Personalized orthotic care to improve functioning in patients with neuromuscular disorders

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To assess the effectiveness and cost-effectiveness of personalized orthotic care to improve functioning in patients with NMD compared to standard orthotic care.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Neuromuscular disorders
Study type	Interventional

Summary

ID

NL-OMON55650

Source
ToetsingOnline

Brief title
'Personalized orthotic care in NMD patients'

Condition

- Neuromuscular disorders

Synonym
flaccid paresis, neuromuscular disorder

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: cost-effectiveness., muscle weakness, orthotic treatment, personalized care

Outcome measures

Primary outcome

The primary outcome measures to evaluate the clinical effectiveness are the change in walking effort (in J/kg/m) from baseline to 6 months post treatment, as measured by the 6-minute walk test, and achievement of personal treatment goals, measured with the goal attainment scale.

Secondary outcome

Secondary outcomes will be: walking speed (6-minute walk test); stability and pain during walking (11-point NRS); gait pattern (3D gait analysis); health-related quality of life (EQ-5D-5L); physical functioning (SF36-physical functioning subscale); perceived fatigue (FSS); fear of falling (FES-1), fall rate (questionnaire); and satisfaction (D-Quest and NRS).

Study description

Background summary

People with neuromuscular disorders (NMD) often experience mobility problems due to reduced leg muscle strength. Walking effort is usually increased and speed diminished with increased risk of falling. To reduce mobility problems, leg orthoses are provided. However, there is large variety in types of orthoses that are applied and they are often insufficiently matched to the complex health needs of NMD patients. Failure to achieve functional success obviously limits the cost-effectiveness of leg orthoses. Therefore, in 2012, a multidisciplinary guideline was developed to provide leg orthoses matched to the patients* individual health needs. Application of such personalized leg orthoses shows promising results with respect to improving functioning when compared to usual care. However, the effectiveness and the cost-effectiveness

of this personalized approach are unknown.

Study objective

To assess the effectiveness and cost-effectiveness of personalized orthotic care to improve functioning in patients with NMD compared to standard orthotic care.

Study design

A prospective randomized open label blinded end-point study with an economic evaluation and measurements at baseline (T1) and at 3 months (T2) and 6 months (T3) follow up.

Intervention

Participants will be randomized (ratio 1:1) to the intervention group, receiving personalized orthotic care delivered by 2 expert centres according to the guideline for leg orthoses of the Dutch Society of Rehabilitation Medicine, or the control group receiving standard orthotic care delivered at general rehabilitation centres and hospitals.

Study burden and risks

Patients are asked to visit the Academic Medical Center minimum 3 times over the study period of 10 months to participate in the study measurements and to fill out questionnaires. The duration of the measurements will be approximately 3.5 hours. Baseline as well as follow-up measurements are non-invasive. Practical relevance of the study is that this extensive evaluation of personalized orthotic care and implementation thereof in rehabilitation care in the Netherlands could result in health benefits for patients and long-term cost savings for society.

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

•minimum age of 18 years;
•weakness of the quadriceps (i.e. MRC score < 5) and/or calf muscles (i.e. MRC score < 5 or not being able to make a heel-rise on one leg > 3 times);
•experiencing walking problems such as increased walking effort, pain and/or instability during standing and/or walking;
•able to walk for 6 minutes at comfortable speed with or without assistive device;
•indicated for an orthosis based upon physical examination and gait analysis;
•motivated to use an orthosis

Exclusion criteria

•insufficient mastery of the Dutch language.

Study design

Design

Study type: Interventional

Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-05-2019
Enrollment:	70
Type:	Actual

Medical products/devices used

Generic name:	leg orthosis
Registration:	No

Ethics review

Approved WMO Date:	05-12-2018
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	05-08-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 26149
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL67268.018.18
Other	NL7511
OMON	NL-OMON26149