A lower-limb powered exoskeleton for stroke patients: a feasibility study

Gepubliceerd: 23-04-2021 Laatst bijgewerkt: 18-08-2022

It is expected that the ABLE-S exoskeleton can provide patient-specific assistance.

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

Samenvatting

ID

NL-OMON28821

Bron
NTR

Verkorte titel
ABLE-AS

Aandoening

Stroke

Ondersteuning

Primaire sponsor: Roessingh Research and Development
Overige ondersteuning: DIH-Hero

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The main outcome parameter is joint angle of the ankle and knee, derived from the position data in sagittal plane. In other words, the dorsiflexion and plantarflexion in the ankle and the extension and flexion in the knee.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: Stroke is one of the leading causes of disability of adults in the European Union. Around 80% of stroke survivors experience deficits in motor control, which results in gait and balance problems. The extent and amount of deficits differ per individual Frequently occurring motor impairments are spasticity of the plantar flexor muscles, muscle weakness of dorsiflexors and/or knee instability. An ankle foot orthoses (AFO) is frequently used to ensure stable and safe walking. However, a passive AFO does not support push-off, which is frequently injured in post-stroke patients. In the current study a powered lower extremity exoskeleton (ABLE-S) will be assessed. It should provide assistance during the push-off to increase forward propulsion and foot clearance and improve knee stability.
Objective: Determine if the ABLE-S exoskeleton can provide subject-specific assistance (in terms of type, level and timing of the assistance) to increase forward propulsion, foot clearance and/or knee stability, in hemiplegic stroke patients.
Study design: The current study is a cross-sectional observational study.
Study population: Five participants with unilateral hemiplegic chronic (> 6 months) stroke will be included in the current study. All participant should have a FAC ≥3 and an age above 18 years.
Main study parameters/endpoints: The main outcome parameters are joint angle of ankle and knee, to assess the ankle and knee movement. In other words, the dorsiflexion and plantarflexion of the ankle and the flexion and extension of the knee.
Nature and extent of the burden and risks associated with participation, benefit and group relatedness: The current study consists of two visits to the lab of Roessingh Research and Development. During these visits several tests will be performed with ABLE-S and Vicon markers. There is no direct advantage for the participants and there are no negative effects of the planned measurements because the study load is low and there is enough room for rest between the different trials. The ABLE-S exoskeleton is not CE-certified and the main risk is a fall risk, this will be handled carefully by close supervision and familiarization with ZeroG.

Doel van het onderzoek

It is expected that the ABLE-S exoskeleton can provide patient-specific assistance.

Onderzoeksopzet

There are two time points. During the first time point gait analysis without the exoskeleton is performed. At this first session, sEMG data, position data, IMU data and ground reaction force will be gatherd, withoud wearing the exoskeleton. Based on the data of this first session the type of assistance (knee, ankle or both) in the second measurement session will be determined. At the second visit, sEMG data, position data, IMU data and ground reaction force will be gatherd while wearing the exoskeleton powered and unpowered.

Onderzoeksproduct en/of interventie

N/A

Contactpersonen

Publiek

Roessingh Research and Development
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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

• Age above 18 years
• Willing to provide informed consent
• Left unilateral ischemic or haemorrhagic chronic (> 6 months) stroke
• Hemiparetic right leg
• Problems with stability in stance, insufficient push-off, problems with foot clearance during swing and/or problems with foot prepositioning in early stance. (Nikamp et al., 2018)
• Functional Ambulation Categories (FAC) score ≥ 3, participants are able to walk without manual assistance on a flat surface.
• Able to walk without walking aids (such as crutch, four-wheeled walker)
• Able to read and understand questionnaires and able to understand and execute commands, both in Dutch.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• High levels of spasticity of muscle tone (resistance to passive movement), as represented

by modified Ashworth scale scores of 3 or higher
• Premorbid disability of lower extremity
• Progressive neurological diseases like, dementia or Parkinson
• Skin lesions or severely impaired sensation at the hemiparetic leg
• Contraindication for mobilization, like lower limb fracture
• Pregnancy

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm

Controle: N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	16-05-2021
Aantal proefpersonen:	5
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Toelichting
N/A

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	NL9428
Ander register	CMO Arnhem Nijmegen issued it as n-WMO : 2021-7491

Resultaten

Samenvatting resultaten
N/A