# Orthese doelmatigheidsstudie

Gepubliceerd: 07-02-2019 Laatst bijgewerkt: 15-05-2024

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

| | |
|---|---|
| **Ethische beoordeling** | Goedgekeurd WMO |
| **Status** | Werving gestopt |
| **Type aandoening** | Neuromusculaire aandoeningen |
| **Onderzoekstype** | Interventie onderzoek |

## Samenvatting

### ID

NL-OMON26149

**Bron**
Nationaal Trial Register

**Verkorte titel**
TBA

### Aandoening

- Neuromusculaire aandoeningen

**Aandoening**

Patients with neuromuscular disorders

**Betreft onderzoek met**
Mensen

### Ondersteuning

**Primaire sponsor:** Amsterdam UMC, location AMC
**Overige ondersteuning:** ZonMW

### Onderzoeksproduct en/of interventie

- Medische hulpmiddelen

**Toelichting**

## Uitkomstmaten

**Primaire uitkomstmaten**

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.

# Toelichting onderzoek

**Achtergrond van het onderzoek**

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.

**Doel van het onderzoek**

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

**Onderzoeksopzet**

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

**Onderzoeksproduct en/of interventie**

Personalized orthotic care

# Contactpersonen

## Publiek

Amsterdam UMC, location AMC
Elza van Duijnhoven

020-5666915

## Wetenschappelijk

Amsterdam UMC, location AMC
Elza van Duijnhoven

020-5666915

# Deelname eisen

**Leeftijd**
Volwassenen (18-64 jaar)
Volwassenen (18-64 jaar)
65 jaar en ouder
65 jaar en ouder

## Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

### Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Insufficient mastery of the Dutch language.

## Onderzoeksopzet

### Opzet

| | |
|---|---|
| Fase onderzoek: | N.V.T. |
| Type: | Interventie onderzoek |
| Onderzoeksmodel: | Parallel |
| Toewijzing: | Gerandomiseerd |
| Blindering: | Open / niet geblindeerd |
| Controle: | N.v.t. / onbekend |
| Doel: | Verzorging |

### Deelname

Nederland

| | |
|---|---|
| Status: | Werving gestopt |
| (Verwachte) startdatum: | 15-09-2019 |
| Aantal proefpersonen: | 70 |
| Type: | Werkelijke startdatum |

### Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

**Wordt de data na het onderzoek gedeeld:** Nog niet bepaald

## Ethische beoordeling

Goedgekeurd WMO

| | |
|---|---|
| Datum: | 05-12-2018 |
| Soort: | Eerste indiening |
| Toetsingscommissie: | MEC Academisch Medisch Centrum (Amsterdam)<br>Kamer G4-214 |

Postbus 22660

1100 DD Amsterdam

020 566 7389

mecamc@amsterdamumc.nl

# Registraties

## Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 55650
Bron: ToetsingOnline
Titel:

## Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

## In overige registers

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

# Resultaten