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A pilot study of an evaluation of a dynamic foot support for wheelchair users with extensor spasms

Submission date
25/04/2014

Recruitment status
No longer recruiting

Registration date
29/05/2014

Overall study status
Completed

Last Edited
06/12/2016

Condition category
Nervous System Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Dystonic cerebral palsy is a condition that can include powerful spasms that cause the whole body to extend and straighten out. The spasms are called 'extensor spasms'. These spasms can result in pain, discomfort and poor posture. Comfort and posture may be able to be improved if the person's seating moves with them during a spasm. It is thought that present dynamic foot supports do not allow sufficient movement, so a new support has been designed. The new support was simulated in use with an adult with extensor spasms by a team of engineers and therapists, just using their hands. The adult reported that his pain was significantly reduced, that he had better head and hand control, and that he could eat and drink more easily. This study will provide the new support to three adults and three children, and evaluate their experiences of using the device for 4 weeks. We will measure how well it works using questionnaires, interviews and some technology that measures the movements of the foot support. We will compare their experiences of sitting during extensor spasms with and without the new foot support.

Who can participate?
Children aged 5 or older affected by dystonic cerebral palsy can participate in the study.

What does the study involve?
The idea of the foot support is to help manage spasms which can be uncomfortable, painful and disrupt daily routines. The participant will be asked to try out the new foot support for 4 weeks and to help us find out how well it works. They will be asked some questions, we will take some measurements, and fit the foot support to the participants wheelchair. If it is satisfactory, we will ask them to use this footrest for 4 weeks. We ask the participant to review the foot support very quickly every day by answering three questions. It is also important they note down any comments or changes in their spasms. If at any time the foot support is uncomfortable or not working for the participant, it can be removed. We will meet up with the participant after 4 weeks to find out what they thought about the footrest, take some final measurements, and to collect any final comments on the foot support.

What are the possible benefits and risks of participating?
The participants therapist will select people who they think this new foot support might be beneficial to. It is intended to reduce discomfort and make it easier for people to join in with activities. However, it is not guaranteed that the foot support will help the participant. There is a risk that it could be slightly uncomfortable for a short while, whilst the participant is getting used to the new foot support.

Where is the study run from?
The study involves three visits to the participant at either their home or where they have therapy. We will agree convenient dates and times with the participant. The study is based in the childrens centre at the Royal United Hospital in Bath (UK) and with an Occupational Therapist who works across the whole country.

When is the study starting and how long is it expected to run for?
The study started in March 2014 and is expected to run until December 2017.

Who is funding the study?
Posture and Mobility Group (UK)

Who is the main contact?
Dr Tim Adlam
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
WBM470/01/v1

Study information

Scientific Title
Evaluation of a foot support for people with extensor spasms (v1)

Study objectives
This study is a pilot to evaluate the feasibility of a method for evaluating an anatomically hinged dynamic foot support that may increase comfort, and improve the ability of people using the support to carry out every-day activities like communicating, eating, playing and working.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee Yorkshire & The Humber - Leeds West, 19/02/2014, ref: 14/YH/0004

Study design
Feasibility/pilot study; multi-centered

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Quality of life

Participant information sheet
https://www.dropbox.com/sh/q5k7tp2v2lksayu/Uj6syMX0uH

Health condition(s) or problem(s) studied
Dystonic cerebral palsy

Interventions
All participants will receive a novel dynamic foot support which will be hinged at the knee and ankle allowing significant knee and foot movement, while maintaining alignment of the foot and providing some weight bearing support.

A dynamic foot support has a locking mechanism to replicate a static foot support to allow comparison in the measures taken before the evaluation period and after the evaluation period. Measures will be taken for both the anatomical dynamic foot support and the static foot support.

Intervention Type
Device

Primary outcome measure
CPCHILD questionnaire - an outcome measure used to measure the care givers' perspectives on the health status, comfort, well being, and ease of care giving of children with severe developmental disabilities, and a useful measure of health related quality of life of these children. Dr Unni Narayanan (CPCHILD author) said adults with severe disabilities issues are much the same, therefore this measure can be used with them as well. CP CHILD Questionnaire will be completed at the fitting appointment (visit 2: consent, baseline assessment and delivery) at the beginning and at the review appointment at the end of the study 5 weeks later (visit 3: Final Assessment). This standard questionnaire will take approximately 1 hour to complete at each of these visits.

Secondary outcome measures
Each of the following outcome measures will be carried out at the fitting appointment (visit 2) and at the review appointment 5 weeks later (visit 3).
1. Data logging (1 hour) - each foot support has a built in load cell which measures the force of the spasms and how often the spasms occur. It will send information to a data logger which will produce graphs. This will be measured with the foot support both in the locked static position and unlocked in the dynamic position for 30 minutes each.
2. Pressure mapping (20 minutes) - a pressure mat will be positioned on the participants seat cushion for 20 minutes. For 10 of these minutes the foot support will be locked and static, and for the other 10 minutes the foot support will be dynamic. The pressures will be continuously recorded on software which will identify peak and mean pressures in both these time periods.
3. Therapist interview (1 hour) - this interview consists of a number of qualitative questions which are open ended to allow the participant to express their experience and use of the foot support with some direction to allow comparison before and after the evaluation period.

Overall study start date
01/03/2014

Completion date
30/12/2017

Eligibility

Key inclusion criteria
1. Experiences whole body extensor spasms
2. Uses a wheelchair or other specialist seating
3. Is aged 5 years or older
4. Diagnosis of cerebral palsy

Participant type(s)
Patient

Age group
Adult

Sex

Both

Target number of participants
6

Key exclusion criteria
1. At risk of harm from the dynamic foot support, to be determined by the patient's own occupational or physiotherapist in consultation with the project team
2. Concurrent medical interventions likely to cause changes in the extensor spasms during the course of the study
3. Other medical conditions that may cause harm or distress to the participant as a result of using the foot support

(The reason for exclusion is so we do not contaminate our results or those of another study with another intervention)

Date of first enrolment
01/03/2014

Date of final enrolment
30/09/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Royal United Hospital
Bath
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BA1 3NG

Sponsor information

Organisation
Designability - Bath Institute of Medical Engineering (UK)

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Sponsor type
Hospital/treatment centre

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ROR
https://ror.org/01datx010

Funder(s)

Funder type
Charity

Funder Name
Posture and Mobility Group (UK) - Small Research Study Funding Scheme

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No