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Indego Exoskeleton in Gait Rehabilitation

User experiences and effects on functioning

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Abstract
In recent years, technology in gait rehabilitation has developed and the use of wearable powered lower limb exoskeletons has increased. Exoskeletons have demonstrated positive clinical outcomes in rehabilitation and have been proven to be safe for individuals with spinal cord injury (SCI) and stroke.

This research was divided into two studies. The objective of the first study was to investigate physiotherapists' user experiences. In second study the objectives were to describe how rehabilitees learn to use the device and study what effects can be gained through exoskeleton assisted walking training, and to study the rehabilitees' user experiences.

In the first study, the survey of physiotherapists' user experiences was utilized to determine usability and feasibility of exoskeleton use within the clinical environment. Physiotherapists in Finnish rehabilitation centers already using the exoskeleton answered a web-survey (August 2019). Responses of the six physiotherapists were then analysed by triangulation from qualitative and quantitative questions.

The second study involved a pre-experimental, one group, pre-test post-test study with five participants. Participants were neurological rehabilitees suffering from hemiparesis due to stroke or traumatic brain injury (TBI) from the Satakunta region. They participated in an eight-week exoskeleton training intervention, involving 60-minute training sessions twice a week in Autumn 2019.

Rehabilitees learnt to walk using the device with the assistance of 2-3 therapists within two sessions and progressed individually. Overall three rehabilitees experienced positive gains in their 10m walk test (10MWT), and four rehabilitees improved their 6min walk test (6MWT) results. The rehabilitees felt that the device was comfortable and safe to use and exercise with.

Based on the findings, Indego exoskeleton may be beneficial to gait rehabilitation with chronic neurological rehabilitees. Both, physiotherapists and rehabilitees were satisfied with Indego as a rehabilitation device.

Key words: exoskeleton device, gait training, neurological rehabilitation, user experience, stroke, traumatic brain injury

CONTENTS

1 DEVELOPMENT OF GAIT REHABILITATION

Gait rehabilitation is one important part of rehabilitation with neurological rehabilitees. Three diagnoses, which causes a large number of disabilities among the population, are stroke, spinal cord injury (SCI) and traumatic brain injury (TBI). These conditions result in damage to the central nervous system, brain and / or spinal cord. Clinical signs include sensorimotor paraparesis or paraplegia, hemiparesis or hemiplegia and problems in motor function and walking. (Paddison & Hexter 2018, 171-173, 191-193; Veerbeek &Verheyden 2018, 131-132, 142-143; Williams 2018, 153-154, 162-164.)

For stroke patients the specificity, intensity including repetition, and application of motor learning principles are required for effective motor rehabilitation training. The individually tailored exercises should be task specific. (Veerbeek & Verheyden 2018, 140.) In the acute or subacute phases with SCI patients, the focus can involve maximizing functions. In the chronic phase, compensatory or assistive approaches are more reasonable (Fehlings et al. 2017, 87S). For gait training there are several evidence-based methods. For individuals with stroke (Veerbeek & Verheyden 2018, 142) and SCI (Fehling et al. 2017, 92S), over-ground walking training and body weight supported treadmill training (BWSTT) are well known and studied.

Costs of treatments and rehabilitation in neurological disorders, especially brain disorders are high. Up to date information is not easily found and estimations between countries differ considerably. In Finland in 2003, the expectant lifelong costs for stroke patients per person were 86 000e (Cerebral infarction and TIA: Current Care Guidelines, 2020). The annual health care cost per person, in 2010 in Europe, were 21 000e for stroke (incident) and 8 366e for TBI (incident) (Olesen et al. 2012, 158-159). Costs for SCI varies considerably due to the level of injury, surgeries in acute phase and

complications. It's stated that individuals with SCI who have the access to rehabilitation as soon as possible gain better outcomes and possess a greater chance to return to their roles in society. (Merritt, Taylor, Yelton & Ray 2019.)

Based on the requirement for task-specific rehabilitation and effective treatments, advanced technology has been developed to assist gait training. Wearable exoskeletons are provided for treadmill-based training and over-ground training. Portable wearable powered lower-limb orthosis allows an individual to walk over-ground, but an assistive device like crutches or a walker is needed. (Chen, Chan, Guo & Yu 2013, 344-345, 349-351.)

Picture 1. Indego exoskeleton (Parker Hannifin corp 2020).

In spring 2020 in Finland, there are currently five Indego wearable robotic lower limb exoskeletons (Picture 1). The first one was purchased in 2017 by Folkhälsan Välfärd ab / Rehab Korsholm (later rehabilitation center in Mustasaari). Also, Laitilan terveyskoti and Validia Kuntoutus in Helsinki (later Validia) have Indego for rehabilitation purposes. Satakunta university of Applied Sciences (SAMK) acquired the device for research purposes in 2018. One device is in personal use. (Folkhälsan 2018; Fysioline; Validia Oy; Iiskala, personal communication on 21.11.2018.)

Quintero et al. (2011) wrote that they had developed a powered lower limb orthosis in order to provide legged mobility for individuals with paraplegia. After these preliminary results in 2011, Indego has been studied and stated to be safe and usable, when used by individuals with SCI, level of injury T4-L2. Individuals with complete or in-

complete SCI have shown progress in independent use of the device and walking ability. (Hartigan et al. 2015, 99; Tefertiller et al. 2018, 84.) There are currently no Indego studies about progress in walking ability without the device. Also, until now Indego studies have not used control groups or randomised controlled trials (RCT).

The Indego exoskeleton is recommended for individuals with lower-limb weakness or paralysis due to neurological diagnosis, to enable them to perform ambulatory function in rehabilitation or personal use with the assistance of specially trained companion (Parker Hannifin Corporation 2016, 7). Until now, larger studies with rehabilitees not having SCI have not been published. One single-person single-session preliminary study, focusing on technical development, indicated that the device could have promise for assisting stroke recovery in walking (Murray, Ha & Goldfarb 2014). Training with other exoskeleton has shown positive results in walking ability with stroke rehabilitees (Calabrò et al. 2018; Guanziroli et al. 2019; Molteni et al. 2017).

Advanced technology for gait rehabilitation is said to be beneficial for physiotherapists by reducing the physical loading on the physiotherapists whilst providing intensive and reproducible training for rehabilitees (Mikolajczyk et al. 2018). The amount of assistance by therapists have been studied with other exoskeletons (Gagnon et al. 2018; Platz, Gillner, Borgwaldt, Kroll & Roscka 2016), but beside the assistance, physiotherapists' user experience has not been documented before the implementation of this study.

The purpose of this study is to provide more information about usability and feasibility of the Indego exoskeleton and effects of exoskeleton training used by individuals with different neurological diagnoses. Another purpose is to study the user experiences of both physiotherapists and rehabilitees. The methods for data collection and chosen tests for outcomes are selected based on earlier studies with SCI participants and those considered suitable for stroke or TBI rehabilitees.

2 GAIT IN NEUROLOGICAL REHABILITATION

The World Health Organization has defined neurological rehabilitation as a process that assists individuals with disability to achieve and maintain optimal function and health, in interaction with their own environment. It is a complex process requiring knowledge, skills, education and advice to support patients and their families. Rehabilitation should be evidence-based and individually tailored for each patient or rehabilitee with chronic, long-term conditions. (Lennon & Bassile 2018, 3-5.)

Within comprehensive, evidence-based rehabilitation the importance of up-right position, weight-bearing and walking have been mentioned in rehabilitation recommendations for stroke (Veerbeek & Verheyden 2018, 141-143), SCI (Paddison & Hexter 2018, 190-193) and TBI (Williams 2018, 163-164). Though robotic assisted gait rehabilitation implemented with exoskeletons is used with individuals with SCI, it is not defined deeply in this paper, because any individual with SCI was not selected in this study.

With reference to evidence-based recommendations, current knowledge and understanding of functional ability, Lennon & Bassile (2018) proposes 10 key principles in the conceptual framework to guide clinicians working in neurological rehabilitation. The International Classification of Functioning, Disability and Health (ICF) should be the framework used in every phase of rehabilitation – in clinical reasoning, goal setting, selecting appropriate interventions and outcome tools. Teamwork (including multidisciplinary teams, the patient and the family) and person-centred care is also important in every phase of rehabilitation. Reasonable prediction of outcomes leads to clearer client expectations and better choices when selecting rehabilitation methods. In respect to neural plasticity, therapists work intensively with motor control, functional movement re-education and skill acquisition. The cornerstones in patient's well-being are self-management and health promotion. (Lennon & Bassile 2018, 5-16.)

In the next chapters, gait rehabilitation in neurological rehabilitation is presented. One should still not forget, neurological rehabilitation should aim to be comprehensive,

including observation, assessment and measurement, to take the wider picture of functional ability into consideration. While studying the usability of the Indego in gait rehabilitation, the gait training is in the focus of the theory base in this paper.

2.1 Neurological diseases and gait rehabilitation

The upright position is important for neurological rehabilitees. Standing has positive effects on soft tissue, bladder and bowel function, quality of life and bone health. Frequent standing can reduce abnormal muscle tone, increase range of motion and reduce bone demineralisation. Also, improvements in cardiovascular function, respiratory function and skin condition have been observed. (Spinal Cord Injury Centre Physiotherapy Lead Clinicians 2013, 8-13.)

Before standing training begins, the rehabilitee must be thoroughly assessed to avoid potential injury. For example, low bone density can cause fractures, low blood pressure can cause orthostatic collapse, headache, dizziness and fatigue. The standing position must be proper in order not to achieve low back pain, muscle spasm, spasticity, pressure wounds or autonomic dysreflexia. (Spinal Cord Injury Centre Physiotherapy Lead Clinicians 2013, 8-13.)

The goals for gait rehabilitation can differ between rehabilitees based on the injury, neurological symptoms and level of recovery. Generally, after stroke or TBI a rehabilitee must first gain the ability to stand before gait training can be implemented (if a person's individual goals and resources allow that). In the acute and subacute phases, the rehabilitation is more intensive. Here regaining walking ability is often a primary goal, whereas in the chronic phase the primary goal may be more directed towards finding a suitable assistive device. (Veerbeek & Verheyden 2018, 141-142; Williams 2018, 161, 163-164.)

2.1.1 Stroke

In Finland, 24 000 individuals suffer from stroke each year, of which 25% are working aged people (Atula & Vaalamo 2019). It is predicted that in 2030 there would be

12 100 – 20 100 new cases a year, depending on ageing of the people and how the decrease of incidence will continue (Sivenius et. al. 2010). About 50% of stroke survivors remain with permanent disability. Stroke is the third most expensive national disease in Finland. (Kaste et al. 2015.)

The most typical physical stroke related impairment is hemiparesis, which usually is more severe in upper limb than lower limb. That causes difficulties or prohibits walking among other symptoms. Aphasia or neglecting the spatial space or own body can influence negatively in the possibilities of rehabilitation. (Kaste et al. 2015.) For more information of causes, changes in brains and consequences see for example the websites of stroke associations (American stroke association, Aivoliitto). Impairments of functioning can be assessed and observed within every component of ICF; body structures and functions, activities, participation, and are related to personal and environmental factors.

Early mobilisation within the first 24 hours is recommended in the acute phase. The rehabilitation phase starts in a subacute phase when the patient is medically stable. (Veerbeek & Verheyden 2018, 136-137.) In the subacute phase, spontaneous recovery can be rapid. The acute and subacute phases, before chronic phase, can last for 3-6 months. (Cerebral infarction and TIA: Current Care Guidelines, 2020.)

For improving functional ambulation after stroke, rehabilitation is recommended to be activity and task-specific, and progressive with sufficient intensity, frequency and duration related to appropriate timing. (Winstein et al. 2016, e127-e129.) With specific walking training in acute, subacute and chronic phases of recovery it is possible to improve walking speed and to some extent walking independence. (Peurala, Karttunen, Sjögren, Paltamaa & Heinonen 2014, 391, 396.)

The most well-studied training interventions are over-ground walking, treadmill training (with or without body weight support) and robot-assisted gait training. Referred evidence for stroke and robot-assisted gait training is based on articles of Lokomat training. (Veerbeek & Verheyden 2018, 142-143.) Mehrholz et al. (2017) stated in their review that with stroke patients the electromechanical-assisted therapy combined with conventional physiotherapy increases more the possibility to achieve independent

walking, than gait training without a device (Mehrholz et al. 2017, 23). Lo, Stephenson & Lockwood (2017) found in their review that robotic training of the lower limb in stroke patients was just as effective as conventional therapy. For patients with severe impairment in walking it produces better outcomes than conventional physiotherapy (Lo, Stephenson & Lockwood 2017, 3072). The devices in the above mentioned reviews were mainly Lokomats.

2.1.2 Traumatic brain injury

Traumatic brain injury (TBI) relates to the damage of brain tissue as the result of an accident or traumatic event, involving high energy impact against the head or brain. Most of the symptoms in TBI are cognitive or neuropsychological, but different physical symptoms are also often observed. These can be paralysis, abnormal tone, difficulties in balance, headache, dysfunctions in speech etc. (Aivovammaliitto 2016, Williams 2018, 154, 158-161.)

In Europe the incidence of TBI requiring hospital care is approximately 200-300 / 100 000. The highest incidence is shown in adolescents and younger adults aged from 15 to 45. (Williams 2018, 154.) Another source states that two out of three are male and the highest risk for TBI is between 30-39 years (Palomäki, Niskakangas, Öhman & Koskinen 2015).

Rehabilitation of an individual with TBI follows the principles of stroke rehabilitation (Palomäki, Niskakangas, Öhman, & Koskinen 2015). Rehabilitation is typically implemented in multidisciplinary teams, in which physiotherapy is also involved. The targets of physiotherapy are to increase the individual's functioning and mobility and to improve balance and poise. (Vartiainen 2012, Williams 2018, 162-163.)

Task practice, key aspects of motor learning and skill acquisition are important factors in rehabilitation when improving performance with TBI rehabilitees suffering from disorders of movement. According to task practicing, if a rehabilitee is having difficulties in walking decreasing functioning or independence, rehabilitation should include gait training. (Williams 2018, 162-164.)

Guidelines for emergency and acute TBI management are found, but evidence-based guidelines for rehabilitation in later phases have not been published. With severe cases, cognitive, behavioural and emotional impairments can have a negative impact on physical intervention and independent practicing. Nevertheless, practice and repetition are essential for improved performance. (Williams 2018, 164-165.)

2.2 Development of robotic-assisted gait rehabilitation

The technology for gait rehabilitation and the use of robotic assistive devices have developed in recent decades. These devices are designed to increase the intensity of therapies, produce multisensory stimulation and reduce costs during rehabilitation. (Mikolajczyk et al. 2018, 3; Poli, Morone, Rosati & Masiero 2013.)

Robotic-assisted gait training (RAGT) was developed to provide body weight support thus reducing physical loading on physiotherapists. Earlier body weight-supported treadmill training (BWSTT) allowed patients to start early gait rehabilitation and to repeat stepping sequences with high intensity, however was loading for physiotherapists. The RAGT-systems like Lokomat (Hocoma, Zyrich, Switzerland) allows natural and symmetric walking patterns in training while the intensity and duration of the training session will increase. (Mikolajczyk et al. 2018, 3.)

Powered lower extremity exoskeletons have been developed to gain robotic assistance during over-ground training (Chen, Chan, Guo &Yu 2013, 348). These devices can also be used as an assistive walking device. All powered exoskeletons require the use of an additional gait aid, e.g. walker or crutches. (Louie, Eng & Lam 2015, 4-5; Palermo, Maher, Baunsgaard & Nash 2017, 238, 240.)

With robotic systems the goal is to exploit the expertise and time of physiotherapists in order to improve the efficacy and efficiency of the rehabilitation program. These assistive robots are not designed to replace the human work force or interaction between a patient and therapist, but function as adjunctive tools. Without a robotic device, therapists have to use a lot of effort to set the paretic limbs or assist with trunk

movement. With these devices the effort can be reduced. (Masiero et al. 2014, 188, 195.)

Gait training with a wearable powered exoskeleton has been shown to elicit trunk muscle activation more than training with Lokomat, when studied in individuals with chronic motor-complete paraplegia (injury level from C7 to T4). Also, able-bodied subjects gained higher trunk muscle activation, when walking with an exoskeleton. (Alamro, Chisholm, Williams, Carpenter & Lam 2018.)

Goffredo & Iacovelli et al. (2019) compared end-effector, over-ground exoskeleton and conventional gait training with subacute stroke patients. They found the results in specific locomotor tasks (measured with tests of walking velocity, capacity and balance) to be clinically significant in the robotic groups only. The small population (8+8+10 in the groups) was not randomized but results are encouraging.

3 WEARABLE POWERED LOWER LIMB EXOSKELETONS

Recent systematic reviews have shown benefits of robot-assisted gait training with Locomat devices compared to other therapy methods with individuals with stroke (Lo, Stephenson & Lockwood 2017, 3072; Mehrholz et al. 2017, 23). The lack of randomized controlled trials with exoskeletons causes the absence of reviewed compared evidence with benefits of gait rehabilitation with powered lower limb exoskeletons (Mehrholz et al. 2017, 22-23; Louie, Eng & Lam 2015, 9). The latest systematic review of non-randomized, non-comparative observational studies of robotic locomotor training includes exoskeletons. The review states that robotic training provides the ability to walk safely, improve walking ability, improve health outcomes and increase psychological well-being for individuals with SCI. (Shackleton, Evans, Shamley, West & Albertus 2019, 732.)

Miller, Zimmermann & Herbert (2016) write in their systematic review, that powered wearable exoskeletons have been shown to allow individuals with SCI to safely ambulate in real-world settings and to yield health benefits. Also, Louie, Eng & Lam (2015) concluded in their review that these devices can provide individuals with thoracic level complete SCI the ability to ambulate at modest speeds. Some studies have suggested that a wearable exoskeleton (Ekso Bionics) is also beneficial for stroke patients' rehabilitation (Calabrò et al. 2018; Goffredo & Guanziroli et al. 2019; Molteni et al. 2017).

Randomized controlled trials are required for SCI (Baunsgaard et al. 2017) and stroke (Molteni et al. 2017, 682), to verify preliminary results and compare robotic over-ground training with other types of gait training. The most well-known commercially available over-ground exoskeletons are ReWalk (Argo Medical Technologies Ltd.), Ekso (Ekso Bionics) and Indego (Parker Hannifin Corp.) (Chen, Chan, Guo & Yu 2013, 349-350).

In an integrating literature review, 25 studies conducted with these three wearable exoskeletons were found. Studies concerning only engineering and development of the device were excluded. A table was compiled of the studies (Appendix 1) and outcomes and results are discussed in the next chapters in more detail.

3.1 Learning to use a wearable exoskeleton

The length of intervention periods in earlier studies varies a lot (Appendix 1). With SCI rehabilitees the amount of sessions ranges from 18 to 26 total, 3 – 5 times per week (Baunsgaard et al. 2017; Gagnon et al. 2018; Juszczak, Gallo & Bushnik 2018; Tefertiller et al. 2018). In over-ground robotic assisted studies with stroke rehabilitees, sessions vary from 12 to 40 total, 3 – 5 times per week (Calabrò et al. 2018; Goffredo & Guanziroli et al. 2019; Molteni et al. 2017). Based on a systematic review, Peurala et al. (2014) suggested that walking training with stroke rehabilitees should happen 3 – 5 times a week and last from 20 to 60 minutes in order to be effective.

After five powered exoskeleton training sessions SCI rehabilitees are typically able to walk over 10 meters using forearm crutches, rolling walker or platform rolling walker. They typically also require minimal or moderate assistance or only supervision of the physiotherapist. Some can also walk outside, over ramps or grass. (Hartigan et al. 2015, 97-98; Platz, Gillner, Borgwaldt, Kroll & Roschka 2016, 6.)

Stroke rehabilitees have shown progress in walking ability within 12-15 sessions of exoskeleton assisted walking training (Goffredo & Guanziroli et al. 2019; Goffredo & Iacovelli et al. 2019; Molteni et al. 2017). Studies with stroke patients have been focusing on clinical outcomes in walking and have not presented that much information on the learning process of walking with the device (Appendix 1).

The level of assistance provided by the therapist in exoskeleton assisted walking is reported in some studies with SCI (Appendix 1). It is mainly measured using a rating scale adapted from the FIM instrument (Functional Independence Measure), where "moderate assistance" refers to participant performing 50-74% of a task, and "minimal assistance" to 75% or more of a task. When a participant is able to perform 100% of a task, the assistance is named "supervision" or "contact guard". If the participant can perform under 50% of a task, the assistance is maximal (25-49%) or total (less than 25%). (Hartigan et al. 2015, 96; Kozlowski, Bryce & Dijkers 2015, 113; Yang et al. 2015, 103.)

Some individuals with complete or incomplete SCI are able to walk with exoskeletons requiring only "supervision" while others need "minimal" to "moderate" hands-on assistance (Louie, Eng & Tam 2015). Hartigan et al. (2015) and Kozlowski et al. (2015) report mainly minimal assistance or supervision / contact guard and some moderate assistance. In addition to minimal, moderate and supervision assist Yang et al. (2015) used the term "modified independence" with almost half of their participants, meaning that he / she did not need any physical assistance. In studies with strokes the level of assistance was not measured (Appendix 1).

3.2 Effects of exoskeleton assisted walking on mobility and functional ability

The outcomes in exoskeleton assisted walking training are usually related to activities and participation with respect to the ICF domains. For example, these include test results for walking velocity, capacity and balance. Inclusion criteria are mainly based on body structures and functions. Some improvements in body functions are reported after exoskeleton training. Individuals with SCI have reported improvements in bowel function, sitting balance, sleeping, and reductions in pain and spasticity after training periods (Kozlowski, Bryce & Dijkers 2015, 116).

Walking velocity and capacity, consisting of speed and distance can be measured using the 10 meter walk test (10MWT) and 6 minute walk test (6MWT). Individuals with SCI have increased results in 10MWT and 6MWT during Indego exoskeleton training periods. Results have shown that patients with lower spinal cord injury gain better outcomes than patients with upper spinal cord injury. (Hartigan 2015, 97-98; Tefertiller 2018, 82-83.)

With subacute stroke patients, clinically significant improvements in clinical outcomes (10MWT, 6MWT and Timed Up and Go) have been found with exoskeleton and end –effector training (Goffredo & Iacovelli, 2019). Goffredo & Guanziroli et al. (2019) found also the over-ground training with exoskeleton to improve clinical and gait outcomes (10MWT, 6MWT) with subacute stroke patients. Chronic stroke patients demonstrated improvement following exoskeleton training, measured with Functional Ambulation Classification (FAC), 10MWT and 6MWT (Molteni et al. 2017, 682). The Calabrò et al. (2018) RCT showed at least minimally clinically important improvement in the 10MWT for chronic phase stroke patients (n=20).

The Indego exoskeleton provides individuals with SCI the ability to ambulate both indoor and outdoor. Some individuals are also capable of donning and doffing the device independently. Walking with exoskeleton is possible in appropriate speed for coping outside of the clinic or in household. (Hartigan et al. 2015, 99; Tefertiller et al. 2018, 84.)

In SCI, spasticity has been shown to decrease significantly during a training period. Positive changes in pain, bowel and bladder function have also been reported. The perceived exertion while walking with an exoskeleton is shown to decrease significantly during the training period. It is typically between light and somewhat hard in the beginning and less than light in the end. (Juszczak, Gallo & Bushnik 2018, 338-340.)

Earlier studies do not discuss functional ability with wearable powered exoskeletons. The Modified Barthel Index (BI) was used within the in-patient setting in a study with subacute stroke patients (Goffredo & Guanziroli 2019). It assesses independence with activities of daily living (ADL) and is recommended in rehabilitation units or inpatient rehabilitation (Shirley Ryan Ability Lab 2020).

Environmental factors have to be taken into consideration when training with exoskeletons. The Indego device is not intended to be used in too cold or warm temperatures and is only used on flat surfaces or ramps with a grade equal to or less than 5° (Parker Hannifin Corporation 2016). Using the device individuals with SCI should be able to perform various tasks in the home environment, in an upright position. In addition, walking speeds have shown to be close to household ambulation speeds. (Tefertiller et al. 2018, 84.) Light perceived exertion in assessments is also used to predict the possible use of the device as an assistive device in different environments (Juszczak, Gallo & Bushnik 2018, 341).

3.3 User satisfaction with wearable exoskeletons

Unlike many other technologies, robotic assisted rehabilitation involves two users; a rehabilitee and a clinician. The perspective of SCI rehabilitees has been studied in a few researches with ReWalk and Ekso, also, with few SCI, MS and TBI rehabilitees with Rex and Ekso (Benson, Hart, Tussler & Middendorp 2015; Platz, Gillner, Borgwaldt, Kroll & Roschka 2016; Zeilig et al. 2012; Sale et al. 2018; Poritz, Taylor, Francisco & Chang 2019).

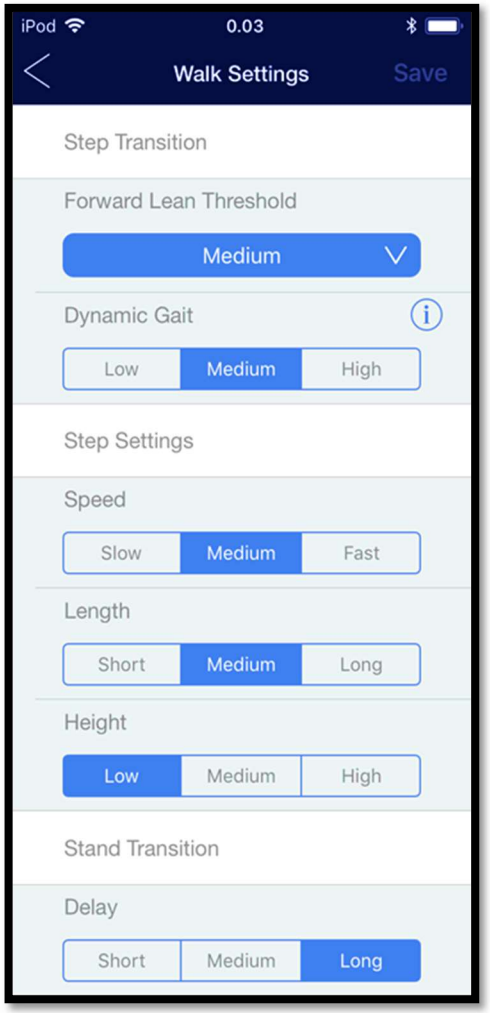
Shackleton et al. (2019) found in their review several ways to measure participant satisfaction. Their conclusion was though that users felt safe and comfortable using the devices and had tendencies towards strong positive statements regarding acceptability and emotional or health benefits of training processes. In addition, in studies of Zeilig et al. (2012), Platz et al. (2016) and Sale et al. (2018) participants stated that the device did not cause considerable pain and they did not have breathing difficulties while training.

The physiotherapists' perspective of over-ground exoskeleton training with Ekso was first published in January 2020 (Read, Woosley, McGibbon & O'Connell 2020), in the middle of the writing process of this study. The physiotherapists' user experiences implementing robotic therapy with an upper limb robotic device have also been studied (Stephenson & Stephens 2018). Both qualitative studies showed positive attitude towards robotic therapy and robotics were considered as adjunctive tools. Requirements for management and clear protocols or guidelines were emphasized. (Stephenson & Stephens 2018; Read, Woosley, McGibbon & O'Connell 2020.) Therapists using the exoskeleton mentioned many benefits for patients and found the using as a privilege. Researchers concluded that working as an exoskeleton expert and physiotherapist requires a high and sustained level of cognitive workload. (Read, Woosley, McGibbon & O'Connell 2020.)

3.4 Indego exoskeleton

The device used in this study is the Indego exoskeleton. It consists of hip part, two upper leg parts and two lower leg parts (Picture 2). The hip part contains the battery and electronics. Powered joints are in knees and hips of the upper legs and integrated ankle foot orthosis are in lower legs. The handheld controller is an Apple iOS device with Indego App, by which the device is enabled, and settings changed, it also shows sessions data (Picture 3). (Parker Hannifin Corporation 2016, 15-16.)

Picture 2. Parts of Indego (Parker Hannifin Corp 2020)



Picture 3. Indego App in iPod (Parker Hannifin Corp 2016)

The Indego exoskeleton has been studied in individuals with SCI (complete or incomplete) but recent studies on individuals with stroke or TBI do not exist (Appendix 1). According to the Finnish Health Technology Assessment (Digi-HTA), Indego exoskeleton can be suitable for use as an adjunctive tool in rehabilitation for individuals with SCI and stroke. It might also have benefits by upright position as reduction of pain and spasticity, changes in functions of bowel and bladder and mental wellbeing. (Fincchta 2020.)

Based on the user manual of Indego exoskeleton, the device is intended to enable individuals with lower limb weakness or paralysis to perform ambulatory functions in a clinical or personal use setting, with the assistance of a specially trained companion. It enables sitting, walking and standing, as well as transitions from sit-to-stand, stand-to-walk, walk-to-stand and stand-to-sit. This device is not intended for sports or stair climbing. (Parker Hannifin Corporation 2016, 7.)

Indego has two software suites, Indego Motion+ (M+) and Indego Therapy+ (T+). With M+ the trajectory-based approach, the patient's role is predominantly passive, with the therapist able to adjust all parameters to support. In T+ the patient's role is more active, initiating movements to control the speed, stride length and step height as much as possible. T+ is intended especially for stroke patients. (Parker Hannifin Corporation 2020.)

The specially trained companion assisting the exoskeleton training must be educated by the instructors of Parker Hannifin Corporation. Indego Specialists, trained by an Indego Trainer or an Indego Instructor, may assess and evaluate patients, fit the device and provide interventions in a clinical setting. Indego Trainers may train other clinical personnel and are trained by an Indego Instructor. Indego Instructors have extensive experience with Indego and are certified to conduct all aspects of the courses for other users. (Parker Hannifin Corporation 2016, 8.)

4 PURPOSE AND AIMS OF THE RESEARCH

Based on the fact that the number of individuals with stroke or SCI will increase and the effectiveness of rehabilitation must progress in the future, technology should be harnessed better to support gait rehabilitation. There are considerably few studies involving exoskeletons and the use of advanced technology in Finland is still moderately limited. While rehabilitees' time and sessions for rehabilitation are limited, it is essential to find out how fast and how much they can learn and how do they consider the usability of the device. The usability and findings associated with using the Indego exoskeleton need to be researched, and the perspective of the physiotherapists needs to be monitored and reported.

The purpose of this research was to study the usability and feasibility of Indego exoskeleton, when used by rehabilitees and physiotherapists in rehabilitation. The purpose was also to investigate the effects of Indego training on walking ability and functional ability.

The research was divided into two parts. The aim of study 1 was to find out how the therapists, who have worked with individuals using the device, consider the usability and feasibility of the Indego exoskeleton. In addition, the benefits or disadvantages for the rehabilitee or therapist were identified. The aim of study 2 was to identify how rehabilitees learn to use the device and training effects their walking velocity, capacity and self-assessed functional ability. In study 2 the aim was also to investigate user experience and how the users consider the usability and feasibility of Indego exoskeleton.

Based on the aims, the following research questions were set:

Study 1: Physiotherapists' user experiences

a. How do physiotherapists consider the usability of Indego exoskeleton in gait rehabilitation?

Study 2: Rehabilitees' user experiences and effects of Indego training

a. How does learning to walk with Indego happen?

b. What effects can be gained during a 6-8 weeks training intervention, with outcomes measured using the 10MWT, 6MWT and questionnaire for functional ability?
c. How do rehabilitees experience the robot-assisted gait rehabilitation with Indego exoskeleton?

5 RESEARCH METHODS

According to the aims, the methods are defined for each study. Methods for study 1, Physiotherapists' user experiences are described in chapter 5.1 and methods for study 2, Rehabilitees' user experiences and effects of Indego training are presented in chapter 5.2. Ethical issues related to both studies are discussed in chapter 5.3.

5.1 Physiotherapists' user experiences

The survey study of physiotherapists' user experiences was a non-experimental research with prospective gathering of self-reported data (Domholdt 2005, 226). As a user experience study the survey method uses both attitudinal and behavioural dimensions, asking how they find the use of the device and also seeking answers to use and benefits. While utilizing both kinds of data from users, this survey is a usability study. (Rohrer 2014.)

The study includes a questionnaire with qualitative and quantitative questions, which enables methodological triangulation. Results from open-ended questions are used to broaden and explain the answers to closed questions. (Kankkunen & Vehviläinen-Julkunen 2017, 68-76.) Using a mixed method perspective, helps to expand the depth of information and maximize the quality of the answers (Andres 2012, 69).

The questions in a survey should be based on a theoretical framework, when phenomenon is operationalized into a measurable form (Vilkka 2015). Physiotherapist's per-

spective using exoskeletons has not previously been studied and a theoretical framework for using exoskeletons lies on technological development and effectiveness on rehabilitee. In that sense it is important to gather data of practical working and user experience.

5.1.1 Settings

The research was implemented in two rehabilitation centers in Finland, where Indego devices have been used for over six months, before implementation of this study. In the rehabilitation center of Folkhälsan in Mustasaari, the clients are outpatient rehabilitees who are suffering from neurological symptoms or diseases (Folkhälsan 2018). Laitilan terveyskoti in Laitila is a rehabilitation center for the elderly and people with neurological symptoms or diseases. Clients with neurological symptoms or diseases are either outpatients or inpatients having rehabilitation periods of couple of weeks. (Laitilan Terveyskoti 2014, Iiskala 2018.)

5.1.2 Study population

In Mustasaari there are 11 physiotherapists working with neurological clients, with four educated in using Indego (Folkhälsan 2018, Pihlaja-Kuhna email 4.4.2019). In Laitila there are six physiotherapists and they all are educated in using Indego (Iiskala 2018). The physiotherapists in these centers have the longest experience of working with Indego in Finland.

5.1.3 Data collection

The experiences of therapists were collected by a short questionnaire, via web (Appendix 2). The questions were formulated by the author, because there are no earlier questionnaires used for asking therapists' experiences in using rehabilitation devices. The author has studied user experience surveys, searching for sources of inspiration, and modified questions into a form suitable for this study (Andres 2012, 65-66). Some questions were formulated based on a questionnaire for service providers in a usability

study for the ICanFunction mobile solution (mICF), of the Finnish National Institute for Health and Welfare (Anttila, Kokko, Hiekkala, Weckström & Paltamaa 2017, liitteet). The questionnaire was piloted with the Indego Specialists in SAMK, who already had experience using the device. Corrections were made based on the pilot feedback.

The questionnaire was divided into four sections: 1) the beginning of using Indego, 2) sessions with rehabilitees, 3) experiences of rehabilitation with Indego, and 4) changes to physiotherapists' work. In the first section the questions were related to learning to use the device. The second section sought answers to practical work, therapy sessions, and periods and diagnoses of treated rehabilitees. The third section on experiences provided more detailed information identifying what is easy or difficult and whether the training had positive or negative influences on rehabilitees' functioning. The last section pointed out changes in professional work and whether the therapists were satisfied with the exoskeleton. (Appendix 2.)

The functioning of rehabilitees in the third section was divided into different functions or activities based on the ICF. Body functions were related to pain, heart and breathing function, bowel and bladder function (defecation and urination), joints and muscles. Activities were related to speaking, moving, washing, toileting and dressing. (Appendix 2.)

The questionnaire-link was delivered via email to physiotherapists in charge in rehabilitation center in Mustasaari and Laitilan terveyskoti on August the 8th, 2019. They delivered the links to other physiotherapists. The answering time was until August the 25th. Due to some technical problems with the form and answering, the answering time was extended until September the 1st.

5.1.4 Data analysis

Closed questions were analyzed with excel. Because of the small sample size, mainly non-parametric methods were used. These can be, for example, distribution-free methods and cross-tabulation (Kankkunen & Vehviläinen-Julkunen 2017, 143). Content analysis was used to interpret the answers to open-ended questions, examining the

content and meaning of answers (Kankkunen & Vehviläinen-Julkunen 2017, 67; Vilkka 2015). The quantitative and qualitative answers were combined using methodological triangulation. Results from qualitative questions were complementary to results from quantitative questions. (Andres 2012, 182; Kankkunen & Vehviläinen-Julkunen 2017, 75-76.)

5.2 Rehabilitees' user experiences and effects of Indego training

The study of Rehabilitees' user experiences and effects of Indego training is a pre-experimental, one group, pre-test post-test study. In the study there was a single group, with multiple cases, with different baselines and backgrounds. A within-group design was employed, in which comparisons are made within the one experimental group. With promising results this research could promote a useful next step to conduct a randomized controlled trial (RCT) in the future. (Domholdt 2005, 127.)

The intervention effectiveness is assessed in an experimental study. The intervention is the independent variable and the measured change, effect, is the dependent variable. In pre-post design, participants are in one group and the change is measured before and after an intervention. (Cowan 2009, 83.)

5.2.1 Settings

Co-operation with rehabilitation service providers in Satakunta offered SAMK the possibility to involve physiotherapists and their patients in the study. This way the research could be carried out in real-life setting. The intervention was carried out in clinics where the participants' regular physiotherapy was provided. The Indego training was always performed with an Indego Specialist and the physiotherapist responsible of carrying out the patient's physiotherapy.

5.2.2 Study population

The convenient sampling was carried out for individuals suffering from stroke, spinal cord injury (SCI) or traumatic brain injury (TBI). The sampling was conducted with neurological physiotherapists, in physiotherapy clinics near SAMK. The participants were adults (18 years or older), willing to participate in and commit to the research. They met the inclusion criteria shown in Table 1, formed by the study plan and criteria for safety using Indego by Parker Hannifin Corporation (2016).

Rehabilitees in the acute phase of recovery were not included due to the unpredictable spontaneous recovering and challenging commitment for the period of intervention. The study participants were not independent walkers and did not have previous experience using over-ground exoskeletons.

Table 1. Eligibility for this study and inclusion and exclusion criteria by Parker Hannifin Corporation (2016).

Eligibility for this study:

- SCI, stroke or TBI
- Subacute or chronic phase
- Not independently ambulatory
- Current physiotherapy period paid by Kela, insurance company, primary health care, rehabilitee himself or some other
- No previous experience of using Indego exoskeleton

Inclusion criteria for safety using:

- Sufficient upper extremity strength to manage approved stability aids
- Passive range of motion at their hips, knees and ankles to neutral or better
- Healthy bone density
- Tolerance for being fully up-right without being symptomatic
- Height 150cm – 190cm (5,1" – 6,3")
- Weight not exceeding 113kg (250lbs)
- Seated hip width not exceeding 42,2cm (16,6")
- Femur lengths 35,5 – 47cm (14 – 18,5")
- Intact skin where person would come in direct contact the Indego device
- Spasticity level 3 or less on the Modified Ashworth Scale (MAS)
- Stable cardiovascular health

Exclusion criteria for safety using:

- Severe vascular disorders of the lower limbs (e.g. unresolved deep vein thrombosis)
- Diminished standing tolerance (caused by, e.g. orthostatic hypotension)
- Poor bone health that places the user at an increased risk for fracture during ambulation
- Contractures at the hips, knees and ankles
- Uncontrolled autonomic dysreflexia
- Uncontrolled hypertension or hypotension
- Poor skin integrity in areas in contact with the device
- Heterotopic ossification that would limit joint range of motion
- Cognitive impairments resulting in inability to follow directions
- Visual impairments which would make ambulation unsafe
- Lower limb prosthesis
- Any condition which in the opinion of a medical doctor prevents the user from using the device

Physiotherapists in clinics conducted preliminary assessments to ensure patient suitability. Before the intervention the participants had a medical examination, by a medical

doctor specialized in neurology and geriatrics. The physiotherapists and the doctor (who did not have any experience with exoskeletons), were prepared in advance about patient requirements for using Indego. A written approval from the medical doctor was required to ensure the participant was suitable for Indego use (Appendix 3). The last control for suitability was conducted by SAMK's Indego Specialists. The participants were insured by their clinics. The physiotherapists and the medical doctor guaranteed the safety of clients involved with the robotic assisted rehabilitation.

5.2.3 Research intervention

The intervention was implemented in Autumn 2019 over an 8-week period, involving 2 sessions per week. The length and frequency of sessions followed the rules of the rehabilitee's financial coverage from Kela, insurance company or other party. The session time in previous exoskeleton studies have been 60-90min (Tefertiller et al. 2018, Baunsgaard et al. 2017 & 2018, Platz, Gillner, Borgwaldt, Kroll & Roschka 2016). The actual walking time is then at the most about 45min due to the time spent preparing, donning and doffing. The session time in this study was 60min.

The progress of the intervention was planned according to the Indego research of Juszczak, Gallo & Bushnik (2018) with SCI patients. During the first session the Indego specialist evaluated the participant size etc., to set the correct settings for each individual. The participants were informed about the use of the device and could test the device. In the first 1-3 sessions the participants were taught how to perform sit-to-stand and stand-to-sit. After achieving competency with these tasks, the next sessions involved training of ambulation indoors on smooth surfaces. If a participant achieved enough proficiency using the device, the training could include more difficult activities, such as managing doors, ramps, outdoor surfaces etc. See the training procedure in Table 2.

Table 2. Training procedure

The number of sessions	Activities
1.	- Completion of necessary measurements - Information and familiarization with using the device - Trying the device on
1.- 3.	- Sit-to-stand, standing, stand-to-sit - Walking a few steps
4.- to the end	Walking on different surfaces - individual progress based on participants skills and proficiency

Gagnon et al. (2018) performed two familiarization sessions for their participants before intervention. They found it important to increase the level of proficiency while learning to safely ambulate with the device. Keeping that in mind, Indego Specialists put an emphasis on familiarization / guiding the rehabilitees in first sessions.

The level of assistance was adjusted as needed for safe training. One assistant was always at the back, holding the handles of the device. Another assistant usually helped the rehabilitee to control the assistive device. When needed, the third assistant guided the rehabilitee's upper body posture. Assistive devices were considered individually, together with the rehabilitee and physiotherapist, with selection based on rehabilitees' usual assistive device, space requirements (e.g for lower limbs when using the Indego) and ability to lean or take a hold of the handle.

Every session was led by one or two Indego specialists, who were also physiotherapists. The participant's physiotherapist was present and could be guided to act as an assistant when needed. The author was supposed to observe every session, but if absent, other physiotherapists could document the achievements or notable issues in the reporting form.

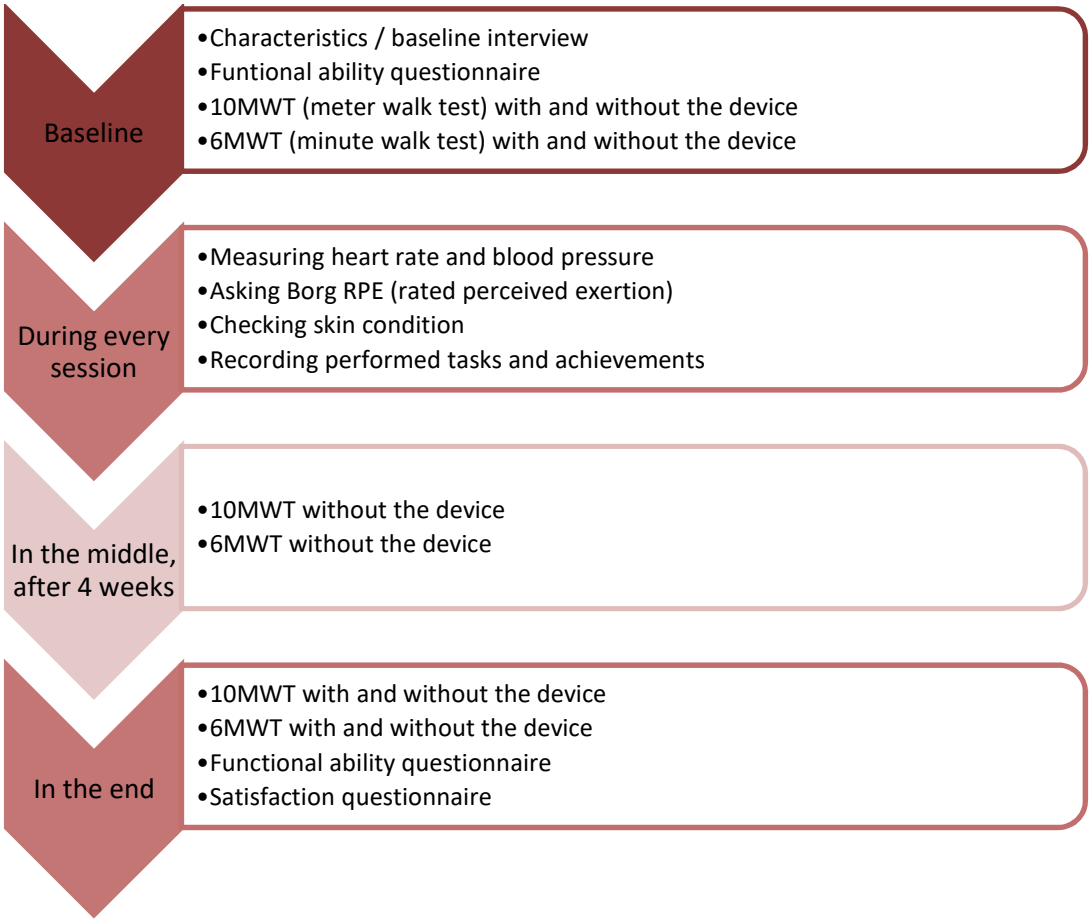
5.2.4 Data collection

Based on ICF, functioning is divided into two components: a) body functions and body structures, and b) activities and participation. Contextual factors are environmental factors and personal factors (World Health Organization 2013, 7). In this study, body functions were acknowledged by measuring functions of the cardiovascular system, endurance, pain, muscle and movement functions due to measure the suitability and

ensuring the safety in the sessions. Body structures were taken into account when assessing suitability and inclusion criteria. Walking tests and functional ability questions related to activities and participation. Environmental factors were included in the process, depending on how participants succeeded in confronting thresholds, different surfaces or outdoor surroundings.

All data was collected by the author during the training intervention. Measurements and timing are shown in Table 3. Interviews and observations were written down on paper and session time, walking time and number of steps were recorded by the Indego device.

Table 3. Research measurements



The baseline information and characteristics were gathered by interviewing the rehabilitees before the intervention (Appendix 4). It included collation of the participant's age, diagnosis, time since injury etc. The Functional Ambulation Classification (FAC) and functional ability were measured in the same session (Appendix 5). With FAC,

rehabilitee's functional mobility can be classified in five categories, ranging from independent walking to non-functional walking (Shirley Ryan Abilitylab 2012).

Functional ability was measured by interviewing the rehabilitees, using selected questions from valid Patient-Reported Outcomes Measurement Information System (PROMIS-questionnaire) in Finnish. It is a set of person-centered measures that evaluates and monitors different domains of functioning. Suitable domains can be selected, and results can be calculated even though not all questions are answered. (Northwestern University 2020.) The selected domains of PROMIS were global health, pain, sleep, fatigue and physical functioning. Translation of bowel and defecation functions was not ready when this study was implemented, so it was not used.

Outcome measures of walking velocity and capacity were measured using valid and reliable tests; 10MWT for speed and 6MWT for endurance (Kantanen, Paltamaa & Peurala 2011; Scivoletto et al. 2011, 739-740). In earlier studies walking tests for SCI rehabilitees utilised the device at a self-selected, comfortable speed. Molteni et al. (2017) and Goffredo & Guanziroli et al. (2019) measured walking tests with stroke rehabilitees without the device. In this study, the testing was performed with the Indego in use. If walking without the device was meaningful and possible, the tests were also performed without the device.

In the beginning the 10MWT and 6MWT were performed, if possible, without the device before training intervention. The 10MWT with the device was performed as soon as a rehabilitee learnt to walk over 10m with the device and 6MWT was performed as soon as walking at least 6min was possible. Tests in the middle of the intervention period were performed after four weeks had passed. Final tests and interviews were conducted during the last two sessions. The walking related outcome measures (10MWT and 6MWT) were performed separately in the beginning of different sessions, so results were not affected by each other.

According to the study aims progress of learning to walk with Indego was collected by writing down the achievements during every session. The author observed and documented activities like sit-to-stand, stand-to-sit, standing balance and performing tasks

while standing during the training. The number of sessions, when the activity was successfully performed and need of assistance was observed and documented. The need of assistance was documented using the terms maximal, moderate or minimal assistance or supervision. Also, the number of physiotherapists needed during the training was documented. The Indego device counted and recorded the number of steps and walking time of a rehabilitee.

The user's satisfaction was measured using a questionnaire (Appendix 6) at the end of intervention, in order to clarify how easy or safe the device is and whether they felt changes in spasticity, pain, bowel movement or fatigue. Their opinions were asked for 10 statements by Likert scale. This questionnaire was used earlier in two studies of ReWalk (Platz, Gillner, Borgwaldt, Kroll & Roschka 2016, 3-4; Zeilig et al. 2012) and in one Ekso study (Sale et al. 2018, 749). The validity and reliability of this questionnaire has not been studied, but since it was used in three other studies and with two different devices, there are possibilities to compare the data. In addition to this questionnaire, participants were asked if they would use the device at home as an assistive device or in rehabilitation later on.

During every session the author or Indego Specialists monitored heartrate (HR), blood pressure (BP) and perceived exertion by Borg rating scale (RPE) to ensure the user's safety. HR and BP were measured in the beginning and end of the session. If needed, they were also measured in the middle of the session. The RPE scale (from 6 to 20) also provided information on how exhausting the training was, similar to the studies of Juszczak, Gallo & Bushnik (2018) and Sale et al. (2018). The Indego Specialists and participant's therapist observed the participant's condition during training in case of dizziness or autonomic dysrefleksia (dysfunction of autonomic nervous system).

Pain and feeling of fatigue were measured verbally using a scale from 0 to 10, in the beginning and end of every session. The condition of the lower extremities' skin was checked before and after every session for the skin irritation. Adverse events were documented.

5.2.5 Data analysis

Excel was used to analyze data from the training intervention and results of measurements. With a small group of participants, it is not meaningful and reasonable to make deep statistical analysis. The purpose was to describe the results and achievements and find out tendencies of similarities and differences in order to answer the research questions.

In this study, interval and ratio values of achievements and walking tests were analyzed as univariate data. Changes are mainly presented as percentages and mean or median values with distribution of values around the average. The relationships and correlations between values might not be trustworthy in such a small sample. Therefore, data interpretation is in the descriptive level. (Cowan 2009, 97-99.) Results of the satisfaction questionnaire are in ordinal scale. Despite of that, they are reported as mean values and standard deviation, like that done in earlier studies by Platz et al. (2016), Sale et al. (2018) and Zeilig et al. (2012).

5.3 Ethical issues

Permission from the ethical board of human sciences in the universities of Satakunta (Ethical Committee of Satakorkea), was applied after the study plan was approved. After ethical approval, permission to perform research in the rehabilitation setting (i.e. private clinics) was applied. The research followed the responsible conduct of research (RCR guidelines), formulated by the Finnish advisory board on research integrity (TENK) (Finnish advisory board on research integrity 2012). Emphasis was placed on respecting the autonomy of the research subjects, avoiding harm and ensuring privacy and data protection.

The author acquainted herself with the topic of the thesis and studied the research methods to be able to conduct a thesis with integrity and quality under her supervisor's tutoring. The author is interested in developing the field of neurological rehabilitation and declares no conflicts of interest. The author is working as a part-time researcher at

SAMK. She conducted the study for SAMK and acted objectively, willing to find advantages and disadvantages of using exoskeletons in rehabilitation. This research is part of a larger project, DigiHealth, which is funded by the Regional Council of Satakunta (Satakuntaliitto) from the EU's regional development fund. The funder does not have special interests in the result of this particular study.

In Study 1, Physiotherapists' user experiences, the participants were given the information of the study with the survey. By answering the web questionnaire, the physiotherapists gave their consent for participation. The anonymity of the physiotherapists in Laitila and Mustasaari could not be totally guaranteed. There were only two places where Indego device had been over 6 months and about 17 physiotherapists working with the device. As such, identity could not be fully hidden. That, and all information about the study and storage of data was explained in the information leaflet of the questionnaire.

In Study 2, Rehabilitees' user experiences and effects of Indego training, the rehabilitees were given information about the intervention and storage of their personal information in plain language, prior to the intervention. Each volunteer participant signed the informed consent form (information and informed consent form is contained in Appendix 7, and the privacy statement is in Appendix 8). Participants were able to ask the author any questions concerning them throughout the intervention (and after). The participants were also able to quit the intervention at any point. Before the intervention, the Indego specialists were informed about the research, data collection methods and the intervention. The specialists were given forms for marking achievements and notes during sessions, especially if the author was not present.

The participants in Study 2 were insured by the clinic's insurance against treatment injury (as they were in their regular therapy). The author negotiated in advance with Kela and agreed that rehabilitees having physiotherapy paid by Kela were allowed to participate in this study (Jokiranta email 8.5.2019). The Indego Specialists were prepared to act in case of adverse event or emergency and call for help if needed.

The data was collected by documenting the achievements and outcome measures of the rehabilitees. Rehabilitees' functional ability, baseline characteristics and user experiences were collected by questionnaire on paper. The data from both studies was handled with dignity and confidentiality. Demographic data and outcome results were coded at the beginning. The data was transferred to file format and saved in the author's personal file in the SAMK's database. SAMK has the necessary rights to have personal registers. The author was the only one to have access to the file and performed analysis with the help of analytic professionals. Excel software was used in analysing process. After coding the data, the tutors of the master thesis and the project leader of DigiHealth at SAMK could be given access to the data. The author and SAMK are able to use the anonymized data after this particular study. The anonymized data will then be stored in SAMK's database, available for further use.

6 RESULTS OF PHYSIOTHERAPISTS' USER EXPERIENCES

6.1 The beginning of using Indego

Six physiotherapists from Mustasaari and Laitilan terveyskoti answered the questionnaire. They were mainly Indego trainers or Indego instructors, with one trained by educated colleagues (Table 4). Two therapists had less than two years of working experience with Indego, one year (n=1) or 5 months (n=1).

Table 4. Physiotherapists' background.

Time of experience	Number of physiotherapists	Education	Was the learning easy or difficult	Need of further education	Adverse events
< 24 kk	2	Instructor (1) Trained by colleagues (1)	Rather easy (1) Neither easy nor difficult (1)	Yes (2)	No (2)
24 kk	4	Trainer (3) Instructor (1)	Rather easy (3) Neither easy nor difficult (1)	No (4)	No (3) Yes (1)

The scale for learning to use the device: easy – rather easy – neither easy nor difficult – rather difficult – difficult.

All respondents considered that learning to use the device was not difficult or rather difficult (Table 4). A therapist, who had been trained by colleagues, needed more information about the purpose of use, to whom the device fits best and how to challenge rehabilitees. Another therapist needed more information about using the iPod in more comprehensive way. One of the therapists, who felt that he / she had no need for further education, stated that further orientation for fine-tuning adjustments / settings would be beneficial.

Only one physiotherapist had had an adverse event, with one stroke rehabilitee. This rehabilitee had strong pain for couple of weeks following Indego use, as a kind of nerve irritation after first standing up. The therapist believed the speed for standing up was too high, even though the patient's range of motion in hip was full in slow motion. One physiotherapist did not mention any specific adverse event, but described situations where dangerous events have been close due to breaking of Indego parts.

6.2 Sessions with rehabilitees

All the physiotherapists (N=6) have had rehabilitees with SCI or stroke in Indego gait training (Table 5). Rehabilitees with SCI have had paraplegia, tetraplegia, complete and incomplete injuries. The responded physiotherapists (n=5) reported having mostly rehabilitees with SCI and least muscle disorders.

Physiotherapists currently have 0-5 sessions with Indego per week, typically 1-3 sessions (Table 5). The sessions last in general 60 or 75 min. The time for measurements and adjustments of the device in the first time, was typically 46-60min. In the beginning of the training period usually two therapists were present. Towards the end, one to two therapists were typically required. They did not have any assisting persons for the training, but family members or personal assistants could be present during the rehabilitation.

The physiotherapists responding the question of how many sessions rehabilitees have in a period (n=3) reported that number varied from 10 to 40 (Table 5). The weekly

frequency of gait training was reported (n=4) to vary from once a week to one to two times per week.

Table 5. Sessions with rehabilitees.

Questions / ID	1.	2.	3.	4.	5.	6.
What diagnosis groups have you had in Indego rehabilitation?	MS, Stroke, SCI, muscle disorders	Stroke, MS, SCI, TBI	SCI, MS, Stroke	SCI, MS, Stroke, Muscle disorders, rare neurological diseases	SCI, Stroke, MS	SCI, Stroke
Which diagnoses the most?	MS, SCI	SCI	equally each	MS	Paraplegia	
Which diagnoses the least?	Muscle disorders	Tetraplegia	Muscle disorders	Muscle disorders	Stroke	
How many Indego sessions do you have weekly on average?	0-2	1-3	1-5	1-3	3	1
How long does it take to do the assessments and measuring in the first time? (min)	46-60	61-75	46-60	46-60	15-30	31-45
How long does one session with a client last, in general? (min)	60	75	60	60	60	60
How many therapists are working with a client in the beginning of a period?	2	2	2	2	2	2
How many therapists are working with a client in the end of a period?	1-2	2	1-2	1	1	1-2
Are there other assistants in gait sessions?	no	no	no	no	no	no
How many Indego training sessions (number) do rehabilitees have in a period on average?	10			10		40
How often do rehabilitees have Indego gait training on average? (times per week)	1-2			1-2	1	1

All the therapists (N=6) mentioned that Kela and insurance companies were the payers for Indego rehabilitation. Most also (n=5) reported public special care and rehabilitee themselves to be the payers. Two therapists mentioned primary care, but no other parties were reported. The most common payers were reported to be Kela (n=2), insurance

companies (n=2), Kela and self-paying rehabilitees (n=1) and all the above-mentioned payers (n=1).

6.3 Experiences of rehabilitation with Indego

Four physiotherapists out of six found using Indego to be "easy". Two therapists found it "neither easy nor difficult" on a scale of very easy – easy – neither easy nor difficult – difficult – very difficult. Four physiotherapists found it easy to put the device on and mentioned that adjustments (via the iPod) were easy, allowing exercises to be tailored day by day. Two reported walking and cooperation with colleagues to be easy. Also, rehabilitee's high motivation, taking off the device, doing the measurements, fitting the device and data saving in the device were found to be easy. Each of these factors were mentioned once.

Five physiotherapists out of six reported difficulties or challenges with the mechanical device. With the older version of the Indego device, problems arose with breaking parts. In particular, the upper leg part has broken and disturbed the progress of therapy. Therapists also mentioned difficulties with higher support in the walker (slightly built and difficult to adjust) (n=1) and putting the parts together (n=1). Updating the iPod or the device were also reported to cause delays.

Two of the therapists reported the settings and fine adjustments in the iPod to be loading or challenging for therapists. One found it difficult to find fitting parts for rehabilitees with the older version of Indego, which has three sizes for every part. Individual therapists also mentioned that the device does not fit everyone, which is sometimes impossible to know in advance. In addition, sitting down with the device and suddenly appearing spasticity (during standing up or walking) are challenging.

Four of responded therapists (n=5) mostly used the Motion+ program (M+), and one used the Therapy+ program (T+). M+, in which the trajectory (stepping) is pre-adjusted by the therapist, was reported to be used always for complete SCI, or when the strength in the lower limbs was too weak. Two mentioned using M+ always in the first session. One used it with almost every rehabilitee with disorders of lower limbs and

one mentioned stroke gait rehabilitation. It was also reported by two therapists that some rehabilitees benefit more from training with M+ even though he / she would be able to use T+. These situations can occur with poor endurance, diminishing spasticity or pain.

Four physiotherapists reported using T+, in which the rehabilitee initiates the stepping, when the rehabilitee has stronger lower limbs and is capable of a physically heavier program. Two therapists preferred the rehabilitee to be familiar with the device and M+ before starting with T+. More possibilities for adjustments and rehabilitees' feelings more natural during walking were mentioned as benefits of T+.

In Table 6, the positive impacts of Indego gait training on functioning (with ICF-codes) are shown to be more common than negative impacts. Therapists reported Indego training to have a positive impact on pain (n=5), exercise tolerance (n=5), defecation functions (n=5), urination functions (n=3), muscle tone functions (n=5), walking or moving around using equipment (n=5), and toileting (n=3).

Negative influence was reported with a scale of "quite a lot" or "moderately" in pain (n=1), muscle tone functions (n=1), involuntary movement reaction functions (n=1) and mobility of joint functions (n=1). Three to five therapists out of six reported no negative influence in every function. With every function at least one therapist reported that negative influence was not assessed or impossible to assess. In addition to positive influences one therapist mentioned better quality of sleep. One therapist also pointed out the difficulty of assessing the influence of Indego training, when rehabilitees always have the conventional physiotherapy in parallel.

Table 6. Positive and negative influences of Indego training on functioning (N=6).

	A lot		Quite a lot		Moder-ately		Some-what little		A little		No in-fluence		Not as-sessed / impossi-ble to assess	
Function (ICF)	pos-itive (+)	neg-a-tive (-)	+	-	+	-	+	-	+	-	+	-	+	-
Pain (b280)	1		3	1	1					1		3	1	1
Exercise toler-ance functions (b455)			2		3							5	1	1
Defecation functions (b525)	1		3		1							5	1	1
Urination functions (b620)			2		1							4	3	2
Mobility of joint functions (b710)					2	1	1		1			4	2	1
Muscle power functions (b730)			1		3		1					5	1	1
Muscle tone functions (b735)			4	1	1							3	1	1
Involuntary movement re-action func-tions (b755)				1	1		1			1		4	3	1
Speaking (d330)											2	4	4	2
Changing basic body po-sition (d410) or transferring oneself (d420)	1				2				1	1		4	2	1
Walking (d450), mov-ing around us-ing equipment (d465)			4				1			1		4	1	1
Washing one-self (d510)					2							5	4	1
Toileting (d530)			2				1					5	3	1
Dressing (d540)					1				1			5	4	1

6.4 Changes in physiotherapists' work

The physiotherapists' (N=6) responses to the amount of change in working with neurological rehabilitees varied from "very little" to "very much". Half of the therapists (n=3) considered that working had changed moderately. They found Indego training to be a good extra tool in neurological rehabilitation. The therapists (N=6) reported that positive changes in working, were more versatile training with more repetitions and longer distances in walking, training in an upright position and control of the trunk. Two wrote about rehabilitees who were motivated and feeling good. Also, positive changes in rehabilitees' outcomes, like diminishing spasticity and pain, improving bowel function and quality of sleep, were found as positive changes in their work. One mentioned the decreased physical load when assisting walking, though another mentioned the physical load for a therapist's hands, arms and elbows to be a negative change.

Results for negative changes in therapists' work did not have a common thread (n=4). One pointed out that when a rehabilitee fancies the Indego training too much, other functions can decrease. Another complaint was the time spent in vain when parts break and you have to wait for new ones.

Therapists emphasized (in results for both negative and positive changes) that Indego training is just one part of qualitive physiotherapy. It cannot replace other kinds of therapies but strengthens each other. This factor should be taken into consideration when planning the implementation of therapy periods.

Four therapists out of six mentioned having a new effective tool, when asked about changes in professional work. One found the physical load for the therapist to be less, while the rehabilitee conducts qualitive gait training. The new technology was found to push physiotherapy in a more scientific direction and informed about recent things in professional way. One therapist reported the changes in explaining the benefits of robotics to rehabilitees and own attitude to robotics.

All the therapists (N=6) were satisfied or moderately satisfied using Indego in therapy. On a scale of 0 – 10, the therapists (N=6) would recommend use of Indego to their

colleagues with a mean value of 8,3 (±0,8). The physiotherapists (n=3) who gave a score of 9 found Indego to improve therapy and gain better results. They underlined repetitions, optimal stepping, versatile training and faster results in outcomes. They appreciated individually tailored adjustments, providing gait therapy for rehabilitees with lower functional ability, and improvements in spasticity, pain and bowel function. Therapists (n=2) who gave a score of 8 were happy for the new tool in rehabilitation but were expecting newer and improved technology to come. A score of 7 was given because the therapist was not happy with the quality of the device and found it difficult to arrange timetables, when two therapists were needed.

When asked, if the therapists wanted to tell more, one recommended to test the device with all rehabilitees. It is important to try and sometimes there is a need for multiple sessions before adjustments are optimal.

7 RESULTS OF REHABILITEES' USER EXPERIENCES AND EFFECTS OF INDEGO TRAINING

7.1 Participants

Six rehabilitees gave their consent to participate. Their characteristics were clarified through interview and they were measured to ensure device fit. One participant was not suitable, as the torso pad did not reach around. Five participants were found to be suitable. See the characteristics in Table 7.

Table 7. Characteristics of the included rehabilitees (N=5)

Gender	60% female, 40% male
Age (MD, years)	62 (range of variation 30-69)
Dg	1 stroke / haemorrage, left paretic 2 stroke / infarction, left paretic 1 stroke / infarction, right paretic 1 TBI, left paretic
Time since injury (MD, years)	7 (range of variation 2,5-32)

Participants included three female and two male rehabilitees, aged from 30 to 69 (median age of 62 years) (Table 7). They had over one year since injury and were in the chronic phase of their condition. No-one had had any fractures. They did not have any previous experience with Indego, however two participants had used Lokomat. The cause for lower limb weakness with the rehabilitees over 60 years was infarction and with the younger ones haemorrhage or TBI. Three participants had paretic left side, two had paretic right side.

Three participants whose rehabilitation was supported through Kela had physiotherapy 45-70 times a year. One participant was having rehabilitation through primary health care, for a 10session period, once a week. One participant had physiotherapy paid by an insurance company, which included two sessions of robotic walking by Lokomat, one session of conventional physiotherapy and one session of pool therapy per week. For the others (n=4) Indego training replaced their conventional therapy. For the participant with insurance company coverage, Indego training replaced the Lokomat training. Three out of five rehabilitees had 15 Indego training sessions, two other had 12 and 8 sessions. There were no dropouts, withdrawals or absence due sickness. One missed session occurred, when one rehabilitee mixed the hours.

7.2 Process of learning to walk with exoskeleton

In the first session, everyone (N=5) succeeded to stand up and sit down with the device. One had difficulties with spasticity and ankle position in the device and was unable to take any steps in the first session. Three rehabilitees walked with the device for 4 – 9 meters and one succeeded to walk all together 23 meters in the first session.

Every participant (N=5) started the training with Motion+ (M+, stepping is trajectory oriented, with settings pre-adjusted by the therapist) using three assistants. Assistive devices, which were used during the intervention were Walkers (of Parker Hannifin, or the rehabilitee's own), platform walker, wheellator (walker-wheelchair), crutch and cane. One rehabilitee changed the program to Therapy+ (T+, rehabilitee initiates stepping) and needed one crutch and two assistants from the second session until the end.

Another rehabilitee used a combination of M+ and T+ from the seventh session, depending on her feeling of strength and endurance. With the walker assistive aid, she required only one assistant, but with a cane in the three last sessions she preferred second assistant beside her.

Four participants managed to achieve a minimal level of assistance from two assistants and one of them contact guard assistance. See the rehabilitees' achievements in Table 8. Two of the rehabilitees needed moderate assistance over ten sessions and two achieved a lower level of assistance in the second or third session. One rehabilitee needed maximal to moderate assistance from three assistants, throughout the intervention.

Table 8. Rehabilitees' (N=5) achievements and number of sessions, when a milestone was achieved. Presented as median values.

	MD	Range of variation
Sessions	15	8-16
Longest walked distance in a session altogether (meters)	245	220-354
Longest walked distance all at once (meters)	109	80-164
10m at once (number of session)	2	1-2
100m in a session (number of session)	5	2-5
Only 2 assistants (number of session)	3,5 (4 rehabilitees)	2-8
Minimal assistance achieved (number of session)	7 (4 rehabilitees)	2-14
Contact guard assistance achieved (number of session)	9 (1 rehabilitee)	9
Change to T+ (number of session)	4,5 (2 rehabilitees)	2-7
Crossing carpets and small thresholds or training with upper limbs (number of session)	6 (3 rehabilitees)	4-10
RPE (mean values, SD)	13,87 (±0,74)	12,00 (±0,93) - 16,83 (±1,53)

RPE = Rated Perceived exertion, T+ = Therapy+ program

All five rehabilitees were able to walk at least 10 meters all at once within the first or second session, three with three assistants, two with two assistants. The rehabilitees (n=2), who managed to walk with T+ during the intervention, were able to walk in

total 100m within one session, during the second or third session. Other participants (n=3) achieved that in the fifth session. Three rehabilitees were able to walk over 100m all at once during a 60min session.

The rated perceived exertion (RPE) at the end of each session varied from extremely light (score of 7) to extremely hard (score of 19) (Table 8). No clear trend of increase or decrease in RPE was found along the process, therefore the results are presented as mean values. RPE differed session by session, based on the effort required to perform ambulation due to adjustments or level of support provided by Indego. Three participants' mean value was somewhat hard (13) or lower, two participants' hard (15) or higher. Three rehabilitees' highest RPE was hard (15) or lower. One rehabilitee rated it once very hard (17) and another once extremely hard (19). The exact values of RPE are shown in Appendix 9.

The walking distances are shown in the Figure 1. All the rehabilitees (N=5) managed to walk altogether over 200m in a single 60min session. Though all succeeded to walk at least 220m in a single session, one had a lot of difficulties. He only reached 220m in the 9th session. In subsequent sessions, distances reduced and the level of assistance required remained high. The distances per session varies also due to other tasks, e.g. balance and coordination tasks while standing. Though time of walking and number of steps were meant to be reported, the iPod recordings had some errors and results are not reported here because of missing data.

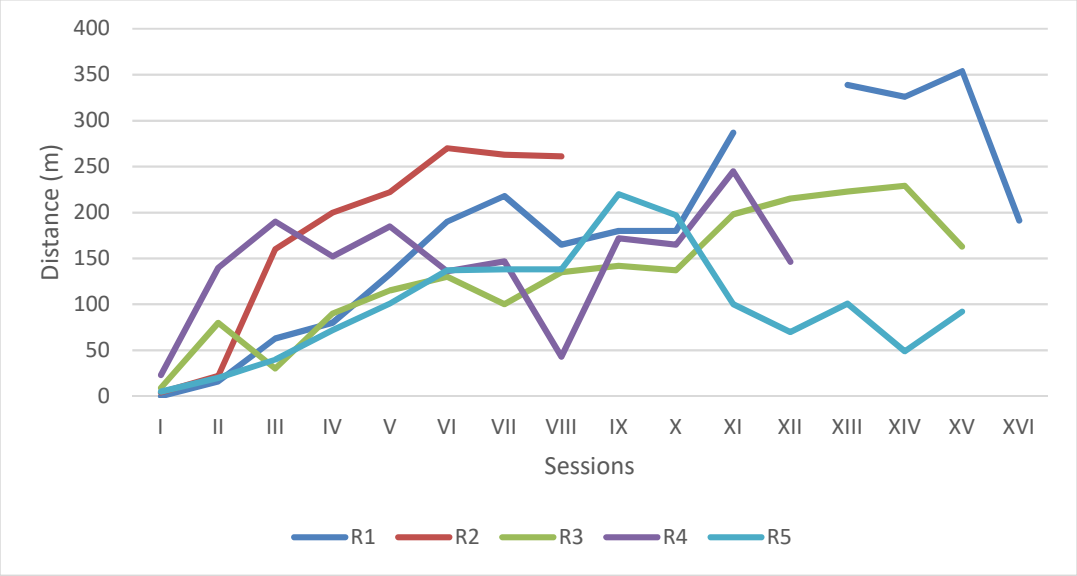


Figure 1. Rehabilitees' (R1, R2, R3, R4 and R5) walking distances in every session.

One participant went with an elevator upstairs and downstairs during her fifth session. She needed contact guard -level assistance and help to keep the elevator door open long enough to enter or exit. Three participants walked over different carpeted surfaces and small thresholds. They also did coordination exercises with their upper limb while leaning the device against a table. Some rehabilitees (n=3) would have enough ability to walk outside in the last half of the intervention period, but it was not appropriate due to cold weather and snow.

With rehabilitees suffering from hemiparesis (N=5), many factors effected the process of learning to walk with Indego (Table 9). Participants (N=5) had minor or major challenges gripping the assistive device with the paretic hand. Problems were also noted in postural control and taking steps.

Table 9. Challenges in rehabilitees (N=5) learning process and solutions.

ID	Challenge	Solution
R1	Spasticity provoked in the ankles when wearing exoskeleton	Use of own orthoses while wearing the exoskeleton
	Problems in taking a grip because of spasticity and pain	Trying several assistive devices but the best was platform walker
R2	Stance phase with healthy lower limb due to tight hamstring muscles and 10 degree limit in extension of the knee	Use of Therapy+ mode and different adjustments with each lower limb
	Pain in paretic stiff upper limb	Use of one crutch
R3	Pusher syndrome provoked by exoskeleton training	Alteration of training in the beginning very close to a wall next to R3's healthy side
	Difficulties in taking a grip due to inactivation of paralyzed upper limb	Use of platform walker
R4	Difficulties in initiating stepping in Therapy+ mode	Manual facilitation in the beginning to help to move the paretic lower limb
	Minor problems in taking a grip due inactivation of paretic hand	Physiotherapists assist of assistive device
R5	Poor awareness of posture in upper body and difficulties in weight sifting to paretic side	Using a mirror in front of the rehabilitee, giving cues by touching the arm
	Difficulties in leaning on the paretic upper limb	Trying several assistive devices, the best were platform walker and Parker Hannifin's walker with high arm support

No severe adverse events happened during the intervention. On four occasions, small dint and two times light redness occurred on the skin. These problems were solved by

using better padding. Two participants experienced pain in their feet during walking, but pain disappeared immediately after taking the device off. During the intervention the research team tried to ease pain through adjustment of the device. Rehabilitees also had some complaints of pain in their back, knee, wrist or big toe. These pain experiences were occasional and were eased by adjusting the device and / or having breaks.

The results of heartrate (HR), blood pressure (BP), pain and fatigue, measured for safety reasons during every session did not show relevant variation. Pain did not prevent training and changes in HR and BP did not cause interruptions during the intervention. Changes in self-estimated fatigue were not alarming.

7.3 Walking ability

In the beginning, participants (N=5) were able to perform all walking capacity and velocity tests with the device within the first five sessions. Times of testing varied among participants. Two rehabilitees did the 10MWT with the device in the second session and three in third session. The 6MWT with the device was tested in the second session with one rehabilitee and in fifth session with four rehabilitees. All the participants (N=5) were able to complete the 10MWT and 6MWT with the device in the beginning and in the end of the intervention period. One participant walked with M+ in the beginning but progressed to use T+ in the end. Three used M+ in all tests and one used T+. The amount of assistance reduced with three rehabilitees at the end. Two managed with two assistants in the end instead of three and one managed with one assistant instead of two. Two rehabilitees had same two or three assistants as they had in the beginning.

In the 10MWT with the device, four rehabilitees improved their time and for three that was also seen in speed after rounding results off to two decimal places (Figure 1). The positive change in time varied from 0,3% to 58%. The decrease in one participant's time was 25,5%. The best speed was gained with T+ -program at 0,37m/s, the lowest speed in 10MWT was 0,14m/s.

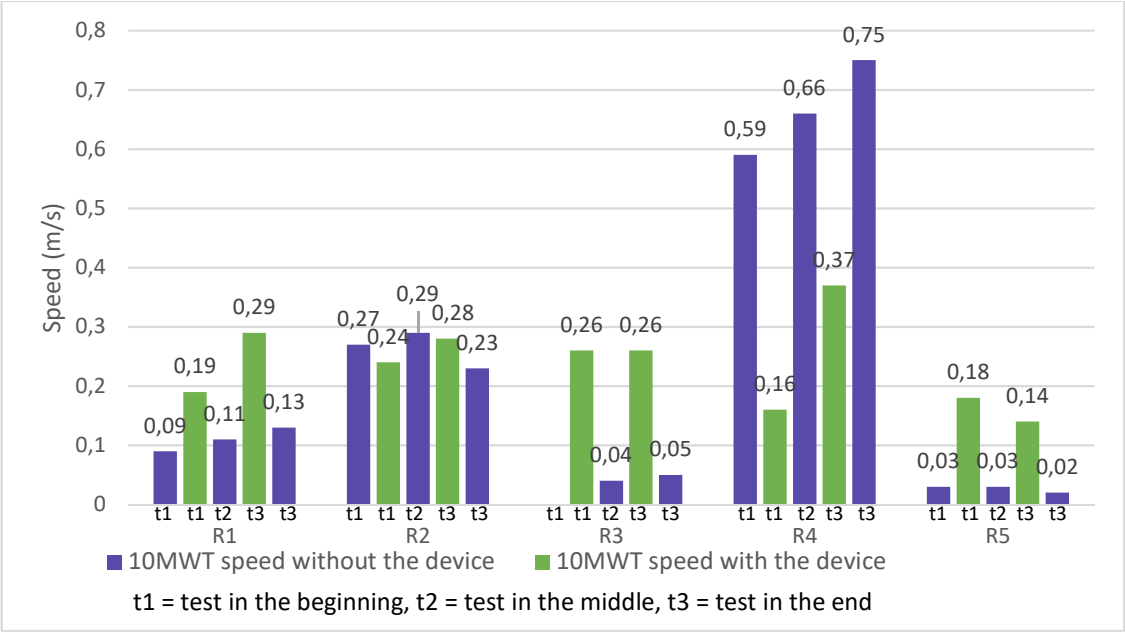


Figure 1. 10MWT results with and without the device.

In the 6MWT with the device, the same four rehabilitees improved the distance walked (Figure 2). The positive change with those four rehabilitees varied from 5,4% to 75%. One rehabilitee had reduced shorter distance in the 6MWT (32,1%).

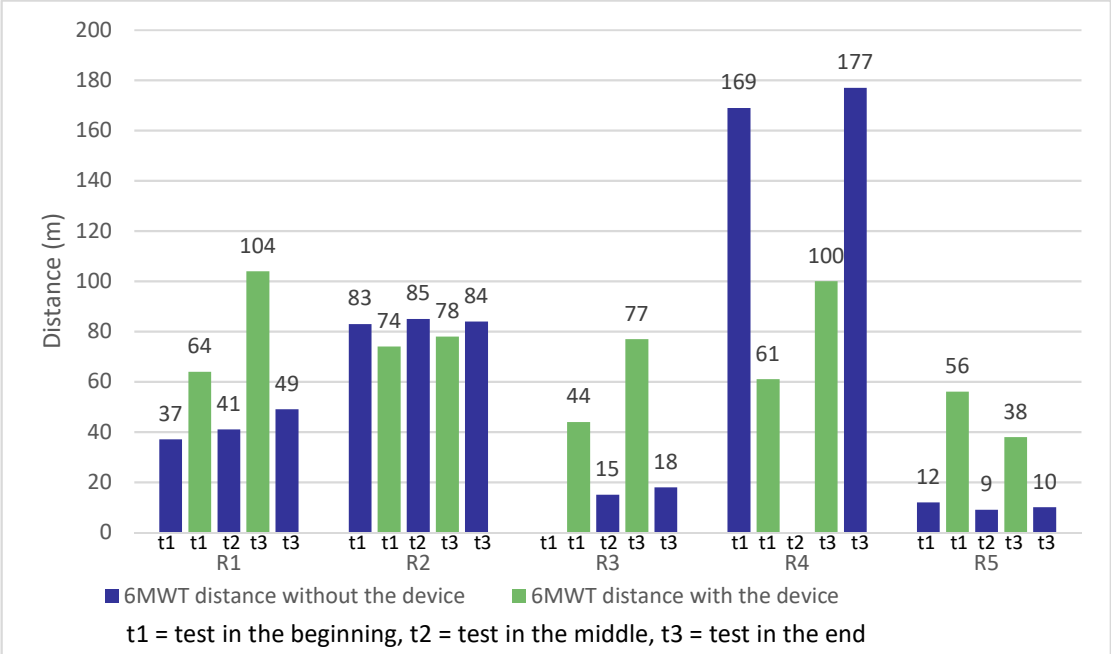


Figure 2. 6MWT results with and without the device.

Four participants were able to perform the 10MWT and 6MWT without the device, at the beginning of the intervention period. All participants (N=5) performed the tests without the device in the end. The tests in the middle of the intervention period were performed only without the device when all rehabilitees (N=5) completed the 10MWT and four completed the 6MWT. No change was seen in the number of assistants or assistive devices in the tests without exoskeleton.

In the 10MWT without the device, three participants improved their time and speed (Figure 1). The positive change varied from 21,0% to 28,0%. All participants (N=5) slightly improved their results in time and speed in the middle of the intervention but two participants failed to improve in the last test. For these two participants results were 16,8% and 19,6% worse, compared to the beginning results. One participant's walking speed without the device was over 0,40m/s already in the beginning improving up to 0,75m/s. The speed for others were at the best lower than 0,30m/s.

In the 6MWT without the device, four rehabilitees improved their distance (Figure 2). The positive change in distance varied from 1,2% to 32,4%. One participant failed to complete the 6MWT in the middle but improved her result in the end. One participant's result decreased both in the middle and in the end, being 16,7% worse in the end compared to the beginning.

7.4 Functional ability

Participants' functional walking ability was assessed based on the Functional Ambulation Classification (FAC) (Table 10). The mean score at the beginning of the study was 2,4 (SD ±0,9). In the end, three rehabilitees found their ability better and two remained the same. The mean score at the end of the study was 3,4 (SD ±0,9).

Table 10. Functional Ambulation Classification

Categories	Beginning of intervention period	End of intervention period
0) Patient cannot walk, or needs help from 2 or more persons		
1) Patient needs firm continuous support from 1 person who helps carrying weight and with balance		
2) Patient needs continuous or intermittent support of one person to help with balance and coordination	4	1
3) Patient requires verbal supervision or stand-by help from one person without physical contact		1
4) Patient can walk independently on level ground, but requires help on stairs, slopes or uneven surfaces	1	3
5) Patient can walk independently anywhere		

All rehabilitees (N=5) reported no change in the use of assistive devices in the home setting. Three reported no changes in their usual mode of action. Two reported increase in self-directed walking training with a walker or holding onto a table for support.

Functional ability was assessed in the beginning and end by interview, with selected questions of the PROMIS-questionnaire. Domains in the PROMIS-questionnaire were global health, pain, sleep, fatigue and physical function. The results are shown in Appendix 10. Changes in answers for global health referred to better results (n=3), no change (n=1) or worsening. Rehabilitee 3 had worse results in the domain of global health, though overall pain decreased by three (on a scale 0-10). Three rehabilitees reported decrease in overall pain, two reported no change. Altogether, answers in the pain domain indicate worsening (n=3), slight improvement (n=1) and no change (n=1). Results in the sleep domain were worse with two rehabilitees and results of fatigue were worse in three rehabilitees. For physical function, four out of five participants reported negative changes and one had no change. Overall, the sum score of changes in all questions were worse for four rehabilitees and better for one rehabilitee.

The direction of change in outcome measurements are shown in Table 11. The results of walking ability and functioning were not aligned. Results in walking tests and functional walking ability were mainly positive but results in functioning (by PROMIS) were mainly negative.

Table 11. Changes in outcome measurements of walking and functioning.

Outcome measurement / ID	R1	R2	R3	R4	R5
10MWT without the device (change in speed)	+	-	+	+	-
6MWT without the device (change in distance)	+	+	+	+	-
FAC (change in category)	+	+	0	0	+
PROMIS (all together)	+	-	-	-	-
PROMIS - Global health	+	+	-	+	0
PROMIS - Pain	+	0	-	-	-
PROMIS - Sleep	0	-	-	0	0
PROMIS - Fatigue	-	-	0	-	0
PROMIS - Physical function	-	-	-	-	-

10MWT = 10m walk test, 6MWT = 6 min walk test, FAC = Functional Ambulation Classification, PROMIS = Patient-Reported Outcomes Measurement Information System
+ positive change, - negative change, 0 = no change

7.5 User satisfaction with Indego exoskeleton

After the training period, all the rehabilitees (N=5) felt comfortable using the device (agreed or strongly agreed) and exercising with it (strongly agreed, agreed or somewhat agreed). All the rehabilitees (N=5) felt safe using it. All responded participants (n=4) felt that the training reduced spasticity (strongly agreed, agreed or somewhat agreed). One participant did not answer on spasticity question, due to not having spasticity. Table 12 contains mean values of results for the satisfaction questionnaire.

Participants opinions were inconsistent for statements of whether the training was complicated, caused pain or improved bowel function, and whether wearing was simple. One participant did not feel that the training improves bowel function. Only that statement of satisfaction questionnaire was strongly disagreed.

Table 12. Results of satisfaction questionnaire and additional questions, as mean values and standard deviations (SD).

Questions	Mean (SD)
1)Training / learning to use the device is not complicated	3,2 (±0,9)
2)Wearing / adjusting the device is relatively simple	3,0 (±0,7)
3)It was comfortable to exercise with the device	4,2 (±0,8)
4)The usage of the device did not cause considerable pain	3,2 (±0,8)
5)I did not feel excessive fatigue while exercising with the device	3,8 (±0,8)
6)After completing the training period, I felt comfortable using the device	4,2 (±0,5)
7)Training with the device diminishes the spasticity in my legs	3,8 (±1,0)
8)I did not have breathing difficulties while training with the device	4 (±1,2)
9)I felt improvement in my bowel movement during the training program	2,4 (±1,1)
10)After completing the training, I felt safe using the device	3,8 (±0,5)
I could imagine using the device as an assistive walking aid at home	2 (±0,0)
I would use the device as a rehabilitation device in the future	4 (±1,7)

Answers in scale 1. Strongly disagree, 2. Disagree, 3. Somewhat agree, 4. Agree, 5. Strongly agree.

None of the participants (N=5) could imagine using the device as an assistive walking aid at home (Table 12). Four of them would use the device in rehabilitation. One rehabilitee would not use the device in rehabilitation (strongly disagreed), though in this study her satisfaction rate towards Indego rehabilitation was 3,8 (±0,8), in 5 step Likert-scale. The median overall satisfaction of all participants (N=5) were 3,4 (±1,2) and satisfaction rates varied from 3 (±0,9) to 4,2 (±0,6).

8 CONCLUSION

8.1 Physiotherapists' user experiences

Overall, physiotherapists did not find it difficult to learn how to use Indego and use it. They reported not having a need for further education, if they had two or more years' experience using Indego. However, fine-tuning iPod adjustments and the uncertainty of which patients could benefit from Indego training was mentioned to be challenging. Physical load was found to be different compared to existing assistive walking rehabilitation approaches. Learning to use the Idego iPod application and fine adjustment settings were also found to be cognitively loading. Serious adverse events to participants' rehabilitees have not occurred.

Physiotherapists reported that they most commonly use Indego with individuals with SCI. Beside of stroke clients also individuals with MS were common. No common features were found in lengths and frequencies of training periods. The required number of supporting physiotherapists in the beginning of training is two and in the end one to two. Physiotherapists reported positive influences on clients' pain, exercise tolerance, defecation, muscle power and tone, and walking or moving around using assistive equipment. Negative influences were reported to a lesser degree, for example, in pain and involuntary movement reaction functions.

Therapists were satisfied with a good extra tool, as it increases the quality of neurological physiotherapy by enabling more versatile training with more repetitions and longer training distances and times. The majority (5/6) of therapists would recommend the use of Indego by number 8 or 9 in scale 0-10. They emphasized the importance of versatility in physiotherapy, and gait training with exoskeleton is a part of this versatility.

8.2 Rehabilitees' user experiences and effects of Indego training

The training with Indego progressed from introduction and familiarization to walking over 200m in a 60 min session within 11 sessions. Rehabilitees suffering from hemiparetisis (N=5) succeeded in walking all at once over 10m within the first two sessions. They used various assistive devices, based on their capability to hold on the device and the level of body control. In the end, the majority of rehabilitees required minimal level of assistance from two therapists and found the training somewhat hard. Rehabilitees progressed at different paces, compared to one-other and needed individual and professional guiding by neurological physiotherapists. No adverse events happened during the intervention.

Rehabilitees having chronic phase stroke or TBI can benefit from Indego training, based on 6MWT and 10MWT results. Increased results in walking without the device were already seen after four weeks of intervention, though improving still after that. Some rehabilitees improved results in FAC, which means that their independence in walking increased. Despite encouraging results, the device is not suitable for all cases. In this study, one participant had to be excluded due to device size and one participant did not benefit from the training. The results on functional ability measured by the PROMIS-questionnaire had poor correlation with the improved results in walking measurements (10MWT, 6MWT, FAC). The changes in results from PROMIS were negative in the physical functioning domain and negative or no change in the sleep and fatigue domains.

Overall, the Indego exoskeleton is comfortable and safe for rehabilitation with chronic neurological rehabilitees but is not suitable or beneficial for everyone. Participants with spasticity felt that the training reduced it. All but one of the chronic rehabilitees with hemiparesis were willing to use the device as a rehabilitation tool in the future, however no-one was willing to use the device as an assistive device in a home setting.

8.3 Conclusions from physiotherapists' and rehabilitees' results

Similarities were investigated in studies 1 and 2. The physiotherapists reported that their clients had had positive influences of Indego gait training on walking ability. This positive effect was also seen in our study 2, where most of the rehabilitees improved clinical outcomes based on the 6MWT (n=4), 10MWT (n=3) and FAC (n=3). Four rehabilitees suffering from spasticity reported Indego training to diminish it. This effect was also noted by the physiotherapists, who reported improvements in muscle tone functions.

However, some issues were not aligned. The physiotherapists reported that Indego training had reduced their clients' pain. This was not clearly shown in results with our rehabilitees. Contradictory to the physiotherapists' report, rehabilitees in our study did not experience improvement in bowel function.

It is not easy to know in advance, who will benefit from exoskeleton assisted walking training. With some rehabilitees it can take several sessions before appropriate settings are found. The physiotherapists were moderately satisfied (n=2) or satisfied (n=6) with the device and rehabilitees somewhat agreed (n=4) or agreed (n=1) with their satisfaction statements. The therapists and the rehabilitees found Indego to be a good training tool for physiotherapy, but the therapists emphasized that it does not replace other methods in therapy.

9 DISCUSSION

The purpose of this study was to investigate the usability and feasibility of Indego exoskeleton and effects of Indego training on functioning. The results and conclusions of the studies with physiotherapists and rehabilitees are discussed here based on the research questions.

9.1 How do physiotherapists consider the usability of Indego exoskeleton in gait rehabilitation?

The aim to study the feasibility and usability from the perspective of physiotherapists turned out to be challenging. The feasibility of using an exoskeleton has been studied by Delgado et al. (2019), within the domains of compliance, intensity and proficiency. Gagnon et al. (2018) defined the feasibility in terms of recruitment, attendance, learnability, performance and safety. Both studies used the rehabilitees' perspective. Feasibility usually refers to assessing projects and usability is mainly seen in developing webpages. In general, user experience studies are implemented with the end user, to support product or project development or identification of problems, in order to make improvements. This study took the user experience one step further, including facilitators' (physiotherapists) experience with exoskeletons.

After the survey of this study had been implemented, the first qualitative study concerning therapists' user experiences of exoskeleton was published (Read, Woolsey, McGibbon & O'Connell 2020). Their study concerned the opinions of three therapists. They highlighted benefits of increased repetitions of stepping and emphasized the issue that exoskeleton training cannot replace conventional physiotherapy. All their participants (N=3) also described mental workload related aspects, like additional know-how, skills and a large set of different considerations. In our study, the results were consistent with the study of Read et al. (2020) about the benefits of more versatile training options with more repetitions and longer distances. The therapists in our study also emphasized that exoskeleton training is just a part of physiotherapy, serving as an additional tool. Contrary to the study of Read et al. (2020), in our study the increased mental workload did not rise up, though some therapists (n=2) mentioned that the iPod settings were loading and challenging.

The small sample size is a limitation in our user experience survey among physiotherapists. One reason for the small size was due to problems sending and answering the questionnaire. The therapists in charge informed the researcher that all their therapists had answered, but only six questionnaires were answered and saved. Answers were comprehensive, contained versatile and common issues and most likely give a truthful

and extensive result of the work with Indego among these physiotherapists and in their clinics.

The questions in the physiotherapists' survey were not validated but were formed by the researcher. The questions were piloted and revised in order to give important information and to avoid misinterpretation. The selection of subjects in the two centers was appropriate, as the respondents had the longest experience with Indego in Finland.

9.2 How does learning to walk with Indego happen?

In our study, achievements like sit-to-stand, stand-to-sit, standing balance and walking 10m straight were completed within two sessions. Similarly, individuals with SCI in the study of Platz et al. (2016) had similar achievements but required more time before walking 10m (mean 4,9 sessions). In the 5-session study of Hartigan et al. (2015), individuals with SCI walked independently, or with minimal or moderate assistance from one therapist on indoor surfaces, including hard flooring, carpet and thresholds. Some of them also walked outdoor. In our study, three rehabilitees succeeded in walking over carpets and thresholds. One managed to use an elevator while wearing the exoskeleton. In elevator the person required help to keep the doors open, like participants in the study of Kozlowski et al. (2015).

The training with one rehabilitee was harder and more difficult in the last half of the training period. There was no clear reason for this trend. Possibilities can be overloading, difficulties in settings / adjustments, cold weather increasing spasticity when arriving to therapy, or poor sleep. This rehabilitee requided maximal to moderate level of assistance from the beginning until the end. That could perhaps be seen as a reason not to begin Indego training in the first hand, while he required a lot of help. No further conclusions can be made based on this study, but we are looking forward to seeing future studies investigating reasons, why not all rehabilitees benefit from exoskeleton rehabilitation.

The rate of perceived exertion (RPE) has been shown to decrease, as individuals with SCI learn to use the exoskeleton (Juszczak, Gallo & Bushnik 2018). In our study, RPE

remained roughly in the same level during the training for each rehabilitee. This may be contributed to the reduced level of support as participants learnt to use the device. Through adjustments to settings, training remained challenging. The overall aim was to improve ability to walk without the device, not only to learn to walk with the device.

In this study we found it important to be able to adjust the settings based on the needs of the rehabilitees. Hartigan et al. (2015) used the same settings for all SCI rehabilitees with Indego, when training five times. Other studies have not reported data about the settings employed. The physiotherapists in our study found it important and useful but a little challenging to set all adjustments properly. In our experience, knowing the rehabilitee and the diagnosis is important, as several aspects must be taken into consideration when deciding on appropriate settings. A strong understanding of neurological physiotherapy is needed to conduct appropriate gait training with neurological rehabilitees. This information is not emphasized in earlier studies.

The required number of therapists did not decrease in each case during the training process in our study. It is though presumable that repetitions in steps and length in distances with exoskeleton and two therapists is a lot higher than with only two therapists and no exoskeleton. Results relating to the level of assistance in studies with SCI rehabilitees cannot be used for comparison with rehabilitees having hemiparesis. With these rehabilitees another therapist is often required to help with an assistive device, as was in our study.

In this study with chronic outpatient rehabilitees it was not appropriate to have more than two therapy sessions per week. That meant that the majority of the rehabilitees (n=4) had no other kind of physiotherapy than exoskeleton training during intervention period. Even with this frequency, rehabilitees in this study still gained benefits. It would be useful to be able to evaluate how much more beneficial the training would be with subacute rehabilitees, when the plasticity of brains is high. In the study of Peurala et al. (2014), among stroke rehabilitees the frequency of gait training should be 3 – 5 times per week. As previously stated, it is important that rehabilitees receive comprehensive therapy, and not only gait training (Read, Woolsey, McGibbon & O'Connell 2020; Calbrò et al. 2018; Goffredo, Iacovelli et al. 2019). This was also the opinion of therapists in our study.

In Finland, the most common payers with chronic rehabilitees are Kela and insurance companies. In the subacute phase the payer is usually public special health care. For rehabilitation frequency to be higher than two sessions per week including gait training and conventional physiotherapy, rehabilitation would need to take place within rehabilitation wards in hospital or rehabilitation centres. Or if rehabilitees live near-by and are willing to include daily physiotherapy in their normal lives. The time for exoskeleton training sessions should be at least 60min, because fitting and adjustment of the device takes time. If exoskeleton rehabilitation will be shown to be effective in subacute phase in future studies, robotic rehabilitation should be implemented in subacute phase. The decision of robotic rehabilitation should be made by the organisations responsible of the treatment in early phase.

The heterogeneity of the study group can be seen as either a benefit or a disadvantage. Due to the variable nature of the condition, it is not possible to make conclusions for one particular diagnosis. On the other hand, this study provides a broad insight into possibilities when implementing exoskeleton assisted walking training with neurological rehabilitees. It also illustrates how different rehabilitees are and how the different situations and symptoms must be taken into consideration by the physiotherapist.

9.3 What effects can be gained during the training intervention?

In our study the majority of participants improved their results in the 6MWT and 10MWT, but the significance of changes was not reasonable to calculate in so small population. Similarly, in the study of Calabrò et al. (2018), chronic stroke patients improved theirs results in the 10MWT and 6MWT. In Molteni et al. (2017), subacute and chronic stroke rehabilitees improved their results in the 6MWT.

Despite the aligned progress in results, speeds were not equal when compared to earlier studies. Speeds from the 10MWT, at the end of earlier studies with strokes, were 0,53m/s (±0,19) (Goffredo, Iacovelli et al. 2019) and 0,56m/s (±0,33) (Molteni et al. 2017). In our study the speed varied from 0,02m/s to 0,75m/s, resulting in a mean of 0,24m/s, which is lower than previous studies. Also, results in the 6MWT were lower

in our study. In earlier studies total distances in the end were 145,50m (±50,41) (Goffredo, Iacovelli et al. 2019) and 92,0m (±59,3) (Molteni et al. 2017). In our study distances varied from 10m to 177m, resulting in a mean value of 67,6m. In the highlighted earlier studies distances at the beginning were higher than at the end of our study.

The improvement in FAC in this study was consistent with Goffredo, Guanziroli et al (2019) and Goffredo, Iacovelli et al. (2019), where subacute stroke rehabilitees gained significant improvements in FAC. The mean FAC value in the study of Goffredo, Iacovelli et al. (2019) was 2,5 (±1,48) at the beginning, and 4,0 (±0,0) by the end. In our study the mean values were at the beginning and end 2,4 (±0,9) and 3,4 (±0,9) respectively.

The results of the PROMIS showed positive changes only in global health. The system is validated and created to be relevant across all conditions for assessments of symptoms and functions. Not all questions are suitable for individuals with wheelchairs and appropriate questions had to be selected in advance. It measures the present situation and past 7 days, though many factors can affect the answering. Participants made contradictory interpretations of the questions and answered based on different interpretation at the beginning and end. The negative changes in PROMIS were not aligned with positive results from the walking tests. Even within similar issue areas (like the pain related questions) participants reported both improvement and worsening in similar questions. The overall change in PROMIS indicated worse results in functional ability for four out of five rehabilitees, though other results and their statements about their active daily living indicated the opposite. Clear conclusions of functioning could not be made based on PROMIS-questionnaire in this group.

The strengths in the study of rehabilitees are clear cause resulting in changes and outcome measures made both pre and post the intervention. In addition, rehabilitees were measured in similar and reliable way. Researcher bias was minimized by ensuring outcome measurements were based upon reliable and valid test protocols. In addition, the researcher acted as an observer during the intervention. Descriptive statistical analysis was conducted, but closer analysis, for example, of causality and correlation was not

carried out due to the small sample size and heterogeneity of the population. Weaknesses in the quality of this study include a lack of control group and small sample size, which limited our ability to make comprehensive conclusions.

Participants had different diagnoses but similar symptoms of hemiparesis. The small sample size allows us to describe results in more detail and from a wider perspective of exoskeleton users in studies. The heterogeneity of participants can be seen as threat or strength to quality. There were no changes in participants' treatment or care, other than intervention, though R1 had conventional and pool physiotherapy in addition to the Indego training (as earlier in addition to Lokomat training). This may be a threat to the quality of results, as other participants lost their conventional physiotherapy for eight weeks.

The absence of earlier Indego studies with stroke and TBI rehabilitees and the small amount of studies with other exoskeletons increases the need for additional studies with exoskeletons, and other rehabilitees than SCI. With these experiences and preliminary results with small population, it is possible to plan new studies and aim to larger study populations.

9.4 How do rehabilitees experience the robot-assisted gait rehabilitation with Indego exoskeleton?

Participants in our study felt comfortable using the device and did not have breathing difficulties while training. Results were aligned with the previous studies of Platz et al. (2016), Sale et al. (2018) and Zeilig et al (2012). Participants in our study felt almost as safe as participants in above mentioned studies (average value in this study was 3,8, in earlier studies it was 4 or higher). In the study of Sale et al. (2018), participants were satisfied with every statement. Results in our study were more similar to the studies of Platz et al (2016) and Zeilig et al (2012), where some statements were also disagreed and somewhat agreed. In the study of Zeilig et al. (2012), participants were least satisfied with simple adjusting / wearing and improvement of bowel movement. In the study of Platz et al. (2016), participants were least satisfied with statements associated with "not feeling excessive fatigue" and "training diminishes the spasticity". In our

study participants were least satisfied with improvement of bowel movement, like in the study of Zeilig et al. (2012).

Despite willingness to use the exoskeleton as a rehabilitation device, rehabilitees in our study were not willing to use the device as an assistive device in the home setting. In this study they required manual assistance from 1-2 therapists, which decreases the independence. In the home setting this would require the presence of an educated proxy or a personal assistant (Parker Hannifin Corp. 2016, 7). The rehabilitees in our study also had difficulties with assistive devices like walkers due to paretic upper limbs, which would possibly also cause problems in the home setting.

The satisfaction questionnaire was not validated, but the researcher performed the questions in a good manner without leading. Though the researcher was already familiar with the participants and this could have led to social desirability bias. The researcher team assumes that rehabilitees answered in a truthful way, though the testing was not blinded.

Similarly, with the SCI study of Gagnon et al. (2018), the attendance in our study was very high but recruitment in the first place challenging. In earlier studies with stroke rehabilitees (Calabrò et al. 2018; Goffredo, Guanziroli et al. 2019; Goffredo, Iacovelli et al. 2019; Molteni et al. 2017), the recruitment rates were not reported. In our study only six rehabilitees in the centers or clinics in the area were suitable following phone screening with physiotherapists (and eventually five were suitable for the device). In order to be able to utilize the exoskeleton more within the stroke population, the device could be wider. In addition, utilizing Indego within therapy requires at least two physiotherapists to be available available.

9.5 Future perspectives

Major opportunities of this study are the future possibilities in this field with the research team. The researcher will be reporting the results of these studies in scientific journals and conferences. A further study with extended setting and methods is about

to begin in SAMK and the research team is discussing international cooperation with Indego exoskeleton.

Future studies with a larger population should investigate more the functional ability in active daily living effected by exoskeleton training. In addition, studies should investigate correlations and arguments to whom the training is most beneficial. In practice the decision of who uses the device in rehabilitation and in what phase, must be made after thorough consideration.

This study showed that exoskeletons can provide benefits to chronic stroke and TBI rehabilitees. However, emphasis could be put into subacute rehabilitation. Incorporating exoskeleton training in rehabilitation offers an extra tool to neurological rehabilitation, thus should be implemented as part of a comprehensive rehabilitation program. Physiotherapists were satisfied with the exoskeleton and rehabilitees felt that the exoskeleton assisted walking was a comfortable and safe way of training ambulation.

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Study	Device	Method	Number of participants	Participants' background (injury level, years since injury)	Training sessions	Weeks	Sessions per week	Duration of sessions (min)	Tests & outcome measures	Conclusions	Other mentions
Farris et al. 2014	Indego	case study	1	SCI T10 complete, 10yrs					TUG, 10MWT, 6MWT, exertion (PCI)	Walking with exoskeleton: increased walking speed, decreased exertion relative to walking with KAFOs	Subject's history: 9yrs walking with KAFOs, 20 times walking with exoskeleton during one year. Tests were conducted in one session
Evans et al. 2015	Indego	single-group test	5	SCI T6-T12 complete, 11±6yrs					6MWT, GXT - respiratory gases	Cardiorespiratory and metabolic demands of EAW OG are at a moderate intensity.	Subjects' history: 6±2 exoskeleton sessions. Tests in comfortable and maximal speed.
Hartigan et al. 2015	Indego	single-group post-test study	16	SCI C5-L1 complete and incomplete	5			90	10MWT, 6MWT, level of assistance, donning & doffing time	With exoskeleton individuals with SCI are able to ambulate in indoors and outdoors. With higher level of injury the use for rehabilitation and exercise, with lower level injury more independent use.	device settings were similar for each participant
Juszczak et al. 2018	Indego	single-group pre-test post-test study	45	SCI T3-L2 complete and incomplete, 3,9yrs	26	8	3-4		spasticity (MAS), QoL (SWLS), exertion (BRPE), self-reported pain and spasticity (0-10), bowel function (change +/-)	EAW in people with SCI decreased spasticity and exertion	

Tefertiller et al. 2018	Indego	single-group study with mid point and final tests (cohort)	32	SCI T4-L2 complete and incomplete,	24	8	3	90	10MWT, 6MWT, TUG, 600MWT, donning / doffing time	The Indego exoskeleton is safe with SCI T4 and below. Many are able to donn and doff independenty. Walking speeds with exoskeleton can be close household ambulation speeds.	AEs: trochanter blister, ankle sprain
Kressler et al. 2014	Ekso	case series	3	SCI T1-T10 complete, ≥1yr	18	6	3	60	10MWT, 2MWT, spasticity (Spinal Cord Assessment Tool for Spastic Reflexes), brain activity (EEG), muscle activity (EMG) exercis condition (e.g.VO_2peak), neuropathic pain (0-10)	Persons with chronic, complete SCI can achieve similar walking speeds and distances with motor-incomplete injured persons when walking with exoskeleton. Results were: low energy cost, 18 sessions reduced pain severity and intensity and sleep interference.	
Kozlowski et al. 2015	Ekso	single-group cohort study	7	SCI C4-L1, complete and incomplete	24		1-2	120	Progress and level of assistance (number of session), walking tolerance (walk time, up time, number of steps, distance walked in longest walk and 2MWT), physical exertion (HR, BP, BRPE)	Regardless of injury level or completeness individuals with para- or tetraplegia can learn to use exoskeleton though some need minimal or moderate assistance after 24 sessions.	Only candidates who succeeded to walk in first trial were selected.
Molteni et al. 2017	Ekso	single-group pre-test post-test study	23	stroke, subacute and chronic	12		3	60	spasticity (Ash), MI, TCT, FAC, 10MWT, 6MWT, WHS	It is possible to influence on outcome of sub-acute and chronic stroke patients after 12 sessions of EAW. It is possible to tailor individual rehabilitation with EAW.	ICF mentioned as framework

Baunsgaard et al. 2017	Ekso	single-group pre-test post-test study	52	SCI C5-L1 complete and incomplete, recently injured ≤1yr / chronic >1yr		8	3	60	training characteristics (up time, walk time, number of steps), BRPE, LEMS. Participants with gait function: 10MWT, TUG, BBS, WISCI II.	Ekso is safe and feasible for individuals with SCI, no matter paraplegia or tetraplegia, recent or chronic, complete or incomplete. Exertion is low and indicates the possibility to use the device longer periods.	Participants had their usual training also, but that was not recorded.
Alamro et al. 2018	Ekso	Descriptive study	8+8	SCI C7-T4 motor-complete, ≥1yr (1-25)					trunk muscle activation (EMG) in Lokomat-training, EAW OG and EAW TM	Trunk muscles are better engaged during EAW than walking in Lokomat. Possible to help recruit and re-train the trunk muscles with EAW OG.	Participants were 8 persons with SCI and 8 able-bodied persons. Same tests were conducted with each participants after familiarization training and ability walk EAW OG at 1km/h.
Calabrò et al. 2018	Ekso	RCT	20+20	stroke, > 1/2 yr		8	5	45	10MWT, RMI, TUG, gait pattern (EMG), FPEC (EEG), CSE & SMI (TMS), Participants having EGT and OGT	EAW could be useful to promote mobility in people with stroke. Better effects on brain plasticity and connectivity re-modulation compared to conventional OGT.	All participants had also 60min conventional PT 5x/week
Gagnon et al. 2018	Ekso	single-group feasibility study	14	SCI C6-T10 complete, 0,8-31,4yrs	18	6	3	60	recruitment rate of potential participants, dropout rate, rate of attendance, progression in the ability in EAW, 10MWT (at the start and end)	EAW OG is feasible and relatively safe in long-term manual wheelchair users with complete SCI. Emphasizes the importance of pre-training program for passive mobility and standing tolerance.	They found difficulties in recruitment and had to exlcude candidates due to limited range of motion. 1 dropout after starting the intervention. 1 AE: calcaneus fracture
Sale et al. 2018	Ekso	single-group pre-test post-test study	8	SCI D1-L2 complete and incomplete, chronic	20	4-5	4-5	45	10MWT, 6MWT, TUG, BRPE, pain & fatigue (VAS), satisfaction questionnaire, spatiotemporal and kinematic parameters (3D GA)	EAW is effective, increases clinical outcomes, spatiotemporal and kinematics parameters. Strengthens results of earlier studies.	

Baunsgaard et al. 2018	Ekso	single-group pre-test post-test study	52	SCI C5-L1 complete and incomplete, recently injured ≤1yr / chronic >1yr		8	3	60	Pain (SCI Pain Data Set), spasticity (MAS), ROM (goniometry), SCIM. Bowel, lower urinary tract function and QoL (SCI Basic Data Sets)	Both recently and chronically injured can benefit from EAW. It is well-tolerated and does not provoke new type of pain. SCIM increased with both recently and chronically injured but QoL score increased in chronically injured patients.	Participants had their usual training also, but that was not recorded.
Goffredo & Guanziroli et al. 2019	Ekso	pilot pre-test post-test experimental study	46	stroke, subacute	15± 2		3-5	60	MBI, MAS, MI, TCT, FAC, WHS, 10MWT, 6MWT, TUG, TAM	EAW OG allows to improve clinical and gait outcomes in subacute stroke patients. It is positively accepted.	ICF mentioned as framework
Goffredo & Iacovelli et al. 2019	Ekso	comparative pre-test-post-test study	26	stroke	15	6	3	60	MI, MAS, MBI, TCT, FAC, TUG, 10MWT, 6MWT, WHS, gait analysis	End-effector and exoskeleton training produce better outcomes in 10MWT, 6MWT and TUG than conventional	In all groups gait training was combined with daily conventional therapy
Delgado et al. 2019	Ekso	single-group observational study	12	SCI	1-6		3	90	safety (AE), feasibility (compliance, intensity incl. 6MWT and RPE, proficiency)	EAW is safe and feasible in SCI acute inpatient rehabilitation for individuals having ambulation goals.	Efficacy was not studied. The length of training differed based on how long the participants stayed in the center.
Poritz et al. 2019	REX & Ekso	experimental case-study	7	MS, SCI, ABI		4-8	5	60	satisfaction questionnaire to compare REX & Ekso	Participants were somewhat likely to use both devices at home and in community. The authors emphasized the meaning of user feedback.	

Esquenazi et al. 2012	ReWalk	single-group post-test study	12	SCI T3-T12 motor-complete, 1-24,3	24	8	3	60-90	6MWT, 10MWT	Training with ReWalk was safe and after 8 weeks participants were able to walk without human assistance close to limited community ambulation speed.	Pain, spasticity and bowel and bladder functions were not formally recorded but based on participants' feedback there were positive signs.
Zeilig et al. 2012	ReWalk	case series, post-test study	6	SCI T5-T12, 3-7yrs	7-24			50	TUG, 6MWT, 10MWT, satisfaction questionnaire, pain & fatigue (VAS)	EAW with ReWalk was safe and well-tolerated	Tests were conducted after each participant managed to walk unassisted with crutches for 100m - on average 13-14 sessions.
Yang et al. 2015	ReWalk	single-group observational study	12	SCI C8-T11, complete and incomplete 1,5-19 yrs	12-102			60-120	10MWT, 6MWT, level of assistance	58% of study participants were able to ambulate at speed for outdoor activity-related community ambulation (≥0,40m/s). ReWalk is safe device for ambulation.	6MWT (including recording for 10MWT) was performed in every session after participant managed to take series of continuous steps without werbal cues. In-hospital study.
Benson et al. 2016	ReWalk	feasibility study	5	SCI C7-L1, complete and incomplete, 1,5-7,25yrs	20	10-31	2	120	10MWT, 6MWT and TUG with and without the device (if possible), pain & fatigue (VAS), Ash, ATD-PA	Considerable challenges in recruitment of participants decreases feasibility. To prevent AEs requires paying attention.	AE: talus fracture. Researchers narrowed the eligibility criteria during the conduct of the study based on adverse events : onset of injury 1-3 yrs before screening, regular (≥3x/wk) upright positioning, weight <90kg.
Platz et al. 2016	ReWalk	single-group observational study	7	SCI T5-L1, complete and incomplete	22	4-5	5	60	achievements in training (7 milestones), satisfaction questionnaire, QoL survey	Standing up, sitting down, keeping balance while standing and walking indoors activities could be performed, at least with close contact by PT. Some subject managed some activities with minimal or no assist. Participants felt comfortable using the device.	63 individuals showed interest in the first place, only 7 were suitable and able to participate this in-patient training. Also other training (therapy) was conducted.

Kozlowski et al. 2017	ReWalk	single-group pre-test post-test study	13	MS	20	8	3	30-90	accessibility, tolerability, risks, learnability, acceptability, MAS, timed 25-foot test, Neuro-QoL, PROMIS	ReWalk could provide opportunities for some individuals though not suitable for many persons with MS.	13 patients enrolled, 5 completed (2 screen failed: joint range of motion, 6 withdrew: transportation issues, walking-related pain, unspecified)
Guanziroli et al. 2019	ReWalk	two-group post test study	15	SCI D4-L4 ≥ 1/2 yr	14-33	8	3	60	6MWT, 10MWT, sit-to-stand time	EAW allows chronic complete SCI patients to walk independently overground in 8 weeks. Lower lesion levels allow a better coordination between upper body and robot.	Groups had same hardware but different software

Terms for abbreviations: SCI = spinal cord injury, 6MWT = 6 min walk test, 10MWT = 10 m walk test, TUG = Timed Up and Go, 2MWT = 2 min walk test, PCI = Physical Cost Index, KAFO = Knee-Ankle-Foot-Orthoses, OG = over-ground, EAW = Exoskeleton Assisted Walking, MAS = Modified Ashworth Scale, QoL = Quality of Life, SWLS = Satisfaction with Life Scale, (B)RPE = (Borg's) Rated Perceived Exertion Scale, EEG = Electroencephalography, EMG = Electro Myography, HR = Heart Rate, BP = Blood Pressure, Ash = Ashworth Scale, MI = Motricity Index, TCT = Trunk Control Test, FAC = Functional Ambulation Classification, WHS = Walking Handicap Scale, TM = Treadmill, PT = Physiotherapy / Physiotherapist, RMI = Rivermead Mobility Index, GA = Gait Analysis, MBI = Modified Barthel Index, FPEC = Frontoparietal Effective Connectivity, CSE = Corticospinal, Excitability, SMI = Sensory-motor Integration, TMS = Transcranial Magnetic Stimulation, EGT = Exoskeleton gait-training, OGT = Over-ground gait-training, AE = Adverse Event, TAM = Technology Acceptance Model, VAS = Visual Analog Scale, LEMS = Lower Extremity Motor Score, BBS = Berg Balance Scale, WISCI II = Walking Index for SCI II, ROM = Range of Motion, SCIM = SCI Independence Measure, ATD-PA = Assistive Technology Device Predisposition Assessment ©, MS = Multiple Sclerosis, ABI = Acquired Brain Injury, PROMIS = Patient-reported Outcomes Measurement and Information System

APPENDIX 2

Kysely fysioterapeuteille

Laitteen käytön aloitus

1. Kuinka kauan olet työskennellyt Indego Exoskeleton kävelyrobotin kanssa?
   ____vuotta____kuukautta

2. Mitä koulutusta olet saanut Indego Exoskeleton kävelyrobotin kanssa työskentelyyn?
   Ei mitään, vertaiskoulutus työpaikalla, indego specialist, indego trainer, indego instructor, muu/mikä?

3. Oliko laitteen käytön oppiminen mielestäsi helppoa/melko helppoa/ei helppoa eikä vaikeaa/melko vaikeaa/vaikeaa?

4. Koetko tarvitsevasi lisäkoulutusta? Ei / Kyllä. Jos vastasit kyllä, minkälaista?

5. Onko terapiatilanteissasi aiheutunut vahinkoja, loukkaantumisia, hiertymiä tai muita haittatapahtumia? Ei / Kyllä. Jos vastasit kyllä, minkälaisia?

Asiakastilanteet

6. Mitä asiakasryhmiä sinulla on ollut tai on Indego kuntoutuksessa?
   Eniten:
   Vähiten:

7. Kuinka monta asiakastilannetta sinulla on keskimäärin viikoittain Indego Exoskeleton kävelyrobotin kanssa?

8. Kuinka kauan kestää 1. kerran mittaukset? <15', 15'-30', 31'-45', 46-60', 61'-75', >75'
   Kuinka kauan kestää yksi asiakastilanne – sis donning & doffing? 30', 45', 60', 75', 90', >90'

9. Montako terapeuttia työskentelee useimmiten Indegoa käyttävän kuntoutujan kanssa terapiajakson alussa? _____
   Ja lopussa? _____
   Onko tilanteissa fysioterapeuttien lisäksi muita avustajia? Keitä ja millaisissa tilanteissa?_____

10. Kuinka pitkiä terapiajaksoja kuntoutujilla on keskimäärin Indego-kuntoutuksessa?
    Viikkoina:___ / kertoina: ___

11. Kuinka usein kuntoutujilla keskimäärin on Indego kävelyterapiaa? ___x/vk

12. Kuntoutujien Indego-kuntoutuksen maksajia voivat olla: Kela, vy, perusturva (kunta), erikoissairaanhoito, itse, muu/mikä? Mikä taho tällä hetkellä on yleisin maksaja?

Kokemukset kävelyrobotin käytöstä

13. Millaista on ollut käyttää Indego exoskeleton kävelyrobottia? (5-luokkainen Likert: erittäin helppoa, helppoa, ei helppoa eikä vaikeaa, vaikeaa, erittäin vaikeaa)
    a. Mikä on ollut helppoa? Mainitse kolme tekijää
    b. Mikä on ollut vaikeaa / haastavaa? Mainitse kolme tekijää

14. Käytätkö harjoittelussa enemmän ohjelmaa Motion+ vai Therapy+?
    Millaisissa tilanteissa käytät Motion+ -ohjelmaa?
    Millaisissa tilanteissa käytät Therapy+ -ohjelmaa?

15. Onko Indego-harjoittelulla ollut positiivisia vaikutuksia asiakkaidesi toimintakykyyn arjen eri osa-alueilla? Likert: paljon, melko paljon, kohtalaisesti, melko vähän, vähän, ei vaikutusta, ei arvioitu / en pysty arvioimaan
    a. Kipu (b280)
    b. Rasituksen sietotoiminnot (sydän ja verisuoni- sekä heng.kapasiteetti) (b455)
    c. Ulostustoiminnot (koostumus, tiheys, pidätyskyky, ilmavaivat, ummetus) (b525)
    d. Virtsaamistoiminnot (tiheys, pidätyskyky, runsasvirtsaisuus) (b620)
    e. Nivelten liikkuvuustoiminnot (b710)
    f. Lihasvoiman ja tehon tuottotoiminnot (b730)
    g. Lihasjänteystoiminnot (tonus / spastisuus) (b735)
    h. Tahdosta riippumattomat liikereaktiotoiminnot (asentoreaktiot, ojennusreaktiot, mukautumisreaktiot) (b755)
    i. Puhuminen (d330)
    j. Asennon vaihtaminen (d410) tai itsensä siirtäminen (d420)
    k. Käveleminen (d450), liikkuminen välineiden avulla (pyörätuoli, kävelyteline, ei tark exoskeleton) (d465)
    l. Peseytyminen (d510)
    m. WC:ssä käyminen (d530)
    n. Pukeutuminen (d540)
    Jokin muu toiminto, mikä?

16. Onko Indego-harjoittelulla ollut negatiivisia vaikutuksia asiakkaidesi toimintakykyyn arjen eri osa-alueilla? Likert: paljon, melko paljon, kohtalaisesti, melko vähän, vähän, ei vaikutusta, ei arvioitu / en pysty arvioimaan (mahd. tarkentava kommentointi)
    a. Kipu (b280)
    b. Rasituksen sietotoiminnot (sydän ja verisuoni- sekä heng.kapasiteetti) (b455)

c. Ulostustoiminnot (koostumus, tiheys, pidätyskyky, ilmavaivat, ummetus) (b525)
d. Virtsaamistoiminnot (tiheys, pidätyskyky, runsasvirtsaisuus) (b620)
e. Nivelten liikkuvuustoiminnot (b710)
f. Lihasvoiman ja tehon tuottotoiminnot (b730)
g. Lihasjänteystoiminnot (tonus / spastisuus) (b735)
h. Tahdosta riippumattomat liikereaktiotoiminnot (asentoreaktiot, ojennusreaktiot, mukautumisreaktiot) (b755)
i. Puhuminen (d330)
j. Asennon vaihtaminen (d410) tai itsensä siirtäminen (d420)
k. Käveleminen (d450), liikkuminen välineiden avulla (pyörätuoli, kävelyteline, ei tark exoskeleton) (d465)
l. Peseytyminen (d510)
m. WC:ssä käyminen (d530)
n. Pukeutuminen (d540)
Jokin muu toiminto, mikä?

Muutos aiempaan

17. Jos ajattelet vastaavien asiakasryhmien terapiaa ennen Indego exoskeleton kävelyrobottia, onko muuttunut? (5-luokkainen likert: erittäin paljon, paljon, kohtalaisesti, vähän, erittäin vähän)
    a. Mitkä asiat ovat muuttuneet positiivisesti? Mainitse kolme asiaa:
    b. Mitkä asiat ovat muuttuneet negatiivisesti? Mainitse kolme asiaa:

18. Miten koet Indegon käytön työvälineenä muuttaneen työtäsi ammatillisesti?

19. Miten tyytyväinen olet robotin käyttöön terapiassa (5-luokkainen Likert: erittäin tyytyväinen, tyytyväinen, kohtalaisen tyytyväinen, tyytymätön, erittäin tyytymätön)

20. Suosittelisitko Indego exoskeleton kävelyrobotin käyttöä kollegoille? Asteikolla 0-10, jossa 0 = en suosittelisi ja 10 = suosittelisin ehdottomasti. Perustele kolmella asialla.

Lisäkommentit

Kokemustesi myötä, mitä muuta haluat kertoa exoskeletonin käyttöön liittyen?

Indego ® - Lääketieteellinen hyväksymislomake (Eurooppa)
(Parker Hannifin Corporation 2016, suom. Taina Jyräkoski, projektitutkija, Samk 2019)

Hyvä Lääkäri,

Potilaanne_____ haluaisi käyttää ja mahdollisesti hankkia Indego exoskeleton –kävelyrobotin.

Henkilöt, joilla on alaraajojen heikkoutta halvauksen tai muun neurologisen diagnoosin vuoksi, voivat käyttää Indego –kävelyrobottia seisoakseen pystyasennossa ja kävelläkseen koulutetun Indego – spesialistin valvonnassa. Indego –kävelyrobotilla käveleminen vaatii apuvälineen käyttöä, kuten rollaattori, korkea kävelytuki (taso-ford, eva-teline tms.), kyynärsauvat tai muu apuväline, jonka Indego –spesialisti katsoo tarkoituksenmukaiseksi.

Indego –kävelyrobotti on motoroitu alaraajaortoosi, joka puetaan henkilön päälle. 12 kilon painoinen laite imitoi luonnollista liikettä asennon mukaisesti (kuten Segway, jolla olisi jalat). Selvittääksenne lisää Indego –kävelyrobotista, vierailkaa ystävällisesti www.indego.com.

Henkilöt, joilla on alaraajojen heikkous halvauksen tai muun neurologisen diagnoosin vuoksi, soveltuvat Indego-harjoitteluun, kun ovat saaneet lääketieteellisen hyväksynnän täyden painon varaamisesta ja kävelyharjoittelusta lääkäriltään.

Potilaan riskit Indego –kävelyrobotin käytössä ovat samanlaiset, kuin kävellessä alaraajaortoosien tai muiden kävelyortoosien sekä apuvälineen kanssa. Riskeihin voi kuulua lihasten kipeytyminen, nivelten turvotus, ihon ärsytys, kaatuminen, luunmurtuma tai jokin muu. Indego-spesialistit tekevät kaikkensa kuntoutujan turvallisuuden eteen Indego-harjoittelussa.

Indego-harjoitteluun soveltuvalla on

- Lonkkien, polvien ja nilkkojen passiivinen liikelaajuus neutraaliasentoon asti tai parempi
- Riittävä luun terveys sietääkseen täyden painon varauksen ja kävelyn apuvälineen turvin ilman suurentunutta luunmurtumariskiä
- Pystyasennon sietokyky ilman siitä aiheutuvia oireita (huimaus verenpaineen laskun vuoksi)
- Pituus 155-190cm, paino 113kg tai alle
- Ehjä iho alueilla, joihin Indego kiinnitetään
- Spastisuus tasolla 3 tai alle, mitattuna Modified Ashworth Scale –asteikolla (MAS)
- Vakaa tila sydän- ja verisuonisairauksien osalta

Lisäksi seuraavat vasta-aiheet tulee harkita:

- Liikerajoitukset lonkissa, polvissa tai nilkoissa
- Selvittämätön syvä laskimotukos
- Heikentynyt pystyasennon sietokyky ortostaattisen hypotension vuoksi
- Kontrolloimaton autonominen dysrefleksia
- Ongelmat ihoalueilla, joihin Indego kiinnitetään

- Uudisluun muodostuminen (heterotooppinen ossifikaatio), mikä rajoittaa nivelen liikelaajuutta lonkissa, polvissa tai nilkoissa
- Alaraajaproteesi
- Kontrolloimaton liian korkea tai matala verenpaine
- Kognitiiviset ongelmat, jotka vaikeuttavat ymmärtämään annettuja ohjeita
- Näköongelmat, jotka häiritsevät turvallista kävelyä
- Muu tila, minkä lääkäri toteaa estävän Indego-harjoittelun kuntoutujalla

Hyvä lääkäri, täyttäkää **vain yksi** alla olevista suositusosioista:

Lääkärin suositus:

Potilaan nimi:_____

Hyvä lääkäri, merkitkää vain 1 alla olevista 3 ruudusta, joka on tarkoituksenmukaisin ilmaus potilaaseen liittyen (2 ruutua, jotka eivät liity kuntoutujaan, voi jättää tyhjäksi):

□ Olen arvioinut potilaan ja hänellä **on suostumukseni** käyttää Indego-kävelyrobottia. Ymmärrän laitteen fyysiset ja fysiologiset tekijät, enkä näe syytä, miksi yllä olevan henkilön ei tulisi käyttää tätä laitetta.

□ Olen arvioinut potilaan ja hänellä **on suostumukseni** käyttää Indego-kävelyrobottia. Ymmärrän laitteen fyysiset ja fysiologiset tekijät, enkä näe syytä, miksi yllä olevan henkilön ei tulisi osallistua, **mutta vaadin varovaisuutta, koska (kuvaile):**

□ Olen arvioinut potilaan ja hänellä **ei ole suostumustani** käyttää Indego-kävelyrobottia. (mikäli tämä ilmaus on merkitty, potilas ei osallistus harjoitteluun)

Allekirjoittanut lääkäri tiedostaa, että Parker Hannifin Corporation, sen johtajat, virkailijat, työntekijät, tytäryhtiöt, asiamiehet ja myyntiedustajat luottavat lääkärin huolelliseen selvitykseen Indegon käytön suhteen. Indego spesialisti voi lääkärin suostumuksesta huolimatta jatkaa tai olla jatkamatta Indego-harjoittelua perustuen omaan arviointiin potilaasta.

Lääkärin allekirjoitus: _____ pvm: _____

Nimen selvennös: _____

Osoite: _____

_____

Sähköposti: _____

Puhelin: _____ Erikoistuminen: _____

APPENDIX 4

Kuntoutujien lähtötilanteen kartoitus

Nimi:

Sukupuoli:

Ikä:

Dg / syy alaraajojen heikkouteen: ____ sy-vamma, vauriotaso: _____

____ aivoinfarkti: pareettinen puoli oik:____ vas:____

____ aivoveren-vuoto: pareettinen puoli oik: ____ vas: ____

____ aivovamma, alaraajojen heikkous toispuoleinen oik: __ vas:_

Molemmin puoleinen____

Kulunut aika vammautumisesta:

Minulla on ollut murtumia kehossani viimeisen X vuoden aikana: ei ____ kyllä_____, missä ja montako

Olen kävellyt aiemmin Lokomat -kävelyrobotilla: ei_____ kyllä_____

Olen kävellyt aiemmin Indego -kävelyrobotilla: ei_____ kyllä_____

Aika ja paikka:
Tutkijan allekirjoitus:

Alku- ja loppukysely
(tutkija täyttää haastattelemalla)

Kävelykykyni (FAC kävelyluokituksen mukaisesti):

en pysty kävelemään tai tarvitsen vähintään kahden henkilön apua	□
Tarvitsen jatkuvaa manuaalista (käsin) ohjausta yhdeltä avustajalta, joka auttaa siirtämään painoa ja säilyttämään tasapainon	□
Tarvitsen jatkuvaa tai ajoittaista tukea yhdeltä avustajalta, Joka auttaa tasapainon ja koordinaation säilyttämisessä	□
Tarvitsen kävelyyn verbaalista (suullista) ohjausta ilman fyysistä kosketusta	□
Kävelen itsenäisesti tasaisella alustalla, mutta tarvitsen apua portaissa, kaltevilla tai epätasaisilla pinnoilla	□
Kävelen itsenäisesti joka paikassa	□

Liikkumisen apuvälineeni: mitä ja missä tilanteissa (koti, työ, terapia)?

_____

_____

_____

Seison seisomatelineessä keskimäärin:	päivittäin	□
	4-6 päivänä/vk	□
	3-4 päivänä/vk	□
	1-2 päivänä/vk	□
	alle 1päivänä/vk	□

Seisomisaikani seisomatelineessä on keskimäärin:	0-15min	□
	16-30min	□
	31-45min	□
	46-60min	□
	yli 60min	□

Yleinen terveyteni:

	Erinomainen	oikein Hyvä	hyvä	tyydyt-tävä	huono
Sanoisitko, että terveytesi on yleensä:	□	□	□	□	□
Sanoisitko, että elämänlaatusi on yleensä:	□	□	□	□	□
Millaiseksi arvioisit psyykkisen terveytesi, kuten mielialasi ja ajattelukykysi, yleensä?	□	□	□	□	□
Millaiseksi arvioisit tyytyväisyytesi sosiaaliseen elämääsi					

ja ihmissuhteisiisi yleensä?	□	□	□	□	□
Millaiseksi arvioisit suoriutumistasi tavallisista sosiaalisista toimistasi ja rooleistasi yleensä (tämä sisältää toimet kotona, työssä ja työyhteisössäsi sekä vastuut vanhempana, lapsena, puolisona, työntekijänä, ystävänä jne.)?	□	□	□	□	□

Viimeisten 7 päivän aikana…	Ei koskaan	harvoin	joskus	usein	koko ajan
Miten usein sinua ovat vaivanneet tunne-elämän ongelmat, kuten ahdistuksen, masentuneisuuden tai ärtymyksen tunteet?	□	□	□	□	□

	Ei uupumusta	vähäinen	kohtalainen	voimakas	hyvin voimakas
Miten arvioit uupumustasi keskimäärin	□	□	□	□	□

Miten arvioisit kipuasi keskimäärin?

□	□	□	□	□	□	□	□	□	□	□
0 ei kipua	1	2	3	4	5	6	7	8	9	10 pahin kuviteltavissa oleva kipu

Tarkentavat osiot:

Kipu

Viimeisten 7 päivän aikana…	Ei kipua	lievää	kohtalaista	voimakasta	erittäin voimakasta
Miten voimakasta kipusi oli pahimmillaan?	□	□	□	□	□
Miten voimakasta kipusi oli keskimäärin?	□	□	□	□	□

	Ei lainkaan	hieman	jossain määrin	melko paljon	hyvin paljon
Kuinka paljon kipu häiritsi elämästäsi nauttimista?	□	□	□	□	□
Kuinka paljon kipu haittasi keskittymiskykyäsi?	□	□	□	□	□
Kuinka paljon kipu haittasi päivittäisiä toimiasi?	□	□	□	□	□
Kuinka paljon kipu vaikutti kykyysi osallistua sosiaaliseen elämään?	□	□	□	□	□

	Ei kipua	lievää	kohtalaista	voimakasta	erittäin voimakasta
Miten voimakasta kipusi on juuri nyt?	□	□	□	□	□

Uni

Viimeisten 7 päivän aikana…	Erittäin heikko	heikko	kohta-lainen	hyvä	erittäin hyvä
Unenlaatuni oli	□	□	□	□	□
	Ei lainkaan	hieman	jossain määrin	melko paljon	hyvin paljon
Minulla oli ongelmia unen kanssa	□	□	□	□	□

Uupumus

Viimeisten 7 päivän aikana…	Ei lainkaan	hieman	jossain määrin	melko paljon	hyvin paljon
Miten uupunut olit keskimäärin?	□	□	□	□	□
Missä määrin uupumuksesi häiritsi fyysistä toimintakykyäsi?	□	□	□	□	□

Fyysinen toimintakyky

	Ilman vaikeuksia	pienin vaikeuksin	kohta-laisin vaikeuksin	suurin vaikeuk-sin	en pysty
Pystytkö tekemään kotitöitä, kuten imurointia tai pihatöitä	□	□	□	□	□
Pystytkö työntämään raskaan oven auki?	□	□	□	□	□
Pystytkö pukeutumaan ja myös solmimaan kengän-nauhasi ja napittamaan vaatteesi?	□	□	□	□	□
Pystytkö käymään ostoksilla ja muilla asioilla?	□	□	□	□	□
Pystytkö kumartumaan ja poimimaan vaatteita lattialta?	□	□	□	□	□
	Ei lainkaan	hyvin vähän	jonkin verran	hyvin paljon	en pysty lainkaan
Rajoittaako terveytesi tällä hetkellä peseytymistäsi tai pukeutumistasi?	□	□	□	□	□
Rajoittaako terveytesi tällä hetkellä roskien viemistä ulos?	□	□	□	□	□

Suolen ja rakon toiminnot

Tämän osion kysymykset otetaan mukaan, mikäli PROMIS-kyselyn käännöstyö valmistuu ennen syksyn harjoittelujaksoa.

Kuntoutuja:
Aika ja paikka:
Tutkijan allekirjoitus:

APPENDIX 6

Tyytyväisyyskysely

Vastaukset 5-luokkaisella Likert -asteikolla: 1 vahvasti eri mieltä, 2 eri mieltä, 3 jotakuinkin samaa mieltä, 4 samaa mieltä, 5 vahvasti samaa mieltä

1. Laitteen käytön harjoittelu / opettelu ei ole monimutkaista
2. Laitteen käyttäminen / säätäminen on melko yksinkertaista
3. Laitteen kanssa harjoittelu oli miellyttävää
4. Laitteen käyttö ei aiheuttanut huomattavaa kipua
5. En kokenut kohtuutonta väsymystä laitteen kanssa harjoitellessani
6. Harjoittelujakson päätyttyä koin, että laitteen käyttö oli miellyttävältä
7. Laitteen kanssa harjoittelu vähensi jalkojeni spastisuutta
8. Minulla ei ollut hengitysvaikeuksia harjoitellessani laitteen kanssa
9. Koin suolen toiminnassani parannusta harjoitteluohjelman aikana
10. Harjoittelun päätyttyä laitteen käyttö tuntui turvalliselta

Lisäkysymykset

1. Voisin kuvitella käyttäväni laitetta kävelyn apuvälineenä kotioloissani
2. Käyttäisin laitetta jatkossakin harjoitteluvälineenä

Kuntoutuja:
Aika ja paikka:
Tutkijan allekirjoitus:

APPENDIX 7

Indego-exoskeleton kävelykuntoutuksessa – fysioterapeuttien ja kuntoutujien käyttökokemukset sekä vaikutukset kävelyyn ja toimintakykyyn Suomessa

Tiedote kuntoutujille ja suostumus tutkimukseen osallistumisesta

Tutkija
Taina Jyräkoski, Fysioterapeutti amk,
Projektitutkija
SAMK, teknologian osaamisalue
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Tutkimuksen taustatiedot
SAMKin hallinnoima tutkimus toteutetaan osana Satakuntaliiton rahoittamaa Satakunta DigiHealth hanketta. Tämä kävelykuntoutukseen liittyvän Indego exoskeleton-robotin tutkimus toteutetaan vuoden 2019 aikana Kuntoutuksen ylemmän ammattikorkeakoulututkinnon opinnäytetyönä.
Tutkimus toteutetaan yhteistyössä mahdollisesti seuraavien tahojen kanssa: Mustasaaren kuntoutuskeskus, Laitilan terveyskoti ja Validia kuntoutus Helsinki. Kokeellisen tutkimuksen toteuttamispaikat täsmentyvät syksyllä 2019.

Tutkimuksen tarkoitus, tavoite ja merkitys
Tässä tutkimuksessa on tarkoitus selvittää Indego-exoskeletonin käytettävyyttä, käyttökokemuksia ja vaikutuksia asiakkailla, joilla on vaikeuksia kävelykyvyssään selkäydinvammasta tai äkillisestä aivovauriosta (aivoinfarkti, aivoverenvuoto tai aivovamma) johtuen.
Tavoitteena on selvittää robottiavusteisen kävelyharjoittelun mahdollisuuksia erilaisten asiakasryhmien kanssa ja edistää tehokkaan kuntoutuksen kehittymistä Suomessa.

Tässä tutkimuksessa kerättävän tutkimusaineiston käyttö, käsittely ja säilyttäminen
Tutkimusaineisto, joka saadaan sinulle tehtyjen kyselyiden vastauksista, harjoittelujaksosta saaduista huomioista ja testaustuloksistasi, säilytetään manuaalisina tutkijan ja tutkimusryhmän käytettävissä sekä digitaalisena tutkijan henkilökohtaisessa tiedostossa SAMK:n tietokannassa.
Digitaaliseen muotoon muutettaessa tiedot koodataan, jolloin henkilötietojasi ja tutkimuksessa kerättyjä tuloksia ei voi yhdistää toisiinsa kuin tutkija. Tunnisteeton materiaali säilytetään SAMK:n tietokannassa salasanan takana ja käyttöoikeus materiaaliin on kyseisen tutkimuksen jälkeen tutkijalla ja SAMK:lla. Jos olet kuntoutuslaitoksen asiakas tutkimuksen aikana, laitoksella on käyttöoikeus tunnisteettomiin tuloksiisi tämän tutkimuksen jälkeen.

Tutkimukseen mukaan tulevat kuntoutujat
Tutkimukseen valitaan kuntoutujat alueen kuntoutusyrittäjien tai kuntoutuslaitosten kautta fysioterapeuttien avulla. Ennen harjoittelujakson aloitusta jokainen tutkimukseen esivalittu kuntoutuja käy lääkärin tarkastuksessa ja saa kirjallisen lausunnon soveltuvuudestaan Indego-kävelyharjoitteluun.
Kuntoutujana sinun tulee sitoutua harjoittelujaksoon, jossa Indego-harjoittelua toteutetaan omassa terapiaympäristössäsi esim. kahdesti viikossa 6-8 vk:n ajan oman fysioterapeuttisi läsnä ollessa.

Harjoittelujakson alussa selvitetään kyselyllä / haastattelulla taustatietosi (nimi, ikä, sairastumisesta kulunut aika jne.), kokemukset kivusta ja jaksamisesta, liikunta- ja toimintakyky. Kävelykykysi testataan jakson alussa, puolivälissä ja lopussa 10m ja 6min kävelytestillä (laitteen kanssa ja mahdollisesti myös ilman). Jokaisella harjoittelukerralla seurataan kipua, jaksamista, ihon tilaa, sydämen sykettä, verenpainetta ja kokemusta kuormittuneisuudesta. Jakson lopussa selvitetään uudelleen kyselyn / haastattelun avulla kokemukset kivusta ja jaksamisesta sekä liikunta- ja toimintakyky. Harjoittelun päätyttyä selvitetään kyselyllä / haastattelulla kokemuksesi laitteen käytöstä. Testaaja on Satakunnan alueella ja Laitilassa tutkimuksen tutkija, ja muilla toteutuspaikkakunnilla kokenut fysioterapeutti.

Harjoittelukerroilla tehdään myös havaintoja oppimisen edistymisestä laitteen pukemisessa ja riisumisessa sekä kävelymatkassa ja jaksamisessa harjoittelukerran aikana.

Tutkimuksen mahdolliset hyödyt ja haitat tutkittaville
Sinulla on mahdollisuus harjoitella kävelyä ja pystyasentoa toiminnallisesti robottiavusteisesti harjoittelujakson ajan. Olemassa olevaa heikkoa kävelykykyä voidaan näin mahdollisesti parantaa muiden pystyasennon hyötyjen ohella – suolen toiminnot, kokemus muiden tasolla toimimisesta, alaraajojen liikkuvuus, luuntiheys. Olet mukana uuden kuntoutusmuodon ja apuvälineen käyttötutkimuksessa, jonka kävelyrobotti voi tulevaisuudessa olla kävelyn apuväline kotiolosuhteissa.

Exoskeleton-harjoittelu voi aiheuttaa ihoon hiertymiä tai alaselän kipuoireita. Etukäteen selvitettävä luuntiheys ja pystyasennon sietokyky vähentävät oleellisesti riskiä luunmurtumista tai kaatumisista. 1-3 fysioterapeuttia on koko harjoittelun ajan lähelläsi avustaen tarvittavan määrän, jotta harjoittelu on turvallista. Jos odottamattomia tapaturmia tai sairaskohtauksia sattuu harjoittelun aikana, terapiahenkilöstö on valmis hälyttämään riittävästi apua välittömästi. Mikäli kuntoutujan hermokudoksen vaurio on totaalinen, ei kävelyrobottiharjoittelulla voida palauttaa kävelykykyä ilman apuvälinettä. Harjoittelu voi olla varsinkin jakson alussa väsyttävää ja raskasta.

Sinulle ei koidu ylimääräisiä kuluja, eikä sinulle makseta korvausta tutkimukseen osallistumisesta.

Miten ja mihin tutkimustuloksia aiotaan käyttää
Tutkimuksen tulokset raportoidaan kirjallisesti ja opinnäytetyö on julkisesti nähtävissä SAMK:n kirjaston tietokannassa ja opinnäytetöiden Theseus -tietokannassa. Tutkimuksen tuloksia esitetään julkisesti erilaisissa seminaareissa Suomessa. Tutkimuksesta kirjoitetaan julkaisuja ja tässä kerättyä tutkimusaineistoa voidaan jatkossa käyttää seuraavien tutkimusten tukena.

Kuntoutujan oikeudet
Osallistuminen tutkimukseen on täysin vapaaehtoista. Sinulla on tutkimuksen aikana oikeus kieltäytyä tutkimuksesta ja keskeyttää tutkimukseen osallistuminen missä vaiheessa tahansa ilman, että siitä aiheutuu Sinulle mitään seuraamuksia. Tutkimuksen järjestelyt ja tulosten raportointi ovat luottamuksellisia. Tutkimuksesta saatavat henkilökohtaiset tiedot tulevat ainoastaan tutkijan ja tutkijaryhmän käyttöön ja tulokset julkaistaan tutkimusraporteissa siten, ettei Sinua voi tunnistaa. Sinulla on oikeus saada lisätietoa tutkimuksesta tutkijalta tai tutkijaryhmän muilta jäseniltä missä vaiheessa tahansa.

Vakuutukset
Harjoittelujakson kävelyharjoittelu tapahtuu terapia-ajallasi, jolloin laitoksen tai terapeutin potilasvakuutus ja toiminnanvastuuvakuutus ovat voimassa, kuten terapiassasi muulloinkin. Tutkittavan tiedot on tallennettu SAMK:n henkilötietorekisteriin, tutkittava saa halutessaan rekisteriselosteen tutkijalta nähtäväkseen.

Kuntoutujan suostumus tutkimukseen osallistumisesta

Olen perehtynyt tämän tutkimuksen tarkoitukseen ja sisältöön, kerättävän tutkimusaineiston käyttöön, kuntoutujalle aiheutuviin mahdollisiin haittoihin sekä tutkittavien oikeuksiin ja vakuutusturvaan. Suostun osallistumaan tutkimukseen annettujen ohjeiden mukaisesti. En osallistu harjoituskerroille tai fyysistä rasitusta sisältäviin tutkimuksiin flunssaisena, kuumeisena, toipilaana tai muuten huonovointisena. Voin halutessani peruuttaa tai keskeyttää osallistumiseni tai kieltäytyä tutkimukseen osallistumisesta missä vaiheessa tahansa. Tutkimustuloksiani ja kerättyä ainestoa saa käyttää ja hyödyntää sellaisessa muodossa, jossa yksittäistä tutkittavaa ei voi tunnistaa.

Päiväys	Tutkittavan allekirjoitus	Nimen selvennys

Päiväys	Tutkijan allekirjoitus	Nimen selvennys

Tietoa tutkimukseen osallistuvalle

Olet osallistumassa Satakunnan ammattikorkeakoulun opintoihin kuuluvan opinnäytetyöhön liittyvään tutkimukseen.

Tämä seloste kuvaa, miten henkilötietojasi käsitellään tutkimuksessa.

Tähän tutkimukseen osallistuminen on vapaaehtoista. Voit myös halutessasi keskeyttää osallistumisesi tutkimukseen. Jos keskeytät osallistumisesi, ennen keskeytystä kerättyä aineistoa voidaan kuitenkin käyttää tutkimuksessa. Tässä tietosuojaselosteessa kerrotaan tarkemmin, mitä oikeuksia sinulla on ja miten voit vaikuttaa tietojesi käsittelyyn.

1. Opinnäytetyön rekisterinpitäjä

Satakunnan ammattikorkeakoulu
Osoite: Satakunnankatu 23, 28101 Pori

Yhteyshenkilö tutkimusta koskevissa asioissa:
Nimi: Taina Jyräkoski
Osoite: Satakunnankatu 23, 28101 Pori
Puhelinnumero: 044 710 3228
Sähköpostiosoite: taina.m.jyrakoski@samk.fi

2. Kuvaus tutkimuksesta ja henkilötietojen käsittelyn tarkoitus

Henkilötietoja käsitellään luottamuksellisesti opinnäytetyön tutkimuksen tekemiseksi. Opinnäytetyössä ”Indego-exoskeleton kävelykuntoutuksessa – fysioterapeuttien ja kuntoutujien käyttökokemukset sekä vaikutukset kävelyyn ja toimintakykyyn Suomessa” tutkitaan robotti-avusteisen kävelyharjoittelun vaikutuksia kuntoutujilla sekä kuntoutujien käyttökokemuksia. Henkilötietoja käsitellään kuntoutujien lähtötilanteen kartoittamiseksi. Henkilötietoja ei käytetä muuhun tarkoitukseen, eikä henkilötiedot ole nähtävillä työn lopullisessa raportissa.

3. Opinnäytetyön tekijä

Nimi: Taina Jyräkoski
Osoite: Satakunnankatu 23, 28130 Pori
Puhelinnumero: 044 710 3228
Sähköpostiosoite: taina.jyrakoski@student.samk.fi

1. Tietosuojavastaavan yhteystiedot

Satakunnan ammattikorkeakoulun tietosuojavastaava on Osmo Santavirta. Häneen saa yhteyden sähköpostiosoitteesta tietosuojavastaava@samk.fi

2. Tutkimuksen suorittajat

Satakunta Digi-Health -hankkeen tutkijat SAMK:ssa.

3. Opinnäytetyön aihe ja kesto

Opinnäytetyön nimi: Indego-exoskeleton kävelykuntoutuksessa – fysioterapeuttien ja kuntoutujien käyttökokemukset sekä vaikutukset kävelyyn ja toimintakykyyn Suomessa

X Kertatutkimus ☐ Seurantatutkimus

Henkilötietojen käsittelyn kesto:
Opinnäytetyö toteutetaan vuosien 2019 – 2020 aikana

4. Henkilötietojen käsittelyn oikeusperuste

Henkilötietoja käsitellään seuraavalla yleisen tietosuoja-asetuksen 6 artiklan 1 kohdan mukaisella perusteella:

X tutkittavan suostumus
☐ rekisterinpitäjän lakisääteisen velvoitteen noudattaminen
☐ yleistä etua koskeva tehtävä/rekisterinpitäjälle kuuluvan julkisen vallan käyttö:
  ☐ tieteellinen tai historiallinen tutkimus tai tilastointi
  ☐ tutkimusaineistojen arkistointi
☐ rekisterinpitäjän tai kolmannen osapuolen oikeutettujen etujen toteuttaminen
mikä oikeutettu etu on kyseessä:

5. Mitä tietoja keräämme ja tallennamme

Henkilön yksilöintitiedoista kerätään ja tallennetaan nimi, ikä ja yhteystiedot. Muita kerättäviä tutkimustietoja ovat henkilön toimintakykyyn liittyvät tekijät, kävelykyvyn testaustulokset ja käyttökokemukset.

A. Arkaluonteiset henkilötiedot

Opinnäytetyössä käsitellään seuraavia arkaluonteisia henkilötietoja:

☐ Rotu tai etninen alkuperä
☐ Poliittiset mielipiteet
☐ Uskonnollinen tai filosofinen vakaumus
☐ Ammattiliiton jäsenyys
☐ Geneettiset tiedot

☐ Biometristen tietojen käsittely henkilön yksiselitteistä tunnistamista varten
X Terveys
☐ Luonnollisen henkilön seksuaalinen käyttäytyminen tai suuntautuminen

Tietosuoja-asetuksen 9 artiklan 2 kohdan mukaan arkaluonteisten tietojen käsittely perustuu seuraavaan oikeusperusteeseen:

X Tutkittavan/osallistujan suostumus
☐ Tieteellinen tai historiallinen tutkimustarkoitus tai tilastollinen tarkoitus
☐ Tutkittava/osallistuja on saattanut käsiteltävät arkaluonteiset tiedot julkisiksi
☐ Muu peruste (mikä?):

☐ Tutkimuksessa tai kehittämistyössä käsitellään rikostuomiota tai rikkomuksia koskevia tietoja.

1. Mistä henkilötietoja kerätään

Henkilötiedot ja toimintakykyyn sekä terveyteen liittyvät tiedot kerätään osallistujilta haastattelemalla ja kyselyillä. Vaikutukset kävelykykyyn testataan kävelykykytesteillä.

2. Tietojen siirto tai luovuttaminen muille

Henkilötietoja ei siirretä tai luovuteta muille osapuolille, ellei erillisellä sopimuksella tutkimusyhteistyötaho ja ko. tahon kuntoutuja sitä halua.

3. Tietojen siirto tai luovuttaminen EU:n tai Euroopan talousalueen ulkopuolelle

Tietoja ei siirretä.

4. Automatisoitu päätöksenteko

Automaattisia päätöksiä ei tehdä.

1. Henkilötietojen suojauksen periaatteet

X Tiedot ovat salassa pidettäviä.

Manuaalisen aineiston suojaaminen: säilytetään SAMK:ssa lukollisessa tilassa, johon vain vastuututkijalla on pääsy

Tietojärjestelmissä käsiteltävät tiedot:
X käyttäjätunnus X salasana ☐ käytön rekisteröinti ☐ kulunvalvonta
☐ muu, mikä:

Suorien tunnistetietojen käsittely:
X Suorat tunnistetiedot poistetaan analysointivaiheessa
☐ Aineisto analysoidaan suorin tunnistetiedoin, koska (peruste suorien tunnistetietojen säilyttämiselle):

2. Henkilötietojen käsittely tutkimuksen tai kehittämistyön päättymisen jälkeen

☐ Tutkimusrekisteri tai muu rekisteri hävitetään
X Tutkimusrekisteri tai muu rekisteri arkistoidaan:
X ilman tunnistetietoja ☐ tunnistetiedoin

Mihin aineisto arkistoidaan ja miten pitkäksi aikaa: Aineisto arkistoidaan SAMK:n tietojärjestelmään ja mahdollisesti siirretään pitkäaikaissäilytykseen kansalliseen järjestelmään

3. Mitä oikeuksia sinulla rekisteröitynä/tutkittavana on ja oikeuksista poikkeaminen

Yhteyshenkilö tutkittavan oikeuksiin liittyvissä asioissa, johon voi ottaa yhteyttä on Taina Jyräkoski.

<u>Suostumuksen peruuttaminen (tietosuoja-asetuksen 7 artikla)</u>
Sinulla on oikeus peruuttaa antamasi suostumus, mikäli henkilötietojen käsittely perustuu suostumukseen. Suostumuksen peruuttaminen ei vaikuta suostumuksen perusteella ennen sen peruuttamista suoritetun käsittelyn lainmukaisuuteen.

<u>Oikeus saada pääsy tietoihin (tietosuoja-asetuksen 15 artikla)</u>
Sinulla on oikeus saada tieto siitä, käsitelläänkö henkilötietojasi hankkeessa ja mitä henkilötietojasi hankkeessa käsitellään. Voit myös halutessasi pyytää jäljennöksen käsiteltävistä henkilötiedoista.

<u>Oikeus tietojen oikaisemiseen (tietosuoja-asetuksen 16 artikla)</u>
Jos käsiteltävissä henkilötiedoissasi on epätarkkuuksia tai virheitä, sinulla on oikeus pyytää niiden oikaisua tai täydennystä.

<u>Oikeus tietojen poistamiseen (tietosuoja-asetuksen 17 artikla)</u>
Sinulla on oikeus vaatia henkilötietojesi poistamista seuraavissa tapauksissa:

a) henkilötietoja ei enää tarvita niihin tarkoituksiin, joita varten ne kerättiin tai joita varten niitä muutoin käsiteltiin
b) peruutat suostumuksen, johon käsittely on perustunut, eikä käsittelyyn ole muuta laillista perustetta
c) vastustat käsittelyä (kuvaus vastustamisoikeudesta on alempana) eikä käsittelyyn ole olemassa perusteltua syytä
d) henkilötietoja on käsitelty lainvastaisesti; tai
e) henkilötiedot on poistettava unionin oikeuteen tai jäsenvaltion lainsäädäntöön perustuvan rekisterinpitäjään sovellettavan lakisääteisen velvoitteen noudattamiseksi.

Oikeutta tietojen poistamiseen ei kuitenkaan ole, jos tietojen poistaminen estää tai vaikeuttaa suuresti käsittelyn tarkoituksen toteutumista tieteellisessä tutkimuksessa.

Oikeus käsittelyn rajoittamiseen (tietosuoja-asetuksen 18 artikla)
Sinulla on oikeus henkilötietojesi käsittelyn rajoittamiseen, jos kyseessä on jokin seuraavista olosuhteista:

a) kiistät henkilötietojen paikkansapitävyyden, jolloin käsittelyä rajoitetaan ajaksi, jonka kuluessa yliopisto voi varmistaa niiden paikkansapitävyyden
b) käsittely on lainvastaista ja vastustat henkilötietojen poistamista ja vaadit sen sijaan niiden käytön rajoittamista
c) yliopisto ei enää tarvitse kyseisiä henkilötietoja käsittelyn tarkoituksiin, mutta sinä tarvitset niitä oikeudellisen vaateen laatimiseksi, esittämiseksi tai puolustamiseksi
d) olet vastustanut henkilötietojen käsittelyä (ks. tarkemmin alla) odotettaessa sen todentamista, syrjäyttävätkö rekisterinpitäjän oikeutetut perusteet rekisteröidyn perusteet.

Oikeus siirtää tiedot järjestelmästä toiseen (tietosuoja-asetuksen 20 artikla)
Sinulla on oikeus saada yliopistolle toimittamasi henkilötiedot jäsennellyssä, yleisesti käytetyssä ja koneellisesti luettavassa muodossa, ja oikeus siirtää kyseiset tiedot toiselle rekisterinpitäjälle yliopiston estämättä, jos käsittelyn oikeusperuste on suostumus tai sopimus, ja käsittely suoritetaan automaattisesti.

Kun käytät oikeuttasi siirtää tiedot järjestelmästä toiseen, sinulla on oikeus saada henkilötiedot siirrettyä suoraan rekisterinpitäjältä toiselle, jos se on teknisesti mahdollista.

Vastustamisoikeus (tietosuoja-asetuksen 21 artikla)
Sinulla on oikeus vastustaa henkilötietojesi käsittelyä, jos käsittely perustuu yleiseen etuun tai oikeutettuun etuun. Tällöin yliopisto ei voi käsitellä henkilötietojasi, paitsi jos se voi osoittaa, että käsittelyyn on olemassa huomattavan tärkeä ja perusteltu syy, joka syrjäyttää rekisteröidyn edut, oikeudet ja vapaudet tai jos se on tarpeen oikeusvaateen laatimiseksi, esittämiseksi tai puolustamiseksi. Yliopisto voi jatkaa henkilötietojesi käsittelyä myös silloin, kun sen on tarpeellista yleistä etua koskevan tehtävän suorittamiseksi.

Oikeuksista poikkeaminen
Tässä kohdassa kuvatuista oikeuksista saatetaan tietyissä yksittäistapauksissa poiketa tietosuoja-asetuksessa ja Suomen tietosuojalaissa säädetyillä perusteilla siltä osin, kuin

oikeudet estävät tieteellisen tai historiallisen tutkimustarkoituksen tai tilastollisen tarkoituksen saavuttamisen tai vaikeuttavat sitä suuresti. Tarvetta poiketa oikeuksista arvioidaan aina tapauskohtaisesti.

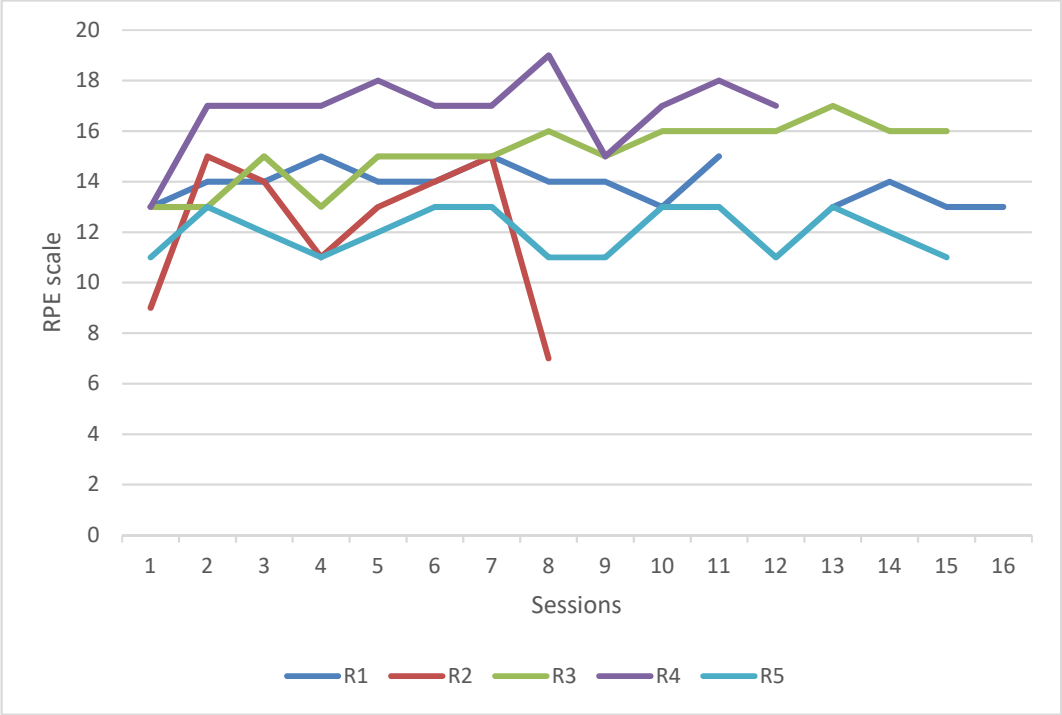
Valitusoikeus
Sinulla on oikeus tehdä valitus tietosuojavaltuutetun toimistoon, mikäli katsot, että henkilötietojesi käsittelyssä on rikottu voimassa olevaa tietosuojalainsäädäntöä.

Yhteystiedot:

Tietosuojavaltuutetun toimisto
Käyntiosoite: Ratapihantie 9, 6. krs, 00520 Helsinki
Postiosoite: PL 800, 00521 Helsinki
Vaihde: 029 56 66700
Faksi: 029 56 66735
Sähköposti: tietosuoja@om.fi

APPENDIX 9

RPE



PROMIS

Questions and scale for answers	Rehabilitees				
	R1	R2	R3	R4	R5
Global Health					
1= excellent, 2= very good, 3= good, 4= fair, 5= poor					
1. t1 In general, would you say your health is:	4	2	4	4	3
1. t3 In general, would you say your health is:	4	2	5	4	4
Change in GH 1	0	0	1	0	1
2. t1 In general, would you say your quality of life is:	4	2	4	3	4
2. t3 In general, would you say your quality of life is:	4	1	5	3	4
Change in GH 2	0	-1	1	0	0
3. t1 In general, how would you rate your mental health, including your mood and your ability to think?	4	3	4	3	3
3. t3 In general, how would you rate your mental health, including your mood and your ability to think?	4	2	4	2	3
Change in GH 3	0	-1	0	-1	0
4. t1 In general, how would you rate your satisfaction with your social activities and relationships?	4	2	3	3	4
4. t3 In general, how would you rate your satisfaction with your social activities and relationships?	3	1	3	3	4
Change in GH 4	-1	-1	0	0	0
5. t1 In general, please rate how well you carry out your usual social activities and roles. (This includes activities at home, at work and in your community, and responsibilities as a parent, child, spouse, employee, friend, etc.)	3	2	3	4	3
5. t3 In general, please rate how well you carry out your usual social activities and roles. (This includes activities at home, at work and in your community, and responsibilities as a parent, child, spouse, employee, friend, etc.)	3	3	4	4	3
Change in GH 5	0	1	1	0	0
1= never, 2= rarely, 3= sometimes, 4= ofte, 5= always					
6. t1 How often have you been bothered by emotional problems such as feeling anxious, depressed or irritable?	4	3	2	2	2
6. t3 How often have you been bothered by emotional problems such as feeling anxious, depressed or irritable?	4	2	3	2	1
Change in GH 6	0	-1	1	0	-1
1= none, 2= mild, 3= moderate, 4= severe, 5= very severe					
7. t1 How would you rate your fatigue on average?	3	2	3	2	2
7. t3 How would you rate your fatigue on average?	3	2	4	3	2
Change in GH 7	0	0	1	1	0
0= no pain, 10= worst pain imaginable					
8. t1 How would you rate your pain on average?	4	3	9	8	2
8. t3 How would you rate your pain on average?	4	2	6	7	2
Change in GH 8	0	-1	-3	-1	0
	Positive change in functioning				
	Negative change in functioning				

Pain					
1= had no pain, 2= mild, 3= moderate, 4= severe, 5= very severe					
1. t1 How intense was your pain at its worst?	3	3	4	4	2
1. t3 How intense was your pain at its worst?	3	2	4	4	3
Change in Pain 1	0	-1	0	0	1
2. t1 How intense was your average pain?	3	2	3	3	1
2. t3 How intense was your average pain?	3	2	3	3	2
Change in Pain 2	0	0	0	0	1
1= not at all, 2= a little bit, 3= somewhat, 4= quite a bit, 5= very much					
3. t1 How much did pain interfere with your enjoyment of life?	2	2	4	3	1
3. t3 How much did pain interfere with your enjoyment of life?	2	2	4	4	2
Change in Pain 3	0	0	0	1	1
4. t1 How much did pain interfere with your ability to concentrate??	3	3	4	4	1
4. t3 How much did pain interfere with your ability to concentrate??	2	3	4	4	3
Change in Pain 4	-1	0	0	0	2
5. t1 How much did pain interfere with your day to day activities?	3	2	3	3	1
5. t3 How much did pain interfere with your day to day activities?	2	3	4	4	2
Change in Pain 5	-1	1	1	1	1
6. t1 How much did pain interfere with your ability to participate in social activities?	1	2	2	3	1
6. t3 How much did pain interfere with your ability to participate in social activities?	1	2	3	4	1
Change in Pain 6	0	0	1	1	0
1= no pain, 2= mild, 3= moderate, 4= severe, 5= very severe					
7. t1 What is your level of pain right now?	1	2	2	2	1
7. t3 What is your level of pain right now?	2	2	3	3	1
Change in Pain 7	1	0	1	1	0
sleep					
1= very good, 2= good, 3= fair, 4= poor, 5= very poor					
1. t1 My sleep quality was	3	3	1	2	4
1. t3 My sleep quality was	2	3	2	2	4
Change in Sleep 1	-1	0	1	0	0
1= not at all, 2= a little bit, 3= somewhat, 4= quite a bit, 5= very much					
2. t1 I had a problem with my sleep	2	2	1	2	4
2. t3 I had a problem with my sleep	3	3	3	2	4
Change in Sleep 2	1	1	2	0	0
	Positive change in functioning				
	Negative change in functioning				

Fatigue					
1= not at all, 2= a little bit, 3= somewhat, 4= quite a bit, 5= very much					
1. t1 How fatigued were you on average?	1	2	3	2	1
1. t3 How fatigued were you on average?	2	3	3	3	1
Change in Fatigue 1	1	1	0	1	0
2. t1 To what degree did your fatigue interfere with your physical functioning?	1	2	3	3	1
2. t3 To what degree did your fatigue interfere with your physical functioning?	1	3	3	3	1
Change in Fatigue 2	0	1	0	0	0
Physical Function					
1= without any difficulty, 2= with a little difficulty, 3= with some difficulty, 4= with much difficulty, 5= unable to do					
1. t1 Are you able to do chores as vacuuming or yard work?	2	3	4	4	5
1. t3 Are you able to do chores as vacuuming or yard work?	3	4	4	5	5
Change in Phys 1	1	1	0	1	0
2. t1 Are you able to push open a heavy door?	2	2	3	4	3
2. t3 Are you able to push open a heavy door?	2	3	3	4	2
Change in Phys 2	0	1	0	0	-1
3. t1 Are you able to dress yourself, including tying shoelaces and buttoning your clothes??	3	5	5	2	2
3. t3 Are you able to dress yourself, including tying shoelaces and buttoning your clothes??	2	3	5	2	5
Change in Phys 3	-1	-2	0	0	3
4. t1 Are you able to run errands and shop?	2	5	4	2	3
4. t3 Are you able to run errands and shop?	3	5	5	2	3
Change in Phys 4	1	0	1	0	0
5. t1 Are you able to bend down and pick up clothing from the floor?	1	2	3	2	2
5. t3 Are you able to bend down and pick up clothing from the floor?	1	4	4	2	3
Change in Phys 5	0	2	1	0	1
1= not at all, 2= very little, 3= somewhat, 4= quite a lot, 5= cannot do					
6. t1 Does your health now limit you in bathing or dressing yourself?	3	2	4	3	4
6. t3 Does your health now limit you in bathing or dressing yourself?	1	3	4	3	4
Change in Phys 6	-2	1	0	0	0
7. t1 Does your health now limit you in putting a trash bag outside?	2	3	4	3	4
7. t3 Does your health now limit you in putting a trash bag outside?	3	4	4	3	5
Change in Phys 7	1	1	0	0	1
Overall change	-1	3	10	5	10
	Positive change in functioning				
	Negative change in functioning				