The role of the relative aerobic load of walking and walking behaviour after spinal cord injury

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

Summary

ID

NL-OMON51917

Source
ToetsingOnline

Brief title
Relative aerobic load and walking behaviour after spinal cord injury

Condition

- Spinal cord and nerve root disorders

Synonym
Spinal cord injury

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Subsidie van Rijndam Revalidatie

Intervention

Keyword: health, spinal cord injury, walking behaviour, walking efficiency

Outcome measures

Primary outcome

The amount of walking in daily life: This is objectively measured over 7 days with an Activ8 activity monitor. In addition, this monitor measures other aspects of exercise behavior (physical activities such as [cycling, wheelchair riding/hand biking], standing and sedentary behavior [lying, sitting]). The Activ8 is a small validated activity monitor that is attached to the thigh. To also gain insight into daily wheelchair use and handbiking, an extra Activ8 is attached to the wheelchair wheel. Relative aerobic load of walking: This is defined as the oxygen uptake during walking, expressed as a percentage of the aerobic capacity.

The oxygen uptake during walking is determined with indirect calorimetry (VO2 in ml/kg/min; (mobile) breath analysis equipment). Aerobic capacity is determined by measuring the peak oxygen uptake during a maximum exercise test (including breath analysis) performed on an electronically braked bicycle ergometer (VO2 peak).

Secondary outcome

• Aerobic capacity

• Energetic load in daily life by walking.

• Overall physical activity

• Body composition

• Bone density

• Cardiometabolic profile

• Participation

• Quality of life

Study description

Background summary

The group of people with spinal cord injury with a walking ability has increased in recent decades. Knowledge about the physical activity in this group is limited, but recent research by our project team suggests that part of this group shows a strongly unfavorable (course in) physical activity in the year after inpatient rehabilitation, including relatively little standing and walking. Less physical activity is associated with higher mortality, poorer health and lower well-being.
The energy consumption during walking, and especially the energy consumption relative to the maximum oxygen uptake (relative aerobic load of walking), probably plays an important role in the extent to which people with a spinal cord injury walk in daily life. This means that relative aerobic load of walking may be an important target for rehabilitation treatment. However, nothing is known about the relationship between the relative aerobic load of walking and the amount of walking of people with a spinal cord injury. Knowledge about this relationship is necessary for the development and personalization of interventions to promote physical activity in this growing population.

Study objective

The primary aim is to determine whether the relative aerobic load of walking is a determinant of the amount of walking in daily life in people with a chronic spinal cord injury with a walking function. Secondary goals are to gain insight into other determinants of the amount of walking, the energy use in daily life as a result of walking, the overall physical activity (besides walking also other physical activities, standing and sedentary behaviour) and their determinants, total energy consumption in daily life, fitness, and health (bone density, body composition, cardiometabolic profile) in the chronic phase.
In addition, the energetic load of walking and exercise behavior in persons with a chronic spinal cord injury is compared with that of persons without disabilities.
Finally, because performing a maximal cycling test with breath gas analysis to determine aerobic capacity (fitness) is time-consuming and costly and not feasible in all patients due to contraindications to maximal exercise, the

utility of an accerelometry-based tool to estimate aerobic capacity (Seismofit) is evaluated in patients with spinal cord injury without the need for exercise.

Study design

Cross-sectional study

Study burden and risks

Participants are invited for 1 (part of a) day for questionnaires, physical examination, clinical testing, an exercise test (bicycle test), a measurement with the Seismofit, and gait test, and for optional blood analysis and a Dexa-scan. Sufficient rest is planned between the activities. Such protocols have been shown to be feasible in previous studies in comparable patient populations (MEC 2010-178; SAB: MEC-2017-523; SCI/MS: MEC-2018-025). For these measurements, 1 (part of the) day has been deliberately chosen to limit the travel load.
Exercise behavior is measured in the home situation for 7 days with two activity monitors that are attached to the thigh (with special skin-friendly foil) and the wrist. Further, a heartrate belt is worn for 2 days. The wearables are small and ensures little load; people can perform their normal daily activities. During this period, participants are asked to keep a diary.
A maximum exercise test with breath analysis is the gold standard for measuring aerobic capacity and is frequently used in regular care and scientific research. The *Safety Guidelines for Maximum Exercise Test* of the Rijndam Movement Lab are followed around the test. Participants are minimally screened for (relative) contraindications and a resting ECG is made immediately prior to the test. During the test, the safety protocol of the Movement Lab applies.
The measurement with the Seismofit to estimate the aerobic capacity is without risk.
Blood sampling (cardiometabolic profile) indicates a low risk of complications; in particular, there is a risk of a hematoma. Blood sampling can be experienced as mentally taxing. Therefore, blood analysis will be optional (target: n=40).
With a single Dexascan (total body and bone density lumbar spine and femur) the radiation load is 0.004 mSv. This means that the risk is very low (category 1). This measurement is optional (target: n=40).
By participating in the study, participants gain insight into their own fitness, energetic load of walking, total exercise behavior and health. This is fed back to individual participants. Further, they have no direct benefit from participating in the study. We expect the study to lead to optimization of treatment in runners with spinal cord injury; the participants of the study may benefit from this in the future.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (16-17 years)
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

At least one year after onset of injury
Age 16 years or older
Spinal cord injury AIS grade A to D
Independent functional ambulation indoors

Exclusion criteria

Missing informed consent
Limited life expectancy
Insufficient mastery of Dutch language

Severe cognitive or intellectual impairments
Pregnancy

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	18-07-2022
Enrollment:	100
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO Date:	08-04-2022
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	08-03-2024
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO Date:	11-12-2024
Application type:	Amendment
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	NL78731.078.21