De zorg rondom handprothesen kan doelmatiger

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON24200

Source
NTR

Brief title
TBA

Health condition

Upper limb defects, including both amputations and congenital deficits.

Sponsors and support

Primary sponsor: Not applicable
Source(s) of monetary or material Support: ZonMW

Intervention

Outcome measures

Primary outcome

Cost-effectiviness of hand prostheses based on the multi-attributable preference response (MAPR) score for hand prosthetics and costs.

With the obtained information an online choice aid for hand prostheses will be developed.

Secondary outcome

EQ-5D

Study description

Background summary

Value-based health care is becoming increasingly important in the current health care system. However, only little research has been done to the effectiveness of hand prostheses. The goal of this research was to determine the effectiveness and cost-effectiveness of different types of hand prostheses. The second goal was to develop a decision aid for hand prostheses. A mixed methods design was used, with both qualitative and quantative research methods. First, the multi-attributable preference response (MAPR) model was used to develop an application to measure the 'users value' of hand prostheses (also called the 'HealthSnapp'). The choice for the attributes in this model is based on a literature review, a focus group and a questionnaire study. Consequently, participants were asked in a second round of questionnaires to complete the 'HealthSnapp', the EQ-5D and a survey about all costs related to having a hand/arm prostheses. With this information the cost-effectiveness/utility from a societal perspective was determined. This information was used as input for a decision aid for hand prostheses. Furthermore, focus groups, surveys and input from a 'developmental team' were used to develop the decision aid for hand prostheses. The decision aid was pilot tested in clinical practice and afterwards last improvements were implemented.

Study objective

We hypothese that the health care for hand prosthesis users can be improved in terms of cost-effectiveness.

Study design

Group 1: Focusgroup in april 2019; one or more additional focus group for the development and evaluation of the online decision aid of hand prostheses.

Group 2: Focusgroup in april 2019; one or more additional focus group for the development and evaluation of the online decision aid of hand prostheses.

Group 3: Complete two rounds of questionnaires (both rounds: between september 2019 and januari 2021).

Contacts

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Eligibility criteria

Inclusion criteria

Group 1 (10-12 persons):
- Persons with upper limb defects who have been using a hand prosthesis for at least six months.

Group 2 (10-12 persons):
- Health care professionals (rehabilitation doctors, prosthetists and therapists) who have at least one year experience in working with hand prosthesis users.

Group 3 (=>200 persons):
- All persons with an upper limb defect at or proximal from the wrist in the Netherlands.

Developmental team decision aid hand prostheses:
- a software developer
- patients from target population decision aid
- health care professionals who are working with target population
- researchers from this project

Exclusion criteria

Group 1:
- Age < 18 years;
- Level of upper limb defect distal from the wrist

Group 2:
- < 1 year of experience in working with persons with an upper limb defect

Group 3:
- Age < 18 years;
- Level of upper limb defect distal from the wrist
- Additional exclusion criteria for second round of questionnaires: not using a hand/arm prosthesis.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Crossover
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-01-2019
Enrollment:	200
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Plan description
If possible and in compliance with privacy regulations, we will release fully anonymized/pseudominized data of this study (semi-)public. If needed, there will be requirements to get acces to the data. Importantly, only the data of participants who agreed on their informed consent with (semi-)public disclosure of the data will be released.

Ethics review

Positive opinion

Date:	18-04-2019
Application type:	First submission

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
NTR-new	NL7682
Other	Medical Ethics Review Board of the University Medical Center Groningen (UMCG) : METc2018/582

Study results