AFO efficacy in Cerebral Palsy.

No registrations found.

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

Summary

ID

NL-OMON27398

Source
Nationaal Trial Register

Brief title
EVO-CP

Health condition

Cerebral Palsy, Cerebrale Parese; children, kinderen; orthotic devices, orthesen; treatment outcome, behandeluitkomsten; mobility, mobiliteit

Sponsors and support

Primary sponsor: VU University Medical Center
Source(s) of monetary or material Support: Johanna Kinderfonds
Phelps Stichting voor spastici

Intervention

Outcome measures

Primary outcome

1. Energy cost of walking (assessed with the Energy Cost of Walking Test (ECWT));

2. The subject's daily activity (assessed with the StepWatch Activity Monitior).

Secondary outcome

1. Gait biomechanics (assessed with 3D- gait analysis);

2. Diversity, intensity and enjoyment of participation (assessed with CAPE);

3. Walking speed (assessed with ECWT).

Study description

Background summary

BACKGROUND:

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'.

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.

PARTICIPANTS:

Children with spastic CP will be recruited from Department of Rehabilitation of the VU University Medical Center, Amsterdam, the Netherlands. Subjects will be aged between 6 and

14 years old, walking with flexed knee pattern, and classified as I or II according to the Gross Motor Function Classification System (GMFCS).

DESIGN:

This is a pre-post experimental study. Baseline measurements (T0) will be done while subjects wear their current (old) AFO. 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.

OUTCOME MEASUREMENTS:

Primary study parameters of this study are:

1. Energy cost of walking (J/kg/m);

2. The child’s daily activity (steps/day).

Study objective

An Ankle-foot otthosis (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. 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. It is hypothesized that acquiring more knowledge about underlying working mechanisms by doing an extensive evaluation of AFO efficacy could improve orthotic management in children with CP.

Study design

1. Baseline (T0): Consists of three measurement moments with two weeks in between (respectively the moments of casting of the leg, fitting the new AFO and delivery of the new AFO;

2. T1K1, T1K2, T1K3: Evaluation measurements of each stiffness (K1,K2,K3) stiffness is worn for 4 weeks. At T1K3, the third stiffness will be evaluated and most optimal stiffness will be selected;

3. T2Kopt; follow-up measurements three months after selecting the optimal AFO.

Intervention

Children will be prescribed a Floor Reaction Orthosis (FRO) that is made out of pre-preg materials. This FRO will be fabricated with an integrated Neuro Swing system ankle joint. Thus to the system's adjustable spring force, alignment and range of motion of the ankle joint, AFO properties can be varied within the same orthosis. This study will investigate the effects of varying stiffness of an AFO in order to select the optimal AFO stiffness for each subject.

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Eligibility criteria

Inclusion criteria

Inclusion criteria for enrolling the study are:

1. Diagnosis of spastic CP;

2. A gait pattern that is characterized by excessive knee flexion;

3. Age range: 6-14 years;

4. Current AFO use > 1 year;

5. Gross motor function classification of I or II according to the Gross Motor Function Classification System (GMFCS);

6. Ability to walk independently for at least 5 minutes at a comfortable walking speed.

Exclusion criteria

1. Any orthopedic surgery or other surgical interventions that might influence mobility in the past six months;

2. Botulinum Toxin A injections in the past three months;

3. Intrathecal Baclofen therapy in the last six months or selective dorsal rhizotomy in the past year;

4. Impairments that could contra indicate fitness testing;

5. Plantarflexion contractures;

6. A knee flexion contracture >10 deg;

7. Hip endorotation <20 deg in midstance;

8. Other medical conditions influencing mobility;

9. Severe behavioural problems.

Study design

Design

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

Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-04-2012
Enrollment:	32
Type:	Anticipated

Ethics review

Positive opinion

Date:	03-05-2012
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 37433
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL3265
NTR-old	NTR3418
CCMO	NL37940.029.11
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON37433

Study results

Summary results
N/A