

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

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		<input type="checkbox"/> Protocol
<b>Registration date</b> 29/05/2014	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 06/12/2016	<b>Condition category</b> Nervous System Diseases	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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

timadlam@designability.org.uk

## Contact information

**Type(s)**

Scientific

**Contact name**

Dr Tim Adlam

**ORCID ID**

<http://orcid.org/0000-0001-7881-4942>

**Contact details**

Designability - BIME

Block D1 Wolfson Centre

Royal United Hospital

Bath

United Kingdom

BA1 3NG

+44 (0)1225 824 103

timadlam@designability.org.uk

## 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

United Kingdom

BA1 3NG

## **Sponsor information**

**Organisation**

Designability - Bath Institute of Medical Engineering (UK)

**Sponsor details**

c/o Nigel Harris

Wolfson Centre

Royal United Hospital

Bath

England  
United Kingdom  
BA1 3NG  
+44 (0)1225 824 103  
director@designability.org.uk

**Sponsor type**

Hospital/treatment centre

**Website**

<http://www.designability.org.uk/>

**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?
<a href="#">HRA research summary</a>			28/06/2023	No	No