2D gait analysis for AFO tuning

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27280

Source
Nationaal Trial Register

Brief title
TBA

Health condition

People with a chronic neurological condition

Sponsors and support

Primary sponsor: Sint Maartenskliniek
Source(s) of monetary or material Support: OIM Orthopedie and PPP-allowance by Health~Holland, Top Sector Life Sciences & Health

Intervention

Outcome measures

Primary outcome

Sum score of the difference from normal knee angle at loading response((LR), midstance (MS) and terminal stance (TS) after tuning: Sum score = SD_LR^2 + 2*SD_MS^2 + SD_TS^2

Secondary outcome

- Shank-to-Vertical Angle (SVA) .

- Spatiotemporal parameters (e.g. walking speed, step length, step width)
- Goal Attainment Scale (GAS)
- D-Quest
- Number of tuning adjustments
- Number of return visits after 3 months
- AFO use after 3 months

Study description

Background summary

Rationale: Ankle-foot-orthoses (AFOs) are commonly prescribed to improve the walking ability of patients with neurological diseases. However, the AFO effectiveness depends on several factors, of which alignment of the AFO is highly important. Optimal alignment is achieved by making fine adjustments to the AFO footwear combination (AFO-FC), which is often referred to as tuning. In clinical practice, the tuning process is performed by observation of gait (observational gait analysis) and alignment is optimized by trial and error. However, observational gait analysis has shown to be ineffective and unreliable, and could therefore result in incorrect AFO alignment. Moreover, incorrect AFO alignment can result in a suboptimal walking pattern and the development of pressure sores, which negatively affects the patient's walking ability, satisfaction and treatment adherence. Furthermore, inadequate AFO tuning may influence the clinical process, as it could result in more tuning adjustments and more return visits before reaching optimal alignment. An alternative to observational gait analysis is 2D gait analysis using cameras and a force plate. The ground reaction force vector can be displayed in a video (force vector overlay), visualizing the GRF in relation to the joints. In this way, optimal AFO alignment can be achieved more objectively and efficiently.
Although 2D gait analysis is used to tune AFOs, it has never been compared to AFO tuning using observational gait analysis (standard orthotic care).
Objective: Investigate the added value of a 2D gait analysis for AFO tuning compared to conventional observational gait analysis.
Study design: Randomized controlled trial (RCT).
Study population: 36 patients (18-80 years old) who are provided with a custom-made AFO aiming to improve gait kinematics and kinetics.
Intervention (if applicable): The intervention group receives 2D gait analysis for AFO tuning followed by standard orthotic care, while the control group receives standard orthotic care including observational gait analysis for AFO tuning.
Main study parameters/endpoints: The primary outcome measure is the knee angle at loading response, midstance and terminal stance after tuning.

Study objective

Both 2D gait analysis and observational gait analysis will result in a normalization of the knee angle. However, the 2D gait analysis will results in more normalized knee angles, and also in increased patient satisfaction and less tuning adjustments and return visits.

Study design

Measurements will be performed before tuning (without AFO), after tuning (with AFO) and after 4 weeks follow-up (with AFO).

Intervention

2D gait analysis for AFO tuning following a standarized protocol.

Contacts

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Eligibility criteria

Inclusion criteria

- Between 18 and 80 years old
- Provided with a custom-made AFO
- AFO with minimal dorsal and plantar flexion
- One-sided AFO use
- At least 6 months post injury-onset to ensure a stable neurological condition
- Able to walk 10 meters without a walking aid

Exclusion criteria

- Abnormal knee extension and dorsal flexion movement
- Knee extensor weakness (MRC < 3)
- Surgery on the lower extremities less than a year ago
- Spasticity treatment during or less than 4 months prior to the study

- Neuropathic and/or orthopedic comorbidities influencing walking ability

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	20-10-2020
Enrollment:	36
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	20-10-2020
Application type:	First submission

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
NTR-new	NL8989
Other	METC Arnhem Nijmegen : 2020-6784

Study results