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The role of foot orthoses in children with developmental coordination disorder

Submission date	Recruitment status	[X] Prospectively registered
13/02/2008	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
04/03/2008	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
20/06/2016	Musculoskeletal Diseases	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
A pilot study to evaluate the benefit of foot orthoses prescribed in the rehabilitation of children with developmental coordination disorder

Study objectives
Developmental coordination disorder (DCD) is a defined as a "motor skill disorder characterised by a marked impairment in the development of motor coordination abilities" (American Psychiatric Association, 2004) and such a condition will affect the execution of everyday tasks. Characteristics of DCD noted within the literature include poor balance, delayed developmental characteristics and a "clumsy" and "awkward" gait (Polatajko and Cantin, 2006). DCD is reported to have an impact upon both fine and gross motor skills which results in limited participation in everyday activities of childhood (Polatajko and Cantin, 2006). Further impact of DCD has been reported as limited academic achievement, reduced participation in sport and implications for psycho-social development; particularly with regards to limited interaction with peers. (Polatajko and Cantin, 2006).

Hypotheses:
1. Do University of California Biomechanics Laboratory (UCBL) foot orthoses improve balance and reduce tripping in children with DCD?
2. Do UCBL foot orthoses normalise the spatial and temporal gait parameters in children with DCD?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Lewisham LREC, 11/06/2008, ref: 08/H0810/38

Study design
Randomised controlled trial. The children will be quasi-randomised into two groups.

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Developmental coordination disorder (DCD)

Interventions

UCBL foot orthoses are being used in the study. The effect of the foot orthoses in the management of DCD diagnosed children will be determined by comparing the two groups of children:
1. One group of children will be prescribed their orthoses at the start of the seven week rehabilitation programme
2. One group of children will be prescribed their orthoses at the end of the seven week programme

This will allow all children who would normally be prescribed orthoses to receive orthoses - no children will be prevented from receiving the treatment that they would normally have because they are participating in the study.

The intervention will be assessed over a period of seven weeks; once at the start of the seven week programme and once at the end. These foot orthoses currently form part of the multi-disciplinary management of children with DCD therefore, the duration will be as long as the subject requires them.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
The GAITRite Gold Footmat will be used in the study to identify spatio-temporal gait parameters. This is a walkway which is embedded with sensors. The GAITRite system can provide measurements of spatial parameters such as step length, stride length, base of gait, angle of progression; it can provide measurements of temporal parameters such as cadence, velocity, stance phase duration, swing phase duration. Previous studies have identified the following parameters as being changed in children with DCD:
1. Single support duration (decreased)
2. Swing phase (decreased)
3. Cadence (increased)
4. Stride length (decreased)

These parameters will be used as primary outcome measures and recorded pre- and post-provision of foot orthoses, assessed at the start and end of the seven week programme.

Secondary outcome measures
The Bruininks-Oseretsky test of motor proficiency (BOT) is a tool that measures improvement in function in children using an individually administered measure of gross and fine motor skills. The score consists of eight subtests which assess:
1. Fine motor precision: seven items (e.g., cutting out a circle, connecting dots)
2. Fine motor integration: eight items (e.g., copying a star, copying a square)
3. Manual dexterity: five items (e.g., transferring pennies, sorting cards, stringing blocks)
4. Bilateral coordination: seven items (e.g., tapping foot and finger, jumping jacks)
5. Balance: nine items (e.g., walking forward on a line, standing on one leg on a balance beam)
6. Running speed and agility: five items (e.g., shuttle run, one-legged side hop)
7. Upper-limb coordination: seven items (e.g., throwing a ball at a target, catching a tossed ball)
8. Strength: five items (e.g., standing long jump, sit-ups)

The data taken from BOT composite scores will be used in secondary analysis. This will include body coordination, strength and agility and total motor composite scores. Secondary outcome measures will be assessed at the start and end of the seven week programme.

Overall study start date
01/06/2008

Completion date
31/05/2010

Eligibility

Key inclusion criteria
The study population will be composed of children entering the multi-disciplinary therapy programme at the Sanderson Child Development Centre, Medway Maritime Hospital. Children entering this programme:
1. Have an established diagnosis of DCD
2. Will be aged 7 years and over

Participant type(s)
Patient

Age group
Child

Lower age limit
7 Years

Sex
Both

Target number of participants
30

Key exclusion criteria
1. Any relevant medical complications that are likely to prevent a change in gait parameters. This includes any condition affecting neuromuscular integrity and orthopaedic condition causing a gait disturbance.
2. Unwilling to wear footwear that is suitable to use with an orthoses (low heeled, fastening, supportive footwear)

Date of first enrolment
01/06/2008

Date of final enrolment
31/05/2010

Locations

Countries of recruitment

England

United Kingdom

Study participating centre
University of East London
London
United Kingdom
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Sponsor information

Organisation
Canonbury Products Ltd (UK)

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Sponsor type
Industry

Website
http://www.canonbury.com/epages/canonbury.storefront

Funder(s)

Funder type
Industry

Funder Name
Canonbury Products Ltd (UK) - supported with a £5000 research prize

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration