Body composition and resting energy expenditure in individuals with spinal cord injury

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To develop a prediction equation to validly estimate the body composition of people with a SCI using bioelectrical impedance analysis (BIA)To develop a prediction equation to validly estimate the resting energy expenditure of people with a SCI from...

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

Summary

ID

NL-OMON46436

Source
ToetsingOnline

Brief title
Body composition and resting energy expenditure in spinal cord injury

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: Chinese Scholarship Council (CSC)

Intervention

Keyword: Body composition, Resting energy expenditure, Spinal cord injury

Outcome measures

Primary outcome

Body composition measured by DXA, Bod Pod, and BIA. DXA and Bod Pod will be used as gold standard to determine fat mass, fat percentage and fat free mass, while the outcomes of BIA will be used to compare with the standard and develop a new formula to predict the fat free mass in people with SCI.

Resting energy expenditure in Kcal/day measured by indirect calorimetry. Fat mass and fat free mass will be included in developing predictive REE formulas for SCI populations.

Primary outcome measures:

- resting energy expenditure in Kcal/day

- Fat mass (kg)

- Fat free mass (kg)

Secondary outcome

Anthropometrics: body mass (kg), height (cm), Bodymass index (BMI), waist circumference (cm), Fat free mass (kg and %), fat mass (kg and %).

Gender, age, lesion level and motor completeness, time since injury, educational level, present co-morbidities, alcohol consumption, smoking habits and ethnicity.

Study description

Background summary

A lower level of resting energy expenditure (REE) comparing with the able-bodied people is a big challenge among spinal cord injury (SCI) patients. With metabolic and physiologic changes combined with physical inactivity, SCI population is more likely to experience positive energy balance during daily life which will naturally increase the risk of obesity. Obesity is regarded as the most common secondary complication, affects SCI patients* health and is associated with many adverse metabolic. The clinical consequences along with decreased physical activity as well as unbalance diets all contribute to the negative changes of body composition and metabolic profiles in people with SCI. Thus, to investigate the prediction equation of energy expenditure and body composition in SCI individuals is clearly warranted.
During daily life, REE comprises the greatest proportion (~70%) of total daily energy expenditure in healthy people and even up to 80% of those sedentary populations. Considering the limited mobility and sedentary lifestyle, REE should be paid much attention in people with SCI in order to control their energy balance and help them to maintain health. In general, body weight and height are often used for the prediction of REE in health people, but this seems not a reliable way to estimate the situation in SCI patients. The reason of this may explained by the changes in body composition and sympathetic nervous system activity. Fat free mass (FFM) is regards as the most important and valuable predictor of REE in both healthy and SCI population. This may due to the numerous high-energy cost processes which occur in organs and muscles. Good management of REE and obesity in people with SCI is really important for their health and quality of life. However, to measure REE, expensive devices are needed and therefore not accessible for large groups. According to the strong correlation between FFM and REE in people with SCI, it seems feasible to add FFM into the equation as well as personal and other characteristics for predicting REE of SCI individuals. To accurately determine the body composition of individuals with spinal cord injury, a new equation model specified on this population should be developed. Bioelectrical impedance analysis (BIA) is an alternative method of dual-energy X-ray absorptiometry (DEXA) scan in measuring body composition which is more practical and convenient with relatively reliable results. An equation model based on Bio-impedance analysis should be developed.

Study objective

To develop a prediction equation to validly estimate the body composition of people with a SCI using bioelectrical impedance analysis (BIA)
To develop a prediction equation to validly estimate the resting energy expenditure of people with a SCI from personal and lesion characteristics and body composition.

Study design

A cross-sectional study will be performed to determine body composition and REE. During one-time visit for 100 individuals with SCI, DXA and Bod Pod will be used as gold standard to determine the body composition. The reactance and resistance outcomes from the BIA together with the personal and lesion characteristics, will be used to develop a new formula to predict the fat free mass in people with SCI. Anthropometrics will also take place.
REE will be determined by indirect calorimetry. A multiple linear regression analysis will be performed to develop predictive REE formulas for SCI populations. Age, gender, time since injury, level of injury (paraplegia or tetraplegia), motor completeness, fat mass, fat free mass will be included as possible predictors in the SCI population.

Study burden and risks

The total burden and risks in participating in this study are low. Although the study population is more fragile, no real burdens are put in the participants.
The study consists of 1 visit if approximately 2 hours where personal and lesion characteristics are collected.
The anthropometric measurements are low in burden, since all measurements are collected passively in either upright sitting position or supine position.
The radiation during a DXA scan are negligible. The radiation of one full body scan is less than half the amount of radiation exposed to surrounding radiation.
All participants will receive a personal report afterwards with outcomes of the body composition and energy expenditure. This can be considered as valuable information, especially for these populations.

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
- Complete or incomplete SCI at or below C5 (i.e. not on a ventilator)
- Chronic (>1 year) SCI

Exclusion criteria

- Presence of metabolic syndrome
- Pregnant
- Presence of menstruation period at day of measurement
- Recent presence (<1 month) of any infection such as urinary or respiratory tract infections
- Presence of a pacemaker
- Presence of pressure ulcers
- insufficient knowledge of the Dutch language to understand the content of the study and questionnaires
- Presence of progressive illness
- Presence of psychiatric disorders
- Presence of edema
- Presence of fever (>39 degrees)

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	03-09-2018
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO

Date:	16-07-2018
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL64704.048.18