Personalized orthotic care to improve functioning in patients with neuromuscular diseases

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Personalized orthotic care is expected to be more effective and cost-effective compared to usual orthotic care.

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

Summary

ID

NL-OMON26149

Source
Nationaal Trial Register

Brief title
Personalized orthotic care

Condition

- Neuromuscular disorders

Health condition

Patients with neuromuscular disorders

Research involving
Human

Sponsors and support

Primary sponsor: Amsterdam UMC, location AMC
Source(s) of monetary or material Support: ZonMW

Intervention

- Medical device

Explanation

Outcome measures

Primary outcome

The primary outcome measures are change in walking effort (J/kg/m) assessed during a 6-minute walk test (6MWT) at comfortable speed and the achievement of personal treatment goals defined with the goal attainment scale (GAS) at 6 months follow up.

Secondary outcome

Secondary outcomes include comfortable speed (6MWT), gait biomechanics (3D gait analysis), stability (10-point NRS), physical functioning (SF36 physical functioning scale), falling (falls questionnaire), satisfaction (D-QUEST and self-designed questionnaire), quality of life (EQ-5D-5L) and costs (cost questionnaire).

Study description

Background summary

Rationale: Leg muscle strength is often impaired in people with neuromuscular disorders (NMD). This leads to mobility problems such as increased walking effort, diminished speed and increased risk of falling. Leg orthoses are commonly provided to improve mobility. A multidisciplinary guideline was developed to provide individually matched leg orthoses. Application of this personalized orthotic care approach shows preliminary effectiveness compared to usual orthotic care in persons with NMD. However, the cost-effectiveness remains to be investigated. Objective: To investigate the effectiveness and cost-effectiveness of personalized orthotic care provided in expert centers compared to usual orthotic care in persons with NMD. Study design: A prospective randomized open label blinded end-point study is performed Study population: 70 patients with NMD exhibiting calf muscle weakness and/or quadriceps weakness, who are indicated for a leg orthosis or high orthopedic shoes. Intervention: Participants are randomly assigned to receive personalized orthotic care provided by expert centers (intervention group) or usual orthotic care (control group). Measurements: Participants are assessed at baseline and at 3 and 6 months follow up. The primary endpoints are the change in walking effort (J/kg/m) and achievement of personal treatment goals. Secondary outcomes include walking speed, gait biomechanics, stability, physical functioning, falling and satisfaction. An economic evaluation will be conducted from a societal and healthcare perspective. Resource utilization and resource use will be based on the EQ-5D-5L and cost questionnaires respectively. Relevance: This study is the first to study

the cost-effectiveness of personalized orthotic care compared to usual care in persons with NMD. Personalized orthotic care is expected to improve mobility more compared to usual care, which could lead to long-term cost savings in health care.

Study objective

Personalized orthotic care is expected to be more effective and cost-effective compared to usual orthotic care.

Study design

Primary and secondary outcomes will be assessed at baseline (T1) and at 3 and 6 months after orthotic treatment (T2 and T3 respectively).

Intervention

Personalized orthotic care

Contacts

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Eligibility criteria

Age
Adults (18-64 years)
Adults (18-64 years)
Elderly (65 years and older)
Elderly (65 years and older)

Inclusion criteria

1. Minimum age of 18 years; 2. Weakness of the quadriceps (i.e. MRC < 5) and/or calf muscles (i.e. MRC < 5 or not being able to make a heel-rise on one leg > 3 times); 3. Experiencing walking problems such as increased effort, pain and/or instability during standing and/or walking; 4. Able to walk for 6 minutes at comfortable walking speed with or without assistive device; 5. Indicated for a leg orthosis or high orthopedic shoes (OS); 6. Motivated to use an orthosis/OS.

Exclusion criteria

1. Insufficient mastery of the Dutch language.

Study design

Design

Study phase:	N/A
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown
Primary purpose:	Supportive care

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-09-2019
Enrollment:	70
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Approved WMO Date:	05-12-2018
Application type:	First submission
Review commission:	MEC Academisch Medisch Centrum (Amsterdam)
	Kamer G4-214
	Postbus 22660
	1100 DD Amsterdam
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Study registrations

Followed up by the following (possibly more current) registration

ID: 55650
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL7511
CCMO	NL67268.018.18
OMON	NL-OMON55650

Study results