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Keep Improving Kinematics in Walking (KIK-Walk):

Functional Electrical Stimulation Based Locomotor Training

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Abstract

The stroke is one of the leading causes of morbidity and mortality or disability among adult population world-wide. Today, the advances in acute medical management of stroke are changing the neurological population. The percentage of individuals that suffered stroke and survived the first month has increase to more than 85%. Therefore, it is critical to find clinically sustainable approaches to improve survivors' quality of live, starting with the most important; walking.

The current evidence shows that many stroke survivors have improved their walking after receiving therapeutic gait training utilizing various modalities in research in research programs internationally, regardless of the time elapsed since their disease onset. One of these recognizable modalities is a functional electrical stimulation (FES), however, despite its common availability compared with expensive robot-based therapies, its use is rather limited world-wide, mainly due to lack of training.

This study is divided into three parts. First, a systematized review is presented to provide evidence concerning the use of FES-walking therapy in stroke rehabilitation. Results related to changes in gait speed and participants' satisfactions compared with the use of standard ankle foot orthosis are provided. Second, a case study involving 5 weeks of FES-walking therapy is presented to assess the feasibility of this approach in a school setting so that the gained knowledge can be applied in standard clinical practice.

The results of this work show that there is enough evidence to apply the FES-walking therapy in rehabilitation setting and that even and individual 14 years post stroke can improve gait pattern significantly. Nevertheless, the problem remains in the lack of training of pertinent physiotherapists and their believes towards this type of therapy modality. Therefore, the author hopes that this work can be used as the first step towards successful incorporation of this modality in standard stroke rehabilitation in Finland.

Key words: Stroke, Hemiplegia, Functional Electrical Stimulation, Gait, Kinematics

CONTENTS

1 INTRODUCTION

Today, the advances in acute medical management of stroke are changing the neurological population. The percentage of individuals that suffered stroke and survived the first month has increase to more than 85% (Meretoja *et al.* 2011). The activity-dependent plasticity of the neural pathways, previously thought to be unresponsive and without ability to recover, gives us the example how the scientific evidence can challenge the assumptions of current clinical practice (Behrman, Bowden & Nair 2006). Activity-based gait therapy, combining research on neural plasticity and the role of spinal cord in stepping and standing is applied to Locomotor Training (LT). LT works to "awaken" dormant neural pathways by repetitively stimulating the muscles and nerves in the lower body. LT is commonly used for stroke survivors and other neurological disorders. The current evidence shows that many stroke survivors have improved their walking after receiving therapeutic gait training utilizing various modalities (e.g., body weight-support treadmill (BWST) training, robot-based locomotor training) in research programs and rehabilitation clinics internationally, regardless of the time elapsed since their disease onset (Mehrholz, Thomas & Elsner 2017). Nevertheless, these modalities require large amount of men power and/or expensive device as BWST or robot.

Functional Electrical Stimulation based LT (FES-walking), on the other hand, can be used in conjunction with parallel bars or over ground walking; decreasing the need of expensive equipment. Further, the recent research has shown that stroke survivors have the capacity to improve voluntary walking function following short-term intensive FES therapy (Howlett, Lannin, Ada & McKinstry 2015; Masani & Popovic 2011). Furthermore, the positive effects seemed to be remaining even after therapy cessation (Howlett, Lannin, Ada & McKinstry 2015; Stein, Fritsch, Robinson, Sbruzzi & Plentz 2015). Therefore, the FES-walking restorative therapy may be possibly used to enhance spinal neuroplasticity, instead of using it as a pure compensatory walking aid (e.g., Bioness or WalkAid) as was done in the past (Masani & Popovic 2011; Popovic & Thrasher 2004).

It has been reported that the FES-walking has positive effects on muscle density, quality of life and walking competence (Wilkie, Shiels, Bulley & Salisbury 2012), and also potential to emulate normal mechanical strains on bone during weight-bearing activity. These strains may stimulate bone formation through alterations in muscle activity that cannot be achieved with BWST- or robot-based LT training alone (Coupaud, Jack, Hunt & Allan 2009).

The first electrical stimulation for drop foot prevention in stroke survivors was introduced already in 1961 (Liberson, Holmquest, Scot & Dow 1961) and benefits of the FES therapies among stroke survivor population compared with conventional exercise programs have been described elsewhere (Howlett, Lannin, Ada & McKinstry 2015; Mehrholz, Thomas & Elsner 2017). Nevertheless, the use of neuromuscular stimulation among physiotherapists and especially in task-oriented therapies (including therapeutic goals as walking, arm function, muscle strength, endurance and sensation, prevention of shoulder subluxation, or decrease of spasticity) is still low. This is mainly due to a lack of training (inability to use the stimulation with proper setting for execution of intended tasks), time and equipment. (Auchstaetter *et al.* 2016.)

In Canada, this limitation has been recently recognized and recommendations concerning incorporation of FES, as one of the key components of activity-based therapy, into the mainstream health care and community programs have been made (Behrman, Ardolino & Harkema 2017). In addition, the use of FES is now included in the Canadian best practice accreditation guidelines in Stroke rehabilitation (Teasell *et al.* 2020). Therefore, this thesis is proposed to introduce the FES in Finland, show potential applications and find out whether potential patients would be satisfied with the FES-walking therapeutic approach if used clinically.

This work is organized as follows. In the second chapter, a brief description of stroke disease, its consequences, as well as possible therapeutic modalities including FES is provided. The third chapter presents insight into recent research concerning FES therapies used in stroke gait rehabilitation via systematized literature review. In the fourth chapter, a case study performed at school facilities and its results (satisfaction with the therapy) is described. All the results are discussed and concluded in the fifth and sixth chapters, respectively. In the last chapter, future prospects are discussed.

2 BACKGROUND

2.1 Stroke

The stroke is one of the leading causes of morbidity and mortality or disability among adult population world-wide. The incidence rate of stroke is about 800 thousand and 1 million of people per year in USA and EU, respectively, estimating that 1 of 6 people will suffer stroke in their lifetime. Although, the surviving rate is increasing, the stroke still accounts for 11.8% of total deaths world-wide, the second leading cause of dead globally. (Benjamin *et al.* 2018.) Further, over 50% of individuals suffering stroke remain with residual disability requiring an assistance for activities of daily living that causes a large burden on health and social care systems (Website of American Stroke association 2020; Website of World Health Organization 2019; Krupinski, Secades & Shiraliyeva 2014).

The definition of stroke as ”a rapidly developing clinical signs of focal (or global) disturbance of cerebral function lasting 24 hours or longer of leading to death, with no apparent cause other than of vascular origin” by World Health Organization was provided in 1970 (Coupland, Thapar, Qureshi, Jenkins & Davies 2017).

In other words, the stroke is a disease that is caused by either blocking or rupturing blood vessels and therefore limiting or interrupting blood supply coming to the brain. As a consequence of this cut in blood supply, the brain doesn’t get enough oxygen causing necrosis of the brain tissue. Based on the stroke’s etiology, two major types of strokes are recognized, hemorrhagic and ischemic. The hemorrhagic stroke is caused by a rupture of a blood vessel when blood is pouring into the brain tissue damaging it. While the ischemic stroke is caused by an infarction of a blood vessel similarly to a heart attack. A cloth or a plaque formed by fatty deposits is obstructing the blood flow to brain causing death of brain cells. The risks of stroke development are primarily related to lifestyle factors as smoking, unhealthy diet or low physical activity levels but also linked to clinical factors such as abdominal obesity. (Website of American Stroke association 2020; Website of World Health Organization 2019.)

2.2 Stroke consequences

The brain is a very complex tissue therefore the stroke consequences are primarily dependent on the nature (hemorrhagic/ischemic), location of the blood supply interruption (sensorial, motor or cognitive systems) and the extent of the brain tissue that was damaged (magnitude of the functional impact). The damage in different brain locations may cause problems as altered feeling (e.g., cold/hot, sharp/dull), articulation deficiency or loss of voluntary motor functions (e.g., flaccid or spastic limbs). In addition, the patient's condition prior stroke's onset and the time poststroke are factors that also affect the extent of recovery. (Prieto, Cano-de-la-Cuerda, López-Larraz, Metrot, Molinari & van Dokkum 2014.)

When considering damage of motor cortex, the stroke usually affects only one side of the cerebral hemisphere resulting in partial (hemiparesis) or complete paralysis (hemiplegia) of the opposite side of the body. The consequences may range from very mild hemiparesis (the voluntary functions are almost preserved) to severe hemiplegia that causes radical reduction or loss of the voluntary functions. (Website of American Stroke association 2020.)

2.3 Physiotherapy approaches used in stroke rehabilitation

The post-stroke physiotherapy and its goals is very dependent on the phase of recovery process. The process can be divided into 4 main stages: acute, early, late and chronic rehabilitation. In the acute stage, hours after the event, the main goal is to start mobilization of affected limbs. In the early stage, up to 3 months post stroke, the main goal moves to increase individual's activities of daily living and participation by re-education of movement patterns or teaching compensatory strategies if needed. In the late stage, up to 6 months post stroke, the main goal is further focused on decreasing individual's limitation in activities of daily living and participation. In the chronic stage, beyond 6 months post stroke, the main rehabilitation goal moves from direct physiotherapy towards support and counseling how to cope with the disability in everyday situation. Although, physiotherapist still concentrate on maintaining or improvement of functional capacity. (Veerbeek *et al.* 2014a; Winstein *et al.* 2016.) See Figure 1 for

graphical representation of the recovery process and timing of particular rehabilitation stages.

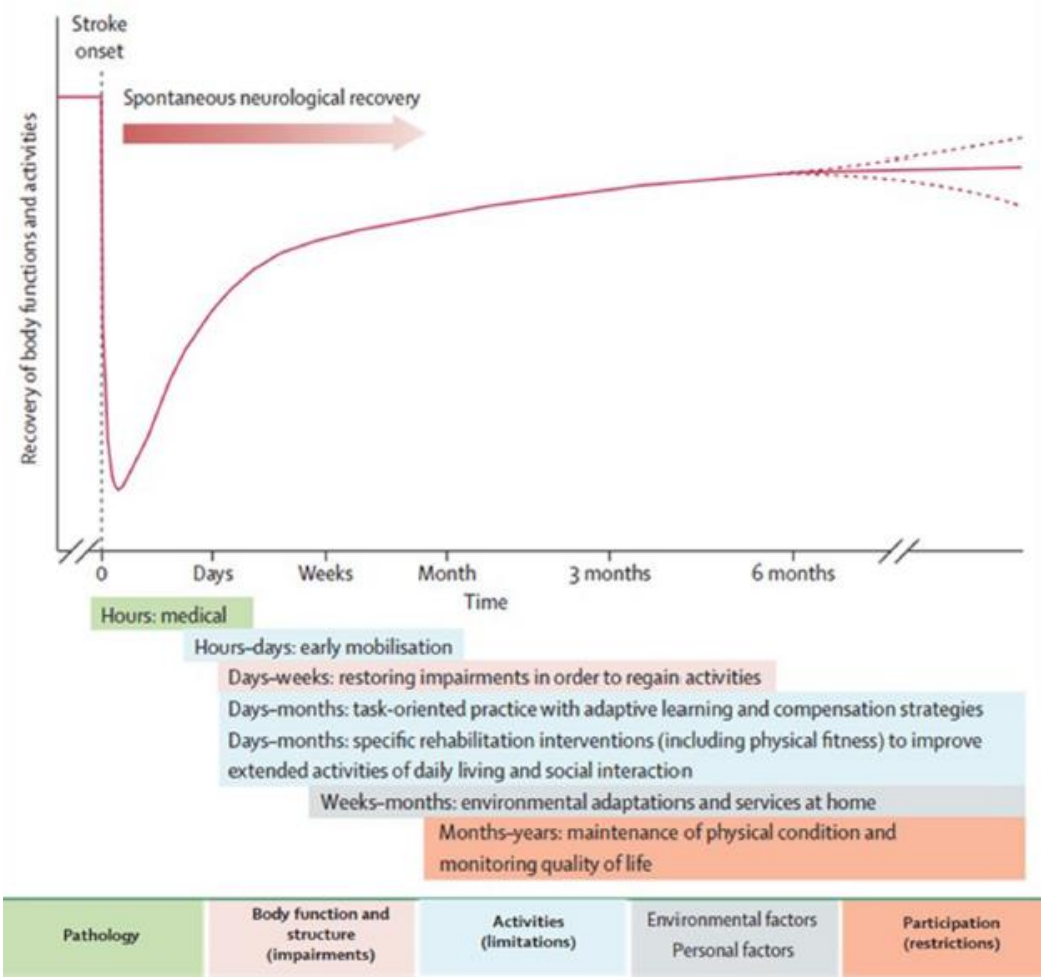

Figure 1: Hypothetical stroke recovery pattern together with goals of intervention for particular time slots. Reprinted from The Lancet (Langhorne, Bernhardt & Kwakkel 2011) with permission from Elsevier.

As can be seen from the Figure 1, the post-stroke recovery follows rather a nonlinear logarithmic pattern. Despite reports of improvements in later rehabilitation stages, it has been shown that the spontaneous recovery together with the greatest physiotherapy outcomes happens during the first 3 months post-stroke (Teasell *et al.* 2020; Veerbeek *et al.* 2014a; Winstein *et al.* 2016). Therefore, the rehabilitation aiming at the improvement of individual's physical/cognitive condition, should be very intensive in this relatively short time window (Coleman *et al.* 2017).

Today, a large variety of treatment concepts is used in stroke rehabilitation. Particular concepts are believed to be superior to others by different schools of physiotherapy,

especially what considers development of motor learning (Teasell *et al.* 2020; Veerbeek *et al.* 2014a; Winstein *et al.* 2016). Nevertheless, results of systematic reviews and meta-analyses suggest that the intensive and high repetitive task-oriented/activity-based training – the combination therapies – may have better outcomes when compared with single concept approach (Belda-Lois *et al.* 2011; Hatem *et al.* 2016; Prieto, Cano-de-la-Cuerda, López-Larraz, Metrot, Molinari & van Dokkum 2014; Veerbeek *et al.* 2014b). Among these combination therapies for improvement of walking competences is the body-weight supported treadmill training and electromechanically-assisted gait training with FES (Veerbeek *et al.* 2014b).

2.4 Electrical Stimulation

2.4.1 General overview

Electrical stimulation is a technique that is using an external device able to generate current pulses (~ up to 200 mA). The current is then delivered to the body tissues (e.g., muscle, nerves) through leads and surface self-adhesive or implanted electrodes placed at appropriate (task specific) locations. The size, shape and frequency of the current pulses depend on the stimulated tissue and desired goals of the stimulation. Generally, the stimulation can be used in wide variety of clinical applications as muscle strengthening and re-education, wound healing, resolving inflammations and edema, pain control or enhancing drug delivery. Nevertheless, in physical rehabilitation, the use of the electrical stimulation can be divided into 3 main categories: transcutaneous electrical nerve stimulation (TENS), neuromuscular electrical stimulation (NMES), and functional electrical stimulation (FES). (Cameron, Shapiro & Ocelnik 2018.)

The TENS category of the electrical stimulation is primarily used for either pain control or tissue healing, although, some studies have successfully used TENS for triggering neuroplasticity (Veerbeek *et al.* 2014b). The TENS uses either very high frequencies with short pulse duration or very low frequencies with longer pulses. Therefore, this type of stimulation is not sufficient for triggering constant muscle tetanic reaction. (Cameron, Shapiro & Ocelnik 2018.)

The NMES and FES terms are used interchangeably throughout the literature as authors define what is a functional exercise according their own believes. Nevertheless, the recent definition provided in guidelines for the Bone health and Osteoporosis Management of Adults with Spinal Cord Injury by the Paralyzed Veterans of America is as follows: "the NMES is defined as the application of an electrical current of sufficient intensity to elicit muscle contraction while FES refers to the process of pairing NMES simultaneously or intermittently with a functional task, such as grasping and moving objects, cycling or rowing" (personal correspondence). This definition is very important as the current research evidence suggest that only the stimulation combined with functional task is providing sufficient stimulation to trigger neuroplasticity (Dolbow *et al.* 2015)

As mentioned above, there is a large variety of current pulse parameters that need to be set according to the application. These parameters include current waveform, amplitude (strength), pulse width (duration), pulse frequency, pulse ramp-up and ramp-down time and on/off time. Their correct setting is vital for successful competition of desired tasks. Although, the theory largely exceeds the limits of this thesis, the setting of these stimulation parameters is very straightforward and the summary of recommended setup for various applications, as suggested by Cameron et al. (Cameron, Shapiro & Ocelnik 2018), is provided in Table 1. In following lines, only brief definition of the parameters and their connection to stimulation of the peripheral nervous system (to produce muscle contractions) as described in book by Cameron et al. will be provided. More extensive information can be found elsewhere (Baker 2000).

2.4.2 Stimulation parameters

Waveform: the biphasic symmetric or asymmetric current pulses are the most common waveforms used in neuromuscular stimulation. The symmetrical setting is used for stimulation of larger muscle groups (e.g., quadriceps) when both electrodes are placed on the muscle belly and equal stimulation under both electrodes is necessary to activate the large muscle bulk. The asymmetrical setting, on the other hand, is used for stimulation of smaller muscles (e.g., extensor digitorum or opponens pollicis) when

Table 1: Recommended stimulation parameters for specific treatment goals. Reproduced from (Cameron, Shapiro & Ocelnik 2018) with permission from Elsevier

Parameter Settings/ Treatment Goals	Pulse Frequency	Pulse Duration	Amplitude	On:Off Times and Ratio	Ramp Time	Treatment Time	Times per Day
Muscle strengthening	35 – 80 pps	150-200 μs for small muscles, 200-350 μs for large muscles	To > 10% of MVIC in injured, > 50% MVIC in uninjured	6-10s on, 50-120s off. Ratio of 1:5 initially but may be reduced	At least 2 s	10-20min to produce 10-20 repetitions	Every 2-3 h when awake
Muscle re-education	35 – 50 pps	150-200 μs for small muscles, 200-350 μs for large muscles	Sufficiently for functional activity	De-pends on functional activity	At least 2 s	Depends on functional activity	N/A
Muscle spasm reduction	35 – 50 pps	150-200 μs for small muscles, 200-350 μs for large muscles	To visible contractions	2-5s on, 2-5s off. Equal on:off times	At least 1 s	10- 30 min	Every 2-3 h until spasm relieved
Edema reduction using muscle pump	35 – 50 pps	150-200 μs for small muscles, 200-350 μs for large muscles	To visible contractions	2-5s on, 2-5s off. Equal on:off times	At least 1 s	30min	Twice a day

MVIC – Maximum voluntary isometric contraction, pps – pulse per second, N/A – not applicable

stimulation just under the specific (small) muscle belly is desired. (Cameron, Shapiro & Ocelnik 2018.)

Pulse amplitude: is the strength of the current, usually measured in milliamperes (mA). Higher the amplitude, higher the amount of current delivered to the tissue. Consequently, more motor units are recruited, and larger muscle force is generated. (Cameron, Shapiro & Ocelnik 2018.)

Pulse width: the duration of the pulse positively affects the amount of total current delivered to the tissue (longer the pulse duration higher the amount of delivered current). Generally, the larger muscle groups need higher amount of delivered current. Therefore, a longer pulse duration is required to generate proper muscle response. In case of smaller muscles or nerves, a shorter pulse duration is sufficient to trigger the desired response. Nevertheless, there is also a minimum combination of pulse duration and current amplitude that needs to be considered (Figure 2). As can be clearly seen, if very short pulse duration (~ 40 μs) is selected, only sensory stimulation of muscle group can be achieved, no matter of the current strength. For motor response in innervated muscles, pulse duration between 150 to 350 μs is selected. However, shorter pulse duration requires greater current amplitude to produce same contraction strength as when longer pulse duration is used. (Cameron, Shapiro & Ocelnik 2018.)

Pulse frequency: it is the amount of pulses per second. In case of symmetrical or asymmetrical waveform, unit Hertz (Hz) or pulse per second (pps) is used, respectively. As can be seen from Figure 3, frequency above 30 Hz/pps is required to achieve smooth tetanic muscle contraction. Increase in the frequency above ~50 Hz/pps will result in greater muscle contraction (strength). Nevertheless, this will also result in more rapid muscle fatigue – time during which muscle will sufficiently react to stimulation will decrease (Figure 4). Therefore, endurance types of activities (e.g., walking, cycling, rowing) require lower frequencies of stimulation (~ 30 Hz/pps). (Cameron, Shapiro & Ocelnik 2018.)

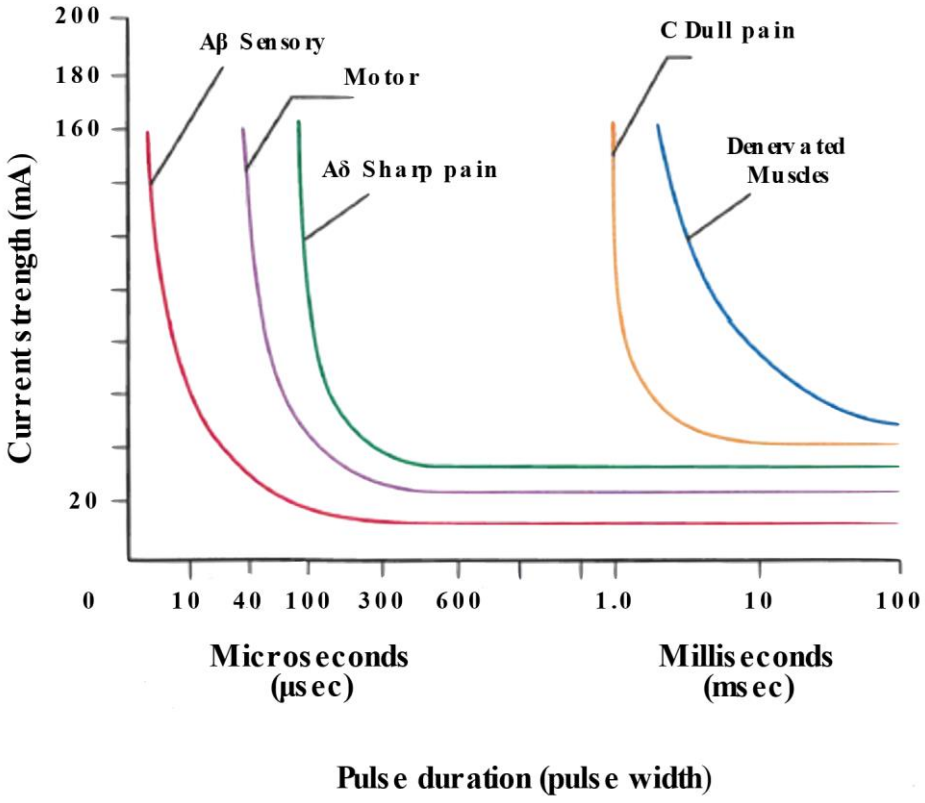

Figure 2: The relationship between current intensity and pulse duration for creating of an action potential in various nerve types. Adapted from (Cameron, Shapiro & Ocelnik 2018) with permission from Elsevier.

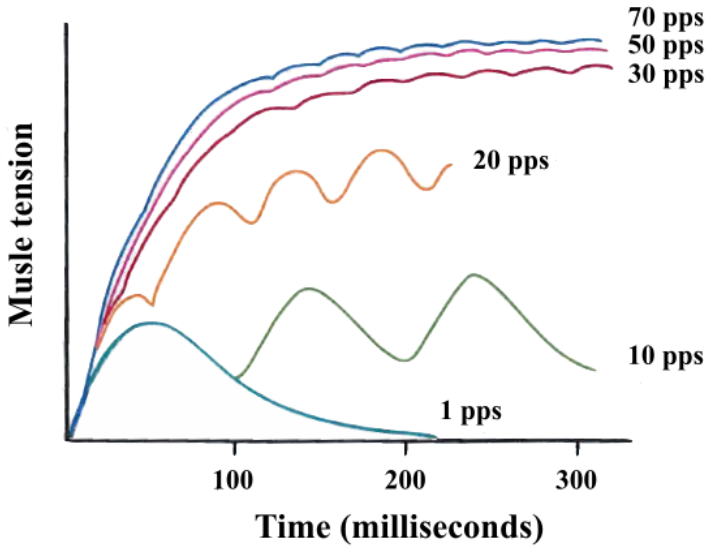

Figure 3: Type of muscle contractions in relation to the frequency of stimulation. Adapted from (Cameron, Shapiro & Ocelnik 2018) with permission from Elsevier

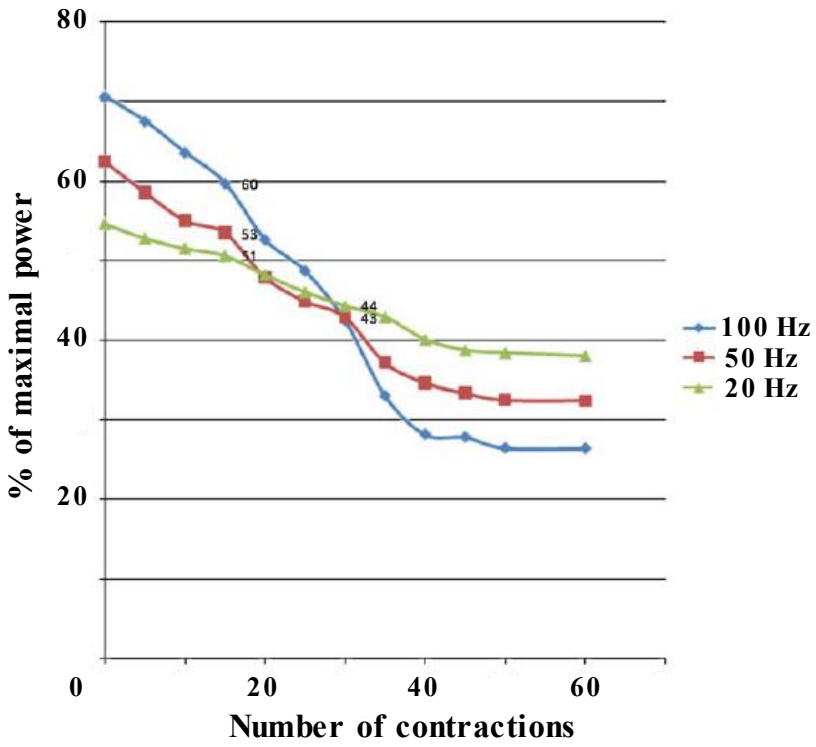

Figure 4: The relation between number and strength of triggered muscle contractions depending on used stimulation frequency. Adapted from (Dreibati, Lavet, Pinti & Poumarat 2010) with permission from Elsevier Masson SAS.

Pulse ramp-up/down time: is the time it takes for the stimulation current to increase from zero intensity to the one set on the stimulator and vice versa. This gradual increase/decrease of the current allows for gradual increase/decrease of muscle contraction and consequently mimic increase/relaxation of voluntary muscle contraction. Longer ramp-up/down times (> 2s) are used to ensure stimulation comfort, especially for individuals with muscle spasticity for whom sudden change in electrical stimulation (sudden muscle contraction) could cause increase in muscle spasticity or even injury. Nevertheless, curtain activities, where rapid contraction and relaxation is needed (e.g., gait training), require shorter ramp-up/down times (< 0.5s). (Cameron, Shapiro & Ocelnik 2018.)

On/off stimulation time: is the time during which the stimulation occurs resulting in muscle contraction or the current flow is interrupted (relaxation time for the muscle), respectively. The relaxation time (off time) is needed to limit the muscle fatigue. In strengthening protocols, the ratio between on/off time (duty cycle) is usually 1:5 at the

beginning of the therapy. Later, the duty cycle decreases to 1:3 or even 1:2. In functional activities as gait training, the duty cycle highly deepens on speed of locomotion or performed movement. For treatment of spasticity, duty cycle of 1:1 is generally used. (Cameron, Shapiro & Ocelnik 2018.)

3 LITERATURE REVIEW

3.1 Aim of the review

Due to the current lack of use of FES treatment in stroke rehabilitation in Finland, a systematized literature search was conducted to provide insight into this neglected tool of neurological physiotherapy. Based on the synthesis of identified literature, outcomes related to change of participants' walking speed and satisfaction with therapy were evaluated to clearly outline the therapy benefits. Considering the large variety of electrical-related studies, only *in-vivo* human studies and those related to facilitation of walking during locomotor treatment of stroke survivors were the focus of this review.

3.2 Methodology

A systematized literature search for peer-reviewed articles was conducted in PubMed. The search included all published reports from 1946 August 23rd ,2019. The search strategy used the following term to maximize manuscript capture of relevant articles and minimize inclusion of irrelevant records:

(stroke [MeSH Terms] OR acute stroke [MeSH Terms] OR cerebral stroke [MeSH Terms] OR brain attack [Title/Abstract] OR (ischemic* [Title/Abstract] AND (stroke* [Title/Abstract] OR cerebrovascular syndrome* [Title/Abstract])) OR hemorrhagic stroke* [Title/Abstract]) AND (electrical stimulation [MeSH Terms] OR FES [Title/Abstract] OR NMES [Title/Abstract] OR (functional [Title/Abstract] AND electri-

cal [Title/Abstract] AND stimulation [Title/Abstract]) OR (neuromusc* [Title/Abstract] AND electrical [Title/Abstract] AND stimulation [Title/Abstract])) AND (gait [Title/Abstract] OR walking [Title/Abstract] OR locomotion [Title/Abstract]).

A total of 169 references were identified. However, the search failed to identify two articles on related topic known to the author (Jung_2018, Springer et al. 2013). Therefore, these articles were also included in the review; having 171 articles in total.

3.3 Selection process

First level of the review focused on screening of abstract title and body of identified studies. During this step, the animal studies not excluded by the search strategy (n = 4), non-English written studies (n = 9), case or case series (n = 14), commentary, reviews or metanalyses (n = 22), studies reporting technical solutions (n = 12), upper limb- related rehabilitation study (n = 1), modeling studies (n = 2), studies using mechanical orthosis (n = 1), conference papers (n = 5), studies using stimulation for other goals than gait – strength training, balance, cycling etc. (n = 15), studies reporting development of activity assessment measures (n = 7), or other interventions than FES (n = 17) were eliminated.

The second level review concentrated on the results sections of the all remaining articles (n = 61) to identify those articles that report participant's satisfaction with FES treatment and/or changes in gait speed. During the second step, studies describing only one time trials (n = 7), case or case series (n = 2), studies involving implanted electrodes (n = 8), studies not using FES training (n = 1), studies reporting other results than satisfaction and gait speed (n = 8) or studies that used FES in supine or side-lying position (n = 4) were also eliminated. Therefore, in the final review, data from 31 articles are included. Detailed article screening process is illustrated in Figure 5.

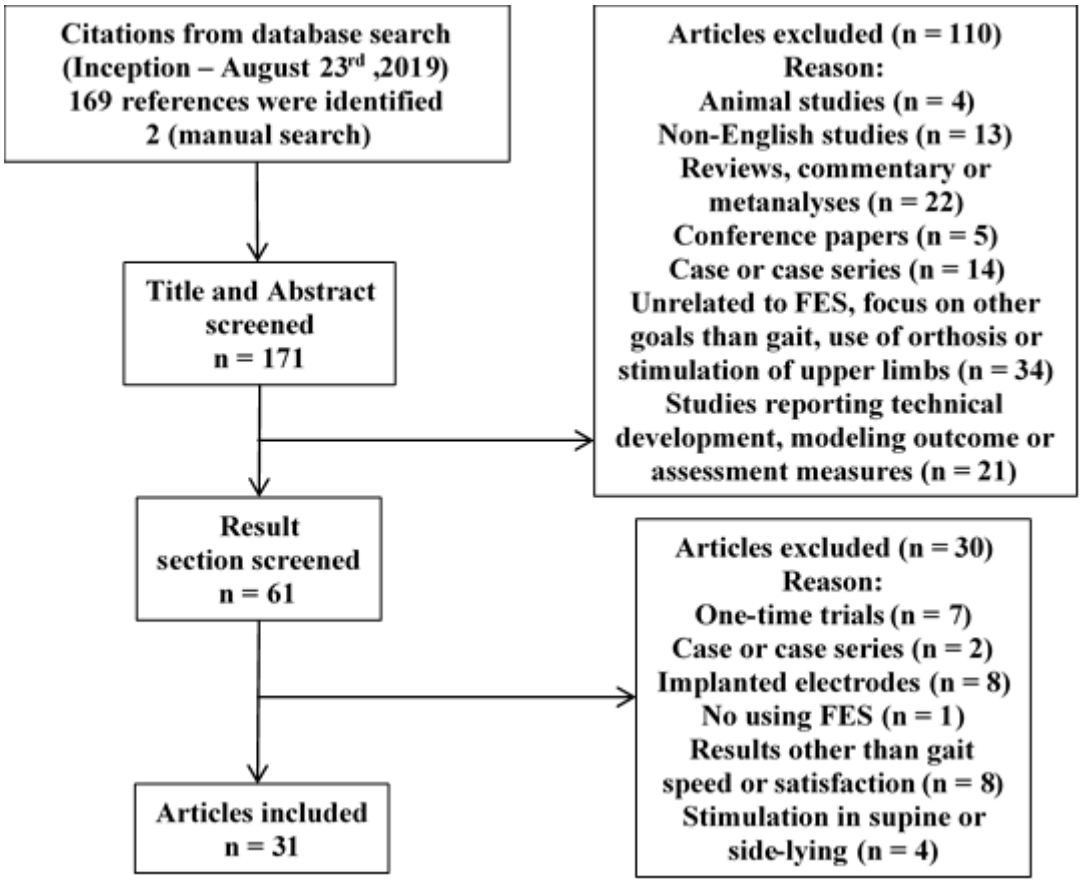

Figure 5: PRISMA flow chart for article inclusion process

3.4 Appraisal of evidence

The following information was abstracted from the selected manuscripts: (1) the material and method section were searched for references regarding participant population (acute, sub-acute or chronic stage of disease, and number of participants), study type (RCT, pre-post longitudinal, cross-sectional or retrospective analysis), device used for stimulation, type of stimulation (number of channels and stimulation parameters), electrode placement, type of used switch, where the gait was trained, and details of intervention (length, number of sessions per week or session duration); and, (2) the results and discussion sections were searched for references regarding gait speed or satisfaction with therapy provided. In addition, these sections were also searched to find any reference regarding adverse events (number and type of adverse events).

3.5 Results

3.5.1 Population and study design

Of the 31 studies selected for inclusion in the review, 12 (39%) focused on chronic, 9 (29%) on mixed sub-acute and chronic stroke population, 6 (19%) on sub-acute population, 2 (6%) did not report the target population and only 2 (6%) studies involved population in acute phase of post-stroke. Over one third of the studies (42%) were randomized control trials (RCT) and pre-post longitudinal studies (39%). Nevertheless, approximately two thirds of the reviewed studies involved groups with less than 20 individuals (65%).

Out of 31 studies, 4 (13%) involved over 20 individuals (Everaert *et al.* 2013; Fernandes, Carvalho & Prado 2006; van Swigchem, Vloothuis, den Boer, Weerdesteyn & Geurts 2010; Xu, Guo, Salem, Chen & Huang 2017), 3 (10%) involved over 50 individuals (O'Dell *et al.* 2014; Taylor, Humphreys & Swain 2013; Taylor *et al.* 1999a), and only 4 (13%) studies involved over 100 individuals (Bethoux *et al.* 2015, 2014; Street, Swain & Taylor 2017; Taylor *et al.* 1999b). Out of these 11 studies, only 3 were RCT (Bethoux *et al.* 2015, 2014; Xu, Guo, Salem, Chen & Huang 2017), 4 pre-post longitudinal studies (Fernandes, Carvalho & Prado 2006; O'Dell *et al.* 2014; Street, Swain & Taylor 2017; van Swigchem, Vloothuis, den Boer, Weerdesteyn & Geurts 2010), 3 retrospective analyses (Taylor, Humphreys & Swain 2013; Taylor *et al.* 1999a, 1999b) and 1 study with cross-over design (Everaert *et al.* 2013).

3.5.2 FES stimulation

Despite the importance of reporting used devices, 13 out of 31 studies (42%) did not report this important detail. Other studies were using either devices widely available on market for use by stroke survivors as WalkAide orthosis, Bioness L300 orthosis and Odstock Pace or 2-channel stimulator, or rarer/laboratory developed devices as Dorsiflex, CyberMedic and Grass S8800,

Twenty-three of the selected studies (75%) used only device with one channel, the majority (N = 21) for stimulation of common peroneal nerve (CPN) together with tibialis anterior muscle (TA). Only 2 studies used one channel for stimulation of hamstring to mobilize stiff knee (Tenniglo, Buurke, Prinsen, Kottink, Nene & Rietman 2018) and foot-arch with dorsum to stimulate nociceptive withdrawal reflex (Spaich, Svaneborg, Jorgensen & Andersen 2014).

Approximately one fourth (N = 8) of the reviewed studies used two channel stimulator, the majority for stimulating ankle dorsi and plantar flexors (Awad, Reisman, Kesar & Binder-Macleod 2014; Awad, Reisman, Pohlig & Binder-Macleod 2016; Hakansson, Kesar, Reisman, Binder-Macleod & Higginson 2011; Reisman *et al.* 2013). Other applications were stimulation of gluteus medius together with CPN+TA (Cho, Kim, Chung & Hwang 2015; Chung, Kim, Cha & Hwang 2014) and quadriceps femoris together with CPN+TA (Ng, Tong & Li 2008; Tong, Ng & Li 2006).

While, it is important to report stimulation parameters as pulse frequency, duration and ramp time used for gait training, 14 studies (45%) did not report used frequency, 15 studies (48%) pulse duration and 28 studies (90%) did not specify ramp-up/down times. From the remining studies, the majority (N = 10) used frequency of 40 Hz/pps and pulse duration of 200 μs (N =4) or 300 μs (N = 6). The ramp time of 0.3s was mentioned by two studies (Ng, Tong & Li 2008; Tong, Ng & Li 2006) and another study reported range of 0 – 2s (Sharif, Ghulam, Malik & Saeed 2017).

3.5.3 Parameters of interventions

Among studies included in the review, the length of intervention was very variable, ranging from 1 week to 48 weeks in case of RCT's or longitudinal studies, and up to 5 years in case of retrospective studies. Nevertheless, the most common (N = 8) length of intervention was 8 weeks (Awad, Reisman, Kesar & Binder-Macleod 2014; Awad, Reisman, Pohlig & Binder-Macleod 2016; Everaert *et al.* 2013; Hakansson, Kesar, Reisman, Binder-Macleod & Higginson 2011; Reisman *et al.* 2013; Sabut, Lenka, Kumar & Mahadevappa 2010b; Sabut, Sikdar, Mondal, Kumar & Mahadevappa 2010a; Salisbury, Shiels, Todd & Dennis 2013). The number of therapy sessions was either 3

times or 5 times per week, or individuals used the stimulation daily during home activities and community walking. These intensities of weekly trainings were rather equally distributed over review studies (~1/3 of studies per each group).

In approximately 1/3 of reviewed studies (N = 9), the session duration lasted throughout the day during home and community activities (Bethoux *et al.* 2015, 2014; Everaert *et al.* 2013; Gervasoni *et al.* 2017; O'Dell *et al.* 2014; Street, Swain & Taylor 2017; van Swigchem, Vloothuis, den Boer, Weerdesteyn & Geurts 2010; Taylor, Humphreys & Swain 2013; Taylor *et al.* 1999b). The second most commonly mentioned intervention session was session lasting 30 min. without any additional specification of training program (N = 7). Two studies specified protocol either 4x6 min. with 1 min. on/off stimulation (Reisman *et al.* 2013) or 6x5 min. on stimulation with 5 min. break between sessions (Hakansson, Kesar, Reisman, Binder-Macleod & Higginson 2011) and 2 studies reported therapy sessions lasting 30 min. that included 27 min. of treadmill training with 1 min. on/off stimulation plus 3 min. of over-ground walking without electrical stimulation (Awad, Reisman, Kesar & Binder-Macleod 2014; Awad, Reisman, Pohlig & Binder-Macleod 2016).

3.5.4 Gait and satisfaction related outcomes

The significant improvements in gait speed after intervention were reported in 18 of 31 studies while 9 of 31 studies did not find any significant change. The typical improvement ranged from 0.1 to 0.18 m/s in 6 min. walk test and only 2 studies reported significant improvements in gait speed of 0.39 and 0.41 m/s in comparison with control group (Ng, Tong & Li 2008; Tong, Ng & Li 2006). Both these studies used FES together with a gait trainer.

In only 1 of 8 studies reporting therapy satisfaction results authors found nonsignificant results of Stroke Impact Scale and Stroke Specific Quality of Life measures when comparing FES group with group that used standard ankle foot orthosis (AFO) throughout the intervention (Bethoux *et al.* 2014). In remaining studies, the satisfaction with use of FES was significantly greater compared with use of AFO (Awad, Reisman, Kesar & Binder-Macleod 2014; Bulley, Shiels, Wilkie & Salisbury 2011;

Everaert *et al.* 2013; Fernandes, Carvalho & Prado 2006; O'Dell *et al.* 2014; van Swigchem, Vloothuis, den Boer, Weerdesteyn & Geurts 2010; Taylor *et al.* 1999a). The primary reasons for participants' satisfaction were being able to move the ankle more freely, reduction in the effort of walking, quality of gait pattern, less likely to trip, and walking safely, independently and with greater confidentiality. Nevertheless, it has to be noted, some individuals were dissatisfied/frustrated with the device and stopped the treatment. The main reasons were difficult electrode positioning, skin-issues, deterioration or mobility improvement and difficulty in use/placement of the equipment ("too much bother"). (Taylor *et al.* 1999a.)

3.5.5 Adverse events

Only 8 of 31 selected studies (26 %) reported serious adverse event as fall (Bethoux *et al.* 2015; Everaert *et al.* 2013; O'Dell *et al.* 2014), knee pain (Gervasoni *et al.* 2017), headache (Johnson, Burridge, Strike, Wood & Swain 2004; Johnson, Wood, Swain, Tromans, Strike & Burridge 2002), tendovaginitis of common peroneal nerve (van Swigchem, Vloothuis, den Boer, Weerdesteyn & Geurts 2010) or edema (Taylor *et al.* 1999a) related to the intervention. Five out of 31 studies (16 %) reported that none of serious adverse events occurred. Nevertheless, the half, 15 of 31 studies (48 %), did not report any detail concerning this important issue.

When reported (N = 10), the minor adverse events as skin irritation, muscle soreness, rash, discomfort, pain or skin allergy were relatively common. The occurrence ratios of these adverse events were not given with exception of one study by Taylor et al (Taylor *et al.* 1999a) were authors reported skin irritation in 22.3% of individuals involved in their study. However, these events did not preclude participants from the therapy continuation and were usually resolved in matter of days.

In summary, only 7 of 31 studies included larger populations (N > 50) and their results may provide unbiased insight into FES gait therapy effectiveness. Thus, the information concerning these interventions, used stimulation and interventions' results is provided in greater detail in Table 2.

Table 2: Summary of data extraction for studies with more than 50 participants per group

Study	Type of study	Population			Stimulation					
		Stage	# in intervention arm	# in control arm	Device	# of channels	Electrode placement	Frequency	Pulse duration	Trigger
Bethoux 2014	RCT	Sub-acute/ chronic	242	253 (AFO)	WalkAid	1	CPN + TA	Not reporter	Not reporter	Tilt sensor
Bethoux 2015	RCT	Sub-acute/ chronic	242	253 (AFO)	WalkAid	1	CPN + TA	Not reporter	Not reporter	Tilt sensor
O' Dell 2014	Pre-post	Sub-acute/ chronic	99	N/A	Bioness L300	1	CPN + TA	Not reporter	Not reporter	Foot switch
Street 2017	Pre-post	Chronic	133	N/A	Odstock Pace	1	CPN + TA	40 Hz	360 µs	Foot switch
Taylor 1999a	Retrospective	Not reported	151	N/A	Odstock Pace	1	CPN + TA	40 Hz	300 µs	Foot switch
Taylor 1999b	Retrospective	Chronic	78	N/A	Odstock Pace	1	CPN + TA	Not reporter	Not reporter	Foot switch
Taylor 2013	Retrospective	Chronic	62	N/A	Odstock Pace	1	CPN + TA	Not reporter	Not reporter	Foot switch

RCT – randomized control trial, N/A – not applicable, CPN – common peroneal nerve, TA – tibialis anterior, # - number

Table 2: Summary of data extraction for studies with more than 50 participants per group (continued)

Study	Intervention			Results	
	Length	**# sessions per week**	**Duration**	**Gait speed**	**Satisfaction**
Bethoux 2014	24 weeks	Every day	Home and community activities	No significant improvement	No significant between-group differences in SIS and SSQoL
Bethoux 2015	48 weeks	Every day	Home and community activities	No significant improvement	Not reported
O' Dell 2014	42 weeks	Every day	Home and community activities	0.12 m/s	Significantly greater satisfaction compared with use of AFO after 30 weeks
Street 2017	20 weeks	Every day	Home and community activities	0.14 m/s	Not reported
Taylor 1999a	18 weeks	Every day	Not reported	Not reported	Reduction in effort of walking and increased level of confidence
Taylor 1999b	1-2 years	Every day	Home and community activities	0.16 m/s	Not reported
Taylor 2013	Mean use of 5 years	Every day	Home and community activities	0.18 m/s	Not reported

- number, AFO – ankle foot orthosis, SIS – stroke impact scale measure, SSQoL – stroke specific quality of life

4 INTERVENTION

4.1 Study objectives

The current study aims at feasibility assessment of implementing the FES-walking therapy for stroke survivors as the first step of knowledge translation from research to standard clinical practice in Finland.

4.1.1 Primary objective

The primary objective of this study is to assess feasibility of implementing the FES-walking therapy in physiotherapy school setting. Specifically, a construct at a patient and program level will be tested: Safety, Adherence and Engagement (Table 3).

Safety as defined as the relative freedom from harm. In this study it refers to an absence of harmful side effects resulting from the use of FES-walking therapy and may be assessed by adverse events and negative change in clinical outcome measures i.e. decreased physical capacity (the Rivermead Mobility Index as a functional independence measure). Safety and tolerability of the FES-walking therapy will be represented by the degree to which minor adverse effects can be tolerated by the participant. Frequency of major adverse events will also be monitored to determine if they occur more frequently.

Adherence as defined in this study is the extent to which the participant continues the agreed-upon mode of treatment, in this case the parameters of the FES-walking therapy under limited direction when faced with conflicting demands (i.e. attendance – 3 days/week). In the case of this study we will monitor frequency and duration of training sessions attended.

Engagement, as defined in this study, is the emotional and intellectual involvement in the FES-walking therapy. For the patients we will use modification of the existing Patient Quality of Services Survey.

4.1.2 Secondary objective

The secondary objective of this study is to evaluate self-reported quality of life (EQ-5D), and changes in participants passive dorsiflexion and spasticity level of affected limb.

Table 3: Summary of features collected for assessment of FES-walking implementation feasibility

Criteria	**Safety**	**Adherence**	**Engagement**
Provider	# Injuries during FES-walking	# Consistency of trainer/participant alignment	# Training sessions attended # Issues addressed
Participants	# Minor/Major events documented	# FES-walking sessions attended # of discharges for FES-walking # of withdrawals	Out-patient Quality of Services Survey

4.2 Site of Study

The proposed study was conducted at the premises of the Satakunta University of Applied Science (SAMK, www.samk.fi) that included needed equipment, the body weight-supported treadmill, weight-supported over ground walking and/or parallel bars, for conduction of this study.

4.3 Study design

4.3.1 Study population

The present study is a single case study that provides an information whether it is feasible to utilize FES-walking therapy as a standard therapeutic tool in clinical practice. The selection of a case study was primarily based on feasibility aspects of the bachelor level of this study.

Potential participants were identified based on discussion with local stroke community that participated at lectures of Neurological physiotherapy at SAMK. The participation in this case study was offered based on the following selection criteria to ensure that the participant has a potential to benefit from the program (see Table 4) and that has the capacity to participate fully in the sessions (see Table 4). Once deemed eligible participant was offered a start date (January 8th, 2020) and time to begin participation. The participant was a 55-year old male (right-handed) with left side hemiplegia as a consequence of hemorrhagic stroke 14 years ago. This study was permitted by the Ethical committee of Satakorkea on December 9th, 2019. The application files as well as the committee statement can be found in the Appendix 1.

4.3.2 FES-walking therapy - implementation

During the initial gait assessment, the participant showed signs of drop-foot, insufficient hip flexion and push-off at the terminal stance phase of the left lower limb. Therefore, it was decided that the participant receives supportive stimulation of common peroneal nerve (CPN) together with tibialis anterior muscle (TA) on the left lower limb to trigger correction of drop-foot and flexion-withdrawal effect for better foot clearance during the gait swing phase. In addition, participant's left calf muscles (CA) was also stimulated to trigger push-off motion at the terminal stance phase and assist with knee flexion during the initial swing phase.

The participant received 15 sessions each involving up to 40 minutes of FES stimulation. Participant attended therapy 1 time per week during the first two weeks of intervention, 2 times per week during the third week and 3 times per week during the rest of the intervention, 7 weeks in total.

During the first three weeks (3 sessions in total), participant underwent a muscle strengthening (conditioning) protocol consisting of stimulation applied to the CPN, TA and CA muscles in 20-s duty cycles (i.e., 10 s extensors/dorsiflexion on and flexors/plantarflexion off followed by 10 s extensors off and flexors on). These exercises

Table 4: Summary of inclusion and exclusion criteria for KIK-Walk study

Inclusion criteria	Exclusion criteria
• Age ≥ 18 years and medically stable condition • Walking independently either with use of assistive devices or with speed < 0.5 m/s (preclusion of being community walker) during a 2-minute walking test. • Willingness and possibility to participate in FES-walking therapy • Responsiveness to electrical stimulation • Proximity to SAMK for realistic access • Access to reliable transportation	• Bilateral stroke • Tendon lengthening surgery in the last 6 months. If greater than 6 months, require surgeon's approval • Contraindications to FES (cardiac pacemakers, skin scratches or grade 2 or 3 pressure ulcers at potential electrode sites, denervation of targeted muscles) • Grade 4 Pressure ulcers anywhere on the lower extremities • Uncontrolled Hypertension or symptoms of orthostatic hypotension when standing for 15 minutes • Subjects with a history of cardiovascular disease, must obtain medical clearance from their primary care physician before inclusion • Amyotrophic Lateral Sclerosis or lower motor neuron disorders • Dependent on ventilator or unable to voluntarily extend head • Painful musculoskeletal dysfunction (e.g., knee deformity) or unhealed fractures • Fixed muscle contracture • Sensory or motor peripheral neuropathy • Unable to follow/understand verbal commands • Pregnancy • Psychological disorders • Uncontrolled seizure disorder • Illegal drug use • MRSA or other infectious diseases requiring contact droplet precautions • Active oncology diagnosis

were performed in four sets of 5 min with 5-min rests in between, with exception of the third session when the participant was able to undergo five sets in row. The slower start of the therapy was selected due to excessive muscle fatigue present during the first weeks of stimulation. FES stimulation was delivered by a preprogramed 2-channel transcutaneous electric stimulator (Cefar Rehab X2, DJO Global Inc., Lewisville,

Texas, USA) using surface self-adhesive stimulation electrodes and automatically triggered stimulation protocol.

The electrodes of the FES stimulator were placed on the subject's skin at the motor points above the nerves corresponding to the muscles targeted with FES (TA, CA) or the nerve (CPN) itself (Figure 6). Electrode size were selected according to the size of a muscle that needs to be activated: TA (electrode size, 2.5 x 2.5 cm), CPN (Ø 2 cm) and CA (2.5 x 2.5 cm). The stimulation used symmetrical, biphasic, current regulated pulses with 300 ms of pulse duration, ramp-up and ramp-down time of 0.2 s and at frequency of 35 Hz. The current varied based on muscle fatigue and stimulated site between 20 – 60 mA. When all targeted muscles were capable of creating joint movement against gravity (i.e., strength of grade 3 or more), the muscle strengthening protocol was terminated and FES-walking therapy began.

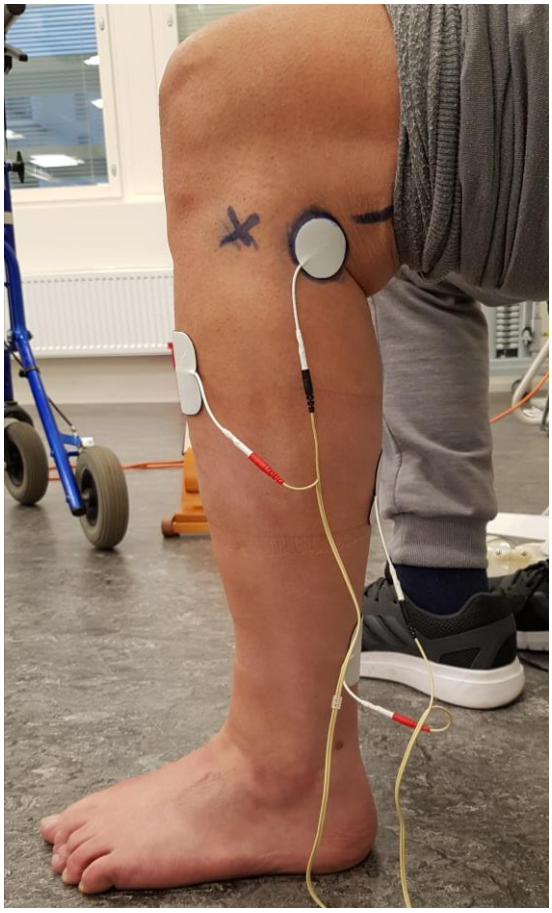

Figure 6: The electrode setup for stimulation of common peroneal nerve, tibialis anterior and calf muscles. The X denotes the head of fibula and vertical line the superior part of popliteal fossa.

The FES-walking therapy was performed on a treadmill with an overhead harness system for safety reasons, taking seated breaks when desired. The body weight support was set such that it was sufficient to assist the participant to achieve standing without knees buckling. The harness was worn on the treadmill at all times for safety.

The participant received 20–40 min of FES-walking therapy per session for 4 weeks, 3 times per week, taking seated breaks when desired. The treadmill speed was selected by attending physiotherapy student with input from the participant so that the walking speed felt comfortable and safe. During therapy, advices concerning gait pattern and correct timing of muscle activation were given to facilitate proper gait.

The FES stimulation was delivered by a 2-channel transcutaneous electric stimulator (O2CHS, Odstock Medical Ltd., Salisbury, UK) using surface self-adhesive stimulation electrodes. The electrodes were of same size and were placed on the same spots as during conditioning program (Figure 6). The stimulation used asymmetrical biphasic (TA and CPN) and symmetrical biphasic (CA), voltage regulated pulses with current between 40 – 70 mA, ramp-up and ramp-down time of 0.2 s, and frequency of 35 Hz. These parameters were individually tailored to guarantee the most optimal setting for gait cycle. The pulse duration varied between 150 – 350 ms based on muscle fatigue and stimulated site.

The gait sequence was triggered using two footswitches, one placed under left heel and the second under 1st metatarsal of left foot, to guarantee more accurate timing of the stimulation. The participant was encouraged to produce the intended movement voluntarily in every step and the stimulation was automatically triggered with a short delay to promote participant's own muscle activation. The TA and CPN stimulation began on toe off and with ramp-down time continued until toe strike. Calf stimulation started just after flat foot (toe strike) and continued to terminal stance.

4.3.3 Timeline and data collected

The intervention/study began on January 8th, 2020 and last until February 19th, 2020. During the baseline visit (January 8th, 2020), the participant filled following self-reported questionnaires (paper version) prior onset the actual intervention:

- Self-reported quality of life (EQ-5D, Appendix 2)
- Rivermead Mobility Index (RMI, Appendix 3)

Further, the participant's age, sex and duration of the disease was also recorded.

During the whole intervention, the number of sessions (frequency), duration of training sessions attended, any occurring injuries or health issues were recorded. Next, the participant was also asked to keep a self-administered diary and record any minor/major adverse event (AE) that occurred outside of the intervention site (e.g. falls, injuries even unrelated to the intervention itself). In addition, for additional safety reasons and to follow any progression in participant's mobility, the RMI questionnaire was filled on weekly basis.

After the therapy cessation (the 15th intervention session), the same questionnaires (EQ-5D and RMI) as during the baseline visit were administered. Further, a written form for self-reported survey of service quality was administered (Quality of Services Survey – Appendix 4) to gather participant's opinion about underwent intervention. In addition, participant's ankle mobility/spasticity was assessed to see whether the intervention had any effect on these parameters in comparison to the state recorded during participant's pre-intervention screening procedure (see details in Appendix 1).

Detailed summary of intervention timeline together with timing of administered questionnaires can be found in Table 5.

Table 5: Summary of timeline of administered questionnaires and data collection during intervention

Week	Date	Session	EQ-5D	RMI	AE reporting	Therapy adherence	QSS
1	8.1.20	Baseline	X	X		X	
2	17.1.20	2			X	X	
3	22.1.20	3		X	X	X	
	24.1.20	4			X	X	
4	27.1.20	5		X	X	X	
	29.1.20	6			X	X	
	31.1.20	7			X	X	
5	3.2.20	8		X	X	X	
	5.2.20	9			X	X	
	7.2.20	10			X	X	
6	10.2.20	11		X	X	X	
	12.2.20	12			X	X	
7	17.2.20	13			X	X	
	19.2.20	14		X	X	X	
	21.2.20	Follow up	X		X	X	X

EQ-5D – Self-reported quality of life, RMI – Rivermead Mobility Index, AE – adverse event, QSS – Quality of Service Survey

4.4 Statistical analysis

As this case study is primarily a qualitative study, only the changes in degrees of dorsiflexion of affected limb and the score changes of RMI questionnaire and spasticity of the affected limb with respect to pre-screening and baseline data are given as descriptive figures. Further, the amount of training sessions planned vs completed, and total, maximum and average time of stimulation as well as the number of minor events and description of issues addressed during training sessions is reported. In addition, the participant's satisfaction with the therapy is presented by pinpointing relevant answers from Quality of Service Survey completed at the end of the intervention.

4.5 Results

The participant was 55-year old male (right-handed) with left side hemiplegia as a result of stroke 14 years ago. He followed the agreed mode of treatment and participated in all 15 planned therapy sessions (therapy adherence was 100%). There were 2 conflicting events (from therapy provider site) during the course of the intervention, nevertheless, participant was always able to reschedule. The stimulation time varied from 20 to 35.5 min. with average duration of the FES intervention being 25 min and total time over course of 6 weeks was 65 min. of muscle conditioning and 315 min. of FES walking. The participants' self-selected comfortable treadmill speed was set to 0.8 km/h during the first week of the FES-walking therapy and to 1.0 km/h thereafter. Therapy adherence form can be seen in Appendix 5.

The ankle testing after the therapy cessation showed that the passive range of motion in dorsiflexion increased from 0 degrees to 15 degrees, spasticity of plantar flexors decreased from score of 4 to 3 in modified Ashworth spasticity scale, clonus related muscle contractions as well as Babinski sign decreased (no reaction when stimulating plantar aspect of affected foot).

The visual inspection of gait pattern (using AFO and wheeler) showed that participant's stride with affected leg is longer and straighter than before, participant's stride begins with clear heel-strike and no extensive leg circumduction was observed as prior the onset of the study – the participant was able to easily fit his affect leg between rear wheels of his wheeler during gait which was not feasible prior study initiation. The change of the gait pattern (the improvement in orthotic effect) during FES-walking therapy on body weight supported treadmill can be seen in video uploaded to YouTube account of Tomas Cervinka (https://youtu.be/vw1esl_3x6g).

While RMI questionnaire did not show any changes in physical capacity over the course of the study – score was constantly at 12 out of 15 points (Appendix 3), the self-reported quality of life (EQ-5D) questionnaire showed improvement in indication of current state of health from 70% to 80% (Appendix 2). In addition, participant's clear satisfaction with the therapy was expressed in the Modified Outpatient Quality

of Service Survey (Appendix 4). Specifically, participant would recommend the therapy to a friend of colleague (score 8 of 10), he was very satisfied with researchers' professionalism, care, time spent, attentiveness towards concerns, concern for privacy and transparency, quality of service and information provided. Further, in the open feedback field, participant provided following comments: "Feeling more relaxed", "spasticity decreased", "walking is straighter", "sleeping got better", "training was hard and tiring but effective", "I am very pleased with training (10+) and I recommend it to the others".

During the therapy, no injuries occurred (related or unrelated to the therapy itself). The only reported adverse therapy effect was mild skin redness on areas were electrodes were placed with exception of one mild adverse event (stiff leg for 24h after the stimulation) reported during week 6 (Appendix 6). The skin redness always disappeared by the end of the intervention day and participant fully recovered from limb stiffness after cancelling the 3rd therapy session during the week 6. In addition, researchers had to address 3 issues related to difficulties with triggering of the stimulation and one related to poor skin conductivity - too dry skin (Appendix 6).

5 DISCUSSION

5.1 Literature review

5.1.1 Population and study design

While the majority of studies selected for inclusion are randomized control trials, only two of them included populations larger than 50 individuals. One may question the undoubtedly difficulties in organizing proper RCTs, especially selection of appropriate participants that must be willing to undergo several weeks/months of intensive treatment with a need to travel to rehabilitation facility and back home. However, the patter obtained from the abstracted data points towards more obvious reason, study costs. The only two RCTs describing results of one study with follow up for 2 years used a

FES-based foot-drop WalkAid orthosis from Axionbionics, LLC and 5 of other studies that involved over 50 individuals were using either FES-based orthosis from Bioness Inc. or Odstock Ldt. Thus, it seems that only producers of foot-drop correcting orthoses, having their interest in spreading their products, have enough financial power to support extensive research. Nevertheless, as the authors always reported their potential conflict of interest, the author of this thesis leaves on the reader his/her position towards the study outcomes and their interpretation.

To reader surprise, it may also appear illogical that only 2 studies focused on acute phase of stroke rehabilitation. While, it is true that the acute phase is the most optimal time to start the rehabilitation to increase individuals' change for faster and significant motor recovery, it is also time with the largest spontaneous recovery – a window of enhanced natural neurophysiological repair and cortical reorganization (Coleman *et al.* 2017). If studying outcomes of new therapy intervention in this phase, investigators need much greater contrast between the experimental intervention and standard care to be able to distinguish whether the improvements in motor recovery occurred as a consequence of tested therapy approach or whether the improvements were triggered spontaneously by body's ability to "heal" itself (Stinear 2016). Therefore, majority of the authors prefer later phases of stroke recovery (sub-acute and chronic stage). During these phases, one may presume that spontaneous recovery is over and only the tested therapy approach may be accounted for all the gains or declinations in participant's condition. Nevertheless, these studies can't give us the needed knowledge about efficacy and effectiveness of tested experimental therapies during the spontaneous recovery phase. Consequently, their translation to acute clinical care can be controversial. (Stinear 2016.)

5.1.2 Electrical stimulation

The majority of the reviewed literature used a one-channel stimulator for correction of a drop foot. While, the drop foot (caused by dorsiflexor weakness of spasticity of plantar flexors) is the major impairment occurring post stroke, it is commonly accompanied by spasticity or weakness of knee and hip flexors/extensors (Wade, Wood, Heller, Maggs & Langton Hewer 1987). Therefore, a simple correction of dorsiflexion would

not be sufficient for ground foot clearance during gait if knee is spastic and fully extended (Li, Francisco & Zhou 2018).

The one-channel stimulation if applied to tibialis anterior and common peroneal nerve triggers the ankle dorsi flexion and flexion withdrawal reflex (a spinal reflex that causes a sudden withdrawal of leg from the potentially dangerous situation as stepping on a sharp object). Thus, this stimulation alone can address the major issue of hemiplegic gait (insufficient foot clearance of affected leg causing leg circumduction and/or hip hiking) by simultaneous stimulation of dorsiflexion and hip and knee flexion. This, together with readily availability of "easy to use" commercial products (WalkAid, Bioness, Odstock Pace), is probably the cause of the extensive research in this field of FES application among stroke survivor population. Although, it is clear that stroke survivors would benefit from multi-channel stimulation simultaneously addressing (i) avoidance of plantar flexion during pre-swing "push off" phase (Awad, Reisman, Kesar & Binder-Macleod 2014; Awad, Reisman, Pohlig & Binder-Macleod 2016; Hakansson, Kesar, Reisman, Binder-Macleod & Higginson 2011; Reisman *et al.* 2013) that may happen when only dorsiflexion triggered by one-channel stimulation is used (Kesar *et al.* 2010), (ii) stabilization of quadriceps and/or hamstrings during stance phase (Ng, Tong & Li 2008; Tenniglo, Buurke, Prinsen, Kottink, Nene & Rietman 2018; Tong, Ng & Li 2006), or (iii) stabilization of gluteus medius during stair walking (Cho, Kim, Chung & Hwang 2015; Chung, Kim, Cha & Hwang 2014). Nevertheless, the use of multi-channel stimulation requires more knowledge concerning device selection and setup, and gait kinematics (Cameron, Shapiro & Ocelnik 2018).

It is a common knowledge, repeated in professional conferences, that every study should provide complete information regarding used procedures to assure inter-study comparability and ensure reproducibility of future studies. Especially in clinical trials, underreporting can be seen as a scientific misconduct (Chalmers 1990). In the current review, this key reporting criteria was not followed in majority of included studies. Nevertheless, it is correct to note that not every stimulation parameter has to be reported as their setting is highly individual depending on performed task, responsivity of targeted nerves or muscles, perceived magnitude of sensation during electrical stimulation, and may vary in time (Cameron, Shapiro & Ocelnik 2018). Reporting ranges, in which parameter as stimulation intensity was set, would not provide any additional

information for design of future studies. Thus, only important parameters as stimulation frequency or pulse duration that affect "rapidness" of fatigue of stimulated muscles, used waveform pinpointing area of greater stimulation effect, or ramp-up/down times affecting swiftness of orthotic effect of stimulated muscles should be described in detail.

One may speculate that this under-reporting is caused by the use of pertinent FES-based foot-drop orthoses from companies as Axionbionics, LLC, Bioness, Inc. or Odstock, Ldt as their devices were use in over half of the studies selected for the review. Further, thirteen other studies did not report type of used stimulator but involved stimulation of TA and CPN, hence the use of FES-based orthoses from above mentioned companies may be presumed. It may be that these companies consider parameter set up as their trade secret and do not provide it freely. However, as presented in Table 2, two studies related to Odstock, Ldt, (Street, Swain & Taylor 2017; Taylor *et al.* 1999a) reported stimulation frequency and pulse duration. Therefore, this under-reporting seems to be more related by dilatoriness in reporting in this field.

5.1.3 Parameters of interventions

The reviewed studies presented a large variety of intervention durations lasting from 1 week up to 5 years long follow up in case of one retrospective study. "While the evidence regarding the optimal intensity of FES exercise therapy is currently unclear" (Teasell, Foley, Hussein, Salter, Cotoi & Richardson 2015), the common study duration (4 to 8 weeks), with training intensity of 3 – 5 sessions per week with session duration lasting ~30 min. corresponds to known timeline of muscular neuroadaptation and intermuscular coordination. The ability to activate more muscle fibers and an increase in the firing rate of neural impulses coming to muscles stays behind increased muscular strength, coordination and improved balance, the key factors for gait re-education even among athletes (Davis & Futrell 2016).

It is perhaps not surprising that studies with the longest duration (≥ 18 weeks) involved devices from the above mentioned 3 companies presenting their economic power and interest in knowing long-term rehabilitation effects of their devices. The economic

power can be also seen from the ability of these companies to provide their devices to study participants for the whole study duration. Therefore, the participants could wear the FES-orthosis throughout the day during their activities at home and community. This is especially important as recent evidence suggests that larger doses of FES exercise therapy (higher training intensity) are associated with better motor function recovery (Hsu, Hu, Luh, Wang, Yip & Hsieh 2012).

Of note, the Odstock, Ldt is a spinoff company of the Salisbury NHS Foundation Trust. Thus, their Pace stimulator is regularly offered to stroke survivors, those that can benefit from this type of support (i.e., are able to stand up from sitting without assistance and to walk with our without assistive aid ~10 m), by NHS as an alternative to standard ankle-foot orthosis (personal communication).

5.1.4 Outcomes of interventions

Walking (gait) speed is one of measures commonly used in studies that investigate and assess benefits/downfalls of experimental therapies in stroke rehabilitation because this measure can help with assessment of an individual functional status, identification of those at-risk of adverse outcomes as falls and can be used as an overall health factor in various populations (Middleton, Fritz & Lusardi 2015). This interest is also caused by the inevitability of physical therapist to prepare stroke survivors for as independent living in community as possible.

In 1995, Perry et al. (Perry, Garrett, Gronley & Mulroy 1995) defined functional categories of gait speed in stroke population as: " < 0.4m/s, Household walking only; 0.4 to 0.58 m/s, Most limited community walking; 0.59 to 0.79 m/s, Least limited community walking; ≥ 0.8 m/s, Community walking. As these cut-off values are relatively narrow, and studies usually involve only limited number of participants, it seems to be necessary to follow any changes in gait speeds during the studies with experimental rehabilitation thoroughly. It has been counted that for detection of gait speed change of 0.08 m/s (40% difference from 0.2 m/s which is the common speed at baseline of stroke rehabilitation) at 5% significance level, the study must include 32 individuals per study arm (group). This increases to 55 individuals if detection of speed change of

0.06 m/s is required. (Johnson, Wood, Swain, Tromans, Strike & Burridge 2002.) Therefore, the meaningful minimally clinically important speed difference of 0.1 m/s during 10 meter walking test and distance difference of 50 m for 6 minute walk test was estimated (Perera, Mody, Woodman & Studenski 2006).

Nevertheless, the cut-off values as defined by Perry at al. (Perry, Garrett, Gronley & Mulroy 1995) may not be valid when we consider safe speeds for passing pedestrian crossings. This study leaves the impression that speeds over 0.8 m/s are sufficient for community walking without issues. Similarly, the study by Asher et al. (Asher, Aresu, Falaschetti & Mindell 2012) showed that the mean speeds of individuals over 65 years old were 0.9 m/s for male and 0.8 m/s for women. However, the same authors pointed out that most of the pedestrian crossings in UK are designed for speeds of 1.2 m/s (estimated average of normal walking speed in able-bodied population), leaving values bellow this threshold insufficient for safe community living. Notwithstanding the fact that the crossing speeds largely vary between countries, mean of 1.32 m/s in United States, range of 0.73 – 0.78 m/s in Singapore, mean of 0.44 m/s in Australia and range of 1.0 – 1.2 m/s in Ontario (Salbach *et al.* 2014), physical therapy should still focus on improving gait speed of stroke survivors so that they would be as close to value of 1.2 m/s as possible at discharge. Although, such speed was only reached in the reviewed studies by those individuals with moderated to mild impairments at therapy onset.

There are number of questionnaires that can be used to evaluate disability and health-related quality of life after stroke. Among these, the most used are the stroke impact scale (Jenkinson, Fitzpatrick, Crocker & Peters 2013) and Stroke Specific Quality of Life (Williams, Weinberger, Harris, Clark & Biller 1999) that take into account relevant domains as mental, physical, mobility, memory, participation etc. Surprisingly, only three studies included in the review used such questionnaires (Awad, Reisman, Kesar & Binder-Macleod 2014; Bethoux *et al.* 2014; Fernandes, Carvalho & Prado 2006). The other studies focused on qualitative outcomes to describe individuals' self-perception (attitudes, preferences, comfort, issues or safety) of underwent therapies. Although, nearly all reported outcomes only favoring the FES-based therapy, someone can question these results because lack of quantitative data ("numbers in black and white"). Nevertheless, as one can't predict the study outcomes and it is very hard to

develop pertinent questionnaires to assess an individual's self-perception, the qualitative approach allowing free "mind" expression may be suitable for these studies in this context (Hammarberg, Kirkman & de Lacey 2016).

5.1.5 Adverse events

Reporting of adverse events is a crucial component of good clinical practice (GCP) guidelines. The transparent and accurate reporting of adverse events is a key factor for "patient safety considerations as well as the importance of balancing assessments of efficacy versus risk profile for therapeutic interventions in clinical trials". (Miller 2012,) While it is constantly reminded throughout the scientific community and mandated by research ethics boards, adverse events remain under documented.

When evaluating included articles, one could think that adverse event reporting improved throughout the time and the most recent publications will follow the GCP guidelines. However, this is not the case. Even the recent publications from year 2017 (Sharif, Ghulam, Malik & Saeed 2017; Xu, Guo, Salem, Chen & Huang 2017) did not provide any commentary concerning this important issue. One may speculate that the authors wanted to conceal a serious adverse event potentially "harming" the experimental therapy design. Nevertheless, the occurrence of such events among reviewed studies is less than 0.01%, pointing more at the authors' inactivity towards accurate reporting. Especially in cases when serious adverse events did not occur and a simple note (no adverse events occurred during the intervention) would suffice.

One may also question the seemingly high rate or minor events as skin irritation that occurred in nearly one fourth of the study participants (Taylor *et al.* 1999a). Nevertheless, the 10-year follow up study, showed that the occurrence of this adverse event was reduced among users of Odstock Pace FES-orthosis to only 2.4% (Dalton & Taylor 2011).

5.2 KIK-walk intervention

5.2.1 Therapy adherence

The current study reported 100% adherence to therapy plan without participant's withdrawal during ongoing intervention. This is mainly cause by the nature of the supervised case study and participant's high motivation to try new therapy approach that could lead to improvement of his life quality. Nevertheless, among longitudinal studies, the therapy adherence rates (proportion of attended planned sessions) usually vary from 65% to 90% (mean of 77%) depending on whether the therapy is supervised or individual, and whether the therapy uses clinic-based or home-based program design with home-based supervised program having the higher rates (Bullard, Ji, An, Trinh, Mackenzie & Mullen 2019; Picorelli, Pereira, Pereira, Felício & Sherrington 2014). The dropout rate (proportion of individuals exiting the program prior cessation of the intervention) is generally very low, reaching up to 5% at maximum (Bullard, Ji, An, Trinh, Mackenzie & Mullen 2019).

5.2.2 Changes in body structures and function

The FES-based therapies showed their effectivity in gait rehabilitation when considering aspects as activity and participation, and are therefore recommended by number of stroke rehabilitation guidelines (Teasell *et al.* 2020; Veerbeek *et al.* 2014a; Winstein *et al.* 2016). Nevertheless, the benefits in body structures and function domain are not that clear when compared with other gait rehabilitation approaches (Pereira, Mehta, McIntyre, Lobo & Teasell 2012).

The re-testing of ankle dorsiflexion showed that the 6-week intervention program was sufficient for decreasing participant's plantar flexor spasticity and consequently ankle passive range of motion. This finding is in line with previous study by Sabut et al. (Sabut, Sikdar, Kumar & Mahadevappa 2011) where authors reported greater improvements in voluntary ankle dorsiflexion, plantar flexor spasticity and dorsiflexor strength when FES stimulation was used in addition to conventional rehabilitation over

course of 12-week intervention study. To date, however, it seems to be the only study addressing this issue (van der Linden & Mercer 2017).

Already during the ongoing intervention, the author noted some changes (reduction in leg circumduction, hip hiking and visible heal strike) when participant walked (having AFO) towards his car post intervention session. These changes further improved until the intervention cessation and were also noted by the participant. Participant described the change as if his affected leg would go straighter during walking and that he can fit it in between rear wheels of his wheeler. Further, he pointed out that his leg feels less stiff and AFO is making clicking sounds during terminal stance of his gait. Although, this study did not involve any proper video analysis of participant's gait, the increase in orthotic effect and consequently the improvement in walking pattern (e.g., visible heel strike, increased weight-shift to the affected site, reduced leg circumduction and hip hiking) over the course of the study is clearly visible from the short recording of participant's gait on the treadmill. These outcomes have been also recognized previously during FES-based gait rehabilitation (Sabut, Lenka, Kumar & Mahadevappa 2010b) together with significant reduction in physical effort of walking (Laufer, Hausdorff & Ring 2009; Sabut, Sikdar, Mondal, Kumar & Mahadevappa 2010a). Thus, the results of this study confirm previous findings.

5.2.3 Changes in activity and participation

Because of the nature of this study – a single case study, the most common measure of activity, the walking speed over course of 10m or interval of 6 min. (van der Linden & Mercer 2017), was not assessed as it would not provide any relevant data. Instead, the researchers assessed participant's mobility in transfers, gait, and balance (not as a measure of community mobility) by weakly RMI questionnaire, specifically developed and validated in individuals post stroke (Chen, Hsieh, Sing, Liaw, Chen & Lin 2007; Forlander & Bohannon 1999), so that any deterioration or improvement in participant's condition could be detected timely. However, no functional deterioration or improvement was detected over the course of the 6-week intervention. As for possible improvement, the intervention was probably too short to observe any changes as the participant already reached a high score prior onset of the intervention.

On contrary, the generic health status questionnaire (EQ-5D) as well as feedback in Modified Outpatient Quality of Service Survey showed clear improvements in participant's self-perception of health and participation. The one aspect, the participant stressed during few last sessions, was improvement in his gait pattern. This improvement (as described in detail in section 5.2.2) helped him during shop visits as he felt much more relaxed, could walk around with greater confidence and comfort. The participant was very surprised and pleased as he did not expect any change that could occur in such a short time.

Nevertheless, positive significant changes in quality of life, as assessed by SF-36 questionnaire, were reported by Fernandes et al. (Fernandes, Carvalho & Prado 2006) only after 7 weeks of FES-based intervention targeting CPN and tibialis anterior. Similarly, Swigchem et al. (van Swigchem, Vloothuis, den Boer, Weerdesteyn & Geurts 2010) reported that the participants (chronic phase) were more satisfied with the use of FES-orhosis (Bioness L300) than with standard AFO regarding walking effort and stability, quality of gait pattern and walked distance after only 8 weeks of their study. Therefore, it may be that huge changes in participation, from participants' self-perspective, can be reached even in chronic stroke population and after relatively short-term therapy.

5.2.4 Adverse events addressed

As mentioned earlier, to date, the description of adverse events occurring during interventions remains underreported. Therefore, one focus of this study was to record any possible difficulties or health issues that arise during the course of this intervention to provide overall picture about complications clinician may face during commencement of this type of therapy.

The adverse effects, constantly occurring during the intervention, were related to a minor skin irritation/redness that disappeared within few hours post treatment. This is a very common consequence of electricity applied on skins via self-adhesive electrodes and reported by various authors (Bethoux *et al.* 2015, 2014; Street, Swain & Taylor 2017; Taylor, Humphreys & Swain 2013). Another mild adverse effect was once reported stiffness of the whole leg that occurred during the following day after

second session of week 6. Because of this, the researchers allowed the participant longer recovery time between consequent therapy sessions. As the effect diminished within two days, it was probably only a delayed onset of muscle soreness (DOMS) that may occur after increasing of training time or intensity and decreasing of the training load is the recommended approach to quickly alleviate the DOMS symptoms (Cheung, Hume & Maxwell 2003). Although, researchers did not alter the stimulation intensity, it may be that the participant was overloaded due to a cumulative training load as he actively visited gym 4 times per week throughout the intervention. Nevertheless, none of these reported effects was serious enough to prohibit continuation of the study.

The other adverse events were related to technical issues with triggering of the electrical stimulation and skin conductivity. Specifically, researchers had to solve technical problem with a footswitch placed under the first metacarpal that wasn't sufficiently pressed during walking (due to elevated first metacarpal in comparison to other foot segments) and consequently not triggering stimulation of plantar flexors at the terminal and pre-swing phase of participant's gait. This was solved by adding paper padding between the participants foot and the footswitch to guarantee proper contact of the footswitch with shoe insole. Further, the poor skin conductivity was solved by proper cleaning of the skin surfaces under electrodes and use of moisturizing cream. None of these issues, however, required long interruption of the therapy and were successfully handled during the sessions (Appendix 6).

5.3 Limitations

There are, however, few issues worth discussion. First, the literature review part of this study was only based on search of one database (PubMed). Thus, identified articles and the abstracted data might not be the proper representation of the current knowledge. Second, the nature of the literature review (systematized review) may have been a cause of a bias in the literature search and data abstraction by itself as all decision-making concerning data inclusion and data evaluation was purely done by the author without any correcting input from another person. Third, the presented intervention is only a case study. Therefore, presented outcomes, should be interpreted with caution and can't be generalized on whole stroke population. And lastly, the study

participant was an individual at chronic stage of the disease without any comorbidities or requirements for special therapy. Thus, the therapy could focus only on retraining of gait pattern without a need to consider any other health related issues.

6 CONCLUSION

The overall aim of this thesis is to introduce the FES for neurorehabilitation in Finland. While, the future is hardly predictable, and the author cannot enforce the use of this approach in clinical practice, this thesis summarizes and provides all necessary knowledge that one needs for clinical application of multi-channel FES in gait rehabilitation. In addition, this thesis presents a successful commencement of a case study showing that the participant was very satisfied with study progress and outcomes. Therefore, the author hopes, that this work provides enough information to encourage physiotherapists in Finland and shows them that such a rehabilitation approach can be also used in relatively low-cost settings.

7 FUTURE PROSPECTS

While everyone in neurorehabilitation field has heard of electrical stimulation, and the FES-based therapy is recommended in many national guidelines (Teasell *et al.* 2020; Veerbeek *et al.* 2014a; Winstein *et al.* 2016) there is still a common fear of electricity among physiotherapists that limits the use of such a rehabilitation approach in clinical practice (Auchstaetter *et al.* 2016). While the author hopes that this study can be used as a example for those that are interested and just do not know how to proceed, future studies should focus on investigation of areas of this therapy that are not yet well described. This includes (i) the benefits of 2 or more stimulating channels for gait training (stimulation patterns which are closer to normal gait patterns in able-bodied population), (ii) the orthotic and training effects of FES (whether the FES can be used to retraining weakened muscles or needs to be used only as an orthotic device), (iii) the

benefits of FES training in walking on uneven surfaces or surfaces with obstacles compared with UFO, (iv) the effect on body functions as ankle dorsiflexion, reduction of spasticity or knee hyperextension, (v) the kinematic of walking in 3D to clearly show the changes in gait pattern (e.g., describing changes in body limping, hip hiking, leg circumduction, hip and knee flexion or ankle dorsiflexion), (vi) the possible reduction of fall incidents (as measured prior and after the intervention), and especially (vii) the cost/time effectiveness of this treatment approach. (van der Linden & Mercer 2017.) Only by providing clear answers and evidence depicting benefits of this rehabilitation approach, one can achieve its wide spreading among physiotherapists. Thus, the next step for future research is to organize a larger scale study in clinical setting as hospital or rehabilitation clinic to address one or all above mentioned issues.

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Appendix 1

Ethical application

COVER LETTER

1. PROJECT IDENTIFICATION

Title	**Keep Improving Kinematics in Walking (KIK-Walk): Functional Electric Stimulation Based Locomotor Training**
Primary Investigator	Tomas Cervinka, Sc.D. (Tech.), MSc. (Biomed. Eng.), PT student (SAMK)
Site of research	Satakunta University of Applied Science, Pori, Finland
Supervisor	Maija Kangasperko, PT(Am) MSc., Senior Lecturer, Degree Program Coordinator, Satakunnan University of Applied Science, Pori, Finland

2. CONTACT DETAILS OF PHYSIOTHERAPY STUDENT

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3. RESEARCH PURPOSE

This bachelor research project is a pilot study designed to prove the feasibility of implementing FES therapy in everyday practice at physiotherapy school setting as the first step of implementing it to standard clinical practice in Finland. It will provide a useful information concerning patient's interest to undergo such an unconventional therapy and the study results will also provide basis for a larger multi-center clinical trial using developed protocol.

4. RESEARCH RATIONALE

Current research indicates that the functional electrical stimulation (FES) based therapy, a key component of activity-based therapy, has a potential to improve walking competence of individual with neurological disorders (e.g., stroke), and consequently their quality of life. As the population is getting older (number of stroke survivors is increasing), the incorporation of FES-based therapies may improve and speed up individuals' recovery.

Nevertheless, the use of neuromuscular stimulation among physiotherapists and especially in task-oriented therapies is still low, mainly due to a lack of training, time and equipment. Therefore, this study aims at introduction and barriers eradication of the FES and specifically the FES-walking therapeutic approach in clinical setting in Finland.

Specifically, the project will evaluate 1) participants safety, 2) adherence to agreed mode of treatment, and 3) engagement of an individual taking part in this uncommon therapy involving electrical stimulation.

Grounds for requesting ethical review: The proposed research involves use of electrical stimulation applied to the participants muscle through surface self-adhesive stimulation electrodes that may potentially affect the safety of study participant.

Keep Improving Kinematics in Walking (KIK-Walk): Functional Electric Stimulation Based Locomotor Training

Primary Investigator Tomas Cervinka, Sc.D. (tech), MSc. (Biomed Eng), Physiotherapy student (SAMK)
Supervisors Maija Kankasperko, PT (Am) MSc., Senior Lecture, Degree Program Coordinator, Satakunnan University of Applied Science, Pori, Finland.

Table of Contents

BACKGROUND

Today, the advances in acute medical management of stroke are changing the neurological population. The percentage of individuals that suffered stroke and survived the first month has increase to more than 85% (Meretoja et al., 2011). The activity-dependent plasticity of the neural pathways, once thought to be unresponsive and incapable of recovery, serves as one prong of scientific evidence challenging the assumptions of current clinical practice (Behrman et al., 2006). Activity-based gait therapy, combining research on neural plasticity and the role of spinal cord in stepping and standing is applied to Locomotor Training (LT). LT works to "awaken" dormant neural pathways by repetitively stimulating the muscles and nerves in the lower body. LT is commonly used for stroke survivors and other neurological disorders. The current evidence shows that many stroke survivors have improved their walking after receiving therapeutic gait training utilizing various modalities (e.g., body weight-support treadmill (BWST) training, robot-based locomotor training) in research programs and rehabilitation clinics internationally, regardless of the time elapsed since their disease onset (Mehrholz et al., 2017). Nevertheless, these modalities require large amount of men power and/or expensive device as BWST or robot.

Functional Electrical Stimulation based LT (FES-walking), on the other hand, can be used in conjunction with parallel bars or over ground walking; decreasing the need of expensive equipment. Further, the recent research has shown that stroke survivors have the capacity to improve voluntary walking function following short-term intensive FES therapy (Howlett et al., 2015; Masani and Popovic, 2011). Furthermore, the positive effects seemed to be remaining even after therapy cessation (Howlett et al., 2015; Stein et al., 2015). Therefore, the FES-walking restorative therapy may be possibly used to enhance spinal

neuroplasticity, instead of using it as a pure compensatory walking aid (e.g., Bioness or WalkAid) as was done in the past (Masani and Popovic, 2011; Popovic and Thrasher, 2004).

It has been also reported that the FES-walking has positive effects on muscle density, quality of life and walking competence (Wilkie et al., 2012), and potential to emulate normal mechanical strains on bone during weight-bearing activity. These strains may stimulate bone formation through alterations in muscle activity that cannot be achieved with BWST- or robot-based LT training alone (Coupaud et al., 2009).

Although, the first electrical stimulation for drop foot prevention in stroke survivors was introduced already in 1961 (Liberson et al., 1961) and benefits of the FES therapies among stroke survivor population compared with conventional exercise programs have been described elsewhere (Howlett et al., 2015; Mehrholz et al., 2017). Nevertheless, the use of neuromuscular stimulation among physiotherapists and especially in task-oriented therapies (including therapeutic goals as walking, arm function, muscle strength, endurance and sensation, prevention of shoulder subluxation, or decrease of spasticity) is still low. This is mainly due to a lack of training (inability to use the stimulation with proper setting for execution of intended tasks), time and equipment (Auchstaetter et al., 2016).

In Canada, this limitation has been recently recognized and recommendations concerning incorporation of FES, as one of the key components of activity based therapy, into the main stream health care and community programs have been made (Behrman et al., 2017). In addition, the use of FES is in the Canadian best practice accreditation guidelines in Stroke rehabilitation. Therefore, this study is proposed to introduce the FES in Finland, show potential applications and find out whether potential patients would be satisfied with the FES-walking therapeutic approach if used clinically.

STUDY OBJECTIVES

The current study aims at feasibility assessment of implementing the FES-walking therapy for stroke survivors as the first step of knowledge translation from research to standard clinical practice in Finland.

The primary objective of this study is to assess feasibility of implementing the FES-walking therapy in physiotherapy school setting. Specifically, a construct at a patient and program level will be tested: Safety, Adherence and Engagement (Table 1).

- **Safety** as defined as the relative freedom from harm. In this study it refers to an absence of harmful side effects resulting from the use of FES-walking therapy and may be assessed by adverse events and negative change in clinical outcome measures i.e. decreased physical capacity (the Rivermead Mobility Index as a functional independence measure). Safety and tolerability of the FES-walking therapy will be represented by the degree to which minor adverse effects can be tolerated by the participant. Frequency of major adverse events will also be monitored to determine if they occur more frequently.
- **Adherence** as defined in this study is the extent to which the participant continues the agreed-upon mode of treatment, in this case the parameters of the FES-walking therapy under limited direction when faced with conflicting demands (i.e. attendance – 3 days/week). In the case of this study we will monitor frequency and duration of training sessions attended.
- **Engagement,** as defined in this study, is the emotional and intellectual involvement in the FES-walking therapy. For the patients we will use modification of the existing Patient Quality of Services Survey (Appendix 1)

The secondary objective of this study is to evaluate self-reported quality of life (EQ-5D).

Refer to the anticipated schedule and data collection section for list of outcome measures and collection time points.

Table 1: Summary of features collected for assessment of FES-walking implementation feasibility

Criteria	Safety	Adherence	Engagement
Provider	• # Injuries during FES-walking	• # Consistency of trainer/participant alignment	• Training sessions attended • Issues addressed
Participants	• # Minor/Major events documented	• # FES-walking sessions attended • # of discharges for FES-walking • # of withdrawals	• Out-patient Quality of Services Survey

RATIONALE FOR FES-WALKING

The FES-walking has a potential to improve walking competence of stroke survivors, and consequently their **quality of life** (Wilkie et al., 2012). As the population is getting older and number of stroke survivors is increasing, the incorporation of FES-based therapies may improve and speed up individuals' recovery (Howlett et al., 2015; Stein et al., 2015). This will result in shorter hospitalization times and improved self-ambulatory and -caring in individual's own home environment. Further, this therapy (i) can also **ease the burden on required manpower** during rehabilitation process – the amount of involved personnel decreases from 3-4 involved in conventional BWST-LT to 1-2 depending on stage of participant progress, (ii) can be used either in combination with treadmill, parallel bars or over-ground walking, (iii) has a potential to improve walking competence and consequently quality of life after **only a short term intensive therapy** (Stein et al., 2015, 2010), and (iv) is **low costs** compared with use of robots (20-fold) enabling its use among small rehabilitation clinics with limited budget. Consequently, incorporation of FES-based therapy may result in **enormous savings in health and social care costs**.

SITE OF RESEARCH

The proposed study will be undertaken at the premises of the Satakunta University of Applied Science (SAMK, www.samk.fi) that include needed equipment, the body weight-supported treadmill, weight-supported over ground walking and/or parallel bars, for conduction of this study.

STUDY DESIGN

Study population

The proposed study is a case study that will provide information whether it is feasible to utilize FES-walking therapy as a standard therapeutic tool in clinical practice. The sample size of 1 participating individual is primarily based on feasibility aspects of the bachelor level of this study.

Potential participants will be identified based on discussion with local stroke community (Aivoliitto). The participation in this case study will be offered based on the following selection criteria to ensure that the participant has a potential to benefit from the program and that has the capacity to participate fully in the sessions.

Inclusion Criteria:

- Age ≥ 18 years
- Medically stable condition

- Walking independently either with use of assistive devices or with speed < 0.5 m/s (preclusion of being community walker) during a 2-minute walking test.
- Willingness and possibility to participate in FES-walking therapy
- Responsiveness to electrical stimulation
- Proximity to SAMK for realistic access
- Access to reliable transportation
- First stroke of cerebrovascular origin with hemiplegia, at least 3 months in duration
- PNS without evidence of uncontrollable knee hyperextension

Exclusion Criteria:

- Bilateral stroke
- Tendon lengthening surgery in the last 6 months. If greater than 6 months, require surgeon's approval
- Contraindications to FES (cardiac pacemakers, skin scratches or grade 2 or 3 pressure ulcers at potential electrode sites, denervation of targeted muscles)
- Grade 4 Pressure ulcers anywhere on the lower extremities
- Uncontrolled Hypertension or symptoms of orthostatic hypotension when standing for 15 minutes
- Subjects with a history of cardiovascular disease, must obtain medical clearance from their primary care physician before inclusion
- Amyotrophic Lateral Sclerosis or lower motor neuron disorders
- Dependent on ventilator or unable to voluntarily extend head
- Painful musculoskeletal dysfunction (e.g., knee deformity) or unhealed fractures
- Fixed muscle contracture
- Sensory or motor peripheral neuropathy
- Unable to follow/understand verbal commands
- Pregnancy
- Psychological disorders
- Uncontrolled seizure disorder
- Illegal drug use
- MRSA or other Infectious Diseases requiring contact droplet precautions
- Active oncology diagnosis

FES-walking therapy

FES-walking therapy will be performed on a BWTS with harness system for safety reasons, taking seated breaks when desired. The body weight support will be set such that it is sufficient to assist the participant to achieve standing without knees buckling. As the therapy progresses, the amount of body weight support will decrease with the goal of achieving no support or assistance.

Depending on the muscle weakness in lower extremities (number of muscle groups with score of 3 or less in manual muscle testing), FES will be delivered using up to two 2-channel transcutaneous electric stimulators using surface self-adhesive stimulation electrodes. The two stimulators will work independently, not being synchronized. The gait sequence of a designated leg will be manually triggered using a footswitch or push button, depending on suitability for the participant. Typically, the therapist activates the push button shortly after heel-off but before the toe-off phase of the gait cycle. However, in cases where a subject has a good balance and control, they will be given the option to control the stimulation by themselves.

The electrodes of the FES stimulator will be placed on the subject's skin at the motor points above the nerves corresponding to the muscles targeted with FES or the nerve itself (peroneal nerve for foot drop

stimulation). Electrode size will vary according to size of muscle that needs to be activated: quadriceps (electrode size, 5 x 10 cm), hamstrings (electrode size, 5 x 10 cm), tibialis anterior/peroneal nerve (electrode size, 2.5 x 2.5 cm) and gastrocnemius (electrode size, 2.5 x 2.5 cm). The stimulation will use balanced, biphasic, and current regulated pulses.

The stimulation parameters will be individually tailored to guarantee the most optimal setting, pulse amplitudes will range from 8 – 125 mA, pulse durations from 0 – 400 μs, and frequencies from 20 – 50 Hz. Pulse-width modulation will be used to regulate temporal activity of the muscle contraction, the pulse amplitude to regulate the strength of the participant's muscle contraction. The participants will be encouraged to produce the intended movement voluntarily in every step. However, if not successful, the movement will be triggered by the FES stimulator. In case of a footswitch, the stimulation will be automatically triggered with a delay after heel-off to promote participant's own muscle activation.

Implementation

The physiotherapy student (Tomas Cervinka), based on discussion with local stroke community, will inform the leading physiotherapist (Maija Kangasperko, SAMK) of an individual who meets the pre-screening (inclusion) criteria for the study. The leading physiotherapist or physiotherapy student together with leading physiotherapist will inform potential participants of the study, explain the nature of the study, along with the purpose, methods and design, anticipated benefits and anticipated risks involved with the study and answer any related questions, and obtain written informed consent if potential participant expresses his/her interest to undergo this study.

All potential participants will be screened by the leading physiotherapist for feasibility. Once deemed eligible participant will be offered a start date and time to begin participation. The eligible participant will receive a battery of initial assessments (the Rivermead Mobility Index and EQ-5D quality of life questionnaire) by the physiotherapy student prior to initiation of the therapy. The participant will receive 15 sessions each involving up to 45 minutes of FES stimulation. Participant will attend therapy 3 times per week, 5 weeks in total. In the case of constant muscle fatigue, a frequency of 2 sessions per week may be used if deemed appropriate by the leading physiotherapist or the physiotherapy student. Re-assessment of participant's performance (Rivermead Mobility Index) will be done on weekly basis, when there is a significant change in participant's conditions or after 15 sessions as per discharge criteria (Appendix 2).

Based on an initial gait evaluation done by the physiotherapy student under supervision of leading physiotherapist, it will be determined whether the participant has a leg that scores 4 or greater on knee flexion/extension, ankle dorsiflexion and plantar flexion in the Manual Muscle Test. If so, the FES stimulation will be only applied to the weak muscles.

During the first three to four sessions, participant undergoes a muscle strengthening (conditioning) protocol consisting of stimulation applied to the weak muscles in 20-s duty cycles (e.g., 10 s extensors on and flexors off followed by 10 s extensors off and flexors on). These exercises will be performed in four sets of 5 min with 5-min rests in between. When all targeted muscle will be capable of creating joint movement against gravity (i.e., strength of grade 3 or more), the muscle strengthening protocol will be terminated and FES-walking therapy will begin. During this muscle conditioning, participant will be seated or placed into an overhead harness system (depending on group of stimulated muscles) to prevent accidental falls due to unexpected reactions during first stimulations.

The FES-walking therapy will be performed on a treadmill with an overhead harness that is attached to cables and pulleys so that a constant upward force is applied to the participant while walking. The harness will be worn on the treadmill at all times for safety. Overground walking with harness or parallel bars may be used as a subsequent step of the therapy, if participant's performance allows it (based on assessment of the leading physiotherapist). The participant will receive the FES-walking therapy for at least 15–30 min

per session, taking seated breaks when desired. The body weight support will be set such that it is sufficient to assist the participant to achieve standing without knees buckling. As the therapy progresses, the amount of body weight support will decrease with the goal of achieving no support or assistance. The treadmill speed will be selected by attending physiotherapy student with input from the subject. During therapy, manual assistance will be applied to the subject's lower extremities and/or lower back when needed to facilitate normal gait. The leading physiotherapist will be present during all assessments and first training session to guarantee the safety of the participant. Further, the leading physiotherapist will have a detailed schedule of the intervention and will visit the sessions regularly on a weekly basis or when requested by the physiotherapy student or the participant.

ANTICIPATED SCHEDULE AND DATA COLLECTION

The estimated time to complete the study presented in this research proposal is 8 months. The study time is divided to 3 periods (preparation, intervention and data analysis). Even though the objectives are challenging, the unique applicant's knowledge, the applicant acquired during PhD, post-doctoral and physiotherapy studies as well as presence of an experience physiotherapist with over 30 years of clinical practice and the straight forward nature of the research plan makes the schedule realistic.

The first stage (preparation part) of the study will begin in **November 2019 and last until January 2020**. During this phase, all research and ethical permits will be obtained, recruitment of potential participants will begin and study place at the SAMK will be prepared for conduction of the second (intervention) stage of this study. All the preparations will be done by the physiotherapy student (Tomas Cervinka) under direct supervision of the leading physiotherapist (Maija Kangasperko).

During this process, the physiotherapy student with supervising leading physiotherapist will assess potential participants in face-to-face interview and 2-minute walking test according to inclusion and exclusion criteria. The interview and test results will be recorded on a checklist forms (Appendix 3 and 4). If an individual meets all the inclusion criteria, potential participant will be provided additional information concerning the study and offered to sign a consent form to continue the progress. The potential participant will be also informed that **he/she can withdraw from the study at any point without giving any reason**.

If the potential participant agrees to participate in the study, the he/she will receive **an identification numerical code** (starting by 001) that will be used on all following testing documents, questionnaires and study results. As the documents (inclusion/exclusion criteria check list and consent form) contain participant's name, given identification numerical code and telephone number, they will be **stored in a separate envelope in a locked cabinet** at the SAMK's office of the leading physiotherapist to prevent any possible identification of study participating person by any unauthorized person. If an individual doesn't meet all the inclusion criteria or will not present his/her interest in undergoing the study, the checklist documents will be shredded and disposed.

The consenting participant will then undergo a face-to-face physiotherapy assessment to evaluate his/her skin integrity, passive range of motion in hips, knees and ankles, and muscle strength of gluteus maximus, quadriceps, hamstring, tibialis anterior and calf muscles by manual muscle testing. These tests will be performed by the leading physiotherapist or the physiotherapy student under direct supervision of the leading physiotherapist to guarantee individual's safety during the locomotion triggered by FES. The results of these test will be recorded on a written form (Appendix 5).

If the consenting participant will pass the safety testing and will be still willing to continue the study, he/she will be offered a start day of the study, the form containing results of the physical assessment will be stored in an envelope in a locked cabinet at the SAMK's office of the leading physiotherapist, and recruitment process will be terminated. If an individual doesn't pass the safety criteria or will not present

his/her interest in undergoing the study, the checklist document will be shredded and disposed, and recruitment process will continue.

The second stage (intervention part) of the study will begin **on January 20th, 2020 and last until February 21st, 2020.** The intervention will take place at the SAMK premises. The starting date may be slightly advanced or postponed based on participants needs. During this phase study participants will undergo muscle conditioning program (3-4 sessions) followed by the FES-walking therapy for 4 weeks with 3 sessions per week.

1. During the baseline visit on January 20th, 2020, the physiotherapy student (under supervision of the leading physiotherapist) will administer following self-reported questionnaires (paper version) to the study participant prior onset the actual intervention:
    a. Self-reported quality of life (EQ-5D, Appendix 6)
    b. Rivermead Mobility Index (RMI, Appendix 7)

    In addition, the physiotherapy student will record participant's age, sex and duration of the disease. **No other personal details will be recorded**.

2. During the intervention participant will be asked to keep a self-administered diary and record any minor/major adverse event that occurred. Investigators (Tomas Cervinka and Maija Kangasperko) will follow-up with these recording at the beginning of every therapy session and record the events on a paper form (Appendix 8). Further, investigators will use the same form to record injuries during therapy and all issues that appeared during the therapy and how they were addressed. In addition, investigators will record on a paper form (Appendix 9) the number of sessions (frequency) and duration of training sessions attended, and ask the participant to fill the RMI on weekly basis.

3. After the therapy cessation, the same questionnaires (EQ-5D and RMI) as during the baseline visit will be administered. In addition, a written form for self-reported survey of service quality will be administered (Quality of Services Survey - Appendix 1) and collected by investigators.

Table 2: Summary of timeline of administered questionnaires and data collection during intervention

Week	Session	EQ-5D	RMI	Adverse event reporting	Therapy adherence	Quality of Service Survey	Collected by
1	Baseline	X	X		X		TC or MK
	2			X	X		TC or MK
	3			X	X		TC or MK
2	4		X	X	X		TC or MK
	5			X	X		TC or MK
	6			X	X		TC or MK
3	7		X	X	X		TC or MK
	8			X	X		TC or MK
	9			X	X		TC or MK
4	10		X	X	X		TC or MK
	11			X	X		TC or MK
	12			X	X		TC or MK
5	13		X	X	X		TC or MK
	14			X	X		TC or MK
	Follow up	X	X	X	X	X	TC or MK

All the questionnaires and data recording will be done by the leading physiotherapist (MK) or by the physiotherapy student (TC) under direct supervision of the leading physiotherapist.

The third stage (data analysis part) of the study will begin in **June 2020 and last until August 2020**. During this phase all collected (de-identified) data will be processed by physiotherapy student (Tomas Cervinka) at the Satakunta University of Applied science and transferred to an electronic form that will be stored on a private OneDrive school account of Tomas Cervinka. **The identifiable forms (inclusion/exclusion criteria) and consent form will remain safely stored in a locked cabinet at the SAMK's office of the leading physiotherapist.** After that, Tomas Cervinka will analyze and evaluate/interpret the data at his private computer at his home. In addition, a bachelor thesis will be written with description of study results.

Please, see details concerning data management in separated data management plan.

RISK ANALYSIS

Strengths

- Implementation of the study protocol is evidence-based
- Experience with use of FES in neurological rehabilitation
- Experienced physiotherapist able to recognize who can benefit from the therapy and any possible threats to the participant
- Dedicated area at SAMK with all necessary equipment for the research
- Medically trained personal available at SAMK facilities
- Use of novel therapeutic approach that is not commonly available at clinical settings.
- No collection of identifiable data with exception of age, sex and duration of disease

Weaknesses

- Lack of financial support to cover participant's expenses (e.g., transportation)
- Physiotherapy school setting, results may not be directly applicable for clinical settings
- Novel therapeutic approach that is unknown to majority of possible participants
- Fear of electricity (electricity-based stimulation)
- Use of electrode system with wires that need to be taped to the participants body during the locomotion
- Possible glue (electrodes) induced skin reactions
- Possible negative effect of the electrical current on participant's skin
- No direct reach of inner-hospital first aid response unit
- Physiotherapy school setting, an individual can be recognized at the premises during the study duration
- No dedicated research office of the leading physiotherapist for data storage (open office)

Opportunities

- Improved quality of life of the participant
- Gaining proved intervention protocol that can be re-usable in ongoing or future research projects at SAMK
- Increase national visibility of the faculty with respect to educational research
- Possible change of clinical practice (therapeutic strategies) when dealing with stroke patients -> with use of FES, patients can stand up and rehabilitate as soon as medically stable
- If knowledge spreads nationwide, possible improvements in stroke survivors' recovery (e.g., decreased spasticity, increased muscle strength and mobility)

Threats

- Not being able to find and appropriate participant that meets all the inclusion criteria, can benefit from the study and can undergo the intervention safely
- Having only one participant that may not finish the study due to health, personal reasons etc.
- Having only one participant, any illness or unexpected life situations can confound the adherence data
- Equipment failure
- Limited time window to perform the intervention

APPLICABILITY OF THE RESULTS AND FUTURE DIRECTION

This is a pilot study designed to prove the feasibility/usability of implementing FES-walking therapy in everyday physiotherapy practice. While it is only a short-term intervention, it will also provide a useful information about participants' interest to undergo this type of unconventional therapy and whether any adverse events occur.

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Keep Improving Kinematics in Walking (KIK-Walk): Functional Electric Stimulation Based Locomotor Training

Primary Investigator Tomas Cervinka, Sc.D. (tech), MSc. (Biomed Eng), Physiotherapy student (SAMK)
Supervisors Maija Kankasperko, PT (Am) MSc., Senior Lecture, Degree Program Coordinator, Satakunnan University of Applied Science, Pori, Finland.

BACKGROUND

Today, the advances in acute medical management of stroke are changing the neurological population. The percentage of individuals that suffered stroke and survived the first month has increase to more than 85%. The activity-dependent plasticity of the neural pathways, once thought to be unresponsive and incapable of recovery, serves as one prong of scientific evidence challenging the assumptions of current clinical practice. Activity-based gait therapy, combining research on neural plasticity and the role of spinal cord in stepping and standing is applied to Locomotor Training (LT). LT works to "awaken" dormant neural pathways by repetitively stimulating the muscles and nerves in the lower body. LT is commonly used for stroke survivors and other neurological disorders. The current evidence shows that stroke survivors have improved their walking after receiving therapeutic gait training utilizing various modalities (e.g., body weight-support treadmill (BWST) training, robot-based locomotor training) in research programs and rehabilitation clinics internationally, regardless of the time elapsed since their disease onset. Nevertheless, these modalities require large amount of men power and/or expensive device as BWST or robot.

Functional Electrical Stimulation based LT (FES-walking), on the other hand, can be used in conjunction with parallel bars or over ground walking; decreasing the need of expensive equipment. Further, the recent research has shown that stroke survivors have the capacity to improve voluntary walking function following short-term intensive FES therapy. Furthermore, the positive effects seemed to be remaining even after therapy cessation.

Although, the first electrical stimulation for drop foot prevention in stroke survivors was introduced already in 1961 and the benefits of the FES therapies among stroke survivor population compared with conventional exercise programs have been described elsewhere. Nevertheless, the use of neuromuscular stimulation among physiotherapists and especially in task-oriented therapies is still low, mainly due to lack of training. Therefore, this study is proposed to introduce the FES in Finland, show potential applications and find out whether potential patients would be satisfied with the FES-walking therapeutic approach if used clinically.

STUDY OBJECTIVES

This study aims at feasibility assessment of implementing the FES-walking therapy for stroke survivors as the first step of knowledge translation from research to standard clinical practice in Finland. Specifically, a construct at a patient and program level will be tested: Safety, Adherence and Engagement. In addition, self-reported quality of life will be evaluated.

RATIONALE FOR FES-WALKING

The FES-walking has a potential to improve walking competence of stroke survivors, and consequently their **quality of life**. As the population is getting older and number of stroke survivors is increasing, the incorporation of FES-based therapies may improve and speed up individuals' recovery. This will result in shorter hospitalization times and improved self-ambulatory and -caring in individual's own home environment. Further, this therapy (i) can also **ease the burden** on required manpower during rehabilitation process – the amount of involved personnel decreases from 3-4 involved in conventional LT to 1-2 depending on stage of participant progress, (ii) can be used either in combination with treadmill, parallel bars or over-ground walking, (iii) has a potential to improve walking competence and consequently quality of life **after only a short term intensive therapy**, and (iv) is **low costs** compared with use of robots (20-fold) enabling its use among small rehabilitation clinics with limited budget. Consequently, incorporation of FES-based therapy may result in **enormous savings in health and social care costs**.

METHODOLOGY

The proposed study will be undertaken at the premises of the Satakunta University of Applied Science (SAMK, www.samk.fi) that include needed equipment, the body weight-supported treadmill, weight-supported over ground walking and/or parallel bars, for conduction of this study.

Potential participants (n = 1) will be identified based on discussion with local stroke community (Aivoliitto). The participation in this case study will be offered based on strict selection criteria to ensure that the participant has a potential to benefit from the program and has the capacity to fully participate.

The eligible participant receives a battery of initial assessments (Functional Independence Measure and quality of life questionnaire) prior to initiation of FES-walking therapy. The participant will receive 15 sessions each involving up to 45 minutes of FES stimulation. Participant will attend therapy 3 times per week, 5 weeks in total. Re-assessment of participant's performance will be done when there is a significant change in participant's conditions and/or after 15 sessions.

Based on an initial gait evaluation, it will be determined whether the participant has a leg that scores 4 or greater on knee flexion/extension, ankle dorsiflexion and plantar flexion in the Manual Muscle Test. If so, the FES stimulation will be only applied to the weak muscles. FES will be delivered using transcutaneous electric stimulators via surface self-adhesive stimulation electrodes. During the first three to four sessions, participant undergoes a muscle strengthening (conditioning) protocol consisting of stimulation applied to the weak muscles in 20-s duty cycles (e.g., 10 s extensors on and flexors off followed by 10 s extensors off and flexors on). These exercises will be performed in four sets of 5 min with 5-min rests in between. When all targeted muscle will be capable of creating joint movement against gravity (i.e., strength of grade 3 or more), the muscle strengthening protocol will be terminated and FES-walking therapy will begin.

ANTICIPATED SCHEDULE

The estimated time to complete the study presented in this research proposal is 8 months. The study time is divided to 3 periods (preparation, intervention and data analysis). The preparation will begin in November 2019 and last until January 2020. The intervention part of the study will be initiated in January 2020 and last until March 2020. The data analysis part will start in June 2020 and last until August 2020.

Paranna kävelyn kinematiikkaa (*engl. KIK Walk*): Funktionaaliseen sähköstimulaatioon perustuva liikkumisharjoittelu

Vastaava tutkija Tomas Cervinka, TkT, fysioterapiaopiskelija (SAMK)

Ohjaaja Maija Kangasperko, (Amk), lehtori, koulutusohjelmakoordinaattori, Satakunnan ammattikorkeakoulu, Pori, Suomi.

TAUSTAA

Aivoinfarktien akuutissa lääkinnällisessä hoidossa vaikuttaa nykypäivän neurologisista oireista kärsivän väestön kokonaistilanteeseen. Aivoinfarktista henkiin jääneiden osuus on ensimmäisen kuukauden jälkeen noussut yli 85%:in. Hermoreiden aktiivisuusriippuvaisen plastisuuden on aiemmin ajateltu olevan kykenemätön palautumaan vakavista haittatapahtumista. Aivoinfarktista toipuminen tarjoavat kuitenkin yhden uuden tieteellisen suunnan ja se haastaa nykyiset kliiniset toimintatavat. Aktiivisuuteen perustuvaa askel-terapiaa, joka yhdistää tutkimustietoa neuroplastisuudesta eli hermostollisesta joustavuudesta sekä selkäytimen roolista kävelyssä ja seisomisessa, sovelletaan lokomotorisessa harjoittelussa (LT, *engl. Locomotor Training*). Lokomotorisessa harjoittelussa alavartalon lihasten ja hermojen toistuva stimulointi toimii uinuvien hermoväylien ”herättäjänä”. Lokomotorista harjoittelua on tavallisesti käytetty aivohalvauksen tai muun neurologisen toimintahäiriön omaavilla henkilöillä. Tämän hetken tieteellinen näyttö kertoo, että useat edellä mainittuun ryhmään kuuluvista potilaista, jotka ovat saaneet terapeuttista askelhoitoa, ovat parantaneet kävelykykyään riippumatta siitä, kuinka kauan aikaa on kulunut heidän sairautensa alkamisesta. Hoitoa on toteutettu tutkimusohjelmissa ja kuntoutusklinikoilla, joissa on hyödynnetty moninaisia työvoimaintensiivisiä tai kalliita laitteita vaativia kuntoutusmuotoja kuten kehonpaino-tuettua juoksumattoharjoittelua (BWST*, engl. body weight-support treadmill*) tai robotiikkaan perustuvaa liikeharjoittelua.

Toisaalta hoitomuotona voidaan käyttää toiminnalliseen sähköstimulaatioon perustuvaa lokomotorista harjoittelua (FES-kävely, *engl. Functional Electrical Stimulation-walking*) yhdessä nojapuu- tai ”ympäriinsä” kävelyn kanssa, jolloin kalliiden laitteiden tarve vähentyy. Tämän lisäksi viimeaikainen tutkimus on osoittanut, että aivoinfarktista selvinneillä on kyky parantaa tahdonalaista kävelytoimintoa lyhytaikaisen intensiivisen FES-hoidon avulla. Positiiviset vaikutukset näyttivät lisäksi säilyvän myös hoidon päätyttyä.

Ensimmäinen sähköstimulaatioon perustuva interventio alaraajojen toimintahäiriöiden ennaltaehkäisyyn aivoinfarktista selvinneillä esiteltiin jo vuonna 1961. Myös FES-hoidon edut kuvattiin aivoinfarktista selvinneillä väestössä tavanomaiseen harjoitusohjelmaan verrattuna jo silloin. Niinpä FES:iin perustuvat hoitomuodot ovat joissain maissa, kuten Kanadassa, osa neurologisen kuntoutuksen Käypähoito-suositusta. Silti neuromuskulaarisen stimulaation käyttö on yhä fysioterapeuttien ja erityisesti toiminnallisten terapioiden joukossa vähäistä johtuen pääasiassa koulutuksen puutteesta. Tämän

tutkimuksen tarkoituksena on selvittää toiminnallisen ja sähköstimuloidun kävelyn (FES) toteuttamiskelpoisuutta niin että FES terapiaa voisi tulla käyttöön kliinisessä kuntoutuksessa Suomessa.

TUTKIMUKSEN TAVOITTEET

Tämän tutkimuksen tavoitteena on arvioida FES-kävelyhoidon soveltuvuutta aivoinfarktista selvinneillä henkilöillä Suomessa. Täten tutkimus on ensiaskel laboratiivisen tutkimustiedon siirtämiseksi kliiniseksi käytännöksi. Hoitomallia testataan erityisesti potilas- ja ohjelmatasolla. Se tarkoittaa turvallisuuden, hoitoon sitoutuneisuuden ja siihen osallistumisen selvittämistä. Lisäksi tutkimuksessa arvioidaan yksilöiden itse arvioitua elämänlaatua ja käytetään fyysisen toimintakyvyn mittareita, jotka kuvaavat yksilön liikkumiskykyä.

FES-KÄVELYN PERUSTEET

FES-kävelyn avulla on mahdollista parantaa kävelykykyä ihmisille joita selvinnyt aivoinfarktista, ja tällä tavoin myös kohentaa heidän elämänlaatuaan. Kun väestö Suomessa ikääntyy ja samaan aikaan aivohalvauksesta henkiin jääneiden lukumäärä kasvaa, FES-perusteisen hoidon liittäminen muihin hoitoihin voi sekä edistää että nopeuttaa yksilöiden parantumista. Tämä puolestaan lyhentää sairaalassaolojaksoja ja kohentaa omaehtoista liikkumista sekä mahdollistaa hoivaa kotiympäristössä. Tähän liittyen uusi hoito voi i) keventää hoitoresursseihin kohdistuvaa taakkaa kuntoutusprosessin aikana, koska tarvittavan hoitohenkilöstön määrä putoaa tavanomaisen lokomotorisen hoidon vaatimasta 3-4 henkilöstä 1-2 henkilöön kuntoutettavan edistymisestä riippuen. Lisäksi lokomotorinen hoito (ii) voidaan yhdistää joko juoksumaton, nojapuiden tai ”ympäriinsä kävelyn” hyödyntämiseen, (iii) se omaa potentiaalia edistää kävelykykyä ja sen myötä elämänlaatua jo lyhyen intensiivisen hoitojakson jälkeen ja lisäksi (iv) lokomotorinen hoito on edullisempaa kustannuksiltaan, kun sitä verrataan esimerkiksi robottien käyttöön (joista syntyy 20- kertaiset kustannukset) ja se mahdollistaa hoidon myös pienillä resursseilla toimivilla kuntoutusklinikoilla. Kaiken kaikkiaan FES-perusteisen hoidon liittäminen osaksi potilaiden kuntoutusta voi johtaa suuriin säästöihin terveys- ja sosiaalimenoissa.

MENETELMÄT

Tutkimus toteutetaan Satakunnan Ammattikorkeakoulussa (SAMK). SAMK tarjoaa BWST valmennuksen käyttöön tarvittavat tutkimustilat ja -laitteet.

Potentiaaliset osallistujat (n = 1) identifioidaan paikallisen aivohalvausyhteisön (Aivoliitto) kanssa. Tarkat valintakriteerit täyttäville potilaille, joilla on arvioitu olevan kuntoutusmuodon vaatima toimintakyky ja mahdollisuus hyötyä ohjelmasta, tullaan tarjoamaan mahdollisuutta lähteä mukaan tutkimukseen.

Tutkimukseen soveltuvat osallistujat testataan ennen FES-kävelyhoidon aloittamista lähtötasoarviossa, johon kuuluvat Rivermeadin liikkumiskyky -indeksi, sekä kyselyllä tehtävä itsearviointi elämänlaadusta. Osallistujille tarjotaan FES-stimulaatiota 15 kertaa 45 minuutin jaksoissa, jotka toteutetaan kolmena käyntinä viikossa viiden viikon ajan. Osallistujien suorituskyvyn uudelleenarviot tehdään, jos/kun on havaittavissa merkittävä muutos osallistujan tilassa ja/tai intervention lopuksi 15 käynnin jälkeen.

Alkutilanteen askelluksen perusteella *Manual Muscle- testissä* määritellään osallistujan alaraajojen lihastoiminnalle pistemäärä, joka on joko neljä tai suurempi polven koukistuksessa/ojennuksessa sekä nilkan dorsaali- ja plantaarifleksiossa. Näissä tapauksissa FES-stimulaatiota sovelletaan vain heikommille

lihaksille. Jos molemmissa jaloissa todetaan yhtäläistä lihasheikkoutta sekä vahvuudessa että toiminnassa, FES-stimulaatiota sovelletaan molempiin jalkoihin. FES tapahtuu käyttämällä itsekiinnittyviä transkutaanisia (ihoaläpäiseviä) sähköstimulaatioelektrodeja. Ensimmäisten kolmen tai neljän käynnin aikana osallistujat saavat lihaksia vahvistavaa hoitoa, jossa stimulaatio kohdistuu heikkoihin lihaksiin 20 vuoron sykleissä (esim. 10 sekunnin ajan ojentajiin, jolloin koukistajat ovat levossa ja seuraavaksi ojentajat ovat levossa, jolloin 10 sekunnin stimulaatio kohdistuu koukistajiin). Nämä harjoitteet tehdään viiden minuutin sarjoissa, joissa on vuoroin viisi minuuttia harjoittelua ja viisi minuuttia lepoa. Kun kaikki kohdelihakset pystyvät tuottamaan nivelen liikettä vetoa vastaan (esim. voima-asteikolla 3 tai enemmän), lihasten vahvistusohjelma päättyy ja FES-hoito voi alkaa.

TUTKIMUKSEN AIKATAULU

Tässä suunnitelmassa esitetty kliininen tutkimus on kestoltaan kahdeksan kuukautta. Tutkimusaika on jaettu kolmeen jaksoon (valmistelu, interventio ja aineisto-analyysit). Valistelu alkaa lokakuussa 2019 ja kestää tamikuun 2020 asti. Intervention alkaa tamikuussa 2020 ja lopuu maaliskuussa 2020. Aineisto-analyysit alkavat kesäkuussa ja kestävät elokuun 2020 lopuun asti.

SUPERVISOR'S CONTACT DETAILS

1. PROJECT IDENTIFICATION

Title	**Keep Improving Kinematics in Walking (KIK-Walk): Functional Electric Stimulation Based Locomotor Training**
Primary Investigator	Tomas Cervinka, Sc.D. (Tech.), MSc. (Biomed. Eng.), PT student (SAMK)
Site of research	Satakunta University of Applied Science, Pori, Finland
Supervisor	Maija Kangasperko, PT(Am) MSc., Senior Lecturer, Degree Program Coordinator, Satakunnan University of Applied Science, Pori, Finland

2. CONTACT DETAILS OF SUPERVISING PHYSIOTHRAPIST

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samk

TUTKIMUKSESTA VASTAAVAN HENKILÖN ARVIO TUTKIMUKSEN EETTISYYDESTÄ

Tutkimuksessa noudatetaan tutkimusta koskevia määräyksiä ja ohjeita. Tutkimukseen vapaaehtoisesti osallistuvaa henkilöä on informoitu omaan osallistumiseensa vaikuttavista asioista. Tutkittava lukee ja allekirjoittaa suostumuslomakkeen, jossa nuo asiat on myöskin kerrottu. Kyseessä on case-tutkimus, jossa on vain yksi koehenkilö. Siinä noudatetaan hyvää eettistä käytäntöä.

Tutkimuksen suorittava henkilö Tomas Cervinka on perehtynyt ja kouluttautunut FES-laitteen käyttöön. Hän on myös suorittanut demonstraation omasta osaamisestaan tutkimuksesta vastaavalle ohjaavalle opettajalle Maija Kangasperkolle.

Tutkimukseen osallistuvan turvallisuudesta on huolehdittu ja mahdolliset riskitekijät arvioitu ja ne on selvitetty koehenkilölle. Tutkimuksesta vastaava henkilö on mukana ensimmäisellä kerralla ja muilla toteutuskerroilla tarvittaessa.

Tutkittavalle on selvitetty, miten hänen tietojaan käytetään, miten ne säilytetään ja kenellä niihin on pääsy.

Maija Kangasperko Degree Programme Coordinator 5.11.2019 Pori

Maija Kangasperko | Degree Programme Coordinator | Date | Place

KIK-Walk Study

Patient Information Form

Title of Study	Keep Improving Kinematics in Walking (KIK-Walk): Functional Electric Stimulation Based Locomotor Training
Primary Investigator	Dr. Tomas Cervinka, PT student (Am)
Supervisors	Maija Kankasperko, PT (Am) MSc.

This is an observational study of a walking training program involving functional electrical stimulation (FES) for stroke survivors. For research purposes, we would like to assess the feasibility of using novel therapy for improvement of Your walking competence in physiotherapy school setting. During the study, we would like to collect information concerning therapy's safety and how well You can follow the requirements of this training program. In addition, we would like to collect outcome measures related to self-reported quality of life and physical functioning (mobility index describing Your ability to stand up, walk, walk the stairs etc.).

Introduction

The brain naturally uses electrical current while communicating with other body parts. When an individual wants to move, the brain sends electrical signals through nervous system to activate/contract muscles that are needed for the particular movement. In individuals with neurological disorder as stroke, these signals may be altered or do not reach the targeted muscles. Therefore, muscles do not contract as needed to perform desired movement.

The FES-based therapy uses an electrical current from an outside source that is directly applied to the skin over nerve controlling paralyzed or weakened muscle, or over the bulk of the muscle itself. This external stimulation simulates the brain function and causes muscle contractions. These contractions can assist the weakened or paralyzed muscles in functional movements as walking. By improving the muscle contractions, the FES-based therapy promotes an increase in muscle strength, mobility, and decreasing pain and muscle spasticity. Consequently, the FES-based therapy may help to prevent muscle loss and/or promote recovery of normal movement functions.

Risks

The FES is generally well tolerated and serious medical complications are rare. The most common problems with FES are discomfort or pain ("pins and needles" like sensation on skin), skin redness or irritation, nausea, light-headedness, or autonomic dysreflexia. The discomfort can range from a mild tingling to almost a burning sensation depending on stimulation parameters. Nevertheless, these parameters can be easily adjusted to decrease the discomfort in most of the cases. The skin redness may be left in places where electrodes were placed on the skin because of glue used on self-adhesive electrodes, but this redness usually disappears within an hour. In rare cases, the non-latex hypoallergenic electrodes have to be used to solve the problem.

Less common risk or rare side effects are skin breakdown, fainting, worsening of muscle spasms, muscle and joint injuries (strains or swelling), bone fractures in case of severe osteoporosis, and mild electrical burns near electrodes in case of improper use or faulty equipment. In case of signs that similar complications should occur, the intervention will be immediately terminated.

Procedures

The FES therapy is planned to last 5 weeks with frequency of 3 sessions per week (15 sessions in total). Each therapy session will take 60min. to complete and all sessions will be held at SAMK premisses. The therapy is divided into two phases. During the phase one, first 3 to 4 sessions, You will undergo a muscle strengthening protocol consisting of stimulation applied to the weak muscles. The stimulation will be performed in four sets of 5 min (in cycles of 10s with stimulation on and 10s off) with 5-min rests in between. This protocol ensures that stimulated muscles can produce sufficient strength for following FES-based walking therapy. The phase two will consist of 11 to 12 sessions during which You will receive the FES-walking therapy on a treadmill with an overhead harness for at least 15–30 min per session, taking seated breaks when needed. During the therapy, you will try to initiate the steps on your own at first. If your muscles will not contract sufficiently to perform the step movement, the supervising physiotherapist or a switch placed into Your shoe will trigger the electrical stimulation that will assist You in performing the movement (step). While on the treadmill, You will always wear the harness for safety to prevent falls. Overground walking or walking between parallel bars may be used later within the therapy, if Your performance allows it.

Timeline and data collection

The study is planned to start on January 20th, 2020. However, in case of time issues, we can slightly postpone or advance the study according Your needs. During the first visit, the physiotherapy student (under supervision of the leading physiotherapist) will give You two paper self-reported questionnaires, related to your life quality and physical functioning, to fill. In addition, You will be asked to provide your current age, sex and time post stroke in months/years. After filling the questionnaires, they will be collected, and the first therapy session will begin. During the first therapy, a short video (view from knees down) of Your walking will be recorded with and without FES stimulation. This video will serve as a baseline information for assessing of the walking progress after the cessation of the intervention. Later, the video will used for promotion of this approach and for educational purposes, as well as in bachelor thesis of Tomas Cervinka.

During the study, You will be asked to fill the questionnaire related to Your physical functioning on weakly basis to follow any possible change in Your condition. In addition, You will be asked to document on daily basis and report to us any adverse event (untoward medical occurrence) that will occur during the study duration. Adverse events are defined as any change in your medical condition, injury, changes in your skin integrity, eczema etc. You will be asked to record everything even if the events may seem to be un-related to the therapy. The purpose of this report is to collect information concerning safety and tolerability of this intensive therapy.

During the last session on February 21st, 2020, the second short video, showing the progress/changes in Your walking pattern after the 5 weeks of intervention will be recorded.

After the last session, You will be again asked to fill paper self-reported questionnaires, related to Your life quality and physical functioning. In addition, You will be also asked to complete a Quality of Services Survey

questionnaire. The purpose of the survey is to learn about your experiences with the FES-walking therapy and whether You would be interested to continue with such a therapy during standard rehabilitation.

The summary of study timeline with specified time points for questionnaire collection, together with information who will be collecting/recording the data, is provided in Table 1.

Table 1: Summary of timeline of administered questionnaires and data collection during intervention

Week	Phase	Session	EQ-5D	RMI	Adverse event reporting	Therapy adherence	Quality of Service Survey	Collected by
1	1	1	X	X		X		TC or MK
		2			X	X		TC or MK
		3			X	X		TC or MK
2		4		X	X	X		TC or MK
	2	5			X	X		TC or MK
		6			X	X		TC or MK
3		7		X	X	X		TC or MK
		8			X	X		TC or MK
		9			X	X		TC or MK
4		10		X	X	X		TC or MK
		11			X	X		TC or MK
		12			X	X		TC or MK
5		13		X	X	X		TC or MK
		14			X	X		TC or MK
		15	X	X	X	X	X	TC or MK

EQ-5D – quality of life questionnaire, RMI – questionnaire related to physical functioning, Therapy adherence – record of the number of sessions and duration of training sessions. All the questionnaires and data recording will be done by the leading physiotherapist (MK) or by the physiotherapy student (TC) under direct supervision of the leading physiotherapist.

Data storage and archiving plan

After signing the consent form, You will receive a unique identification (ID) number and only this ID will be used on all paper forms, questionnaires and videos that will be later collected by investigators Tomas Cervinka or Maija Kangasperko during the study. Concerning personal information, **only age, sex and time post stroke will be recorded** in addition to your name and telephone number.

All collected data, except the videos, will be stored in envelopes in a locked cabinet at the SAMK's office of the leading physiotherapist. However, a key file linking Your information (name and telephone number) to the ID together with consent form will be stored separately from the other collected data in a closed envelope to prevent Your possible identification by an unauthorized person. The video recordings of Your gait (view from knees down) will be stored in personal storage cloud of Tomas Cervinka without Under given ID and protected by a password. Data collected during the study will be stored for research purposes for 10 years upon completion of the study.

Confidentiality

If You participate in this study, it is important to note that a copy of Your signed consent form and the data that follows will be stored at the Satakunta University of Applied Science (SAMK). Only Your data related to your age and sex, time post stroke, count of adverse events, study adherence and engagement, results

of self-reported questionnaires (quality of life, physical functioning, patient quality of service survey) and video of your gait pattern will be stored in paper and electronically and may be shared outside of the SAMK. Nevertheless, all research study data collected and stored in Your research file will not be shared with anyone except with Your consent or as required by law.

All collected personal information (Your name and phone number) will be removed from the collected data and will be replaced with a number. A list linking the number with your name, together with consent form, will be kept separately from data collected during the study in an envelope in a locked cabinet of the leading physiotherapist (Maija Kangasperko). If the results of the study are published, Your name will not be used and no information that discloses Your identity will be released or published without Your specific consent to the disclosure.

Nevertheless, we have to inform You that despite of our best intention to not reveal Your name, You may be noticed at the school premises during your visits and faced with questions related to the reason why You visit the school premises regularly.

Data ownership and usage rights

By signing the consent form and agreeing to participate in the study, You will give Your permission to use all collected de-identified data for future analyses and other research purposes. It also means that the data collected during this study (age and sex, time post stroke, count of adverse events, study adherence and engagement and results of self-reported questionnaires) may be shared outside of the Satakunta University of Applied Science with permission from investigators.

Conflict of Interest

Investigators/researchers have an interest in completing this study. However, their interests should not influence Your decision to participate in this study.

Rights as a Participant

If you volunteer to be in this study, You may withdraw at any time point without giving reason. If You withdraw from the study, You have the option of removing any or all of Your data from the study, with the exception of data already published or reported in research forums.

If during the course of the study, we identify an unanticipated abnormality or reaction. We notify Your primary healthcare provider (family physician or physiatrist) with the results so You can receive the appropriate follow-up care.

If You are harmed as a direct result of taking part in this study, all necessary treatment will be made available to You through physiotherapy school insurance.

Questions About the Study

If You have any questions, concerns or would like to speak to the study team for any reason, please call: the physiotherapy student Tomas Cervinka +358 xx xxx xxxx or please call the study supervisors and leading physiotherapist Maija Kangasperko PT, MSc. +358 xx xxx xxxx.

KIK-Kävely tutkimus

Potilaan tiedonantolomake

Tutkimuksen aihe	KIK-kävely (Keep Improving Kinematics in Walking): Functional Electric Stimulation Based Locomotor Training
Päätutkija	Tohtori Tomas Cervinka, fysioterapiaopiskelia (AMK)
Ohjaaja	Maija Kankasperko, fysioterapeutti (AMK), MSc.

Tämä on havainnoiva tutkimus uudesta kävelyharjoitusohjelmasta, johon kuuluu toiminnallista sähköstimulaatiota (functional electrical stimulation, FES) aivoinfarktista selviytyneille. Tämän tutkimuksen tarkoituksena on arvioida terapian soveltuvuutta kävelykyvyn parantamiseen. Tutkimuksen aikana keräämme tietoa terapian turvallisuudesta ja osallistujien kyvystä toteuttaa harjoitusohjelmaa. Lisäksi haluamme seurata osallistujien omia kokemuksia mahdollisista elämänlaatuun ja fyysiseen toimintakykyyn vaikuttavista muutoksista tutkimuksen aikana.

Esittely

Luonnostaan aivot käyttävät sähkövirtaa kommunikoidessaan muiden kehon osien kanssa. Kun ihminen haluaa liikkua, hänen aivonsa lähettävät sähköisiä signaaleja pitkin hermostoa aktivoidakseen/supistaakseen lihaksia joita tarvitaan halutun liikkeen suorittamiseen. Yksilöillä, joilla on neurologisia ongelmia (esimerkiksi aivoinfarkti), nämä signaalit saattavat muuttua eivätkä välttämättä saavuta kohdelihaksia. Tästä johtuen lihakset eivät supistu kuten halutun liikkeen toteuttamiseksi vaadittaisiin.

Toiminnalliseen sähköstimulaatioon (FES) perustuva terapia käyttää ulkoista sähkövirtaa, joka johdetaan joko iholle halvaantunutta tai heikentynyttä lihasta säätelevän hermon päälle tai suoraan lihaksen päälle. Tämä ulkoinen stimulaatio matkii aivojen lähettämiä signaaleja saaden aikaan lihassupistuksia. Nämä supistukset voivat auttaa heikentyneitä tai halvaantuneita lihaksia suorittamaan toiminnallisia liikkeitä, kuten kävelyä. Kehittämällä lihassupistuksia FES-terapia edistää lihasvoiman kehittymistä, liikkuvuutta sekä vähentää kipua ja lihasspastisuutta. Tästä johtuen FES-terapia voi auttaa ehkäisemään lihaskatoa ja/tai edistää normaalien liiketoimintojen palautumista.

Riskit

Toiminnallinen sähköstimulaatio (FES) on yleensä hyvin siedetty. Yleisimpiä esiintyviä haittavaikutuksia ovat ihon punoitus, ärtyminen, kipu/ihon kihelmöinti, pahoinvointi, huimaus sekä autonomisen hermoston toimintahäiriöt. Näitä haittoja voidaan vähentää säätämällä iholle johdettavan sähköärsykkeen voimakkuutta. Iholle laitettavien elektrodien liimapinta voi aiheuttaa punaisia jälkiä, joka yleensä häviää tunnin sisällä elektrodien irrottamisesta. Lateksiallergisille henkilöille käytetään lateksittomia hypoallergisia elektrodeja. Harvinaisina vakavampina sivuvaikutuksina voi esiintyä ihon rikkoutumista, lihasten venähdyksiä tai lihaskouristuksia sekä nivelturvotusta. Vaikeaa osteoporoosia sairastavalla luunmurtumariski on suurentunut. Lievät palovammat elektrodien lähellä niiden vääränlaisen käytön tai viallisten välineiden vuoksi ovat mahdollisia. Yllämainittujen oireiden ilmaantuessa terapia keskeytetään välittömästi.

Menetelmät

Terapian on suunniteltu kestävän 5 viikkoa, jonka aikana tapaamisia järjestetään 3 kertaa viikossa (yhteensä 15 tapaamista). Jokainen fysioterapiakerta kestää 60 minuuttia ja toteutetaan SAMK:in (Satakunnan Ammattikorkeakoulu) tiloissa. Fysioterapia jaetaan kahteen osioon:

Ensimmäinen osio

Ensimmäisillä 3-4 tapaamiskerralla pyritään vahvistamaan heikkoja lihaksia stimuloimalla niitä sähkövirran avulla. Tämä stimulaatio tapahtuu neljässä viiden minuutin jaksossa. Yhden jakson aikana lihasta stimuloidaan kerralla 10 sekuntia jota seuraa 10 sekunnin lepo. Jaksojen välillä pidetään viiden minuutin tauko. Näin varmistetaan että stimuloidut lihakset pystyvät tuottamaan riittävästi voimaa FES-kävelyterapian toteuttamiseksi ja voidaan siirtyä fysioterapian toiseen vaiheeseen.

Toinen osio

Seuraavilla (11-12) tapaamiskerralla terapia toteutetaan juoksumatolla, jossa osallistujalle annetaan FES-terapiaa. Terapiaa annetaan vähintään 15-30 minuuttia jokaisella tapaamiskerralla pitäen tarvittaessa istumataukoja tarvittaessa. Terapian aikana osallistuja yrittää ensin ottaa askelia omatoimisesti. Jos lihakset eivät supistu riittävästi askeleiden onnistumiseksi, fysioterapeutti tai kenkään kiinnitetty katkaisija antaa lihaksiin sähköstimulaation, joka auttaa askeleen ottamisessa. Juoksumatolla osallistuja on kytkettynä yläpuolella oleviin valjaisiin turvallisuussyistä. Terapian edetessä voidaan siirtyä myös rinnakkaisten puomien välissä tai lattialla kävelyyn osallistujan suoristuskyvyn sen salliessa.

Aikataulu ja tietojen keräys

Tutkimuksen on suunniteltu alkavan tammikuun 20.päivä, 2020. Ensimmäisellä tapaamiskerralla teitä pyydetään täyttämään 2 kyselylomaketta, joissa on kysymyksiä liittyen elämänlaatuun ja fyysiseen toimintakykyyn. Lisäksi teitä pyydetään kertomaan ikänne, sukupuolenne ja aivoinfarktistanne kulunut aika kuukausissa/vuosissa. Sekä ensimmäisellä että viimeisellä tapaamiskerralla kävelystänne kuvataan lyhyt video (kuvaus polvista alaspäin) alkutilanteen ja terapiahoidon aiheuttaman muutoksen arvioimiseksi. Myöhemmin näitä videoita käytetään terapiamuodon esittelemiseksi, opetustarkoituksissa sekä osana Tomas Cervinkan opinnäytetyötä.

Tutkimuksen aikana teitä pyydetään täyttämään kysely fyysisestä toimintakyvystänne viikoittain. Lisäksi toivomme teidän ilmoittavan meille kaikista vointiinne liittyvistä muutoksista tai oireista, joita ilmenee tutkimuksen aikana, vaikka nämä eivät vaikuttaisikaan olevan yhteydessä terapiaan. Tällaisia oireita ovat esimerkiksi ihottuma, tapaturmat ja muutokset terveydentilassa.

Viimeisen tapaamisen jälkeen pyydämme teitä jälleen täyttämään kyselyn koskien elämänlaatua ja fyysistä toimintakykyä sekä kyselyn saamastanne fysioterapiapalvelusta. Kyselyn tarkoituksena on oppia kokemuksistanne FES-terapian aikana sekä mahdollisesta halukkuudestanne jatkaa FES-terapiaa normaalin kuntoutuksen ohessa.

Yhteenveto tutkimuksen aikataulusta ja tarkat kyselyiden ajankohdat, sekä tieto siitä, kuka tiedon tulee keräämään, löytyy taulukosta 1.

Taulukko 1: Yhteenveto kyselyjen jakamis aikataulusta ja tiedon keräämisestä tutkimuksen aikana

Viik-ko	Osio	Tapaa-minen	EQ-5D	RMI	Haitallisten tapahtumien ilmoitukset	Terapian edistyminen	Palvelun laatu-kysely	Kerääjä
1	1	1	X	X		X		TC tai MK
		2			X	X		TC tai MK
		3			X	X		TC tai MK
2		4		X	X	X		TC tai MK
	2	5			X	X		TC tai MK
		6			X	X		TC tai MK
3		7		X	X	X		TC tai MK
		8			X	X		TC tai MK
		9			X	X		TC tai MK
4		10		X	X	X		TC tai MK
		11			X	X		TC tai MK
		12			X	X		TC tai MK
5		13		X	X	X		TC tai MK
		14			X	X		TC tai MK
		15	X	X	X	X	X	TC tai MK

EQ-5D – elämänlaatu-kysely, RMI – fyysinen toimintakyky- kysely, terapian edistyminen – tapaamisten lukumäärä ja sessioiden kesto. Kaikki kyselyt ja tiedonkeruu tapahtuvat valvovan fysioterapeutin (MK) tai fysioterapiaopiskelijan (TC) toimesta, jota ohjaa vastaava fysioterapeutti.

Tiedon säilytys, arkistointi ja luottamuksellisuus

Suostumuslomakkeiden allekirjoittamisen jälkeen saatte yksilöllisen tunnistenumeron (ID), jota tullaan käyttämään kaikissa teistä kerätyissä tiedoissa (kyselyt, videot yms.). Tunnistenumerolla varustetut lomakkeet säilytetään SAMK:in toimistossa lukitussa kaapissa ohjaavan fysioterapeutin toimesta. Avaintiedosto, joka yhdistää teidän tietonne (nimen ja puhelinnumeron) ID-numeroon sekä suostumuskaavake varastoidaan erillään kerätystä materiaalista tietoturvan varmistamiseksi. Videot teidän kävelystänne säilytetään Tomas Cervinkan henkilökohtaisessa pilvipalvelussa salasanalla suojattuna. Kerätty tieto säilytetään tutkimustarkoituksessa 10 vuoden ajan.

Mitään teitä koskevaa tietoa ei tulla jakamaan kenellekään ilman teidän lupaanne tai lain velvoitusta. Jos tutkimustuloksia julkaistaan, teidän nimeänne ei tulla käyttämään, eikä tietoja, joista teidän henkilöllisyytenne voitaisiin todeta, tulla julkaisemaan ilman teidän suostumustanne.

Oikeutenne osallistujana

Jos päätätte osallistua tähän tutkimukseen, voitte koska tahansa vetäytyä siitä joutumatta selittämään päätöstänne. Jos vetäydytte tutkimuksesta, teillä on mahdollisuus poistaa kaikki tutkimuksessa kerätty teitä koskeva tieto, lukuun ottamatta tietoa joka on jo ehditty julkaisemaan.

Jos tutkimuksen aikana huomataan jotakin odottamatonta tai normaalista poikkeavaa reaktiota, ilmoitamme tästä teitä hoitavalle taholle (lääkärillenne tai fysiatrillenne), jotta saatte asianmukaista jälkihoitoa.

Jos teille aiheutuu vahinkoa tähän tutkimukseen osallistumisesta kaikki tarvittavat hoidot tehdään teille mahdollisiksi koulun vakuutuksen kautta.

Kysymykset tutkimuksesta

Jos teillä on kysymyksiä tai huolenaiheita liittyen tutkimukseen tai haluaisitte muuten puhua tutkijoiden kanssa mistä syystä tahansa, olkaa hyvä ja soittakaa: fysioterapiaopiskelija Tomas Cervinkalle: +358 xx xxx xxxx tai tutkimusta ohjaavalle fysioterapeutille, Maija Kangasperkolle: +358 xx xxx xxx.

KIK-Walk Study

Suostumus

Tutkimuksen otsikko	Keep Improving Kinematics in Walking (KIK-Walk): Functional Electric Stimulation Based Locomotor Training
Tutkija	Tomas Cervinka, TkT, Ft opiskelija (Am)
Vastaava ohjaaja	Maija Kankasperko, Ft (Am) MSc.

Olen saanut yllä mainittua tutkimusta koskevaa tietoa ja lukenut saamani kirjallisen tiedotteen, jossa on selvitetty tutkimuksen tarkoitus, luonne sekä käytettävät tutkimusmenetelmät. Tiedotteessa on selvitetty tutkimuksesta tutkimushenkilölle koituva hyöty sekä mahdolliset riskit ja haitat. Minulla on ollut mahdollisuus esittää tutkijoille kysymyksiä tutkimuksesta ja siihen osallistumisesta sekä saada vastaukset kysymyksiini.

Minulle on selvitetty, että tutkimuksessa kerätty aineisto tullaan säilyttämään Satakunnan Ammattikorkeakoulussa (SAMK), joka on turvallisesti säilytetty lukollisessa kaapissa vastaavan fysioterapeutin toimistossa. Vain tiedot, jotka liittyvät ikääsi, sukupuoleesi, kuluneeseen aikaan aivohalvauksesta tai muusta vauriosta, vaurion kestoon, haitallisten vammojen lukumäärään, hoitoon sitoutumiseen ja osallistumiseen, ja kyselyistä saatuihin tietoihin (fyysisen toimintakyvyn-, elämänlaatu- sekä potilaspalvelun laatua koskevat kyselyt) tallennetaan sähköisesti OneDrive -pilvipalveluun joka on suojattu henkilökohtaisin käyttäjätunnuksin ja salasanoin. Käyttöoikeus anonymisoituun aineistoon voidaan hakemuksesta antaa muille tutkijoille vain tutkimustarkoituksessa. Kerättyä aineistoa saa käyttää vain tiedotteessa mainittuun tarkoitukseen. Tutkimustuloksia julkaistaessa henkilöllisyyttäni ei missään vaiheessa paljasteta.

Minulla on ollut riittävästi aikaa harkita tutkimukseen osallistumista. Suostun vapaaehtoisesti tähän tutkimukseen ja annan tutkijoille edellä esitetyn mukaisesti luvan kerätä, rekisteröidä ja käyttää minua koskevia tutkimukseen liittyviä tietoja. Tiedän, että voin halutessani milloin tahansa syytä ilmoittamatta perua tämän suostumukseni.

Lisäys

Annan tutkijoille luvan alaraajan kuvaamiseen. Allekirjoittamalla tämän suostumuksen ymmärrän, että minua koskevia valokuva- tai videotallenteita voidaan hyödyntää opinnäytetyössä; koulutustarkoituksiin, sekä materiaali on esillä julkisessa Linked-In:ssa ja YouTube-videontoistopalvelussa.

Tämä suostumuslomake on allekirjoitettu kahtena kappaleena, joista toinen jää minulle ja toinen tutkijoille arkistoitavaksi.

KIK-Walk Study

Suostumuksen antaja	päiväys	Allekirjoitus
	etunimet	sukunimi
	puhelin	
Suostumuksen vastaanottaja	päiväys	allekirjoitus
	arvo/ammatti FT opiskelija	nimenselvennys Tomas Cervinka
	puhelin +358 xx xxx xxxx	muut yhteystiedot xxxxx.xxxxxxx@student.samk.fi

OTHER MATERIAL USED IN THE STUDY

Appendix 1: Modified Outpatient Quality of Service Survey (QuestionPro)

Participant ID: _____ Date: _____

Q1. On a scale of 0-10, considering your complete experience with our physiotherapy clinic, how likely would you be to recommend us to a friend or colleague? (0 being Very Unlikely and 10 being Very Likely)

☐

Q2. Please state your level of satisfaction with the process of booking an appointment with your physiotherapist.

☐ Very Satisfied ☐ Satisfied ☐ Neutral ☐ Unsatisfied ☐ Very Unsatisfied

Q3. Are you currently covered under a private health insurance plan?

☐ Yes ☐ No

Q4. When requesting an appointment, were you given a chance to see your primary physiotherapist?

☐ Always ☐ Sometimes ☐ Never

Q5. How long did you have to wait (past the appointment time) to meet the physiotherapist?

☐ 0-30 minutes ☐ 30-60 minutes ☐ More than an hour ☐ More than two hours

Q6. Is this physiotherapy clinic the one you usually visit in case of a need for rehabilitation?

☐ Yes ☐ No

Q7. Since how many months/years have you been visiting this physiotherapy clinic?

☐ < 6 months ☐ > 6 months to a year ☐ ≥ 1 but < 3 years ☐ ≥ 3 but < 5 years ☐ ≥ 5 years

Q8. In the past year, how frequently did you visit this physiotherapy clinic?

☐ Not at all ☐ 1x ☐ 2x ☐ 3x ☐ 4x ☐ 5x ☐ ≥ 5x

Q9. On average, how often do you visit a physiotherapy clinic in a given year?

☐ Less than 1 visit ☐ 1-2 visits ☐ 3-5 visits ☐ More than 5 visits

Q10. How often did you receive conflicting information from different medical care professionals at this clinic?

☐ Always ☐ Sometimes ☐ Never

Q11. Were you informed about possible side effects and/or adverse symptoms of the therapy prescribed to you?

☐ Yes ☐ No

Q12. How satisfied were you with the following during your treatment at our physiotherapy clinic?

	Very Satisfied	Satisfied	Neutral	Unsatisfied	Very Unsatisfied
Professionalism of our staff	☐	☐	☐	☐	☐
Hygiene at the clinic	☐	☐	☐	☐	☐
Care provided by personnel	☐	☐	☐	☐	☐
Time that a PT spent with you	☐	☐	☐	☐	☐
Attentiveness towards concerns	☐	☐	☐	☐	☐

Q13. Were you asked today, if you had seen any health care providers besides us since your last visit?

☐ Yes ☐ No

Q14. Do you feel that our work hours are well suited to treat you?

☐ Strongly Agree ☐ Agree ☐ Neutral ☐ Disagree ☐ Strongly Disagree

Q15. How convenient is our facility's location for you?

☐ Somewhat Convenient ☐ Convenient ☐ Neutral ☐ Inconvenient ☐ Somewhat Inconvenient

Q16. How easy was it to find your way to the clinic across the shopping center?

☐ Very Easy ☐ Easy ☐ Neutral ☐ Difficult ☐ Very Difficult

Q17. How would you rate us on the following parameters?

	Very Good	Good	Average	Poor	Very Poor
Our concern for your privacy and transparency	☐	☐	☐	☐	☐
Quality of service received	☐	☐	☐	☐	☐
Information provided	☐	☐	☐	☐	☐

Q18. Do you know about all the healthcare services we offer?

☐ I was told about all of them without asking

☐ I was told after I asked for them

☐ I was not told about them

Q19. How easy was it to get a follow-up appointment?

☐ Very Easy ☐ Easy ☐ Neutral ☐ Difficult ☐ Very Difficult

Q20. Have we helped you find other services you need that we do not provide?

☐ Yes ☐ No

Q21. Do you have any other feedback for us?

Modified from a free template available at https://www.questionpro.com/survey-templates/hospital-patient-satisfaction/

Liite 1: Muokattu avohoitopotilaan palvelun laatua koskeva mielipidekysely (QuestionPro))

Osallistujan nro: _____ Päivä: _____

K1. Vastatkaa asteikolla 0 - 10, kun ajattelette kokemustanne fysioterapiaklinikallamme kokonaisuutena, kuinka todennäköisesti suosittelisitte meitä ystävällenne tai työtoverillenne? (0 merkitsee Hyvin epätodennäköisesti ja 10 merkitsee Hyvin todennäköisesti)

☐

K2. Esittäkää mielipiteenne, kuinka tyytyväinen olette fysioterapeuttiajan varaamiseen.

☐ Hyvin tyytyväinen ☐ Tyytyväinen ☐ En osaa sanoa ☐ Tyytymätön ☐ Hyvin tyytymätön

K3. Onko Teillä tällä hetkellä voimassa olevaa yksityistä terveysvakuutusta?

☐ Kyllä ☐ Ei

K4. Kun varasitte tapaamisaikaa, oliko teillä mahdollisuus varata aika omalle fysioterapeutillenne??

☐ Aina ☐ Joskus ☐ Ei koskaan

K5. Kuinka kauan Teidän täytyi odottaa yli varatun tapaamisajan fysioterapeutille pääsyä?

☐ 0-30 minuuttia ☐ 30-60 minuuttia ☐ Enemmän kuin yksi tunti ☐ Enemmän kuin kaksi tuntia

K6. Onko tämä fysioterapiaklinikka se paikka, jossa yleensä käytte tarvitessanne kuntoutusta?

☐ Kyllä ☐ Ei

K7. Kuinka kauan (kuukautta/vuotta) Olette käyneet tällä fysioterapiaklinikalla?

☐ vähemmän kuin 6 kuukautta ☐ enemmän kuin 6 kuukautta - vuoden ☐ enemmän kuin vuoden mutta alle 3 vuotta ☐ 3 – 5 vuotta ☐ enemmän kuin 5 vuotta

K8. Viimeksi kuluneen vuoden aikana, kuinka usein kävitte tällä fysioterapiaklinikalla?

☐ En yhtään kertaa ☐ 1x ☐ 2x ☐ 3x ☐ 4x ☐ 5x ☐ ≥ 5x

K9. Kuinka usein keskimäärin käytte fysioterapiaklinikalla vuoden aikana/vuosittain?

☐ Vähemmän kuin kerran ☐ 1-2 kertaa ☐ 3-5 kertaa ☐ Enemmän kuin 5 kertaa

K10. Kuinka usein saitte klinikallamme ristiriitaista tietoa eri lääketieteen edustajien taholta?

☐ Aina ☐ Joskus ☐ En koskaan

K11. Kerrottiinko Teille mahdollisista sivuvaikutuksista ja/tai vastakkaisista oireista, joita Teille määrätty hoito voi aiheuttaa?

☐ Kyllä ☐ Ei

K12. Kuinka tyytyväinen olitte seuraavissa fysioterapiaklinikkaamme koskevissa seikoissa hoitonne aikana?

	Hyvin tyytyväinen	Tyytyväinen	En osaa sanoa	Tyytymätön	Hyvin tyytymätön
Henkilökuntamme ammattitaito	☐	☐	☐	☐	☐
Klinikkamme hygienia	☐	☐	☐	☐	☐
Henkilöstön tarjoama hoiva	☐	☐	☐	☐	☐
Aikaan, jonka fysioterapeutti vietti kanssanne	☐	☐	☐	☐	☐
Huomiot huolianne kohtaan	☐	☐	☐	☐	☐

K13. Kysyttiinkö Teiltä tänään, että oletteko käyneet hoitomme ohella viime kerran jälkeen jonkin muun terveysammattilaisen luona?

☐ Kyllä ☐ Ei

K14. Tuntuuko Teistä siltä, että työaikamme on sopiva hoitamiseenne?

☐ Täysin samaa mieltä ☐ Samaa mieltä ☐ En osaa sanoia ☐ Eri mieltä ☐ Täysin eri mieltä

K15. Kuinka sopiva palvelujemme sijainti on Teille?

☐ Melko sopiva ☐ Sopiva ☐ Neutraali ☐ Hankalaa ☐ Hieman hankalaa

K16. Kuinka helppoa Teidän oli löytää klinikalle ostoskeskuksen läpi?

☐ Hyvin helppoa ☐ Helppoa ☐ En osaa sanoa ☐ Vaikeaa ☐ Hyvin vaikeaa

K17. Kuinka arvioisitte meitä seuraavissa tekijöissä?

	Oikein hyvä	Hyvä	Keskinker-tainen	Heikko	Hyvin heikko
Huolemme yksityi-syydestäsi ja avoimuutemme	☐	☐	☐	☐	☐
Annetun palvelun laatu	☐	☐	☐	☐	☐
Tarjottu tieto	☐	☐	☐	☐	☐

K18. Tiedättekö kaikista tarjoamistamme terveyspalveluista?

☐ Minulle kerrottiin niistä kysymättä.

☐ Minulle kerrottiin niistä kysyttyäni.

☐ Minulle ei kerrottu niistä.

K19. Kuinka helppoa oli saada seuraava käyntiaika?

☐ Erittäin helppoa ☐ Helppoa ☐ En osaa sanoa ☐ Vaikeaa ☐ Hyvin vaikeaa

K20. Olemmeko auttaneet Teitä löytämään muita tarvitsemianne palveluita, joita emme itse tarjoa?

☐ Kyllä ☐ Ei

K21. Onko Teillä jotain muuta meille annettavaa palautetta?

Modified from a free template available at https://www.questionpro.com/survey-templates/hospital-patient-satisfaction/

Appendix 2: Discharge Criteria

Participants may be withdrawn from the study if they exhibit the following:

i. Participant has met all the requirements of the KIK-Walk Protocol

ii. In the best professional judgment of the participant fails to demonstrate consistent compliance with on-site therapy.

ii. Physician discharges participant from the study.

iv. Participant/family elects to discontinue services.

v. Participant for any reason is not able to meet 80% of their scheduled appointments. If patient will miss 5 or more consecutive treatment sessions.

Appendix 3: Inclusion criteria check list

Participant ID: _____ Date: _____

Assessed by: _____

- ☐ Age ≥ 18 years
- ☐ Medically stable condition
- ☐ Walking independently either with use of assistive devices or with speed < 0.5 m/s (preclusion of being community walker) during a 2 minute walking test.
- ☐ Willingness and possibility to participate in FES-walking therapy
- ☐ Responsiveness to electrical stimulation
- ☐ Proximity to Tutoris Oy for realistic access
- ☐ Access to reliable transportation

SCI specific

- ☐ Traumatic or incident caused motor incomplete SCI with non-progressive spinal cord lesion at level T10 or above; (T11 and T12 may be considered in absence of lower motor neuron signs)
- ☐ Duration of injury at least 18 months with stable with no deteriorating medical condition

Stroke specific

- ☐ First episode of hemiplegia at least 3 months in duration as a result of a stroke with a stable neurology
- ☐ PNS without evidence of uncontrollable knee hyperextension

Appendix 4: Exclusion criteria check list

Participant ID: _____ Date: _____

Assessed by: _____

- ☐ Motor Complete SCI or bilateral stroke
- ☐ Tendon lengthening surgery in the last 6 months. If greater than 6 months, require surgeon's approval
- ☐ Contraindications to FES (cardiac pacemakers, skin scratches or grade 2 or 3 pressure ulcers at potential electrode sites, denervation of targeted muscles)
- ☐ Grade 4 Pressure ulcers anywhere on the lower extremities
- ☐ Uncontrolled Hypertension or symptoms of orthostatic hypotension when standing for 15 minutes
- ☐ Untreated autonomic dysreflexia
- ☐ Subjects with a history of cardiovascular disease, must obtain medical clearance from their primary care physician before inclusion
- ☐ Amyotrophic Lateral Sclerosis or lower motor neuron disorders
- ☐ Dependent on ventilator or unable to voluntarily extend head
- ☐ Painful musculoskeletal dysfunction (e.g., knee deformity) or unhealed fractures
- ☐ Fixed muscle contracture
- ☐ Sensory or motor peripheral neuropathy
- ☐ Unable to follow/understand verbal commands
- ☐ Pregnancy
- ☐ Psychological disorders
- ☐ Uncontrolled seizure disorder
- ☐ Illegal drug use
- ☐ MRSA or other Infectious Diseases requiring contact droplet precautions
- ☐ Active oncology diagnosis

Appendix 5: Passive range of motion and manual muscle testing assessment form

Participant ID: _____ Date: _____

Assessed by: _____

Passive range of motion

	Right limb		Left limb	
	Flexion	Extension	Flexion	Extension
Hip	☐	☐	☐	☐
	Flexion	Extension	Flexion	Extension
Knee	☐	☐	☐	☐
	Dorsi Flexion	Plantar Flexion	Dorsi Flexion	Plantar Flexion
Ankle	☐	☐	☐	☐

Manual muscle testing

Muscle	Score right limb	Score left limb
Gluteus maximus	☐	☐
Quadriceps	☐	☐
Hamstring	☐	☐
Tibialis anterior	☐	☐
Calf	☐	☐

Appendix 6: self-reported quality of life (EQ-5D)

Terveyskysely

Suomenkielinen versio Suomea varten

(Finnish version for Finland)

Olkaa hyvä ja merkitkää rastilla (x), yksi rasti kunkin alla olevan ryhmän kohdalle, mikä väitteistä kuvaa parhaiten terveydentilaanne tänään:

Liikkuminen

Minulla ei ole vaikeuksia kävelemisessä ❑

Minulla on jonkin verran vaikeuksia kävelemisessä ❑

Olen vuoteenomana ❑

Itsestään huolehtiminen

Minulla ei ole vaikeuksia huolehtia itsestäni ❑

Minulla on jonkin verran vaikeuksia peseytyä tai pukeutua itse ❑

En kykene peseytymään tai pukeutumaan itse ❑

Tavanomaiset toiminnot *(esim. ansiotyö, opiskelu, kotityö, vapaa-ajan toiminnot)*

Minulla ei ole vaikeuksia suorittaa tavanomaisia toimintojani ❑

Minulla on jonkin verran vaikeuksia suorittaa tavanomaisia toimintojani ❑

En kykene suorittamaan tavanomaisia toimintojani ❑

Kivut / vaivat

Minulla ei ole kipuja tai vaivoja ❑

Minulla on kohtalaisia kipuja tai vaivoja ❑

Minulla on ankaria kipuja tai vaivoja ❑

Ahdistuneisuus / Masennus

En ole ahdistunut tai masentunut ❑

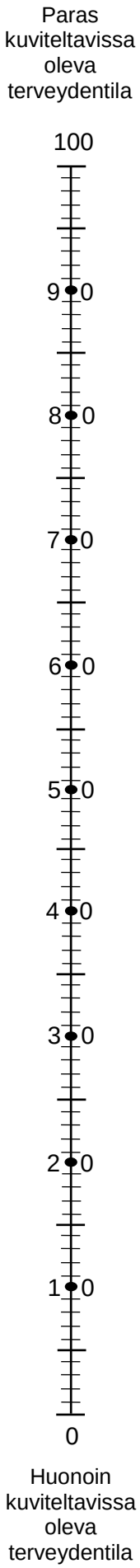
Olen melko ahdistunut tai masentunut ❑

Olen erittäin ahdistunut tai masentunut ❑

Auttaaksemme ihmisiä sanomaan, kuinka hyvä tai huono jokin terveydentila on, olemme piirtäneet lämpömittaria muistuttavan asteikon. Parasta terveydentilaa, jonka voitte kuvitella, merkitään siinä 100:lla ja huonointa 0:lla.

Haluaisimme Teidän osoittavan tällä asteikolla, miten hyvä tai huono Teidän terveytenne on mielestänne tänään. Olkaa hyvä ja tehkää tämä vetämällä alla olevasta laatikosta viiva siihen kohtaan asteikolle, joka osoittaa, miten hyvä tai huono terveydentilanne on tänään.

Terveydentilani tänään



Appendix 7: Rivermead Mobility Index

RIVERMEAD MOBILITY INDEX

Kuntoutujan nimi _____ Testaaja_____
Pvm ___.___.____

Pisteytysohje: Jokaisesta kyllä-vastauksesta saa yhden pisteen. Mikäli henkilö arvioi, ettei pysty suoriutumaan tehtävästä, pistemäärä on 0. Maksimi on 15 pistettä. Tehtävä numero 5 havainnoidaan.

	Pisteet
1. Kääntyminen sängyssä Pystytkö kääntymään selinmakuulta kylkimakuulle ilman apua?	
2. Makuulta istumaan Pystytkö nousemaan makuuasennosta sängyn reunalle istumaan itsenäisesti?	
3. Istumatasapaino Pystytkö istumaan sängyn reunalla ilman tukea vähintään 10 sekuntia?	
4. Istumasta seisomaan nousu Pystytkö nousemaan tuolilta seisomaan enintään 15 sekunnissa ja seisomaan 15 sekuntia? Voit käyttää apuna käsiä ja tarvittaessa apuvälinettä.	
5. Seisominen tuetta Pystytkö seisomaan tuetta 10 sekuntia (havainnoidaan)	
6. Siirtyminen Pystytkö siirtymään sängystä tuoliin ja takaisin ilman apua?	
7. Käveleminen sisällä Pystytkö kävelemään 10 metriä sisällä, tarvittaessa apuvälinein?	
8. Portaat Pystytkö nousemaan portaita yhden kerrosvälin ilman apua?	
9. Käveleminen ulkona Pystytkö kävelemään ulkona asfaltilla ilman apua?	
10. Käveleminen sisällä ilman apuvälineitä Pystytkö kävelemään sisällä 10 m ilman apuvälineitä tai toisen henkilön tukea?	
11. Esineen poimiminen Pystytkö nostamaan esineen 5 metrin kävelymatkan päästä ja palamaan takaisin?	
12. Käveleminen ulkona maastossa Pystytkö kävelemään epätasaisessa maastossa, esim. ruohikolla, soralla tai jäällä?	
13. Kylpeminen Selviydytkö suihkuun/kylpyyn menosta ja tulosta sekä peseytymisestä itsenäisesti?	
14. Neljä porrasta Pystytkö kulkemaan neljä porrasta ylös ja alas ilman kaidetta, tarvittaessa apuvälinein?	
15. Juokseminen Pystytkö juoksemaan tai kävelemään ontumatta neljässä sekunnissa 10 metriä?	
YHTEENSÄ	

Lähde: Collen FM, Wade DT, Robb GF, Bradshaw CM. The Rivermead Mobility Index: a further development of the Rivermead Motor Assessment. Int Disabil Stud 1991; 13:50–4.

Suomennos on laadittu vuonna 2002 Suomen aivotutkimus- ja kuntoutuskeskus Neuronissa englanninkielisestä lomakkeesta. Käännöstyöryhmään kuuluivat Sinikka Peurala, Ina Tarkka, Kauko Pitkänen ja Juhani Sivenius

Appendix 8: Event reporting

Participant ID: _____

Date DD/MM/YY	**Event**	**Action**	**Initials**

Appendix 9: Therapy adherence form

Participant ID: _____

Session no.	Date DD/MM/YY	Attended	Therapy description	Duration min	Initials
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					

11					
12					
13					
14					
15					

KIK-Walk Study

Data Management Plan

Title of Study	Keep Improving Kinematics in Walking (KIK-Walk): Functional Electric Stimulation Based Locomotor Training
Primary Investigator	Dr. Tomas Cervinka, PT student (Am)
Supervisors	Maija Kankasperko, PT (Am) MSc.

Timeline, Data Collection and Analysis

The study will start in November 2019 and last until August 2020. The study will be divided into three phases, preparation, intervention and data analysis. The preparation part will begin in November 2019 and last until January 2020. The intervention part will start on January 20th, 2020 and last until February 21st, 2020, and outcome assessment part will begin in June 2020 and last until August 2020. Recruitment will start on December 1st and last until 1 individual will agree to participate in the study.

The baseline visit (the first day of intervention) will take place at the Satakunta University o Applied Science (SAMK) on January 20th, 2020. However, the starting date may be slightly advanced or postponed based on participants needs. The intervention will last 5 weeks, and all sessions will be held at SAMK. The longitudinal follow-up testing will take place after the last intervention on February 21st, 2020.

The processing and transfer of collected data to an electronic format will take place at SAMK at the end of February 2020. The electronic files will be stored on a private OneDrive school account of Tomas Cervinka. The data analysis, evaluation and interpretation will start on June 1st, 2020 and last until August 31st, 2020.

A table outlining the study plan, and detailed information concerning questionnaires and data collection is presented below (Table 1 and 2).

Table 2: Timeline of the study

Period		Preparation	Recruitment		Intervention		Processing	Analysis		Location
Nov 2019	PHASE I	X		PHASE II		PHASE III				SAMK
Dec 2019		X	X							SAMK
Jan 2020			X		X					SAMK
Feb 2020					X		X			SAMK
Mar 2020										
Apr 2020										
May 2020										
Jun 2020								X		TC home
Jul 2020								X		TC home
Aug 2020								X		TC home

1) First stage

   a. Recruitment

      During this process, the physiotherapy student (Tomas Cervinka) with supervising leading physiotherapist (Maija Kangasperko) will assess potential participants in face-to-face interview and 2-minute walking test according to inclusion and exclusion criteria. The interview will take place at SAMK facilities. The interview and test results will be recorded on a **paper checklist forms** (Appendix 3 and 4). If an individual meets all the inclusion criteria, potential participant will be provided additional information concerning the study and offered to sign a consent form to continue the progress. The potential participant will be also informed that **he/she can withdraw from the study at any point without giving any reason**.

      If the potential participant agrees to participate in the study, the he/she will receive **an identification numerical code** (starting by 001) that will be used on all following testing documents, questionnaires and study results. As the documents (inclusion/exclusion criteria check list and consent form) contain participant's name, given identification numerical code and telephone number, they will be **stored in a separate envelope in a locked cabinet** at the SAMK's office of the leading physiotherapist to prevent any possible identification of study participating person by any unauthorized person. If an individual doesn't meet all the inclusion criteria or will not present his/her interest in undergoing the study, the checklist documents will be shredded and disposed.

   b. PT assessment

      The consenting participant will then undergo a face-to-face physiotherapy assessment to evaluate his/her skin integrity, passive range of motion in hips, knees and ankles, and muscle strength of gluteus maximus, quadriceps, hamstring, tibialis anterior and calf muscles by manual muscle testing. These tests will be performed by the leading physiotherapist or the physiotherapy student under direct supervision of the leading physiotherapist to guarantee individual's safety during the locomotion triggered by FES. The tests will be performed at SAMK facilities and the results will be recorded on a **paper form** (Appendix 5).

      If the consenting participant will pass the safety testing and will be still willing to continue the study, he/she will be offered a start day of the study, the form containing results of the physical assessment will be stored in an envelope in a locked cabinet at the SAMK's office of the leading physiotherapist, and recruitment process will be terminated. If an individual doesn't pass the safety criteria or will not present his/her interest in undergoing the study, the checklist document will be shredded and disposed, and recruitment process will continue.

2) Second stage

   During the baseline visit (January 20th, 2020), the physiotherapy student (under supervision of the leading physiotherapist) will administer and collect following **self-reported questionnaires** to the study participant prior onset the actual intervention:

   a. Self-reported quality of life (EQ-5D, Appendix 6)
   b. Rivermead Mobility Index (RIM, Appendix 7)

   The test results will be recorded on **paper forms** as provided in appendixes. Further, the physiotherapy student will record participant's age, sex and duration of the disease. **No other personal details will**

be recorded. In addition, the physiotherapy student will record a short video of participant's gait on a treadmill prior the use of FES-stimulation during week 1, and with the use of FES during week 1 and week 5 to observe the intervention progress. The video will be recorded only in view from knees down, therefore, the participant can't be identified.

During the intervention participant will be asked to keep a self-administered diary and record any minor/major adverse event that occurred. Investigators (Tomas Cervinka and Maija Kangasperko) will follow-up with these recording at the beginning of every therapy session and record the events on a **paper form** (Appendix 8). Further, investigators will use the same form to record injuries during therapy and all issues that appeared during the therapy and how they were addressed. In addition, investigators will record on a **paper form** (Appendix 9) the number of sessions (frequency) and duration of training sessions attended, and ask the participant to fill the RMI on weekly basis.

After the therapy cessation (February 21st, 2020), the same questionnaires (EQ-5D and RMI) as during the baseline visit will be administered and collected by the physiotherapy student under supervision on the leading physiotherapist. In addition, a written form for self-reported survey of service quality will be administered (Quality of Services Survey - Appendix 1) and collected by investigators.

Table 2: Summary of timeline of administered questionnaires and data collection during intervention

Week	Session	EQ-5D	RMI	Adverse event reporting	Therapy adherence	Quality of Service Survey	Video	Collected by
1	Baseline	X	X		X		X	TC or MK
	2			X	X			TC or MK
	3			X	X			TC or MK
2	4		X	X	X			TC or MK
	5			X	X			TC or MK
	6			X	X			TC or MK
3	7		X	X	X			TC or MK
	8			X	X			TC or MK
	9			X	X			TC or MK
4	10		X	X	X			TC or MK
	11			X	X			TC or MK
	12			X	X			TC or MK
5	13		X	X	X			TC or MK
	14			X	X			TC or MK
	Follow up	X	X	X	X	X	X	TC or MK

All the questionnaires and data recording will be done by the leading physiotherapist (MK) or by the physiotherapy student (TC) under direct supervision of the leading physiotherapist.

3) Third stage

All collected (de-identified) data will be processed by physiotherapy student (Tomas Cervinka) at the Satakunta University of Applied science and transferred to an electronic form that will be stored on a private OneDrive school account of Tomas Cervinka. The identifiable forms (inclusion/exclusion criteria) and consent form will remain safely stored in a locked cabinet at the SAMK's office of the leading physiotherapist. After that, Tomas Cervinka will analyze and evaluate/interpret the data at his private computer at his home. As this is a case study, the statistical testing is not applicable and analysis will only include basic data comparison (differences pre-post intervention), and evaluation of

adherence and self-perceived satisfaction with the intervention. In addition, a bachelor thesis will be written with description of study results and all the adverse events or difficulties that investigators or participant had to face during the intervention.

Data storage, confidentiality and archiving plan

After signing the consent form, the participant will receive a unique identification (ID) number and only this ID will be used on all paper forms and questionnaires that will be later collected by Tomas Cervinka or Maija Kangasperko during the intervention. Concerning personal information, **only age, sex and time post stroke will be recorded** in addition to the name and telephone number. The ID will be given to the participant so that the identifying information (name and telephone number) can be removed from the collected data. Further, a video recording of participants gait (view from knees down) will be stored in personal storage cloud of Tomas Cervinka without any personal details and protected by a password.

All collected data, except the video recordings, will be stored in envelopes in a locked cabinet at the SAMK's office of the leading physiotherapist. However, a key file linking participant information (name and telephone number) to the ID together with consent form and inclusion/exclusion criteria forms will be stored separately from the other collected data in a closed envelope to prevent any possible identification of study participating person by any unauthorized person. The video recording (without personal details) will be used for introduction of this intervention approach at social media as YouTube or LinkedIn of Tomas Cervinka. In addition, the video will be used for educational purposes and in bachelor thesis of Tomas Cervinka.

During the analysis part of the study, Tomas Cervinka will transfer the collected data to an electronic form. However, the only patient related information that will appear in the electronic databases and bachelor thesis of Tomas Cervinka, will be age, sex, and time post stroke. The identifiable forms (inclusion/exclusion criteria) and consent form will remain safely stored in a locked cabinet at the SAMK's office of the leading physiotherapist.

All stored documents of consenting participant will be retained for research purposes for 10 years upon the study competition. If potential participant declines to participate or doesn't get through the selection assessment chain, his/her collected documents/data will be shredded and disposed immediately.

Data ownership and usage rights

By signing the consent form and agreeing to participate in the study, the study participants will give their permission to use all collected data for future analyses and other research purposes. It also means that the data collected during this study (age and sex, time post stroke, count of adverse events, study adherence and engagement and results of self-reported questionnaires may be shared outside of the Satakunta University of Applied Science with permission from investigators.

KIK-Walk Study

Research Ethics

Title of Study	Keep Improving Kinematics in Walking (KIK-Walk): Functional Electric Stimulation Based Locomotor Training
Primary Investigator	Dr. Tomas Cervinka, PT student (Am)
Supervisors	Maija Kankasperko, PT (Am) MSc.

Potential Risks to Participants

The functional electrical stimulation (FES) is generally well tolerated and serious medical complications are rare. The most common problems with FES are discomfort or pain ("pins and needles" like sensation on skin), skin redness or irritation, nausea, light-headedness. The discomfort can range from a mild tingling to almost a burning sensation depending on stimulation parameters. Nevertheless, these parameters can be easily adjusted to decrease the discomfort in most of the cases. The skin redness may be left in places where electrodes were placed on the skin because of glue used on self-adhesive electrodes, but this redness usually disappears within an hour. In rare cases, the non-latex hypoallergenic electrodes have to be used to solve the problem.

Less common risk or rare side effects are skin breakdown, fainting, worsening of muscle spasms, muscle and joint injuries (strains or swelling), bone fractures in case of severe osteoporosis, and mild electrical burns near electrodes in case of improper use or faulty equipment. In this cases, the intervention will be immediately terminated.

Ethical Considerations

The research will be conducted according to the Finnish Advisory Board on Research Integrity (TENK 2012), the Administrative Procedure Act (434/2004) Section 28, and the Finnish Personal Data (Data Protection Regulation). Research Ethics Board approval will be sought at the Ethics Board of Satakunta District (school site). The patient information will not be stored apart from the name and telephone number on a consent form, name on check list forms related to inclusion/exclusion criteria, and age, sex and duration of disease for reporting purposes. The afore mentioned forms will be stored in a separate envelope in a locked cabinet at the SAMK's office of the leading physiotherapist to prevent any possible identification of study participating person by any unauthorized person.

The participant will receive a unique identification (ID) number to be used on all other forms and in electronic databases. A key file linking participant information to the ID will be stored in the afore mentioned separate envelope so that identifying information can be removed from the collected data. All other forms and study data files will be stored in separate envelope from the afore mentioned in a locked cabinet of the leading physiotherapist. During the recruiting process, all Individuals who indicate that they are not interested in participating will not be contacted further. Written informed consent will be obtained from participant prior to testing of physical suitability for the FES intervention. Participant will be informed that due to visits in physiotherapy school setting, and despite collecting only minimum identifiable data, he/she can be recognized at school premises and asked questions related to his/her numerous school visits during the intervention. In addition, the participant will be informed that he/she can withdraw from the study at any time without giving reasons.

In case, there is a need to modify the study protocol during the ongoing study in a way that it would deviate from the approved version, researchers will suspend the study and apply for new ethical permit by a research plan addendum. Upon successful application, the participant will be given addendum of the previous conflict of interest and patient information form. If the participant indicates that he/she is not interested in participating the updated protocol, he/she will not be contacted further.

Potential Benefits of the Proposed Research

The benefits of the FES therapies among Stroke are well known from various research studies and described in the best practice accreditation guidelines in Stroke rehabilitation of some countries. These benefits include muscle hypertrophy and associated increased vascularization, faster extremity motor recovery resulting in improved recovery of independent walking (a major goal of an individual rehabilitation plan), and improvements in overall health and well-being. Health improvements can include better cardiovascular and pulmonary function, increased bone density and decreased spasticity. Nevertheless, the use of neuromuscular stimulation among physiotherapists and especially in task-specific practices, one of the key components of activity-based therapies, is still low.

Therefore, this case study is proposed to introduce and eradicate barriers of the FES and specifically the FES-walking therapeutic approach in clinical setting in Finland. The study, developed protocol, may be used to improve current rehabilitation strategies, used by health care professionals in rehabilitation clinic nationwide, targeting "out-patient" individuals with Stroke. It is anticipated that implementing this new protocol will provide opportunities for enhanced clinical care, education and professional development as well as new research opportunities for the Satakunta University of Applied Science Research Program. Further, the study will provide a sound foundation for future prospective longitudinal studies of FES-based therapies in acute patient care. The incorporation of FES-based therapies may improve and speed up individuals' recover. This will result in shorter hospitalization times and improved self-ambulatory and -caring in individual's own home environment. Consequently, incorporation of FES-based therapy will result in enormous savings in health and social care costs. Given the low of risk associated with participation and the benefit to the community the risk: benefit ratio is favourable.

Knowledge Translation

KIK-Walk project thesis presentation session will be held at Satakunta University of Applied Science to increase awareness of FES-based therapies in neurological population among staff, students and visitors. A summary of the results and information on KIK-Walk project will be submitted to the magazine of Finnish Physiotherapy association, which reaches about 9000 individuals 7 times per year. The results will be published in Bachelor thesis of Tomas Cervinka. The results may also be presented in national scientific conferences to facilitate knowledge translation to researchers and health care providers.

Conflict of Interest

Investigators do not have any financial conflicts of interest and have only the interest in completing this study as results will be used as a part of Bachelor thesis of Tomas Cervinka. However, this interest will not influence decision made by eligible individuals to participate in this study.

Appendix 2

Quality of life – EQ-5D

Participant's ID : 001

Date : 03/01/20

Terveyskysely

Suomenkielinen versio Suomea varten

(Finnish version for Finland)

Olkaa hyvä ja merkitkää rastilla (x), yksi rasti kunkin alla olevan ryhmän kohdalle, mikä väitteistä kuvaa parhaiten terveydentilaanne tänään:

Liikkuminen

Minulla ei ole vaikeuksia kävelemisessä ☐

Minulla on jonkin verran vaikeuksia kävelemisessä ☒

Olen vuoteenomana ☐

Itsestään huolehtiminen

Minulla ei ole vaikeuksia huolehtia itsestäni ☒

Minulla on jonkin verran vaikeuksia peseytyä tai pukeutua itse ☐

En kykene peseytymään tai pukeutumaan itse ☐

Tavanomaiset toiminnot *(esim. ansiotyö, opiskelu, kotityö, vapaa-ajan toiminnot)*

Minulla ei ole vaikeuksia suorittaa tavanomaisia toimintojani ☐

Minulla on jonkin verran vaikeuksia suorittaa tavanomaisia toimintojani ☒

En kykene suorittamaan tavanomaisia toimintojani ☐

Kivut / vaivat

Minulla ei ole kipuja tai vaivoja ☐

Minulla on kohtalaisia kipuja tai vaivoja ☒

Minulla on ankaria kipuja tai vaivoja ☐

Ahdistuneisuus / Masennus

En ole ahdistunut tai masentunut ☒

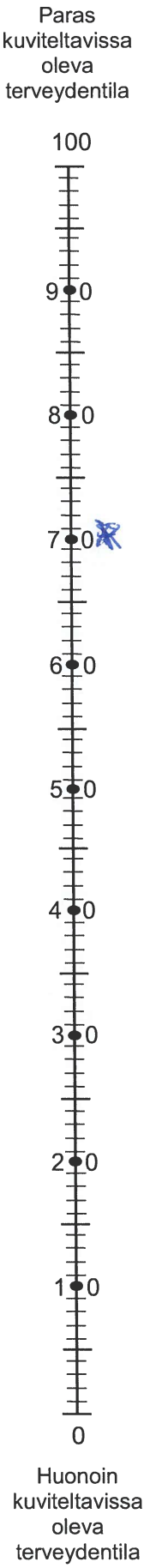
Olen melko ahdistunut tai masentunut ☐

Olen erittäin ahdistunut tai masentunut ☐

Auttaaksemme ihmisiä sanomaan, kuinka hyvä tai huono jokin terveydentila on, olemme piirtäneet lämpömittaria muistuttavan asteikon. Parasta terveydentilaa, jonka voitte kuvitella, merkitään siinä 100:lla ja huonointa 0:lla.

Haluaisimme Teidän osoittavan tällä asteikolla, miten hyvä tai huono Teidän terveytenne on mielestänne tänään. Olkaa hyvä ja tehkää tämä vetämällä alla olevasta laatikosta viiva siihen kohtaan asteikolle, joka osoittaa, miten hyvä tai huono terveydentilanne on tänään.

Terveydentilani tänään



Participants ID: 001 Date: 21/02/20

Terveyskysely

Suomenkielinen versio Suomea varten

(Finnish version for Finland)

Olkaa hyvä ja merkitkää rastilla (x), yksi rasti kunkin alla olevan ryhmän kohdalle, mikä väitteistä kuvaa parhaiten terveydentilaanne tänään:

Liikkuminen

Minulla ei ole vaikeuksia kävelemisessä	☐
Minulla on jonkin verran vaikeuksia kävelemisessä	☒
Olen vuoteenomana	☐

Itsestään huolehtiminen

Minulla ei ole vaikeuksia huolehtia itsestäni	☒
Minulla on jonkin verran vaikeuksia peseytyä tai pukeutua itse	☐
En kykene peseytymään tai pukeutumaan itse	☐

Tavanomaiset toiminnot *(esim. ansiotyö, opiskelu, kotityö, vapaa-ajan toiminnot)*

Minulla ei ole vaikeuksia suorittaa tavanomaisia toimintojani	☐
Minulla on jonkin verran vaikeuksia suorittaa tavanomaisia toimintojani	☒
En kykene suorittamaan tavanomaisia toimintojani	☐

Kivut / vaivat

Minulla ei ole kipuja tai vaivoja	☐
Minulla on kohtalaisia kipuja tai vaivoja	☒
Minulla on ankaria kipuja tai vaivoja	☐

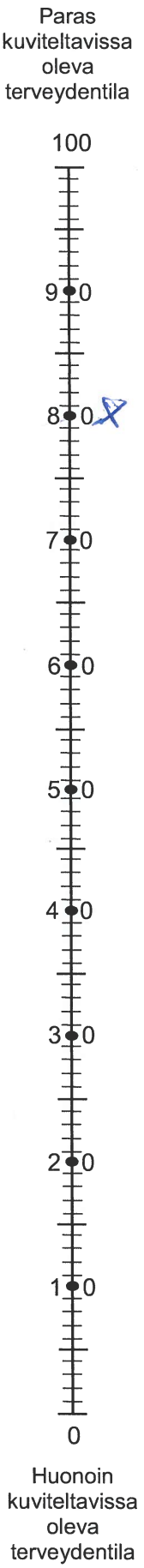
Ahdistuneisuus / Masennus

En ole ahdistunut tai masentunut	☒
Olen melko ahdistunut tai masentunut	☐
Olen erittäin ahdistunut tai masentunut	☐

Auttaaksemme ihmisiä sanomaan, kuinka hyvä tai huono jokin terveydentila on, olemme piirtäneet lämpömittaria muistuttavan asteikon. Parasta terveydentilaa, jonka voitte kuvitella, merkitään siinä 100:lla ja huonointa 0:lla.

Haluaisimme Teidän osoittavan tällä asteikolla, miten hyvä tai huono Teidän terveytenne on mielestänne tänään. Olkaa hyvä ja tehkää tämä vetämällä alla olevasta laatikosta viiva siihen kohtaan asteikolle, joka osoittaa, miten hyvä tai huono terveydentilanne on tänään.

Terveydentilani tänään



Appendix 3

Rivermead Mobility Index

RIVERMEAD MOBILITY INDEX

Kuntoutujan nimi 001 Testaaja Tomas Cervinka
Pvm 08.01.20

Pisteytysohje: Jokaisesta kyllä-vastauksesta saa yhden pisteen. Mikäli henkilö arvioi, ettei pysty suoriutumaan tehtävästä, pistemäärä on 0. Maksimi on 15 pistettä. Tehtävä numero 5 havainnoidaan.

	Pisteet
1. Kääntyminen sängyssä Pystytkö kääntymään selinmakuulta kylkimakuulle ilman apua?	X
2. Makuulta istumaan Pystytkö nousemaan makuuasennosta sängyn reunalle istumaan itsenäisesti?	X
3. Istumatasapaino Pystytkö istumaan sängyn reunalla ilman tukea vähintään 10 sekuntia?	X
4. Istumasta seisomaan nousu Pystytkö nousemaan tuolilta seisomaan enintään 15 sekunnissa ja seisomaan 15 sekuntia? Voit käyttää apuna käsiä ja tarvittaessa apuvälinettä.	X
5. Seisominen tuetta Pystytkö seisomaan tuetta 10 sekuntia (havainnoidaan)	X
6. Siirtyminen Pystytkö siirtymään sängystä tuoliin ja takaisin ilman apua?	X
7. Käveleminen sisällä Pystytkö kävelemään 10 metriä sisällä, tarvittaessa apuvälinein?	X
8. Portaat Pystytkö nousemaan portaita yhden kerrosvälin ilman apua?	X
9. Käveleminen ulkona Pystytkö kävelemään ulkona asfaltilla ilman apua?	X
10. Käveleminen sisällä ilman apuvälineitä Pystytkö kävelemään sisällä 10 m ilman apuvälineitä tai toisen henkilön tukea?	X
11. Esineen poimiminen Pystytkö nostamaan esineen 5 metrin kävelymatkan päästä ja palamaan takaisin?	X
12. Käveleminen ulkona maastossa Pystytkö kävelemään epätasaisessa maastossa, esim. ruohikolla, soralla tai jäällä?	
13. Kylpeminen Selviydytkö suihkuun/kylpyyn menosta ja tulosta sekä peseytymisestä itsenäisesti?	X
14. Neljä porrasta Pystytkö kulkemaan neljä porrasta ylös ja alas ilman kaidetta, tarvittaessa apuvälinein?	
15. Juokseminen Pystytkö juoksemaan tai kävelemään ontumatta neljässä sekunnissa 10 metriä?	
YHTEENSÄ	12

Lähde: Collen FM, Wade DT, Robb GF, Bradshaw CM. The Rivermead Mobility Index: a further development of the Rivermead Motor Assessment. Int Disabil Stud 1991; 13:50–4.

Suomennos on laadittu vuonna 2002 Suomen aivotutkimus- ja kuntoutuskeskus Neuronissa englanninkielisestä lomakkeesta. Käännöstyöryhmään kuuluivat Sinikka Peurala, Ina Tarkka, Kauko Pitkänen ja Juhani Sivenius

RIVERMEAD MOBILITY INDEX

Kuntoutujan nimi 001 Testaaja Tomas Cervenka

Pvm 22.01.20

Pisteytysohje: Jokaisesta kyllä-vastauksesta saa yhden pisteen. Mikäli henkilö arvioi, ettei pysty suoriutumaan tehtävästä, pistemäärä on 0. Maksimi on 15 pistettä. Tehtävä numero 5 havainnoidaan.

	Pisteet
1. Kääntyminen sängyssä Pystytkö kääntymään selinmakuulta kylkimakuulle ilman apua?	X
2. Makuulta istumaan Pystytkö nousemaan makuuasennosta sängyn reunalle istumaan itsenäisesti?	X
3. Istumatasapaino Pystytkö istumaan sängyn reunalla ilman tukea vähintään 10 sekuntia?	X
4. Istumasta seisomaan nousu Pystytkö nousemaan tuolilta seisomaan enintään 15 sekunnissa ja seisomaan 15 sekuntia? Voit käyttää apuna käsiä ja tarvittaessa apuvälinettä.	X
5. Seisominen tuetta Pystytkö seisomaan tuetta 10 sekuntia (havainnoidaan)	X
6. Siirtyminen Pystytkö siirtymään sängystä tuoliin ja takaisin ilman apua?	X
7. Käveleminen sisällä Pystytkö kävelemään 10 metriä sisällä, tarvittaessa apuvälinein?	X
8. Portaat Pystytkö nousemaan portaita yhden kerrosvälin ilman apua?	X
9. Käveleminen ulkona Pystytkö kävelemään ulkona asfaltilla ilman apua?	X
10. Käveleminen sisällä ilman apuvälineitä Pystytkö kävelemään sisällä 10 m ilman apuvälineitä tai toisen henkilön tukea?	X
11. Esineen poimiminen Pystytkö nostamaan esineen 5 metrin kävelymatkan päästä ja palamaan takaisin?	X
12. Käveleminen ulkona maastossa Pystytkö kävelemään epätasaisessa maastossa, esim. ruohikolla, soralla tai jäällä?	
13. Kylpeminen Selviydytkö suihkuun/kylpyyn menosta ja tulosta sekä peseytymisestä itsenäisesti?	X
14. Neljä porrasta Pystytkö kulkemaan neljä porrasta ylös ja alas ilman kaidetta, tarvittaessa apuvälinein?	
15. Juokseminen Pystytkö juoksemaan tai kävelemään ontumatta neljässä sekunnissa 10 metriä?	
YHTEENSÄ	12

Lähde: Collen FM, Wade DT, Robb GF, Bradshaw CM. The Rivermead Mobility Index: a further development of the Rivermead Motor Assessment. Int Disabil Stud 1991; 13:50–4.

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RIVERMEAD MOBILITY INDEX

Kuntoutujan nimi 001 Testaaja Tomas Cervinka

Pvm 29.1.2020

Pisteytysohje: Jokaisesta kyllä-vastauksesta saa yhden pisteen. Mikäli henkilö arvioi, ettei pysty suoriutumaan tehtävästä, pistemäärä on 0. Maksimi on 15 pistettä. Tehtävä numero 5 havainnoidaan.

	Pisteet
1. Kääntyminen sängyssä Pystytkö kääntymään selinmakuulta kylkimakuulle ilman apua?	X
2. Makuulta istumaan Pystytkö nousemaan makuuasennosta sängyn reunalle istumaan itsenäisesti?	X
3. Istumatasapaino Pystytkö istumaan sängyn reunalla ilman tukea vähintään 10 sekuntia?	X
4. Istumasta seisomaan nousu Pystytkö nousemaan tuolilta seisomaan enintään 15 sekunnissa ja seisomaan 15 sekuntia? Voit käyttää apuna käsiä ja tarvittaessa apuvälinettä.	X
5. Seisominen tuetta Pystytkö seisomaan tuetta 10 sekuntia (havainnoidaan)	X
6. Siirtyminen Pystytkö siirtymään sängystä tuoliin ja takaisin ilman apua?	X
7. Käveleminen sisällä Pystytkö kävelemään 10 metriä sisällä, tarvittaessa apuvälinein?	X
8. Portaat Pystytkö nousemaan portaita yhden kerrosvälin ilman apua?	X
9. Käveleminen ulkona Pystytkö kävelemään ulkona asfaltilla ilman apua?	X
10. Käveleminen sisällä ilman apuvälineitä Pystytkö kävelemään sisällä 10 m ilman apuvälineitä tai toisen henkilön tukea?	X
11. Esineen poimiminen Pystytkö nostamaan esineen 5 metrin kävelymatkan päästä ja palamaan takaisin?	X
12. Käveleminen ulkona maastossa Pystytkö kävelemään epätasaisessa maastossa, esim. ruohikolla, soralla tai jäällä?	
13. Kylpeminen Selviydytkö suihkuun/kylpyyn menosta ja tulosta sekä peseytymisestä itsenäisesti?	X
14. Neljä porrasta Pystytkö kulkemaan neljä porrasta ylös ja alas ilman kaidetta, tarvittaessa apuvälinein?	
15. Juokseminen Pystytkö juoksemaan tai kävelemään ontumatta neljässä sekunnissa 10 metriä?	
YHTEENSÄ	12

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RIVERMEAD MOBILITY INDEX

Kuntoutujan nimi 001 Testaaja Tomas Cervinka

Pvm 5.2.2020

Pisteytysohje: Jokaisesta kyllä-vastauksesta saa yhden pisteen. Mikäli henkilö arvioi, ettei pysty suoriutumaan tehtävästä, pistemäärä on 0. Maksimi on 15 pistettä. Tehtävä numero 5 havainnoidaan.

	Pisteet
1. Kääntyminen sängyssä Pystytkö kääntymään selinmakuulta kylkimakuulle ilman apua?	X
2. Makuulta istumaan Pystytkö nousemaan makuuasennosta sängyn reunalle istumaan itsenäisesti?	X
3. Istumatasapaino Pystytkö istumaan sängyn reunalla ilman tukea vähintään 10 sekuntia?	X
4. Istumasta seisomaan nousu Pystytkö nousemaan tuolilta seisomaan enintään 15 sekunnissa ja seisomaan 15 sekuntia? Voit käyttää apuna käsiä ja tarvittaessa apuvälinettä.	X
5. Seisominen tuetta Pystytkö seisomaan tuetta 10 sekuntia (havainnoidaan)	X
6. Siirtyminen Pystytkö siirtymään sängystä tuoliin ja takaisin ilman apua?	X
7. Käveleminen sisällä Pystytkö kävelemään 10 metriä sisällä, tarvittaessa apuvälinein?	X
8. Portaat Pystytkö nousemaan portaita yhden kerrosvälin ilman apua?	X
9. Käveleminen ulkona Pystytkö kävelemään ulkona asfaltilla ilman apua?	X
10. Käveleminen sisällä ilman apuvälineitä Pystytkö kävelemään sisällä 10 m ilman apuvälineitä tai toisen henkilön tukea?	X
11. Esineen poimiminen Pystytkö nostamaan esineen 5 metrin kävelymatkan päästä ja palamaan takaisin?	X
12. Käveleminen ulkona maastossa Pystytkö kävelemään epätasaisessa maastossa, esim. ruohikolla, soralla tai jäällä?	
13. Kylpeminen Selviydytkö suihkuun/kylpyyn menosta ja tulosta sekä peseytymisestä itsenäisesti?	X
14. Neljä porrasta Pystytkö kulkemaan neljä porrasta ylös ja alas ilman kaidetta, tarvittaessa apuvälinein?	
15. Juokseminen Pystytkö juoksemaan tai kävelemään ontumatta neljässä sekunnissa 10 metriä?	
YHTEENSÄ	12

Lähde: Collen FM, Wade DT, Robb GF, Bradshaw CM. The Rivermead Mobility Index: a further development of the Rivermead Motor Assessment. Int Disabil Stud 1991; 13:50–4.

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RIVERMEAD MOBILITY INDEX

Kuntoutujan nimi 001 Testaaja Tomas Cervinka
Pvm 12.2.2020

Pisteytysohje: Jokaisesta kyllä-vastauksesta saa yhden pisteen. Mikäli henkilö arvioi, ettei pysty suoriutumaan tehtävästä, pistemäärä on 0. Maksimi on 15 pistettä. Tehtävä numero 5 havainnoidaan.

	Pisteet
1. Kääntyminen sängyssä Pystytkö kääntymään selinmakuulta kylkimakuulle ilman apua?	X
2. Makuulta istumaan Pystytkö nousemaan makuuasennosta sängyn reunalle istumaan itsenäisesti?	X
3. Istumatasapaino Pystytkö istumaan sängyn reunalla ilman tukea vähintään 10 sekuntia?	X
4. Istumasta seisomaan nousu Pystytkö nousemaan tuolilta seisomaan enintään 15 sekunnissa ja seisomaan 15 sekuntia? Voit käyttää apuna käsiä ja tarvittaessa apuvälinettä.	X
5. Seisominen tuetta Pystytkö seisomaan tuetta 10 sekuntia (havainnoidaan)	X
6. Siirtyminen Pystytkö siirtymään sängystä tuoliin ja takaisin ilman apua?	X
7. Käveleminen sisällä Pystytkö kävelemään 10 metriä sisällä, tarvittaessa apuvälinein?	X
8. Portaat Pystytkö nousemaan portaita yhden kerrosvälin ilman apua?	X
9. Käveleminen ulkona Pystytkö kävelemään ulkona asfaltilla ilman apua?	X
10. Käveleminen sisällä ilman apuvälineitä Pystytkö kävelemään sisällä 10 m ilman apuvälineitä tai toisen henkilön tukea?	X
11. Esineen poimiminen Pystytkö nostamaan esineen 5 metrin kävelymatkan päästä ja palamaan takaisin?	X
12. Käveleminen ulkona maastossa Pystytkö kävelemään epätasaisessa maastossa, esim. ruohikolla, soralla tai jäällä?	
13. Kylpeminen Selviydytkö suihkuun/kylpyyn menosta ja tulosta sekä peseytymisestä itsenäisesti?	X
14. Neljä porrasta Pystytkö kulkemaan neljä porrasta ylös ja alas ilman kaidetta, tarvittaessa apuvälinein?	
15. Juokseminen Pystytkö juoksemaan tai kävelemään ontumatta neljässä sekunnissa 10 metriä?	X
YHTEENSÄ	12

Lähde: Collen FM, Wade DT, Robb GF, Bradshaw CM. The Rivermead Mobility Index: a further development of the Rivermead Motor Assessment. Int Disabil Stud 1991; 13:50–4.

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RIVERMEAD MOBILITY INDEX

Kuntoutujan nimi 001 Testaaja Tomas Cervinka

Pvm 17. 2. 2020

Pisteytysohje: Jokaisesta kyllä-vastauksesta saa yhden pisteen. Mikäli henkilö arvioi, ettei pysty suoriutumaan tehtävästä, pistemäärä on 0. Maksimi on 15 pistettä. Tehtävä numero 5 havainnoidaan.

	Pisteet
1. Kääntyminen sängyssä Pystytkö kääntymään selinmakuulta kylkimakuulle ilman apua?	X
2. Makuulta istumaan Pystytkö nousemaan makuuasennosta sängyn reunalle istumaan itsenäisesti?	X
3. Istumatasapaino Pystytkö istumaan sängyn reunalla ilman tukea vähintään 10 sekuntia?	X
4. Istumasta seisomaan nousu Pystytkö nousemaan tuolilta seisomaan enintään 15 sekunnissa ja seisomaan 15 sekuntia? Voit käyttää apuna käsiä ja tarvittaessa apuvälinettä.	X
5. Seisominen tuetta Pystytkö seisomaan tuetta 10 sekuntia (havainnoidaan)	X
6. Siirtyminen Pystytkö siirtymään sängystä tuoliin ja takaisin ilman apua?	X
7. Käveleminen sisällä Pystytkö kävelemään 10 metriä sisällä, tarvittaessa apuvälinein?	X
8. Portaat Pystytkö nousemaan portaita yhden kerrosvälin ilman apua? JOS KAIDE	X
9. Käveleminen ulkona Pystytkö kävelemään ulkona asfaltilla ilman apua?	X
10. Käveleminen sisällä ilman apuvälineitä Pystytkö kävelemään sisällä 10 m ilman apuvälineitä tai toisen henkilön tukea?	X
11. Esineen poimiminen Pystytkö nostamaan esineen 5 metrin kävelymatkan päästä ja palamaan takaisin?	X
12. Käveleminen ulkona maastossa Pystytkö kävelemään epätasaisessa maastossa, esim. ruohikolla, soralla tai jäällä?	
13. Kylpeminen Selviydytkö suihkuun/kylpyyn menosta ja tulosta sekä peseytymisestä itsenäisesti?	X
14. Neljä porrasta Pystytkö kulkemaan neljä porrasta ylös ja alas ilman kaidetta, tarvittaessa apuvälinein?	
15. Juokseminen Pystytkö juoksemaan tai kävelemään ontumatta neljässä sekunnissa 10 metriä?	
YHTEENSÄ	12

Lähde: Collen FM, Wade DT, Robb GF, Bradshaw CM. The Rivermead Mobility Index: a further development of the Rivermead Motor Assessment. Int Disabil Stud 1991; 13:50–4.

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RIVERMEAD MOBILITY INDEX

Kuntoutujan nimi 001 Testaaja Tomas Cervinka
Pvm 21.02.2020

Pisteytysohje: Jokaisesta kyllä-vastauksesta saa yhden pisteen. Mikäli henkilö arvioi, ettei pysty suoriutumaan tehtävästä, pistemäärä on 0. Maksimi on 15 pistettä. Tehtävä numero 5 havainnoidaan.

	Pisteet
1. Kääntyminen sängyssä Pystytkö kääntymään selinmakuulta kylkimakuulle ilman apua?	X
2. Makuulta istumaan Pystytkö nousemaan makuuasennosta sängyn reunalle istumaan itsenäisesti?	X
3. Istumatasapaino Pystytkö istumaan sängyn reunalla ilman tukea vähintään 10 sekuntia?	X
4. Istumasta seisomaan nousu Pystytkö nousemaan tuolilta seisomaan enintään 15 sekunnissa ja seisomaan 15 sekuntia? Voit käyttää apuna käsiä ja tarvittaessa apuvälinettä.	X
5. Seisominen tuetta Pystytkö seisomaan tuetta 10 sekuntia (havainnoidaan)	X
6. Siirtyminen Pystytkö siirtymään sängystä tuoliin ja takaisin ilman apua?	X
7. Käveleminen sisällä Pystytkö kävelemään 10 metriä sisällä, tarvittaessa apuvälinein?	X
8. Portaat Pystytkö nousemaan portaita yhden kerrosvälin ilman apua?	X
9. Käveleminen ulkona Pystytkö kävelemään ulkona asfaltilla ilman apua?	X
10. Käveleminen sisällä ilman apuvälineitä Pystytkö kävelemään sisällä 10 m ilman apuvälineitä tai toisen henkilön tukea?	X
11. Esineen poimiminen Pystytkö nostamaan esineen 5 metrin kävelymatkan päästä ja palamaan takaisin?	X
12. Käveleminen ulkona maastossa Pystytkö kävelemään epätasaisessa maastossa, esim. ruohikolla, soralla tai jäällä?	
13. Kylpeminen Selviydytkö suihkuun/kylpyyn menosta ja tulosta sekä peseytymisestä itsenäisesti?	X
14. Neljä porrasta Pystytkö kulkemaan neljä porrasta ylös ja alas ilman kaidetta, tarvittaessa apuvälinein?	
15. Juokseminen Pystytkö juoksemaan tai kävelemään ontumatta neljässä sekunnissa 10 metriä?	
YHTEENSÄ	12

Lähde: Collen FM, Wade DT, Robb GF, Bradshaw CM. The Rivermead Mobility Index: a further development of the Rivermead Motor Assessment. Int Disabil Stud 1991; 13:50–4.

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Appendix 4

Quality of Services Survey

Osallistujan nro: 001 Päivä: 21.2.2020

K1. Vastatkaa asteikolla 0 - 10, kun ajattelette kokemustanne fysioterapiaklinikallamme kokonaisuutena, kuinka todennäköisesti suosittelisitte meitä ystävällenne tai työtoverillenne? (0 merkitsee Hyvin epätodennäköisesti ja 10 merkitsee Hyvin todennäköisesti)

[8]

K2. Esittäkää mielipiteenne, kuinka tyytyväinen olette fysioterapeuttiajan varaamiseen.

[X] Hyvin tyytyväinen [ ] Tyytyväinen [ ] En osaa sanoa [ ] Tyytymätön [ ] Hyvin tyytymätön

K3. Onko Teillä tällä hetkellä voimassa olevaa yksityistä terveysvakuutusta?

[ ] Kyllä [X] Ei

K4. Kun varasitte tapaamisaikaa, oliko teillä mahdollisuus varata aika omalle fysioterapeutillenne??

[ ] Aina [ ] Joskus [X] Ei koskaan

K5. Kuinka kauan Teidän täytyi odottaa yli varatun tapaamisajan fysioterapeutille pääsyä?

[X] 0-30 minuuttia [ ] 30-60 minuuttia [ ] Enemmän kuin yksi tunti [ ] Enemmän kuin kaksi tuntia

K6. Onko tämä fysioterapiaklinikka se paikka, jossa yleensä käytte tarvitessanne kuntoutusta?

[ ] Kyllä [X] Ei

K7. Kuinka kauan (kuukautta/vuotta) Olette käyneet tällä fysioterapiaklinikalla?

[X] vähemmän kuin 6 kuukautta [ ] enemmän kuin 6 kuukautta - vuoden [ ] enemmän kuin vuoden mutta alle 3 vuotta [ ] 3 – 5 vuotta [ ] enemmän kuin 5 vuotta

K8. Viimeksi kuluneen vuoden aikana, kuinka usein kävitte tällä fysioterapiaklinikalla?

[ ] En yhtään kertaa [ ] 1x [ ] 2x [ ] 3x [ ] 4x [ ] 5x [X] ≥ 5x

K9. Kuinka usein keskimäärin käytte fysioterapiaklinikalla vuoden aikana/vuosittain?

☐ Vähemmän kuin kerran ☒ 1-2 kertaa ☐ 3-5 kertaa ☐ Enemmän kuin 5 kertaa

K10. Kuinka usein saitte klinikallamme ristiriitaista tietoa eri lääketieteen edustajien taholta?

☐ Aina ☐ Joskus ☒ En koskaan

K11. Kerrottiinko Teille mahdollisista sivuvaikutuksista ja/tai vastakkaisista oireista, joita Teille määrätty hoito voi aiheuttaa?

☒ Kyllä ☐ Ei

K12. Kuinka tyytyväinen olitte seuraavissa fysioterapiaklinikkaamme koskevissa seikoissa hoitonne aikana?

	Hyvin tyytyväinen	Tyytyväinen	En osaa sanoa	Tyytymätön	Hyvin tyytymätön
Henkilökuntamme ammattitaito	☒	☐	☐	☐	☐
Klinikkamme hygienia	☒	☐	☐	☐	☐
Henkilöstön tarjoama hoiva	☒	☐	☐	☐	☐
Aikaan, jonka fysioterapeutti vietti kanssanne	☒	☐	☐	☐	☐
Huomiot huolianne kohtaan	☒	☐	☐	☐	☐

K13. Kysyttiinkö Teiltä tänään, että oletteko käyneet hoitomme ohella viime kerran jälkeen jonkin muun terveysammattilaisen luona?

☐ Kyllä ☒ Ei

K14. Tuntuuko Teistä siltä, että työaikamme on sopiva hoitamiseenne?

☐ Täysin samaa mieltä ☒ Samaa mieltä ☐ En osaa sanoia ☐ Eri mieltä ☐ Täysin eri mieltä

K15. Kuinka sopiva palvelujemme sijainti on Teille?

☐ Melko sopiva ☒ Sopiva ☐ Neutraali ☐ Hankalaa ☐ Hieman hankalaa

K16. Kuinka helppoa Teidän oli löytää klinikalle ostoskeskuksen läpi?

☒ Hyvin helppoa ☐ Helppoa ☐ En osaa sanoa ☐ Vaikeaa ☐ Hyvin vaikeaa

K17. Kuinka arvioisitte meitä seuraavissa tekijöissä?

	Oikein hyvä	Hyvä	Keskinker-tainen	Heikko	Hyvin heikko
Huolemme yksityi-syydestäsi ja avoimuutemme	☒	☐	☐	☐	☐
Annetun palvelun laatu	☒	☐	☐	☐	☐
Tarjottu tieto	☒	☐	☐	☐	☐

K18. Tiedättekö kaikista tarjoamistamme terveyspalveluista?

☒ Minulle kerrottiin niistä kysymättä.

☐ Minulle kerrottiin niistä kysyttyäni.

☐ Minulle ei kerrottu niistä.

K19. Kuinka helppoa oli saada seuraava käyntiaika?

☒ Erittäin helppoa ☐ Helppoa ☐ En osaa sanoa ☐ Vaikeaa ☐ Hyvin vaikeaa

K20. Olemmeko auttaneet Teitä löytämään muita tarvitsemianne palveluita, joita emme itse tarjoa?

☒ Kyllä ☐ Ei

K21. Onko Teillä jotain muuta meille annettavaa palautetta?

Rennompi olo pastisuus väheni
kävelystä tuli suorempaan uni tuli paremmin
harjoittelu aika raskasta ja väsyttävää mutta
tehokasta, olen tyytyväinen harjoitteluun
10 p suosittelen terapiaa muillekin,

Modified from a free template available at https://www.questionpro.com/survey-templates/hospital-patient-satisfaction/

Appendix 5

Therapy adherence form

Participant ID: 001

Session no.	Date DD/MM/YY	Attended	Therapy description	Duration min	Initials
1	08/01/20	X	Lihasten vahvistus (TA, CPN, Gastro) 4x5min on/5min off	20	TC
2	17/01/20	X	—"—	20	TC
3	22/01/20	X	Lihasten vahvistus (TA, CPN, Gastroc) 5x5min on/5min off	25 ~~30~~ TC 22/01	TC
4	24/01/20	X	Juoksumatto Lävely (TA, CPN, Gastroc) 1x8min + ~~1x~~5min, nopeus 0,8km/h	23	TC
5	27/01/20	X	Juoksumatto Lävely (TA, CPN Gastroc) 30min (12min nopeus 0,8km/h, 18min 1,0km/h)	30	TC
6	29/01/20	X	Juoksumatto Lävely (TA, CPN, CA) 5min (0,8km/h) + 2x2min (1km/h) + + 19,36 min (1km/h)	28,5	TC
7	31/01/20	X	Juoksumatto Lävely (TA, CPN, CA) 20min + 5min (1km/h)	25	TC
8	3/02/20	X	Juoksumatto Lävely (TA, CPN, CA) 10 min (0,8km/h) + 23,23min (1km/h)	33	TC
9	5/02/20	X	Juoksumatto Lävely (TA, CPN, CA) 14min + 8min, nopeus 1,0km/h	23	TC
10	7/02/20	X	Juoksumatto Lävely (TA, CPN) 10min + 6min + 6min 1,0km/h	22	TC

11	10/02/20	X	Juoksumatto kävely (CPN, TA, CA) 7,5+6min (1km/h) Overground walking with rolator 4 + 2,7 min	20	TC
12	12/02/20	X	Juoksumatto kävely (CPN, TA, CA) 9,5+5min (1km/h) Overground walking with rolator 2,5+ 3,5 min	20	TC
13	17/02/20	X	Juoksumatto kävely (CPN, TA, CA) 13+7min (1km/h) Overground walking with rolator 5,5 min	25,5	TC
14	19/02/20	X	Juoksumatto kävely (CPN, TA, CA) 12,5+ 17,5 min (1km/h) Overground walking with rolator 5,5 min	35,5	TC
15	21/02/20	X	Juoksumatto kävely (CPN, TA, CA) 12+10min (1km/h) Overground walking with rolator 5,5 min	27,5	TC

Appendix 6

Event reporting form

Participant ID: 001

Date DD/MM/YY	Event	Action	Initials
29/01/20	Problems with triggering CA stimulation via footswitch placed under 1st metatarsal	Tried repositioning of the switch but were unsuccessful. The triggering was switched to react only on switch under heel	TC
31/01/20	Problems with triggering CA stimulation via footswitch placed under 1st metatarsal	Tried to switch stimulation manualy but it was hard to find proper timing. Situation was solved by placing ticker paper	TC
		sheet under the footswitch so proper contact between switch and shoe was restored	TC
3/02/20	Problems with triggering CPN stimulation via footswitch placed under ~~1st meta~~ heel after 25 min stimulation	New shoes were used and heel part sot softer, not pressing switch. Situation was solved by placing paper sheet under the switch	TC
7/02/20	Client reported that his stimulated leg was very stiff after the last session on 5.2. (normally spasticity decreased)	The situation improved the following day when he removed new insoles from shoes, possible overstimulation was considered	TC
		for the session on 7.2. when only CPN with TA were stimulated to decrease calf spasticity	TC
10/02/20	Problems with skin conductivity - too dry skin	Cleaned the skin with water to improve the current flow to tissue	TC