

Effective care of lower limb prostheses

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Appropriate use and prescription of a lower limb prosthesis for people with leg amputation through or above the knee, can increase the efficiency of the integrated care around the leg prosthesis.

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON21556

Bron

NTR

Verkorte titel

TBA

Aandoening

limb amputation

Ondersteuning

Primaire sponsor: not applicable

Overige ondersteuning: ZonMW

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Prosthesis Evaluation Questionnaire, Utrechtse Schaal voor Evaluatie van Revalidatie-Participatie (USER-P), activity monitor

Toelichting onderzoek

Achtergrond van het onderzoek

A correct choice of the components of the prosthesis is of great importance for the best possible outcome of the rehabilitation process. An important innovation for patients with a lower limb amputation through or above the knee is the development of auto-adaptive knee units (AAKs). The total annual costs per user of a leg prosthesis have increased by 37% over the last 5 years: from € 3,110 in 2012 to € 4,260 in 2016. Whether this increase in costs is related to more frequent prescribing of (a more expensive) AAK, and whether this cost increase also leads to an increase in effectiveness, has not been investigated so far. In this study we compare the effectiveness and cost-effectiveness of an AAK with that of a conventional mechanical prosthetic knee (CMK). In addition, we determine the (cost)effectiveness of integrated care with regard to lower limb prostheses by examining the extent of appropriate use of the lower limb prosthesis in relation to the costs of integrated care. Appropriate use is the effective use of the most adequate lower limb prosthesis, tailored to the real needs of the user. To implement the knowledge in clinical practice, we develop an online decision aid for users of lower limb prostheses and a national database for caregivers in order to optimally meet the needs and possibilities of the user to match the characteristics of the prosthesis.

Doel van het onderzoek

Appropriate use and prescription of a lower limb prosthesis for people with leg amputation through or above the knee, can increase the efficiency of the integrated care around the leg prosthesis.

Onderzoeksopzet

Baseline, 3 AAK en 3 CMK measure points

Onderzoeksproduct en/of interventie

autoadaptive prosthetic knee

Contactpersonen

Publiek

University Medical Center Groningen
Aline Vrieling

0625649878

Wetenschappelijk

University Medical Center Groningen
Aline Vrieling

0625649878

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- age > 18 years
- unilateral transfemoral amputation or knee articulation > 1 year ago
- prosthetic device with CMK in a stable phase
- Medicare Functional Classification K level 2-4 (i.e. the participant is at least able to walk outside with or without walking aid over uneven ground and can climb stairs)
- sufficient understanding of the Dutch language to be able to follow instructions and to complete questionnaires
- one of the two indications for AAK as described in detail in the AAK addendum to the PPP protocol: 1. need for extra security and stability, 2. high dynamic use

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

not applicable

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Cross-over
Toewijzing:	N.v.t. / één studie arm
Blinding:	Enkelblind

Controle: Geneesmiddel

Deelname

Nederland

Status: Werving nog niet gestart

(Verwachte) startdatum: 01-12-2019

Aantal proefpersonen: 35

Type: Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Ja

Ethische beoordeling

Niet van toepassing

Soort: Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7887
Ander register	METC UMCG : in progress

Resultaten