Optimizing orthotic management in children with cerebral palsy to improve mobility and participation

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Congenital and peripartum neurological conditions
Study type	Interventional

Summary

ID

NL-OMON37433

Source
ToetsingOnline

Brief title
AFO efficacy in Cerebral Palsy

Condition

- Congenital and peripartum neurological conditions

Synonym
brain damage, spasticity

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Johanna Kinderfonds en de Phelps stichting voor spasticity

Intervention

Keyword: Cerebral Palsy, Mobility, Orthotic devices, Treatment outcome

Outcome measures

Primary outcome

Primary study parameters of this study are:

- energy cost of walking (J/kg/m)

- the child*s daily activity (steps/day)

Secondary outcome

Secondary study parameters are:

- gait biomechanics

- diversity, intensity and enjoyment of participation

- walking speed (m/s)

Study description

Background summary

An ankle-foot orthosis (AFO) is a commonly prescribed rehabilitation intervention in children with Cerebral Palsy (CP). AFOs have the purpose to reduce gait deviations in order to enable or improve standing and walking, thereby enhancing the child*s mobility and participation. Although AFOs in children with CP are commonly prescribed, insight in underlying working mechanisms and a clear concept of AFO design in relation to prescription goals is largely lacking. At present, the decision-making process of AFO prescription seems to rely primarily on current best available evidence and expert*s experience and opinion, resulting in differences in AFO design. Literature shows that AFO use is not always effective in children with CP and can even have detrimental effects on the child*s functioning, e.g. by increasing energy cost of walking or reducing walking speed. This suggests that AFO prescription is inadequate in some patients, and underlines the importance and urgency of acquiring more knowledge about the working mechanisms of AFOs. This requires a extensive evaluation of AFO efficacy on a broad range of outcome measures, i.e. using outcome measures that are related to both components of the International

Classification of Functioning, Disability and Health (ICF); *body functions and structures* and *activities and participation*.

Study objective

The primary objective of this study is to evaluate AFO efficacy in children with spastic CP using outcome measures related to ICF the components of *body functions and structures* and *activities and participation*. The secondary aim is to identify prognostic factors for success of AFO treatment on outcome measures related to the ICF component *activities and participation* in children with spastic CP.

Study design

This is a pre-post experimental study. Baseline measurements (T0) will be done while subjects wear their shoes. Additional measurements (energy cost of walking and 3D gait analysis) will be performed with de subject's current (old) AFO (if applicable). Then, the intervention AFO will be prescribed, of which stiffness (K) will be varied (n=3, rigid, stiff and flexible). Sequence of AFO stiffness will be blockrandomized (3x2x1=6 blocks). Subjects will accommodate to each AFO stiffness for 4-8 weeks, after which AFO efficacy will be tested (T1K1, T1K2 and T1K3). Then, the subject's optimal AFO will be selected and subjects will wear this optimal AFO for 12-20 weeks. After this period, follow-up measurements (T2) will be done.

Intervention

Subjects will get an Floor Reaction Orthosis (FRO), composed out of pre-preg material (e.g. impregnated carbon fibres), which will be fabricated with integrated Neuro Swing® system ankle joint. This system has an adjustable spring force, alignment, and range of motion of the ankle joint. This study will investigate the effects of varying stiffness (spring force) of the AFO on gait to select the subject*s optimal AFO.
The shaft of the new FRO will hold a small notch in which the @monitor will be attached. Since the monitor will be merged within the shape of the FRO, it will not cause any side effects or burden to the patient.

Study burden and risks

It is expected that AFO treatment will improve walking ability of the patient. Furthermore, this extensive evaluation of AFO efficacy could contribute to improving orthotic management in CP in the (near) future. It is therefore assumed that relevance of the study is in balance with the burden for the subjects.

Patients will enrol the study at the moment they are indicated to get new AFOs.

Consequently, patients are not asked to participate in an additional therapy on top of their regular medical program. Participation in this study enables selection of the subject*s optimal AFO, implicating the possibility of a more beneficial AFO treatment compared to their usual care. Consequently, the subject might experience direct benefits of his or her new AFO. Since the intervention AFO will be custom made, it is assumed that the orthosis will not cause greater burden or more pain compared to a conventional AFO.

Measurements of the study are non-invasive. Markers, sensors and cables might somehow increase the burden during the measurements compared to normal walking and fatigue or pain might occur. However, the risk of pain will be minimal and subjects can quit the measurements if pain occurs. Subjects might get fatigued during some of the measurements (e.g. fitness tests). The researcher will therefore ensure that the subjects and parent(s) are completely informed before starting the measurements and subjects will get sufficient time to recover from all tests.

Considering the positive effects of optimizing AFOs as shown in preliminary research, it can be concluded that the benefits outweigh the burden and the minimal risk associated with this study.

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

- children diagnosed with spastic Cerebral Palsy
- children aged between 6 and 14 years
- a gait pattern that is characterized by excessive knee flexion
- Gross motor function classification score (GMFCS) I - III, provided that the patient is able perform a 3D-gait analysis without walking aids
- ability to walk independently for at least five minutes at a comfortable walking speed (CWS).

Exclusion criteria

- orthopaedic surgery or other surgical interventions that might influence mobility in the past 6 months
- Botulinum Toxin A injections in the past three months
- intrathecal Baclofen (ICB) therapy in the last six months or selective dorsal rhizotomy (SDR) in the past year
- impairments that contra indicate fitness tests
- severe joint contractures
- severe behavioural problems

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	05-06-2012
Enrollment:	32
Type:	Actual

Medical products/devices used

Generic name:	Ankle-Foot Orthosis
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	08-03-2012
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	23-01-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 27398
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL37940.029.11
OMON	NL-OMON27398