Promoting physical activity in individuals with spinal cord injury

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

Summary

ID

NL-OMON34094

Source
ToetsingOnline

Brief title
ACT-ACTIVE

Condition

- Spinal cord and nerve root disorders

Synonym
spinal cord injury, spinal cord lesion

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Kinderfonds Adriaan Stichting en Johanna Kinder Fonds

Intervention

Keyword: active lifestyle, intervention, physical fitness, spinal cord injury

Outcome measures

Primary outcome

The evaluation will primary contain objectively measured level of everyday physical activity (accelerometry-based activity monitor during 5 days). This measurement will be performed in both the FIT and Behave+FIT group at the beginning of the intervention period (T1), at discharge from the rehabilitation center (T2), 6 months after discharge (T3), and 1 year after discharge (T4).

Secondary outcome

Secondary parameters are: subjectively measured level of everyday physical activity (questionnaire), the effects on physical fitness (aerobic capacity), anthropometry (body mass index and waist circumference) and metabolic fitness (biochemical markers). Questionnaires will be used for functionality, fatigue, secondary problems, pain, social and sports participation, quality of life, self-efficacy, attitude, coping, and depression. Measurements will be performed in both groups at T1, T2, T3 and T4.

Study description

Background summary

Persons with spinal cord injury (SCI) often have an inactive lifestyle which may result in poor physical fitness, and consequently in further inactivity. In individuals with SCI a higher activity level has found to be associated with less pain, fatigue and depression, with higher life satisfaction, and with higher quality of life. Furthermore, physical activity has been associated with a lower risk for cardiovascular disease and type 2 diabetes in individuals with

SCI. Fitness can be regarded as a prerequisite for physical activity, and is more and more part of the regular treatment. However, a higher fitness level will probably not automatically lead to a more active lifestyle. There is initial evidence that behavioural interventions can improve physical activity levels in individuals with SCI.

Study objective

The general objective of this project is to evaluate, for persons with a SCI, on the short and long term, the added value of a behavioural focused intervention, on top of a physical exercise intervention, on the level of everyday physical activity. To obtain insight in the working mechanisms of the intervention the study will specifically focus on the role of (changes in) physical activity level and fitness level for patient well-being. We hypothesize that the combination of a behavioural and physical exercise intervention will lead to larger improvements in activity level compared to only physical exercise. The addition of a behavioural intervention is expected to be crucial for the maintenance of effects after discharge from the rehabilitation center.

Study design

Multi-center single blind randomized controlled trial.

Intervention

The intervention will start 2 months before discharge from the rehabilitation center. Subjects will be randomized into two groups (FIT and Behave+FIT). Both groups receive an exercise intervention and sports advice. The Behave+FIT group (n=30) in addition will receive a behavioural intervention. The exercise intervention consists of a handcycle training program aimed at increasing physical fitness (24 sessions). Sports advice consists of informing about sport possibilities and giving the opportunity to try different kinds of sports at the rehabilitation center or accompany when visiting another sports center. The behavioural intervention consists of individual counseling on movement behaviour based on motivational interviewing (13 sessions). The behavioural intervention includes setting up action plans and coping strategies and giving feedback by using cycle counters which can register the amount of kilometres travelled with a wheelchair. Moreover, the intervention includes a home visit and additional information will be provided about relevant topics related to physical activity such as barriers and facilitators and health benefits.

Study burden and risks

All subjects will perform the handcycle training (45-60 minutes) during the last 2 months of inpatient rehabilitation 3x/week.The Behave+FIT group will in

addition get a behavioural intervention 2x/month starting 2 months before discharge till 3 months after discharge, and the following 3 months 1x/month. All measurements will be performed by all subjects at 4 measurement periods. Performing the measurements in the lab will take about 2 hours per measurement period and filling in the questionnaires will take about another 2 hours per measurement period. Furthermore, subjects will wear the activity monitor 4 times for 5 days, but during these periods subjects can do everything they would normally do. All subjects will possibly benefit from the exercise intervention with increased fitness. In addition the Behave+FIT group will possibly benefit from the behavioural intervention with a higher activity and fitness level on the long term.

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

- Recent spinal cord injury
- Between 18 and 65 years of age
- Sufficient comprehension of the Dutch language to understand the purpose of the study and its testing methods
- No progressive disease or a psychiatric condition that may interfere with participation

Exclusion criteria

- Contraindications for exercise
- Not able to perform the handcycle training intervention
- Prognosis of becoming mainly ambulatory

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	21-01-2011
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO

Date:	29-06-2010
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

ID: 29073
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL32183.078.10
OMON	NL-OMON29073