Preservation of functional capacity after prosthetic rehabilitation: an explorative cohort-study into the declination of functional outcome.

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON33705

Source
ToetsingOnline

Brief title
Preservation of functional capacity after prosthetic rehabilitation.

Condition

- Other condition

Synonym
amputation, removing (of body part)

Health condition

amputatie van de onderste extremiteit

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: amputation, declination, functional capacity, rehabilitation

Outcome measures

Primary outcome

Primary study parameter is the functional capacity of the patient, measured on activity and participation level. Tests to objectify this are the L-test, 2 MWT, movement registration, LCI-5 and the IPA.

Secondary outcome

Secundary study parameters are the experiences, expectations and needs of the patients relating to functioning at home. With help of a semi-structured interview with the study population, these factors will be identified.

Study description

Background summary

An important aim of prosthetic rehabilitation is functioning independently at home. During the rehabilitation period the treatment team tries to achieve this aim by training towards an optimal level of (physical) functioning. However, the professionals of the treatment team all share the same concern: the declination of functional outcome after discharge from the rehabilitation centre. This concern most of all focuses on the older amputees. The problem is that this concern has never been objectified.

Current scientific literature does not bring any clarification on this subject. Most of the articles on functional outcome of patients with a lower limb amputee concern the so-called cross-sectional design. In other words the

functional outcome has been measured at one specific time after the amputation and is not related to the level of functional outcome at discharge from the rehabilitation centre. The few follow-up studies that are conducted do show contradictory results: stabilisation of the functional level after two months versus declination of the functional outcome after six months. The differences in time of follow-up and the several different measurements that are used, can easily account for this diference.

This research project is designed to objectify the professionals concern and to identify the factors that may affect the preservation of functional capacity after prosthetic rehabilitation.

The results of this research project will be used to improve the existing treatment program. The factors that are of influence on functioning at home can be integrated in the treatment program. The assumption is that the amputees will be better prepared for functioning at home. Secondary, this project will enable the professionals with measurement tools to evaluate their treatment evidence based.

Study objective

The objective of this study is twofold:
1) To objectify if amputee patients show a decline in level of functional capacity after discharge from the rehabilitation centre.
2) To identify which factors according to the patients may effect the preservation of functional capacity after prosthetic rehabilitation.

Central questions of this research project are:
1) Does the functional capacity of patients with a lower limb amputation decline after discharge from the rehabilitation centre?
2) Which factors may effect the preservation of functional capacity after prosthetic rehabilitation?

Study design

The study design used is an explorative cohort study. Quantitative research methodology will be used to answer the first research question. Therefore the functional capacity will be measured by using two physical perfomance tests, movement registration and two questionnaires. The measurements will take place at discharge (T0) and three (T1) and six months (T2) after discharge.

Qualitative research methodology will be used to answer the second research question. By means of a semi-structured interview patients with a lower limb amputation will be asked which factors may affect their functioning at home.

Study burden and risks

The measurements used in this research project are especially developed for this diagnose group. On top of that they relate to the normal movement patterns of amputees (like walking or standing up from a chair). The patients are not at risk by participating in this research project.
Participation in this research project means that patients have to deal with an extra time-effort. By scheduling the measurements at the same time as the (control-) visits to the doctor, patients do not need to spend extra time on travelling.

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

- The patient has an unilateral amputation.
- The patient is older than 40 years.

- It is the expectation of the treatment team that the patient will be able to walk at home with a prosthesis.
- The patient has participated in a rehabilitation programme at the Center for Rehabilitation-UMCG.
- The patient understands and is able to speak the Dutch language.

Exclusion criteria

- The patient has a bilateral amputation.
- The patient has a prosthesis for cosmetic reason only.
- The patient is re-admitted at the rehabilitation centre for malfunctioning at home.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	02-06-2009
Enrollment:	25
Type:	Actual

Ethics review

Approved WMO

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	NL26238.042.09