Personalized cardiorespiratory fitness training in patients with incomplete spinal cord injury during primary rehabilitation.

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

Summary

ID

NL-OMON56193

Source
ToetsingOnline

Brief title
FIT@HOME I

Condition

- Spinal cord and nerve root disorders

Synonym
incomplete spinal cord injury, partial paralysis

Research involving
Human

Sponsors and support

Primary sponsor: Sint Maartenskliniek

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Cardiorespiratory fitness, High Intensity Interval Training, Incomplete spinal cord injury

Outcome measures

Primary outcome

The primary endpoint is the change in CRF (expressed as VO2peak) after the

6-weeks intervention period.

Secondary outcome

Secondary outcomes are gait capacity, pulmonary function, neurological status,

muscle force, cardiometabolic risk factors, secondary complications, QoL,

functional independence and exercise self-efficacy.

Study description

Background summary

Despite advances in medical care, spinal cord injury (SCI) patients have significantly lower survival rates compared to the general population. The *Koepelproject*, an unique world-leading multi-center research project, discovered that SCI patients have a decreased pulmonary function, which is linked to poor cardiorespiratory fitness (CRF). This leads to respiratory and cardiovascular diseases, which are important predictors of death in SCI patients. However, there are limitations of the *Koepelproject* which highlight the need for the proposed project *FIT@HOME*. The Rehabilitation knowledge in SCI patients is primarily focused on those with a complete lesion, while there has been changes in the characteristics of the SCI population over the last few decades. The diagnosis of an incomplete SCI (iSCI) is more common and requires different insights and skills compared to patients with complete lesions. Therefore, insight in the effect of personalized rehabilitation strategies focussed on CRF during primary rehabilitation will provide important information to support healthy ageing in iSCI patients.

Study objective

The primary aim of this study is to assess the effect of a personalized training intervention on CRF during primary rehabilitation. Secondary aims of this study are to determine the effect of this intervention on gait capacity, pulmonary function, neurological status, muscle force, cardiometabolic risk factors, quality of life (QoL), functional independence and exercise self-efficacy.

Study design

The proposed study design is an explorative randomized controlled trial.

Intervention

The intervention includes 2-3 personalized CRF-focused training sessions per week. The control group receives usual care.

Study burden and risks

iSCI patients who participate in this study may benefit from an improvement in their CRF, resulting in a better health status. The maximal exercise test on the arm cycle ergometer and the use of an electrocardiogram (ECG) can be seen as a screening tool, determining safe exercise limits prior to the start of the primary rehabilitation program. Furthermore, the risks of exercise testing are low and patients will be continuously monitored by a physician during the maximal exercise test. The measurements will be scheduled so that they do not interfere with the rehabilitation program. Most of the study is conducted within the usual rehabilitation program, therefore the patient burden associated with participation in this study is minimal. The extra time investment to participate in the study is estimated to be 4-5 hours in total for both groups.

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

* Diagnosis of incomplete spinal cord injury (SCI) based on a stable cause (e.g. traumatic)
* Spinal cord injury classification C or D on the American Spinal Injury Association (ASIA) impairment scale
* During this study in the subacute phase (< 6 months post injury)
* Hospitalized in the Sint Maartenskliniek for a primary, inpatient rehabilitation program
* Aged 18 years or older
* Able to understand and perform study related procedures
* Capable to sit at least 3 times a day for 2 hours (prerequisites to start the active rehabilitation program)
* The ability to use an arm ergometer

Exclusion criteria

* Unable to give informed consent (IC)
* Language barrier
* Participating in another interventional study targeting CRF
* Have contraindications to perform exercise during the rehabilitation program

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	11-01-2024
Enrollment:	32
Type:	Actual

Ethics review

Approved WMO Date:	28-02-2023
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	02-10-2023
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	22-11-2023
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL81465.091.22