Improving gait in hereditary spastic paraplegia: towards evidence-based and individually tailored rehabilitation

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

Summary

ID

NL-OMON48504

Source
ToetsingOnline

Brief title
MOVE-HSP

Condition

- Neuromuscular disorders

Synonym
Hereditary spastic paraplegia (HSP) and Strumpell disease

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: Jacques and Gloria Gossweiler Foundation

Intervention

Keyword: C-Mill training, Gait adaptability, Hereditary spastic paraplegia, Rehabilitation

Outcome measures

Primary outcome

Gait adaptability, as measured with the obstacle subtask of the Emory Functional Ambulation Profile (EFAP).

Secondary outcome

The secondary study parameters are the number of falls and the scores on the 10 meter walk test, 6min walk test and ladder gait test.

In addition we will investigate whether individual improvement in gait adaptability as measured with the Mini-BEST test is statistically related to individual balance capacity, more than to lower extremity muscle strength or muscle tone. Furthermore, we will measure physical activity in daily life by wearable sensors.

Study description

Background summary

Hereditary spastic paraplegia (HSP) is a relatively common, slowly progressive movement disorder that seriously impacts on gait capacity. Patients with HSP experience incremental muscle stiffness, muscle weakness and balance problems and, as a consequence, increasing difficulties to adjust their gait pattern to changing environmental demands, for instance when avoiding obstacles or negotiating steps. This is a major problem as such *gait adaptability* is critical for independent and safe mobility in daily life. Impaired gait adaptability will also result in falls and fall-related injuries and reduce quality of life. Therefore, there is an urgent need for evidence-based rehabilitation interventions to improve gait adaptability in patients with HSP. Currently, it is unknown whether task-specific training is effective to improve

gait adaptability in patients with HSP.

Study objective

We aim to establish an essential step towards evidence-based and individually tailored gait rehabilitation in patients with HSP using the following objectives:
1. This study aims to identify the effect of ten 1-hour sessions C-mill training on gait adaptability in patients with pure HSP.
2. This study aims to identify the key determinants of C-mill training efficacy in patients with pure HSP

Study design

A block-randomized intervention study.

Intervention

The intervention group will receive a 5-week C-mill, whereas the control group will first enter a 5-week waiting period of usual care, after which they receive the same 5-week C-mill training. Before and after the intervention, physical activity during daily life will be recorded by activity monitors. Both groups will be followed up for 15 weeks before and after the training has been completed.

Study burden and risks

The risk associated with participation will be negligible, according to the risk classification of the NFU. Burden associated with the measurements will be limited, as the number of measurements, three or four, will be relatively low. Since the participants will receive training on gait adaptability, participants may even benefit from the study. The C-Mill training is provided by a physiotherapist with C-Mill certification. This can be a physical therapist in the current environment of the participant.

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

- Diagnosis of pure HSP based on molecular diagnosis (e.g. SPG-4 mutations) or based on inheritance.
- Age between 18 and 70 years old.
- Being able to independently walk barefoot on a level ground for 50 meters without a walking aid (use of orthopaedic devices or made-to-measure footwear is allowed).

Exclusion criteria

-Other neurological or serious orthopaedic or psychiatric co-morbidity as well as previous surgical interventions of the lower extremities.

Study design

Design

Study type: Interventional

Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	02-12-2019
Enrollment:	36
Type:	Actual

Ethics review

Approved WMO Date:	31-10-2019
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	14-01-2020
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	18-02-2020
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	09-09-2020
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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
CCMO	NL70295.091.19