Assessment of the physical activity levels during rehabilitation of lower limb amputees: A pilot study

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Primary Objective:To evaluate the efficacy of the rehabilitation program currently used for lower limb amputees, by comparing the intensity and efficacy of this program with the ACSM requirements regarding the minimum intensity requirements....

Ethical review	Approved WMO
Status	Will not start
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON36145

Source
ToetsingOnline

Brief title
Activity levels during rehabilitation

Condition

- Other condition

Synonym
Lower limb amputations

Health condition

Lower limb amputations

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Amputees, Circulatory and respiratory physiological phenomena, Exercise therapy, Rehabilitation

Outcome measures

Primary outcome

Parameters measured during training:

maximal oxygen uptake (VO2max in l/min), maximal carbon dioxide output (VCO2max in l/min), maximal heart rate during (HRmax in beats per minute), heart rate reserve (HRR), peak power output (PPO in W), maximal workload (W).

Secondary outcome

Gross Efficiency (% of external work performed to the total production of energy), metabolic equivalent of exercising (MET in 3.5 ml O2 /kg/min), average heart rate (HR in beats per minute), oxygen input (VO2 in litre per minute), carbon dioxide output (VCO2 in litre per minute), anaerobic threshold (AT), blood pressure (BP in mmHg), breathing frequency (BF in breaths per minute) maximal ventilation (VE litre per minute), respiratory exchange rate (RER in %), rate of perceived exertion (RPE in 10 point Borg-scale) and daily activity log.

Study description

Background summary

Lower limb amputation is generally associated with poor physical condition, reduced physical activity and psychological burdens. Physical activity has a positive effect on both physical and psychological wellbeing, thus improving the overall quality of life. Therefore, physical activity and sports is an essential part of the rehabilitation process of lower limb amputees. The lower limb amputees follow a rehabilitation program which combines physiotherapy, walking school and sports. However, it is unknown what the physical activity level of amputees is during the rehabilitation period. Moreover, it is not determined whether the current rehabilitation program is in accordance with the general recommendations in the field, 30 min per day minimal 3 times a week with a minimum intensity of 60% of the maximum heart rate (ACSM). Therefore the effectiveness of the program in improving the physical fitness is yet unclear.

Study objective

Primary Objective:
To evaluate the efficacy of the rehabilitation program currently used for lower limb amputees, by comparing the intensity and efficacy of this program with the ACSM requirements regarding the minimum intensity requirements.

Secondary Objective(s):
To assess the daily activity levels of lower limb amputees during their outpatient rehabilitation.
To provide recommendations for the development of a standardized training protocol, for lower limb amputees, effective in increasing the physical fitness.

Study design

Within subject design

Subjects will be asked to perform three discontinuous exercises (one sub-maximal and two maximal tests) on a combined arm-leg ergometer (Cruiser). A discontinuous incremental test protocol will be used because it is more effective compared to the continuous protocol.
The sub-maximal test will take place at the beginning of the test period. The first maximal test will take place two or three days after the sub-maximal test and the second maximal test will take place six weeks after the first maximal test. Every test will last for maximum 30 minutes each. These tests will take place at the Centre for Rehabilitation, UMCG, location Beatrixoord.
Subjects will be asked to report their daily physical activities together with the rate of perceived exertion and time interval of these physical activities in a daily activity log.
Additionally they will have to wear a portable heart rate frequency monitor during their physical activities which take place during their regular visits at the rehabilitation centre.

Study burden and risks

Nature and extent of burden:

The entire study will take 6 (six) weeks, between inclusion and last maximal test.
During this time subjects will perform three exercise tests on an combined arm-leg ergometer. One test will be sub-maximal and the other two will be maximal tests (until exhaustion). Every test will take maximum 30 minutes.
During their time spent outside the rehabilition centre, subjects will be asked to report their daily physical activities, together with the rate of perceived exertion and time interval of these physical activities in a daily activity log.
Additionally they will have to wear a portable heart rate frequency monitor during their physical activities, which take place during their regular visits at the rehabilitation centre.

Risks associated with participation:

All exercise tests will be supervised by a physician, who is familiar with normal and abnormal response during exercises and is able to prevent adverse events. All personnel are trained to perform cardiopulmonary resuscitation (CPR). A defibrillator is available. According to the survey of Myers et al. (2000), the risks and ratio of serious events is very low in subjects with a risk of coronary artery disease during exercise testing, 1.2/10.000. Their conclusion was that exercise testing is a very safe diagnostic tool for this population.

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

Inclusion criteria:
* Lower limb amputation, more proximal than the foot
* Subjects are at the beginning of their rehabilitation program
* The amputees follow an outpatient rehabilitation program.
* Subjects are 18 years old or older
* Subjects signed the participation agreement form.

Exclusion criteria

The subjects will be excluded from this study if there is evidence or serious suspicion of coronary disease, stress or test related pain in the chest, untreated symptomatic arrhythmia*s (ventricular tachycardia or any rhythm significantly compromising cardiac function), acute pulmonary embolus, bilateral lower limb amputations or upper limb amputation, mental impairment leading to inability to cooperate or inability to obtain consent.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	10
Type:	Anticipated

Ethics review

Approved WMO

Date:	24-08-2011
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL36816.042.11