Chapter 1, the general introduction, describes the background, the objective and the outline of the thesis. Approximately 2.5 million people worldwide live with a spinal cord injury (SCI). In the Netherlands approximately 12,500 people. SCI is a catastrophic event and causes the most drastic changes for an individual regarding physical status and lifestyle. Pressure ulcers (PUs) are the most prevalent secondary complication in individuals with an SCI, and of individuals admitted to a Model Systems facility within 24 hours of SCI 34% developed at least one PU during acute care or rehabilitation. The prevalence in chronic SCI is unacceptably high, throughout their lives, up to 85%. McKinley et al (1999), and others identified PU’s as the most common secondary complication in all years after injury; and stated that an increased prevalence was associated with greater time since injury.

A PU is any lesion caused by unrelieved pressure resulting in damage of underlying tissue, involving the skin, fat, fascia, muscle, and bone. Therefore, unfortunately PUs are a common problem for wheelchair users such as individuals with an SCI, as they are constantly sitting, unable to stand or walk. When a PU occurs it often does at bony prominences such as the ischial tuberosities, the trochanters or sacral region. Treatment can either be conservative or operative and very often consists of mandatory bed rest to release pressure of the wound(s) and of surgery, leading to radical consequences such as decreased mobility and independence, delayed rehabilitation, and exclusion from work and social activities. This has a tremendous effect on the individual's physical and psychological condition. The consequences (of the treatment, and mining revenues), also result in high costs for the community.

Current PU preventive measures are insufficient. They are all extrinsic methods ('from outside the body'), trying to reduce pressure load, but unfortunately PUs still occur often. A problem with all the measures mentioned above is that they are passive measures that do not activate the muscles, which therefore do not ameliorate intrinsic risk factors ('from inside the body') for developing PU’s such as muscle atrophy and decreased circulation. Electrical stimulation (ES) can induce paralysed muscle contractions and thus activate the muscle. It can, therefore, possibly be an active method to prevent these wounds.

Electrical stimulation (ES)-induced muscle activation may be a useful intervention that helps to prevent complications like PUs and allows immobilized individuals to remain seated or supine for prolonged periods of time, reducing the necessary frequency of assisted repositioning, and, most importantly, reducing the development of PUs. These periodically induced contractions may support or parallel the effects of passive methods like pressure-
relief movements (voluntary or assisted repositioning), which are standard methods for PU prevention. The combination of intensity and duration of the pressure on soft tissue determines the total load and the deformity of the soft tissue. Tissue tolerance for deformity determines if the total load of pressure is harmful, causing a PU to occur or not. Tissue health and its tolerance for deformity therefore is important.

ES-induced muscle contractions could be helpful in increasing tissue health and its tolerance for deformity. ES-induced muscle contractions could theoretically reduce (interface) peak pressure, and improve intrinsic factors, like muscle volume and circulation. This could possibly be an active, instead of passive manner to reduce risk factors for developing PU's, and could be used in addition to the above-mentioned passive methods.

Physicians and therapists to date often seem not familiar with treatment options like ES. Both practical use of ES, and research in the field of PU prevention in SCI is difficult. There are limited scientific data available of each specific type of ES device. There are unanswered questions for example regarding the best ES protocol, optimal ES dose – response, what muscles to activate, and for how long before these muscles will stop contracting due to fatigue, and many more questions. Therefore, ES has long been a largely unknown and poorly understood modality. The prevention of PU's in clinical practice is not surprisingly generally empirical, and seems (logically) often based on dogma and rhetoric, rather than on evidence-based results. Objective of this thesis was to identify the updated evidence of effects of ES induced muscle activation and to investigate feasibility of a new PU prevention method. We used specially developed ES-shorts and evaluated different protocols of surface intermittent ES to gluteal and hamstrings muscles in wheelchair-bound people with a SCI, in an attempt to develop this method.

Chapter 2 gives a literature overview of the worldwide studies (between 1980 and 2014) that investigated effects of ES on risk factors for developing PU's in persons with an SCI. It shows that ES-induced exercise can have positive effects on factors reducing the risk of pressure sore development. Based on available data there is evidence that ES has positive influence on several risk factors for developing pressure ulcers (ischial tuberosities pressure, muscle volume, blood circulation, tissue oxygenation) in people with an SCI. However there is a lack of controlled studies, disallowing definite conclusions. It is hard to give a definite recommendation regarding the most adequate mode of ES, the optimal ES dose -response, training intensity, frequency or duration. There are indications nevertheless, and usable protocols. ES is safe and relatively simple to apply, and costs of applying ES are low. Results suggest that ES should be used more often in clinical practice and further study needs to be performed to study the relation between ES, risk factors for the development of PU's and PU prevention.

Chapter 3 presents a pilot study designed as a randomised clinical trial, in which we
have studied the effects of surface ES of the gluteal muscles on the interface pressure. In thirteen participants with an SCI the gluteal muscles were activated using alternating and simultaneous surface electric stimulation protocols. Both stimulation protocols caused a significant decrease in interface pressure and pressure gradient during stimulation periods compared with rest periods. There was no significant difference in effects between the 2 protocols. We concluded that surface electric stimulation of the gluteal muscles in persons with SCI causes a decrease in interface pressure. This might restore blood flow in compressed tissue and help prevent pressure ulcers. We wondered whether positive effects on the interface pressure would increase if more and larger muscles were activated, besides the gluteal muscles only.

Therefore in chapter 4 case control series are presented that compare the effects of electrically-induced activation of gluteal and hamstring muscles versus gluteal muscles only on sitting pressure distribution in individuals with a SCI. Furthermore the usability of the newly developed ES-shorts used, was evaluated. Ten participants underwent two electrical stimulation (ES) protocols applied using a custom-made electrode garment with built-in electrodes (‘ES shorts’). In all participants, both protocols of gluteal and both gluteal and hamstrings ES-induced activation caused a significant decrease in IT pressure. IT pressure after both gluteal and hamstrings muscles activation was reduced significantly by 34.5% compared with rest pressure, whereas a significant reduction of 10.2% after activation of gluteal muscles only was found. The general usability of the ES-shorts was good, although there were some recommendations for improvement, like a solution for the ultrasound gel that came through the pockets during use, soiling the clothes.

In chapter 5 the effects of on-off two duty cycles (protocol 1:1 versus 1:4 sec.) are studied during 3 hours of ES-induced gluteal and hamstring activation on interface pressure distribution in ten sitting individuals with a SCI, and the usability of the newly, and further developed, ES-shorts were investigated again. In both protocols ES caused a significant decrease in average IT pressure compared to rest (or: no ES-induced muscle activation). On average 35% for protocol 1:4, and 13% for protocol 1:1. The ES on-off duty cycle 1:4s showed less muscle fatigue. Participants scored the usability of the ES-garment in general as satisfactory.

We found no extensive literature describing the effect of ES on ischial oxygenation. Therefore in a pre and post intervention cohort 12 participants performed pressure-relief movements (PRMs) (like bending forward while sitting in the wheelchair), and then after finishing the PRMs in succession received surface ES to the gluteal and hamstring muscles while sitting in their own wheelchair. Chapter 6 compares acute effects of ES-induced gluteal and hamstring muscle activation with pressure relief movements on interface pressure, blood flow and oxygenation. PRMs acutely reduced IP and improved oxygenation and BF in sitting
wheelchair users with SCI. Although muscle activation also reduced IP, it may have been inadequate for all subjects to increase BF and oxygenation. The currently used method can therefore not replace the PRMs, but may be used additionally. Although acute effects may not be as good as those from PRMs, prolonged muscle activation may in contrast induce positive structural changes in muscle tissue, circulation, and pressure distribution.

In chapter 7 the feasibility of ES induced (paralysed) leg muscle activation was studied during prolonged overnight use. We studied muscle fatigue, sleep quality, and the usability of ES-shorts in people with a SCI when using overnight ES. The ES-shorts have not yet been tested for extended stimulation protocols, lasting longer than 3 hours, and only acute effects have been studied. Activating paralysed muscles overnight instead of during the daily routine prevents potential hinder of ES shorts in the wheelchair. We replaced the ultrasound gel for hydrofile granules that also conducted well, but did not leave the pockets and gave no spots on the sheets. Furthermore some participants in our previous studies considered muscle activation at night as ‘an ideal hassle free manner to prevent PU occurrence’. We activated the gluteal, hamstrings and quadriceps muscles in a 2-weeks overnight stimulation protocol, 8 hours per night, using specially developed ES-shorts. After 8 hours of activation muscles still contracted, although fatigue occurred and mean contraction size was lower at the end of the night (p=0.03). SQ-VAS (0-100) after intervention was 75, and 66 after 4 weeks without overnight ES (p=0.04) indicating ES improves sleep quality. The usability of the ES shorts was good. Therefore we concluded that overnight ES-induced muscle activation using ES-shorts in SCI is a new, feasible method that does not interfere with sleep.

The general discussion in chapter 8 reflects on the main findings and discusses the clinical implications. The study design and limitations of the study and future perspectives are considered. ES-induced muscle activation should be implicated in (medical) SCI rehabilitation programs in order to activate muscles and gain fitness and prevent complications like PUs. ES can be used for every person with an SCI during day and/ or overnight. In fact all persons are at risk for developing complications after a part of their body has got paralysed. The method used in our studies is usable for SCI (para- or tertaplegs) with intact reflexes, an upper motor neuron lesion. ES can be used in addition to the standard rehabilitation programs. People with an SCI need to continue to be trained in traditional rehabilitation programs, but in addition ES can be delivered during prolonged period of time during the day or overnight. For example, a person could continue to learn how to perform pressure relief movements (PRMs) in order to reduce continuous pressure loading of the buttocks, and also activate his paralysed leg muscles overnight while asleep (using ES).

Implications for clinical practice are the above ES-induced activation of paralysed muscles to be included in the SCI rehabilitation programs. Activate those muscles. There are
sufficient reasons to advise to do this several moments per week a whole life long. Future research should firstly focus on ES induced reduction of incidence of PUs. For preventing PU’s it will be necessary to determine which reduction of pressure is clinically relevant and therefore how often ES should be applied. The best method to gain more insight in the effects of ES on PU incidence is by conducting a longitudinal study with a control group. This could be a randomised clinical trial (RCT) comparing 2 groups of people with a SCI, with a follow-up period.

This thesis answered several questions. They are summarised here. Activation of both hamstrings and gluteal muscles of people with an SCI induces a larger interface pressure decrease while sitting than activation of gluteal muscles only. The ES protocol with an ‘on-off’ ratio of 1:4 seconds gives more interface pressure decrease in people with an SCI than with a 1:1 ratio, without marked muscle fatigue. ES-induced muscle activation in people in a wheelchair is not as effective in reducing interface (sitting) pressure on the short term, as pressure relief movements (PRM’s) (like bending forward) are. But the frequency of this muscle activation is so much higher that in the longer term it is much more likely to be effective in preventing PU’s of the buttocks than PRM’s. Moreover muscle activation has several other positive effects, like increase of muscle volume and increase of blood circulation. Paralysed muscles can be activated for a prolonged period of eight consecutive hours, under the condition that after 30 minutes of activation, there is a period of 30 minutes of rest. ES-induced muscle activation overnight (while lying in bed sleeping) using ES-shorts is a feasible method that does not disturb sleep. Using loose electrodes, or a specially designed ES garment are both methods to transcutaneously apply ES. An big advantage of the ES garment over loose electrodes is that the electrodes do not have to be placed separately every time. According to our participants the ES garment with electrical stimulator is feasible for daily use.