Act-Active.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON29073

Source
NTR

Brief title
Act-Active

Health condition

Spinal cord injury

Sponsors and support

Primary sponsor: Erasmus MC
Source(s) of monetary or material Support: JKF / KFA

Intervention

Outcome measures

Primary outcome

The evaluation will primary contain objectively measured level of everyday physical activity (accelerometry-based activity monitor during 5 days).

Secondary outcome

Secondary parameters are:

2. Subjectively measured level of everyday physical activity (questionnaire);

2. Physical fitness (aerobic capacity);

3. Anthropometry (body mass index and waist circumference);

4. Metabolic fitness (blood pressure, biochemical markers).

Questionnaires will be used to assess functionality, fatigue, secondary problems, pain, social and sports participation, quality of life, self-efficacy, attitude, coping, and depression.

Study description

Background summary

N/A

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

Measurements 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).

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 during inpatient rehabilitation. The Behave+FIT group (n=30) in addition will receive a behavioural intervention from the last 2 months before discharge till 6 months after discharge from the rehabilitation center. 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 accompanying when visiting another sports center. The behavioural intervention consists of individual counseling on movement behaviour (everyday physical activity and sports) based on motivational interviewing (total of 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.

Contacts

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Eligibility criteria

Inclusion criteria

Persons are eligible for inclusion if they are able to perform the handcycle training, are between 18 and 65 years of age, have sufficient comprehension of the Dutch language to understand the purpose of the study and its testing methods, and do not have a progressive disease or a psychiatric condition that may interfere with participation.

Exclusion criteria

Persons are excluded from the study if they have cardiovascular contraindications for exercise, a resting diastolic blood pressure greater than 90mmHg or a systolic blood pressure greater than 180mmHg, severe overuse injuries of the upper extremity, neck or back, and

other medical conditions for which maximal effort is not desirable. A medical doctor will check for contraindications when a patient meets the inclusion criteria and is considering participation in the study. Persons who have a prognosis of becoming mainly ambulatory will be excluded. Persons who expect to be unable to come to the rehabilitation center for testing during outpatient rehabilitation will not be included in the study.

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2010
Enrollment:	60
Type:	Anticipated

Ethics review

Positive opinion

Date:	22-07-2010
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 34094
Bron: ToetsingOnline

Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL2318
NTR-old	NTR2424
CCMO	NL32183.078.10
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON34094

Study results

Summary results
N/A