Evaluating body composition and resting energy expenditure after neuromuscular electrical stimulation therapy in persons with chronic spinal cord injury

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Primary Objective: To evaluate potential changes in body composition and REE after NMES therapy at home for 12 weeks.We hypothesize that NMES therapy would result in hypertrophy of gluteal and hamstring muscles, and an increase in LL-LBM, total LBM…

Ethical review	Approved WMO
Status	Pending
Health condition type	Spinal cord and nerve root disorders
Study type	Observational invasive

Summary

ID

NL-OMON50889

Source
ToetsingOnline

Brief title
Body composition, resting energy expenditure after electrical stimulation

Condition

- Spinal cord and nerve root disorders

Synonym
spinal cord injury

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit

Source(s) of monetary or material Support: China Scholarship Council

Intervention

Keyword: body composition, neuromuscular electrical stimulation, resting energy expenditure, spinal cord injury

Outcome measures

Primary outcome

Body composition: LL-LBM (kg and %), REE(kcal/day).

Secondary outcome

Body composition: whole body-LBM (kg and %), whole body-FM (kg and %), whole body-impedance (*), LL-FM (kg and %), LL-impedance (*), muscle thickness (cm), muscle cross-sectional area (cm^2), fascicle length (cm) and pennation angle (°) of gluteal and hamstring muscles. Anthropometrics: body mass (kg), BMI (kg/m^2), waist circumference (cm).

Study description

Background summary

A spinal cord injury (SCI) is damage to the spinal cord that causes devastating changes in its function. SCI affects the conduction of sensory and motor signals across the sites of injury, which leads to the loss of sensation and muscle function. Thus, paralysis commonly occurs below the level of injury and people with SCI can subsequently become physically inactive along with paralyzed muscle atrophy and metabolic disorder. Because of these lifestyle and physiological alterations, people with SCI suffer the decline of lean body mass (LBM) and subsequently the decline of resting energy expenditure (REE) as well as the increase of fat mass (FM) (Tanhoffer, Tanhoffer, Raymond, Hills, & Davis, 2014). These changes in body composition can easily cause a higher risk of obesity and many adverse metabolic sequelae such as insulin resistance, hyperlipidemia, and cardiovascular diseases (Bauman, Adkins, Spungen, & Waters, 1999; Maki et al., 1995; Garshick et al., 2005). Meanwhile, the lower limbs (LL), including gluteal and hamstring muscles which are two major muscle groups in the control of hip and knee, are naturally exposed to those negative

pathological adaptations as a result of immobilization after injury (Gorgey & Dudley, 2007; Spungen et al., 2003). Therefore, it is of great importance to investigate whether there is an effective method that could counteract the unfavourable trend in body composition, especially LL-body composition, and REE after SCI.

Surface neuromuscular electrical stimulation (NMES) has been proposed as an effective alternative method to exercise the paralyzed muscles below the level of injury (Creasey et al., 2004; Dudley-Javoroski & Shields, 2008). It has been shown that NMES could evoke skeletal muscle hypertrophy and decrease ectopic adipose tissue in people with chronic spinal cord injury (Gorgey & Shepherd, 2010; Ryan, Brizendine, Backus, & McCully, 2013). Furthermore, as numerous high-energy cost processes occur in organs and muscles, the increase of LBM might lead to a higher REE (Buchholz, Rafii, & Pencharz, 2001). In fact, NMES has already been used as a therapy program for people with chronic SCI in overcoming muscle weakness and improving muscle mass and strength (Mc Cormack et al., 2010; Dudley-Javoroski & Shields, 2008; Gorgey et al., 2012). However, it has not been extensively evaluated to what extent NMES therapy could improve body composition and subsequently REE.

Several techniques have been used to assess body composition such as dual-energy X-ray absorptiometry (DXA), computed tomography (CT), magnetic resonance imaging (MRI), bioelectrical impedance analysis (BIA), and ultrasound. Ultrasound can measure changes in muscle architecture and composition such as muscle thickness, muscle echogenicity, pennation angle and fascicle length (Strasser, Draskovits, Praschak, Quittan, & Graf, 2013; Stringer & Wilson, 2018). These parameters are related to muscle size and strength. Kositsky et al. reported that ultrasound is a reliable and valid measurement of hamstring muscles cross-sectional area in the general population when compared with the gold standard MRI (Kositsky et al., 2020). An amenable protocol was developed by Whittaker and Emery to investigate the morphology of gluteal muscles in healthy adolescent soccer players using ultrasound (Whittaker & Emery, 2014). Ultrasound has the benefits of portability, cost-effectiveness and efficiency compared to the current gold standards: DXA, CT and MRI. This could make it become a potential diagnostic tool in clinical practice (Stringer & Wilson, 2018). Thus, measuring with ultrasound could be valuable to evaluate the potential changes of LL muscles after NMES therapy.

Another method that is more practical and convenient with relatively reliable results is BIA. Buchholz et al. suggested that after adding some relevant parameters including age, gender, height, and weight to BIA results, the method can be used as a standard for defining body composition in people with SCI (Buchholz, McGillivray, & Pencharz, 2003). Numerous studies have already started to use BIA as a standard to measure body composition in people with SCI (Eriks-Hoogland et al., 2011; Han et al., 2015; Zwierzchowska et al., 2014).

Regarding REE measurement, the most commonly used method for measuring REE in both laboratory and field settings is indirect calorimetry. It is considered as an accurate, reliable and non-invasive measurement of REE nowadays (da Rocha, Alves, & da Fonseca, 2006). Many studies about REE in people with SCI have used indirect calorimetry as a reference method (Chun, Kim, & Shin, 2017; Farkas,

Gorgey, Dolbow, Berg, & Gater, 2019; Nightingale & Gorgey, 2018).

Study objective

Primary Objective: To evaluate potential changes in body composition and REE after NMES therapy at home for 12 weeks.

We hypothesize that NMES therapy would result in hypertrophy of gluteal and hamstring muscles, and an increase in LL-LBM, total LBM, and REE, while a decrease in LL-FM and total FM would take place.

Study design

The study is an exploratory prospective cohort study to evaluate the potential effects of regular NMES therapy. Participants will receive NMES therapy for LL which is part of their regular care in Reade, center for rehabilitation and rheumatology. The regular NMES care normally consists of one screening session, two or three instruction sessions in Reade and long-term NMES therapy at home. The period of NMES therapy varies individually. Based on the NMES therapy routine in Reade and previous papers, we set up the study period for 12 weeks since the effects of NMES on body composition could be detected in 8-12 weeks among people with chronic SCI (Carty et al. 2013; Gorgey et al. 2012). Therefore, people with SCI who will receive LL NMES therapy for at least 12 weeks will be included. To evaluate the potential changes, body composition and REE will be measured at baseline and after 6 and 12 weeks using ultrasound, BIA and indirect calorimetry devices. These measurements are normally not included in regular care, so participants will be asked to go to Reade for two extra times (at 6 weeks and 12 weeks). Personal and lesion characteristics including age, gender, lesion level, lesion completeness, time since injury will be registered at the first visit.

Intervention

NMES therapy for LL including the combination of strength and endurance programs by an electrical muscle stimulator for 12 weeks.

Study burden and risks

NMES is part of the standard care at rehabilitation center Reade in Amsterdam. Therefore, there are no additional risks present in this study. Benefits for patients may be present when they have the opportunity to get a very accurate insight into their body composition and REE and how these parameters change during 12 weeks NMES. This might motivate them to continue NMES therapy in the future. The burden for participants will be keeping therapy diaries after each NMES, recording dietary intake before every measurement occasion, and the

measurements of body composition and REE.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

-Age between 18 and 75 years
-Time since injury > 1 year
-Expected NMES therapy period > 12 weeks

Exclusion criteria

-Autonomic dysreflexia result of NMES

-Presence of pacemaker, implantable cardioverter-defibrillator, or other implanted electrical devices
-Presence of stimulation in the neck and head region
-Presence of wounds or sores on the stimulated sites
-Presence of piercings
-History of epileptic seizures
-Pregnancy
-Recent or current participation in an electrical stimulation-induced exercise program or study (up to 6 months prior to this study)

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2022
Enrollment:	30
Type:	Anticipated

Medical products/devices used

Generic name:	COMPEX SP 2.0
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	07-12-2021
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL77980.078.21