A randomized controlled trial on the effectiveness of a cardiovascular aerobic exercise program in recent lower limb amputees on physical fitness, physical activity and mobility

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In this randomized controlled trial we study whether physical fitness, physical activity and mobility improve more in recent lower limb amputees that receive an aerobic exercise program of 12 weeks next to the regular rehabilitation program compared...

Ethical review	Approved WMO
Status	Will not start
Health condition type	Bone and joint therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON46567

Source
ToetsingOnline

Brief title
AMPFIT

Condition

- Bone and joint therapeutic procedures

Synonym
lower limb amputation

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: exercise, lower limb amputation, physical fitness

Outcome measures

Primary outcome

Physical Fitness

At T0 and T1 physical fitness will be assessed by a maximal exercise test with expiratory gas analysis. VO2 max will be determined on a Cruiser ergometer (Enraf-Nonius, Delft, the Netherlands, 2011), which is a combined arm leg ergometer. The participant sits on a comfortable seat (low seat height) and places the foot of the unaffected limb against a non-moving, adjustable footrest in front. The stump of the amputated limb is placed on a special support connected to the seat. When a patient with an amputation uses the Cruiser ergometer without wearing a prosthesis, the residual limb can be positioned securely on another support especially made for patients with an amputation. The footrest is used to push the sliding seat backwards and the patient can move the seat forwards again by pulling the two-lever arm. In this cyclic process, the sound leg, trunk, and arms are used to provide power output into the ergometer, and thus the patient exercises (an)aerobically. The ergometer is set to operate at a constant power between 35 and 60 rpm. Subjects are instructed to maintain 50 rpm. The accuracy of the Cruiser ergometer is ± 10% for power output and ± 2 rpm for speed. Gas exchange is measured using a

breath-by-breath gas analysis system. At start of the test, expiratory gas analysis is performed in subjects at rest during three minutes. An educated ergometry laboratory technician performs the test under supervision of a physician. Safety will be monitored by means of a 12-lead electrocardiogram (ECG) and standard cuff blood pressure measurements before and after the exercise test. The exercise test starts with a workload of 10 Watt and the load will be increased every minute by 5, 10 or 15 Watt depending on the subject*s fitness.

Reasons for ending the test are severe fatigue, dyspnoea or not being able to maintain a cycling rate of 50 rpm on the Cruiser. For safety reasons the ergometry laboratory technician can discontinue the test in case of ECG abnormalities or other indications for cardiovascular problems. The cardiorespiratory variables for physical fitness (VO2 max, RCP, AT) are measured with Oxycon software.

Secondary outcome

Physical activity

Physical activity is measured by accelerometer and a questionnaire at T0, T1 and T2. Patients will be fitted with an accelerometer (Sensewear-BodyMedia, Pittsburgh Philadelphia USA). An accelerometer is a small lightweight physical activity monitor. The subjects will be instructed to wear the accelerometer for seven consecutive days. Accelerometry has been shown to be a reasonably valid method to objectively assess physical activity in adults. The accelerometer will be programmed to measure the time someone*s activity level is * 4 metabolic equivalents. The Metabolic Equivalent Task (MET) is a physiological

measure expressing the energy cost of physical activities. 1 MET is equal to the energy produced per unit surface area of an average person sealed at rest. In the Netherlands > 4 MET is considered as moderate-intensive exercise for adults.

The SQUASH (Short QUestionnaire to ASsess Health enhancing physical activity) is a commonly used instrument in the Netherlands to assess physical activity. It was developed by the Dutch National Institute of Public Health and the Environment (RIVM) to measure physical activity with respect to occupation, leisure time, household, transportation means and other daily activities. The SQUASH was designed to give an indication of the habitual activity level and was structured in such a way that it would be possible to assess compliance to physical activity guidelines. It has been shown to be valid in measuring physical activity among the Dutch population.

Mobility

At T0, T1 and T2 we use the Special Interest Group in Amputation Medicine (SIGAM) scale to measure mobility. This scale, proposed by the British Society of Rehabilitation Medicine, is a self-administered questionnaire comprising 21 closed questions (yes or no responses). It evaluates walking in terms of help from others, walking aids, walking distance and ability to walk on different surfaces and in different meteorological conditions. This questionnaire can be analysed simply by using a defined algorithm that provides perfect reproducibility of analysis. This questionnaire also shows good validity as

compared with the Timed Walking Test and the Rivermead Mobility Index and good sensitivity to change. Therefore, the scale seems appropriate to obtain an objective clinical description of functional mobility in patients with lower-limb amputation. We use the Dutch version (SIGAM-WAP).

Study description

Background summary

Lower limb amputees experience a decline in physical fitness due to limited physical activity prior to and after the amputation, cardiovascular disease, sedentary behavior and smoking habits. Studies demonstrated that cardiorespiratory fitness in amputees was clearly lower than in able-bodied individuals. This causes problems in walking with a prosthesis because energy expenditure in walking with a prosthesis is much higher than in walking with two sound legs. To walk with a prosthesis at a functional level of activity, it is very important that the amputee is able to meet the high energy expenditure demands. Ascending levels of amputation appear to be associated with increased energy expenditure in walking.

The burden on the cardiorespiratory system of amputees is considerably high, especially in patients with an amputation due to vascular disease. If it is possible to improve the physical fitness of the amputee, a reduction of the burden on the cardiorespiratory system of the amputee can be expected. Therefore, improvement of physical fitness seems to be an important factor related to functional outcome of the amputee.

There is strong evidence that aerobic exercise training can result in improvement in cardiorespiratory fitness and in functional gains. The American College of Sports Medicine (ACSM) guidelines for persons with chronic diseases and disabilities, including people with a lower limb amputation recommend that achieving an aerobic training effect requires exercising of large muscle groups at a frequency of 3-5 times a week, for a duration of 20-60 minutes at an intensity of 40-70% heart rate reserve. To provoke an adaptation in cardiorespiratory fitness it is important to respect these guidelines and apply them in the rehabilitation program.

Aerobic exercise training may increase the functional walking ability of amputees. In regular rehabilitation programs physical fitness of amputees is trained in daily walking courses, sports and during fitness exercises. However, an individually tailored cardiovascular aerobic exercise program based on the

outcomes of a maximal exercise test is not daily practice.

Whether the current rehabilitation programs are strenuous enough for the patient to improve cardiorespiratory fitness is unclear. In a study involving patients after stroke, limb amputation and spinal cord in a clinical rehabilitation setting was found that these patients experience adequate cardiorespiratory strain to potentially induce an aerobic training effect. On the other hand, in a study on lower limb amputees was shown that a training program that only covers walking training with a prosthesis, did not improve maximal aerobic capacity to the level of able-bodied persons. After providing the lower limb amputees with a 12 week aerobic exercise training amputees the anaerobic threshold (AT) and maximum oxygen uptake (VO2max) increased significantly compared to their levels before the training, respectively 36.5 and 26.0%, and were similar to able-bodied subjects. However, in this research only young traumatic amputees were included which is not reflective for the general amputee population.

Study objective

In this randomized controlled trial we study whether physical fitness, physical activity and mobility improve more in recent lower limb amputees that receive an aerobic exercise program of 12 weeks next to the regular rehabilitation program compared to lower limb amputees that receive only the regular rehabilitation program. In this study we include lower limb amputees with different causes of amputation including cardiovascular patients. We hypothesize that a 12-week cardiovascular aerobic exercise program will lead to a clinical relevant and significant improvement of physical fitness. Due to better physical fitness patients will be able to increase their activity level and mobility.
Primary Objective:
To study the effect of an aerobic exercise program of 12 weeks in recent lower limb amputees on physical fitness.

Secondary Objective(s):
To study the effect of an aerobic exercise program of 12 weeks in recent lower limb amputees on physical activity and mobility.

Study design

The study is a randomized controlled study with two arms. Recent unilateral transtibial, knee exarticulation and transfemoral lower limb amputees referred for inpatient or outpatient rehabilitation in the UMCG Center for Rehabilitation will be asked to participate in the study. The participants will be randomized into the regular rehabilitation program group or the group that receives an additional cardiovascular aerobic exercise program of 12 weeks. Stratification will be done for cause of amputation (vascular versus other

cause for amputation), since we expect cardiovascular disease to have an important influence on the physical fitness. Follow-up measurements will be performed at 12 and 24 weeks after inclusion.

Intervention

In the intervention group an aerobic exercise program is added to the standard rehabilitation program. The aerobic exercise program consists of a supervised training of 12 weeks in the rehabilitation center. The intervention is fully tailored and based on the patient*s individual aerobic capacity. Before the exercise training, a symptom-limited maximal exercise test on the combined arm-leg ergometer, named Cruiser ergometer, will be performed to determine the respiratory capacity threshold (RCT). The intensity of aerobic training is prescribed on the basis of RCT. All patients start at 50% intensity according to the RCT and intensity increases over the ensuing weeks (week 1-4: 50%, week 5-6: 60%, week 7-10: 70% and week 11-12: 75%). When RCT is not reached the anaerobic threshold (AT) is used for prescription of training intensity with similar percentages.
Training sessions are performed three times per week for 30 minutes per session on the Cruiser ergometer and are supervised by experienced physiotherapists. The aerobic exercise training will include a warm-up before and a cool-down after the training. After 12 weeks the intervention is finish and patient who have not reached their rehabilitation goals will continue the regular rehabilitation program.

Study burden and risks

Subjects included in the intervention group perform aerobic training 3 x 30 minutes per week during 12 weeks . This training is planned during their regular rehabilitation program. No extra visits to the rehabilitation center are required. All subjects perform a maximum exercise test at the start and at 12 weeks after inclusion. This test provides important clinical data that form the foundation for an effective and safe exercise prescription. In case of abnormalities on the maximum exercise test subjects are referred to a cardiologist. Risk that a SAE will occur is not higher than in care as usual. Subjects in the intervention group can benefit from participating in the study when the aerobic exercise training results in better physical fitness. In addition, counselling on sports activities during and after finishing the rehabilitation program can support the subjects in maintaining a healthy and active life style. We perform the study in recent lower limb amputees since in this group we expect physical fitness to be reduced importantly due to immobility. The measurement at 24 weeks will be combined with a regular control to the rehabilitation center.

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

- unilateral transtibial, knee exarticulation or transfemoral amputation
- amputation was performed < 6 weeks before inclusion
- motivated for rehabilitation
- intent of functioning with a lower limb prosthesis
- cause of amputation: vascular, infection, trauma or cancer

Exclusion criteria

- serious wound healing problems of the stump that impede the regular rehabilitation program
- severe psychiatric illness

- not able to perform a maximal exercise test, according to ACSM guidelines (e.g. recent cardiovascular event, acute pulmonary embolism, blood pressure systolic > 200 mmHg / diastolic 120 mmHg (www.ACSM.org)

Study design

Design

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

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	44
Type:	Anticipated

Ethics review

Approved WMO

Date:	22-05-2018
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	NL65000.042.18