MED FØTTENE INNTIL HVERANDRE

INSTRUKSJON: Sett føttene inntil hverandre og stå uten støtte.

( ) 4 Kan selv sette føttene inntil hverandre og stå sikkert i 1 minutt
( ) 3 Kan selv sette føttene inntil hverandre og stå i 1 minutt med tilsyn
( ) 2 Kan selv sette føttene inntil hverandre, men kan ikke stå slik i 1 minutt
( ) 1 Trenger hjelp for å innta stillingen, men kan stå i 15 sekunder med føttene inntil hverandre
( ) 0 Trenger hjelp for å innta stillingen og kan ikke stå i stillingen i 15 sekunder

8 STREKKER SEG FRAMOVER MED UTSTRAKT ARM I STÅENDE

INSTRUKSJON: Løft armen opp til 90 grader. Strekk fingrene. Strekk deg framover så langt du kan. *(Undersøkeren fester eller holder en linjal, alternativt et papir, markert med 0, 5, 12 og 25 cm mot veggen. Nullpunktet skal være på høyde med langfingerens fingertupp når armen holdes strukket frem i 90 grader. Fingrene eller armen skal ikke berøre veggen. Mål på linjalen/papiret hvor langt fingertuppen kommer når pasienten strekker seg så langt frem som mulig. Når det er mulig, skal pasienten benytte begge armer når han/hun strekker seg fram for å unngå rotasjon av kroppen)*

( ) 4 Kan strekke seg fremover mer enn 25 centimeter på en sikker måte
( ) 3 Kan strekke seg fremover mer enn 12 centimeter på en sikker måte
( ) 2 Kan strekke seg fremover mer enn 5 centimeter på en sikker måte
( ) 1 Strekker seg fremover men trenger tilsyn
( ) 0 Mister balansen ved forsøket/trenger ytre støtte

Oversatt til norsk av Astrid Bergland, Jorunn L. Helbostad og Torunn Askim i 2004. Oversatt tilbake til engelsk av Sherry Heckler

9 STÅ OG TA OPP EN GJENSTAND FRA GULVET

INSTRUKSJON: ***Ta opp skoen/tøffelen som ligger foran føttene dine***

( ) 4 Kan ta opp skoen på en enkelt og sikker måte
( ) 3 Kan ta opp skoen men trenger tilsyn
( ) 2 Kan ikke ta opp skoen, men når 2,5 – 5 cm fra skoen og vedlikeholder balansen
( ) 1 Kan ikke ta opp skoen og trenger tilsyn under forsøket
( ) 0 Mister balansen ved forsøket/trenger ytre støtte

10 VRI SEG OG SE BAK OVER HØYRE OG VENSTRE SKULDER I STÅENDE

INSTRUKSJON: ***Vri kroppen og se bak deg over venstre skulder. Gjør det samme mot høyre.***
(For å få til en bedre rotasjon kan undersøkeren stå bak pasienten og holde en gjenstand som pasienten oppmuntres til å se på)

( ) 4 Ser bak seg til begge sider og roterer i hele kroppen og det foregår "tyngdeoverføring"
( ) 3 Ser bak seg til den ene siden, har mindre rotasjon til den andre siden
( ) 2 Vrir seg bare til siden, men opprettholder balansen
( ) 1 Trenger tilsyn under utførelsen
( ) 0 Trenger støtte for ikke å miste balansen eller falle

11 SNU SEG 360 GRADER

INSTRUKSJON: ***Snu deg rundt en hel omgang. Stans. Snu deg så rundt en hel omgang den andre veien.***

( ) 4 Kan snu seg sikkert 360 grader på 4 sekunder eller mindre
( ) 3 Kan snu seg sikkert 360 grader på 4 sekunder eller mindre kun en retning
( ) 2 Kan snu seg sikkert 360 grader, men trenger mer enn 4 sekunder
( ) 1 Trenger tilsyn eller muntlige ledetråder
( ) 0 Trenger støtte under vendingen

12 STÅ UTEN STØTTE OG PLASSER VEKSELVIS EN OG EN FOT PÅ ET TRINN ELLER EN SKAMMEL

INSTRUKSJON: ***Sett vekselvis høyre og venstre fot opp på trinnet/skammelen. Fortsett til hver fot har berørt trinnet/ skammelen 4 ganger***

( ) 4 Kan stå selvstendig og trygt og greier (eller klarer) å sette hver fot 4 ganger på trinnet i løpet av 20 sekunder
( ) 3 Kan stå selvstendig og klarer å sette hver fot på trinnet på mer enn 20 sekunder
( ) 2 Kan klare å sette opp hver fot 2 ganger på trinnet uten hjelp men med tilsyn
( ) 1 Kan klare mer enn 1 gang på hver fot med minimal hjelp
( ) 0 Trenger hjelp for ikke å falle/er ikke i stand til å prøve

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13 STÅ UTEN STØTTE MED EN FOT FORAN DEN ANDRE (DEMONSTRER FOR PASIENTEN)

INSTRUKSJON: ***Sett den ene foten rett foran den andre*** *(tandemstilling).* ***Hvis du ikke greier å sette foten rett foran den andre, prøv å sette foten så langt frem at hælen på den forreste foten er lenger fram enn den bakerste fotens tær****. (For å få 3 poeng, må den forreste fotens hæl plasseres lenger fram enn den bakerste fotens tær og sideveis avstand mellom føttene er omtrent som for pasientens normale stegbredde ved gange)*

( ) 4 Kan selv plassere føttene i tandemstilling og stå der i 30 sekunder
( ) 3 Kan selv sette en fot foran den andre og stå der i 30 sekunder
( ) 2 Kan selv flytte en fot et lite skritt fram og stå der i 30 sekunder
( ) 1 Trenger hjelp med å flytte en fot fram, men kan stå i stillingen i 15 sekunder
( ) 0 Mister balansen under steget eller i stillingen

14 STÅ PÅ ETT BEN

INSTRUKSJON: ***Stå på ett ben så lenge du kan uten støtte***

( ) 4 Kan selv løfte benet og stå der i 10 sekunder
( ) 3 Kan selv løfte benet og stå der i 5 sekunder
( ) 2 Kan selv løfte benet og stå der i 3 sekunder
( ) 1 Forsøker å løfte benet, men kan ikke stå på ett ben i 3 sekunder, men kan likevel stå på egen hånd
( ) 0 Kan ikke eller forsøker ikke å løfte benet, eller trenger hjelp for ikke å falle

Oversatt til norsk av Astrid Bergland, Jorunn L. Helbostad og Torunn Askim i 2004. Oversatt tilbake til engelsk av Sherry Heckler

BWSLT protocols

Study 1: BWSLT with manual assistance protocol

PRATISK GJENNOMFØRING AV INTENS GANGTRENING I TREDEMØLLE VED REHABILITERNINGSSENTER NORD-NORGES KURBAD:

Pasients innleggelse skjer dagen før selv intervensjonen starter ved Rehabiliteringssenteret Nord-Nord Norges kurbad (RNNK). Prosjektkoordinator, avdelingsleder på fysikalsk avdeling og inntakskoordinator samarbeider nært om dette. Ved innleggelses dag pasienten får en innleggelsessamtale med lege, og treffer prosjektkoordinator eller treningsansvarlig fysioterapeut. Pasientens epikrise/henvisning fra Sunnaas sykehus sendes til RNNK før innleggelse. Alle forsøkspersonene har blitt evaluert og testet ved Sunnaas sykehus så fysioterapeut trenger ikke gjennomføre funksjonstester.

Under oppholdet ved RNNK vil pasient få et rom tilpasset rullestolbruker og pasienten vil få hjelp til ADL funksjoner og stell fra pleiepersonell om det er behov for det. Det er daglig oppfølging av fysioterapeut og behandlingsteam. Pasienten vil få sykemelding under intervensjonsperioden dersom han/hun er i arbeid. RNNK tilstreber å trene 2 pasienter samtidig så at alle pasientene i intervensjonsgruppe er ferdig med trening i etter 2 år.

Trening i intervensjonsgruppen er totalt 12 uker fordelt på 3-4 treningsopphold som varer 3- 4 uker. Pasienten har 4 uker intensiv gangtrening og 4 uker pause slik at det totalt blir 12 ukers effektiv gangtrening og tilstreber opptil 60 treningsdager. Hvis pasienten ikke tåler trening i 4 uker på rad må man redusere trening til for eksempel 6x2 uker, men fortsatt slik at det blir totalt 60 treningsdager. Dette vurderes individuelt i samråd med pasienten, treningsansvarlig fysioterapeut og prosjektkoordinator.

FØR TRENING:

- Pasienten må ha vært på toalett eller være katetrisert umiddelbart før trening. Spastisiteten øker hvis man har full blære.
- Pasienten skal bruke shorts eller bukser som kan brettes slik at knær og ankler er synlige.
- Pasienten skal ha avlastningsvest på seg. Størrelsen på vesten skal være den samme hele tiden. Vesten kles på i liggende hvis pasienten ikke har selvstendig ståfunksjon, eller stående hvis pasienten har ståfunksjon fra før.
- Man må inspisere pasientens bein for å se etter sår.
- Ordne vann/saft pasienten kan drikke i pauser. Eller be pasient ta med seg vannflaske.

- Treningsdagbok skal være tilstede og føres. Egen perm. Man skal registrere fortløpende brukt avlastning, hastighet, avvik fra normalgangmønster for eksempel økt spastisitet i ve. u.ex.
- Man må høre hvordan pasientens dagsform er; hvordan det gikk etter treningsøktene dagen før.
- Det registreres spastisitet/søvn siste natt (dårlig, bra, svært bra), smerter (VAS skala) og medisinbruk siste døgn, eventuelt tegn for sår osv. i Pasientarkiv.
- Tøye begge siders underex. Det tar ca 5-15 min å gjennomføre tøyninger. Treningsansvarlig fysioterapeut instruerer og bestemmer tøyningens regime for den aktuelle pasienten.
Foreslåtte tøyninger:
O Bakside av lår: pasienten ryggliggende. Fysioterapeuten tøyer strak bein så langt pasienten tåler det.
O Innside lår: Pasienten ryggliggende. Tøyer strakt bein i abduksjon. Kan tøye begge bein samtidig.
O Forside lår: Pasienten mageliggende. Mest mulig strak hofte. Fysioterapeuten bøyer i kneet.
O Legger: Pasienten ryggliggende. Bøyer ankel med strakt kne.
O Tøyninger gjøres i forbindelse med hver treningsøkt på tredemølle for å minske spasmetendens og løse opp spenninger.

NÅR PASIENTEN KOMMER PÅ TREDEMØLLEN:
- Pasienten skal føle seg trygg hele tiden
- En fysioterapeut skal stå bak pasienten og 2 fysioterapeuter støtter knærne under oppreisning fra rullestol til stående stilling.
- En fysioterapeut skal ha ansvaret for å feste vesten til avlastningssystemet.
- En fysioterapeut skal ha ansvaret for å innstille avlastningsvekten.
- En fysioterapeut skal ha ansvaret for å feste sikkerhetslinen

TRENING PÅ TM:
- Det er 60 minutter til disposisjon på TM på 1. Økt og 30 min på 2. økt. Pasienten har 2 treningsøkter totalt 90 min pr. dag.
- Man tilstreber totalt 30-50 minutter effektiv gangtrening, minst 20 min effektiv gangtrening av god kvalitet.

- Man skal veksle mellom lav hastig for å trene stabilitet, og høy hastighet for maksimalisere sensorisk/motorisk input. Minst 5 min truncus stabilitetstrening med minst mulig guiding i bekken, hofter og underekstremiteter med lav hastighet i løpet av en treningsøkt
- Pasienten bruker tynne såler på skoene for å maksimere de sensoriske impulser fra fotbladene.
- Under gangtrening tilstrebes normalisert gangstilling. Dette innebærer press mot spasmer for å oppnå strekkfase i hofter og knær og fotavvikling fra hæl til tå.
- Man må prøve seg frem med tanke på hvilken ganghastighet og avlastning som gir minst spasmer og best gangfunksjon. Jo mer av kroppsvekten pasienten kan belaste og samtidig holde normalt gangmønster under trening, desto bedre.
- Hver gangøkt kan variere fra 1 min – 5 min, deretter pause.”Bouts of exercice” kan vare for eksempel 20x 2 minutter sa at vi får samlet opp 40 min effektiv gangtrening med pauser. Pausetiden kan variere avhengig av hvor sliten pasienten er. Gangtiden og ”bouts of exercise” må justeres etter gangmønster idet normalisert gangmønster skal tilstrebes.
- Fysioterapeuten må hele tiden høre med pasienten hvordan det går.
- Treningsansvarlig fysioterapeut skal avgjøre forandringer i forhold til avlastning, hastighet og teknikk.
- Fysioterapeut som arbeider med pasienten må variere posisjon. Som oftest står en fysioterapeut bak pasienten, og en fysioterapeut har ansvar for hvert av pasientens bein. Det er 4-5 hjelpere som jobber sammen.
- En fysioterapeut skal stå ved siden av pasienten og gi instruksjoner til pasienten og andre fysioterapeut underveis hvis det er nødvendig.
- Man bruker sjekkliste som står på speilet ved TM aktivt. Opprettholdelse av normal og oppreist holdning, evt. ved hjelp av manuell støtte av bekken. Normal kinematikk ved gange i hofter, knær og ankler – her vil man bruke manuelle hjelpere der hvor dette er nødvendig, f.eks til styring av føtter, stabilisering av bekken, osv.
- Man må avklare hvem som skal styre klokken på TM.
- Man må tenke på progresjon hele tiden.
    - O Hvordan skal kvaliteten bli bedre?
    - O Er det rett hastighet? Er det rett avlastning?
    - O Bruker vi rett teknikk? Er koordinasjon mellom F’ene god nok?
    - O Er gangtiden rett?
- Minske eller eliminere sensoriske impulser som virker mot en normal gangfunksjon (for eksempel stimulering av knehasen under ståfasen eller akillessenen i svingfasen).

- Man må avklare hvem som skriver med aktuelle notat etter hver gangøkt. Viktige momenter er: avlastningsvekt, hastighet, gangtid, kvalitativ bedømmelse, pasientens informasjon.
- Ved ståtrening skal man tilstrebe full ekstensjon i hofter og knær og at hælen kommer ned i underlaget. Avlastningen reduseres til lavest mulig.
- Etter avsluttet trening pasienten hjelpes ned til rullestol. En fysioterapeut tar av sikkerhetslinen, en fysioterapeut støtter i bak bekken, og 2 fysioterapeuterr støtter i knærne for å plassere pasienten trygt til sittende i rullestol. Hvis pasienten blir dårlig under trening i TM må pasienten hjelpes umiddelbart ned fra TM. En fysioterapeut tar av sikkerhetslinen, en fysioterapeut støtter i bak bekken, og 2 fysioterpeuter støtter i knærne for å plassere pasienten trygt i sittende i rullestol. Ved en akutt forverring i pasientens situasjon må husets lege hentes umiddelbart. Aldri la pasienten være alene i TM uten sikring av fysioterapeut.

ETTER TRENING I TM:

- En fysioterapeut skal stå bak pasienten hele tiden, og 2 fysioterapeuter støtter i knær.
- En fysioterapeut skal ha ansvaret for å ta av sikkerhetslinen
- En fysioterapeut skal ha ansvaret for å senke avlastningsvekten.
- En skal ha ansvaret for å ta avlastningssystemet av vesten.
- Pasienten plasseres rolig i rullestol.
- Tøye som før treningsøkten 5-15min.
- Bekrefte tidspunkt for neste treningsøkt.

Trening på Vigor Gym – Pasienten trener på kne- og hoftebøy med økende frekvens, men med relativt lav belastning. Bør ikke overstige 100 ganger per økt. Pasienten starter på trinn 0 (horisontal brett) og øker ettersom pasienten klarer det. Derved økende belastning. Økende tid og antall knebøyninger per økt. Trenes 1 ganger per dagen. Dette trenes hvis pasienten funksjon og dagsform tillater det. Tid kan variere individuelt fra 5 – 20min

Gangtrening over golvet/ ståtrening – Tidligste mulig å igangsette tilsvarende trening over gulv (uten tredemølle), men med avlastning/støtte i bekken/knær om nødvendig for å få stå/gang funksjon. Det vil si å overflytte av ferdighetene som pasienten har oppnådd i TM til golv. Det kan bruke avlastningsenhet, gangbane osv. for å gjøre dette. Treningsansvarlig fysioterapeut bestemmer treningsformen.

Hvis treningsansvarlig fysioterapeut er usikker så han skal ta kontakt til prosjektkoordinator.

Lengden på hver treningsøkt med gang- og ståtrening på tredemølle er i utgangspunktet 60 minutter, men tilpasses basert på 1) pasientens utholdenhetsnivå 2) evnen til å vedlikeholde normal kinematikk i hofter, knær og ankler, 3) opprettholdelse av normal gangrytme.

Hvile – Pasienten skal ha minst en hviledag i løpet av uken for å unngå belastningsskader, og for restitusjon etter treningsøktene. Ellers vurderes dette individuelt. Pasienten skal få også tilbud om ekstra tøyninger eventuelt bløtvevs mobilisering på søndager. Her man kan benytte RNNK søndagsvaktordning.

Det føres daglige notater om pasientens dagsform, avlastning, hastighet, minutter i løpet av en treningsøkt og total varighet av treningssesjon i RNNK sin journalsystem.

Før hjemreise - innlæring av hjemmetreningsprogram som vektlegger de samme prinsipper med tanke på vektbæring og god kvalitet på stå-gå trening etter lokomotor prinsippene.

Registrening og journalskriving:
Dag 1
a. Innskriving hos lege
b. Lab for rutine sjekk
c. Oppstart med trening

Treningsdagbok: egenskjema/perm hos treninsgsansvarlig fys. Det registreres fortløpende brukt vektavlastning, hastighet, tid, ganglengde, avvik fra normal gangmønster
Pasientarkiv: Daglige notater: spastisitet/søvn sist natt, smerter (VAS skala) og medisinbruk i siste døgn, tegn for sår osv.

Siste dag
Utskriving hos lege:
O I epikrisen bør det stå at det er avtalt et nytt opphold (sette inn dato for pasienten kommer til det neste oppholdet om 4 uker). Dette fungerer også som henvisning for neste opphold.
O Epikrisen sendes bare til fastlege. Det er viktig at vi foreløpig ikke sender epikrise til Sunnaas pga testpersonene er blindet ved Sunnaas og de skal ikke vite noe om hva pasientene

har gjort i mellomtiden. Det bør står i selve epikrisen som påminnelse til fastlege at epikrise skal ikke gå til Sunnaas pga studiens utforming.

Fysioterapirapport

a. Skrives som vanlig med daglige notater. Fysioterapirapport bør være ferdig 2-3 dager før avreise.

i. Fys.aktuelt

ii. Status presens

iii. Terapi mål

iv. Behandlingsplan

v. Slutt status

vi. Basert på trening på tredemølle/gangtrening over golv, subjektive endringer

Alle pasienter har fått godkjenning for oppstart av trening fra lege på Sunnaas sykehus.

Registration sheet of training session in Study 1				
ATLET - REGISTRERINGSSKJEMA FOR TRENINGSØKTER VED RNNK				
Dato:			PASIENT:	
Team:				
Vektavl (lbs)	Hastighet (mph)	Tid (min)	Lengde (m)	Kommentar
Mest brukt avlastning	Snitthast.	Tot. eff. gåtid	Total Lengde	Mest brukt hastighet

Study 2: BWSLT with robot assistance protocol

PRATISK GJENNOMFØRING AV INTENS GANGTRENING I TREDEMØLLE MED ROBOT ASSISTANSE:

Trening i intervensjonsgruppen skal tilstrebe i alt 60 ganger á 60min i tredemølle. Ved trening kun 3 dager i uken vil intervensjonen vare i 20-24 uker. Tidspunkt for trening vurderes på grunnlag av pasientens fysiske form, generelle timeplan og arbeidssituasjon, individuelt i samråd med pasient, treningsansvarlig fysioterapeut og prosjektkoordinator. Treningen vil gå kontinuerlig. Klinikken tilstreber å trene minst 3 pasienter om dagen slik at alle pasientene har gjennomgått intervensjon i løpet av 2 år.

Det er beregnet at man bruker 1,5 timer til en treningsøkt. Dette vil innebære:
- tøyninger i sittende før/etter trening i TM
- av- og påkledning av vest og ortose
- Selve treningen i TM

1 FØR TRENING:

- Pasienten må ha vært på toalettet eller katetrisert umiddelbart før trening. Spastisiteten øker om man har full blære.
- Pasienten skal bruke tynne treningsbukser og sko som egner seg til gange i tredemølle (joggesko med tynnere såle eller ”pen”sko med hælkappe som man bruker til daglig).
- Man må inspisere pasientens ben for å se etter sår.
- Ordne vann/saft som pasienten kan drikke i pauser. Be pasienten ta med seg vannflaske til trening.
- Treningsdagbok skal være tilstede og føres. Egen perm.
- Man må høre hvordan pasientens dagsform er; hvordan det gikk etter treningsøktene dagen før.
- Pasientens dagsform registreres, avvik fra det normale.

1.1 Tøyninger før/etter trening:

- Tøye begge siders underex i sittende. Det tar ca 5 min å gjennomføre tøyninger. Treningsansvarlig fysioterapeut instruerer og bestemmer tøyningens regime for den aktuelle pasienten. Foreslåtte tøyninger:

- Bakside av lår: Hold en hand overfor kne, hold rolig press nedover. Fysioterapeut tøyer strakt bein så langt pasienten tåler det men unngår hyperekstensjon.
- Legger: Pasienten er sittende i rullestol med ryggen mot en vegg for å ikke tippe over. Fysioterapeuten strekker ut pasientens fot og bøyer i ankelen med strakt kne.
- Innside lår: Pasienten er i stående i tredemøllen, står med hjelp av vektavlastning. Pasienten kan støtte seg i tillegg i gelendrene. Før strakt bein i abduksjon, en fot om gangen.
- Tøyninger gjøres i forbindelse med hver treningsøkt på tredemøllen for å minske spasmetendens og løse opp spenninger.

2. 1 NÅR PASIENTEN KOMMER PÅ TREDEMØLLEN:

- Pasienten skal føle seg trygg hele tiden
- Fysioterapeut skal tilpasse vest i sittende eller liggende. Målingen gjøres i sittende for å tilpasse ortosen. Pas. skal ha på seg sko som han/hun skal bruke under treningen. Mål fra trochanter til condylys dist. femur. (Min 37 cm maks 47 cm). Mål lengde av leggen fra knespalte ned til golvet. Sjekk rett størrelse på mansjettene for lår, legg og ankel i sittende stilling. Deretter justeres robot klar for pasient. Størrelsen på vesten skal være samme hele tiden, hvis det kommer tilpasnings problemer ta kontakt med prosjektkoordinatoren.
- Kjør pasienten til tredemøllen på rampen.
- Fysioterapeut skal feste vesten til avlastningssystemet.
- Fysioterapeut skal hjelpe pasienten fra rullstol til stående stilling ved hjelp av avlastningssystem.
- Bruk så mye avlastning at pasienten har ikke kontakt med underlag. Plassere roboten bakfra. Fest og stram raskt ortosen og stroppene rundt lår, legg, ankel, fotblad og bekken. Pass på at putene for bekkenstøtte støtter mot begge trochanter. Fest sikkerhetslinen. Fysioterapeut skal innstille avlastningsvekten.
- Start gåing med full vektavlastning slik at pasienten har klar utgangstilling og har tatt noen steg i luft før senking av avlastning. Deretter justeres gangparametrene etter pasientens behov.

2.2. TRENING PÅ TM:

- Det er 60 minutter til disposisjon på tredemølle pr. dag.
- Man tilstreber minst 20 min effektiv gangtrening med god kvalitet
- ”Bouts of exercice” kan vare for eksempel 2-3x 10-20 minutter slikt at vi får samlet opp 40-60 min effektiv gangtrening med pauser. Pausetiden kan variere avhengig av hvor sliten pasienten er. Pause er aktiv pause i stående med den minst mulig vektavlastning pasienten må ha for å holde oppreist stilling. Gangtiden og ”bouts of exercise” må justeres etter gangmønster idet normalisert gangmønster skal tilstrebes.
- Under gangtrening tilstrebes normalisert gangstilling.
- Man må prøve seg frem med tanke på hvilken ganghastighet og avlastning som gir minst spasmer og best gangfunksjon. Man skal tilstrebe normal ganghastighet; Lokomat og tredemølle har max hastighet 3 km/h, og tredemølle uten bruk av Lokomat max 5km/h. Jo mer av kroppsvekten pasienten kan belaste og samtidig holde normalt gangmønster under trening, desto bedre. Man skal veksle mellom lav hastig for å trene stabilitet, og høy hastighet for maksimalisere sensorisk/motorisk input. Minst 5 min truncus stabilitetstrening med minst mulig guiding i bekken, hofter og underekstremiteter med lav hastighet i løpet av en treningsøkt.
- Det er ønskelig å bruke mindre enn 50% vektavlastning under gangtrening hvis gangmønster tillater det (pasient svikter ikke i knærne i tredemølle dvs. klarer ikke å holde knærne ekstendert i ståfasen). Det er mulig man i begynnelse må gå litt med høyere vektavlastning for å oppnå god gangkvalitet og aktivitet i uex.
- Fysioterapeuten må hele tiden observere pasientens tilstand.
- Fysioterapeuten skal sjekke på robot for å få tilbakemelding om hvor mye egeninnsats pasienten bidrar med.
- Treningsansvarlig fysioterapeut skal avgjøre forandringer i forhold til avlastning, hastighet, og andre parametre som påvirker gangkvaliteten. Man må ha tilstrekkelig ekstensjon i hofte og knær osv.
- Fysioterapeuten skal stå ved siden av pasienten og gi instruksjoner til pasienten underveis hvis det er nødvendig.
- Fysioterapeut skal styre robot via PC.
- Man må tenke på progresjon hele tiden.
    - Hvordan skal kvaliteten bli bedre?
    - Er det rett hastighet? Er det rett avlastning?
    - Er gangtiden rett?

- Fysioterapeuten skriver ned aktuelle notater etter hver økt. Viktige momenter er: avlastningsvekt, hastighet, gangtid, kvalitativ bedømmelse, pasientens informasjon.
- Ved ståtrening skal man tilstrebe full ekstensjon i hofter og knær, og at hælen kommer ned i underlaget. Avlastningen reduseres til lavest mulig.

Det må *alltid testes ved den første og siste trenings dagen "Lokomat assements tools L-Stifness og L-Force"* og lagre informasjon på Lokomat PC'en.

Hvis pasienten blir dårlig under trening må han/hun hjelpes umiddelbart ned fra TM. Tilkall hjelp hvis det er nødvendig. Ta av robot ortosen. Fysioterapeuten tar av avlastning og plasserer pasienten trygt i sittende i rullestol. Ta av vesten. Ved akutt forverring i pasientens situasjon må husets lege hentes umiddelbart. Aldri la pasient være alene i TM uten sikring av fysioterapeuten. Se flere detaljer under kapittel "Nødsituasjon".

2.3 Gangtrening over gulvet/ ståtrening

Tidligste mulig å igangsette tilsvarende trening over gulv, men med avlastning/støtte i bekken/knær om nødvendig for å få stå/gang funksjon. Det vil si overflytting av ferdighetene som pasient har oppnådd i TM til golv. I denne delen av studien kan det brukes avlastningsenhet i tredemølle for å gjøre dette slik at øvelse blir gjort i tredemølle. Treningsansvarlig fysioterapeut bestemmer treningsformen/øvelsene i samråd med prosjektkoordinator. (Pasientens funksjonsnivå bestestemmer øvelsene.) Foreslåtte øvelser:

- Pasienten står med hjelp av vektavlastning uten Lokomat og minst mulig støtte fra armene. Pasienten holder knærne ekstendert så lenge han/hun kan. 1-5x5-10 ganger
- Knebøy 1-5x10 rep.
- Stå i gangutgangsstilling: tyngdeoverføring fra tyngde på bakerste fot til fremste fot.
- Eventuelt stå på en fot vekselvis hvis pasienten er i stand til det (1-5x10 rep).
- Gangtrening uten Lokomat med minst mulig vektavlastning hvis pasienten har en viss grad av gangfunksjon.

3. ETTER TRENING I TM:

- Etter avsluttet trening skal pasienten hjelpes ned rullestolen.
- Fysioterapeuten løsner ortosen, senker ned avlastning, plasserer pasienten i sittende, tar av vest og ortose, og passer på at pasienten kommer sikkert ut av tredemøllen.

- Tøye som før treningsøkten 5 min, hvis behov.
- Bekrefte tidspunkt for neste treningsøkt.

Hvile –Treningen vil gå kontinuerlig, pausene pga sykdom/ferie må godkjennes av prosjektkoordinator og treningsansvarlig fysioterapeut.

Daglige notater - Det føres daglige notater om pasientens dagsform, avlastning, hastighet, minutter i løpet av en treningsøkt og total varighet av økten i PC som er tilknyttet Lokomat. I tillegg skal man bruke egen skjema/treningsdagbok for avlastning, hastighet, minutter i løpet av en treningsøkt og total varighet av økten.

Se på egen **bruksanvisning LOKOMAT** for bruk og tilpasning av robot/ortose. Ta kontakt til prosjektleder/ Marja Haartsen i Akumed/ konsulent ved Hocoma hvis det er noe som er uklart.

Lengden på hver treningsøkt med gang- og ståtrening i tredemølle er i utgangspunktet 60 minutter, men tilpasses basert på 1) pasientens utholdenhetsnivå 2) evnen til å vedlikeholde normal kinematikk i hofter, knær og ankler, 3) opprettholdelse av normal gangrytme.

Egenaktivitet hjemme: Pasienten skal gjøre de ADL-aktivitetene som han/hun er vant til å gjøre for å klare seg hjemme. I de dagene pasienten ikke har trening ved klinikken kan pasienten ha lett stå- og gangtrening hjemme dersom det er nødvendig for å minske spastisitet, vedlikeholde nåværende funksjonsnivå osv. Eventuelt andre problemstillinger i forhold aktiviteter hjemme avgjøres individuelt i samråd med pasient, treningsansvarlig fysioterapeut og prosjektkoordinator. Pasienten skal ikke drive annen type intens trening så lenge trening i ATLET studien pågår.

Prosedyre detaljert om Lokomat trening

- Slå på tredemøllen, deretter hovedlås. Tast inn personalia på pasient. Dette gjøres bare ved oppstart av treningen.

- Mål lengde på lår og legg. Pasienten sitter. Løft foten litt opp fra gulvet, og eventuelt la foten hvile på foten din. Mål avstand fra trochanter major til leddspalte kne. (Du kan justere denne målingen rett i femur delen i roboten). Registrer mål i dataprogrammet. Mål deretter avstand fra leddspalte kne til gulv. Registrer mål i dataprogrammet.

- **Finn riktig størrelse på 2 mansjetter.** Mansjett 1: Mål 4 fingerbredder superiort for patella, 4 fingerbredder inferiort for patella. Mansjett 2: mål 3 fingerbredder superiort for mediale malleol. Mansejettene bør sitte tett uten at de stopper sirkulasjon.
- **Fest mansjettene til roboten.** Pass på at borrelåsene blir plasser på siden så du får lettere festet pasientens bein. Stram godt. Det kan av og til være nødvendig med ulik størrelse på de to sidene.
- **Finn riktig størrelse på korsett og lyskestropper.** Festes på pasienten i sittende eller ryggliggende på benk. Vær obs på å få korsettet langt nok ned. Lyskestroppene festes på korsettet før det settes på pasienten. Korsettet strammes deretter godt.

Det fins 3 ulike størrelser i lyskestroppene: S, M og L har bare lengde forskjell. Menn: Lyskestroppene festes bakfra og festes på frem side de laveste låsene i vesten. Kvinner: Lyskestroppene festes bakfra og festes på fremside de høyeste låsene i vesten. OBS. Pass. På at urinkateterslange eller hud blir klemt.

Det fins 4 ulike vest størrelser:

XS – Truncus delen er kort og omkrets er kortere enn i vest størrelse S

S – Truncus delen er standart men omkrets er kortere enn i veststørrelse M

M - Truncus delen er standart men omkrets er kortere enn i veststørrelse L

L - Truncus delen er standart men omkrets er størst

- **Pasienten trilles inn på tredemølla og festes til vektavlastningssystemet.** Senk vektavlastningsenheten ned, fest veststroppene i avlastningskrokkene. Sjekk at korsettet sitter godt på.
- **Pasienten heises opp i lufta. Bruk så mye vektavlastning at pasienten har ikke bakkekontakt med beina. Vær presis og rask når du fester stroppene. Snakk fortløpende med pasienten.**
- **Stolen trilles ut og døra til Lokomat lukkes.**
- **Sjekk at hoftene i frontalplanet er symmetrisk (ingen rotasjon frem eller bakover eller tilting kaudalt eller kranialt).**
- **Tilpass høyden på Lokomat til høyden på pasientens hofter.** Hofteputer på Lokomat skal ligge rett over fingeren som palperer trochanter major. Drei på hjulet som fører Lokomat inntil pasientens hofter.
- **Fest bekkenbelte rundt pasienten og fest stroppene fra roboten til vesten som forbinder pasienten til Lokomat. Strammes godt.**

- Sjekk at knehasene er på høyde med omdreiningspunkt for kne på Lokomat. Juster evt. lårlengden dersom dette ikke samsvarer.

- Fest mansjettene til pasienten. Start ovenfra. Legg evt. beskyttelsesputer mellom pasientens bein og mansjett. Juster evt. legglengde til Lokomat slik at mansjetter ligger ca 3 fingerbredder superiort for mediale malleol. For å lette ditt arbeide og tilpasse pasientens bein i Lokomat kan du bøye Lokomats "kneledd" slik at du får bedre arbeidsforhold for tilpasning.

- Sjekk 5 punkt:

1) Omdreiningsakse for hofte på Lokomat ca 1 cm foran pasientens trochanter major.

2) Samsvar mellom den longitudinale aksen til Lokomatens lårbein og pasients femur.

3) Omdreiningsakse for kne på Lokomat skal ligge i bakre tredjedel av pasientens kne.

4) Lokomatens leggakse skal falle rett bak laterale malleol.

5) Ekstensjonsgrad på Lokomat tilstrekkelig med tanke på pasientens ekstensjonsbehov.

Justeringene gjøres ved hjelp av å justere mansjettene i anterior-posterior retning. Full Locomat kneekstensjon = full pasient kneekstensjon!

- Juster skrittbredden ved å justere mansjettene i lateral-medial retning.

- Fest fotstroppene. La ankelen være litt dorsalflektert. Juster etter evt. overpronasjon.

- **SJEKK AT PASIENTEN HAR DET BRA!**

- Forklar hva som skal skje

- Still inn i startposisjon

- La pasienten starte med å gå noen skritt i luften før han langsomt senkes ned på båndet.

- Sjekk pasient co-effisiens! Synkroniser Lokomatens fart (skritt/min) mot møllefart. Dette er viktig element for å få god gangkvalitet. Deretter å justere andre parametrer i forhold til hofte ekstensjon osv. Tilstrekkelig ekstensjon i hofte er ekstrem viktig!

- Justéèr hastighet, avlastning og pasientens grad av egeninnsats etter behov. Vedrørende avlastning: start med minst 50 % av pasientens vekt. La "nåla" bevege seg i det grå feltet på måleren. Bruk evt. ekstra avlastningstau for å redusere bevegelse opp/ned.

Om vektavlastning:

Hvilken funksjon har rad 1 knapper i fjernkontroll og når brukes? Brukes for å justere dynamisk vektavlastning

Hvilken funksjon har rad 2 knapper og når brukes? Brukes for å heise pasient opp/ned og justering av ønsket fluktuasjon (bevegelse) når pasienten går.

"Range of motion indicator":

Stilling 0: Ingen vektavlastning

Stilling /_/_/_/: Full vektavlastning. "Patient scale" display viser pasienten sin vekt i hver tid.

Nålen bør variere mellom 0 og /_/_/_/ symbol når pasienten går. Kan justeres underveis når pasient går uten at man trenger avbryte treningen.

Pasient monitor - Feedback (L-WALK)

Linear Graf – 2 for hofter, 2 for knær. Gul linje markerer sving fase, rød linje markerer stand fase. Hvite linje markerer Lokomats kraft uten at pasienten går.

Smiley – markerer generell utføring av gange over et steg. Jo mer pasienten prøver desto bredere smil.

Thermometer – den blåe fargen indikerer pasients generelle innsats over en viss periode av et visst antall steg.

Nødsituasjon

1. Trykk nødstopp, tilkall/rop hjelp (ev. ring til 113)
2. Heis pasienten opp i lufta og løsne evt ekstra avlastningstau
3. Løsne alle mansjetter (start ovenfra) og fotstropper.
4. Løsne pasienten fra Locomaten. Før Locomaten ut.
5. En person går foran og sikrer føttene til pasienten. En person går bak og passer på at pasienten kommer ned i stolen, evt ned på båndet.
6. Evt stabilt sideleie ++

Testing ved første og siste Lokomat treningsøkt

Pasienten heises opp med full vektavlastning slikt at pasientens føtter er ikke i kontakt med tredemøllebåndet. Fjern fotstroppene (footlifters) før teststart.
Velg ”Assesment tools” fra PC . Pass på at L-Force og L-Stiff boksene er krysset i menyen ”pasient setting screen” slikt at testdata blir lagret på PC’en.

Testing av L-Force:

Tester isometrisk muskelstyrke. 4 muskelgrupper testes: fleksjons- og ekstensjonsmuskulatur i hofte og fleksjons- og ekstensjonsmuskulatur i kne.
Instruer pasienten grundig i hva som kommer til å skje. Du kan demonstrere bevegelsesretning for pasienten først før du starter testingen. Det tas bare en test i hvert ledd og hver bevegelsesretning.

Utgangstilling: Lokomat beveger passivt beina til 30◦ fleksjon i hofte og 45◦ fleksjon i kne.

1. Velg ledd og bevegelsesretning. Start alltid fra hoftene og høyre side.
    i. Start med fleksjon i høyre/venstre hofte.
        1. Be pasienten flytte fokus til testområdet. Instruksjon: Løft høyre/venstre kne opp så godt du kan.
    ii. Test ekstensjon i høyre/venstre hofte.
        1. Be pasienten å flytte fokus til testområdet. Instruksjon: Strekk ut høyre/venstre hofte så godt du kan.
    iii. Test fleksjon i høyre/venstre kne.
        1. Be pasienten å flytte fokus til testområdet. Instruksjon: Bøy høyre/venstre kne slik at hælen berører setet, så godt du kan.
    iv. Test ekstensjon i høyre/venstre kne.
        1. Be pasienten å flytte fokus til testområdet. Instruksjon: Strekk ut høyre/venstre kne så godt du kan.
2. Trykk Start knappen. Det er 3 sek nedtelling før selve testingen, deretter skal pasienten bruke sin maksimale styrke i ønsket område og bevegelsestrening. Under nedtellingen skal pasienten være helt passiv!
3. Trykk ”skip” hvis målingen er mislykket.
4. Trykk ”repeat” for å gjenta målingen i samme ledd.
5. Testtiden er begrenset til 3 min og blir automatisk stoppet hvis den overstiges.

Testing av L-Stiff:

L-Stiff måler spastisitet. Lokomat tester mekanisk motstand (stivhet) hos pasienten under passive bevegelser.
Hvert ledd (hofte og kne)blir passivt beveget i sekvenser med 3 ulike hastigheter og 2 repetisjoner.
Instruer pasienten til å være helt passiv under målingene!

1. Les instruksjonene på dataskjermen
    a. Fjern fotstroppene. Pasienten er heist opp i full vektavlastning og har ingen bakkekontakt med føttene. Kontroll trykk fjernkontroll for terapeut.
    b. Trykk startknappen på skjermen. Ved nødssituasjon trykk "emergency release operator switch" eller nødssituasjon knappen.
    c. Etter målinger, sjekk ut resultatene i "Evaluation" panel.

2. Trykk Startknappen
    a. Lokomat begynner å bevege knær fra ekstensjon til fleksjon. Disse bevegelsene gjentas 2 ganger for hver fot i 3 ulike hastigheter (30, 60 og 120 gr/s). Samme bevegelsene gjentas for hofter. Det vil ta ca 2,5 min å gjennomføre målingene. Progresjon av målingen vises på skjermen.

Alle pasienter har fått godkjenning for oppstart av trening fra lege på Sunnaas sykehus.

Registration sheet of training sessions in Study 2 addition to training log from the Lokomat device

ATLET - Registreringsskjema for treningsøkter ved FVK

Dato: PAS. NAVN: Behandler:

Dag	Dato	Vektav (kg) (min-max)	Hastighet (km/h) (min-max)	Anvendtid (min)	Lengde (m)	Mest brukt hastighet (km/h)	Mest brukt avlastning (Kg)	Total effektive gangtid (min)	Bouts of exercise	Brukt Guid. Force Hø.	Ve.	Vektavlast Dyn.	Stat.	Kommentarer

Control group - Training diary registration sheet / Trenings dagbok

Trenings dagbok for _____

Dato	**Trenings økt antall**	**Aktivitet**	**Varighet (min)**	**Intensitetsnivå 1= lett 2=Moderat 3=hard**	**Kommentarer**