ISRCTN11890421 https://doi.org/10.1186/ISRCTN11890421

3D-printed hand orthotics for the management of spasticity in cerebral palsy

Submission date
10/01/2018

Recruitment status
No longer recruiting

Registration date
02/02/2018

Overall study status
Completed

Last Edited
02/02/2018

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
Cerebral palsy is a highly debilitating disorder that results from brain damage during development or birth. It can cause motor and language disabilities. Spasticity is one common complication of cerebral palsy which makes movement of upper and lower limbs difficult and often causes joint deformities. To manage spasticity, less intrusive recommendations include the use of hand orthotics. However, in resource-constrained areas, orthotics are often unaffordable and poorly constructed. 3D-printed orthotics could provide an innovative solution, as they utilize high precision manufacturing with low-cost materials. The aim of this study is to determine whether 3D printed orthotics are as effective as conventional orthotics at preventing hand deformities in children with cerebral palsy.

Who can participate?
Children under 12 years old with cerebral palsy

What does the study involve?
Participants are randomly allocated to use either 3D-scanned-and-printed hand orthoses or conventional orthoses hand-made by an orthopedist. The total length of orthotics use is 4 months. Participants receive the orthotics and maintenance service free of cost. In case of side effects, such as the developments of blisters, all treatment costs are covered by the researchers. After 4 months, improvements in hand range of movement are compared between users of 3D-printed orthoses and conventional orthoses.

What are the possible benefits and risks of participating?
Immediate benefits include monitoring of hand function for participants and guaranteed replacement of the orthoses if they break. Also, if the orthoses prove to be equivalent and effective, participants are given access to them after the study. The main risks include the development of skin blisters that can be prevented with proper use of the orthoses. Participants are provided with instructions and are monitored for side effects.

Where is the study run from?
Hospital de Rehabilitacion del Callao (Peru)

When is the study starting and how long is it expected to run for?
May 2017 to February 2018

Who is funding the study?
National Council of Science and Technology of Peru (CONCYTEC)

Who is the main contact?
Miguel Moscoso-Porras
miguel.moscoso.p@upch.pe

Contact information

Type(s)
Scientific

Contact name
Mr Miguel Moscoso-Porras

ORCID ID
http://orcid.org/0000-0001-9518-4241

Contact details
Armendariz 497, Miraflores
Lima
Peru
Lima 18
+51 (0)991163962
miguel.moscoso.p@upch.pe

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
67122

Study information

Scientific Title
An equivalence trial comparing 3D-printed hand orthotics and conventional orthoses in maintaining the range of wrist extension and the management of spasticity among children with cerebral palsy

Study objectives
The results of wrist extension ranges in the group treated with 3D-printed hand orthotics are better than the ranges in the group treated with conventional orthoses.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Institutional Ethics Committee for Humans of Cayetano Heredia University, 04/04/2017, ref: 182-21-16

Study design
Single-blind two-group randomized equivalence trial

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 to request a patient information sheet

Health condition(s) or problem(s) studied
Children diagnosed with cerebral palsy

Interventions
One hundred children <12 years old diagnosed with cerebral palsy will be recruited from a local rehabilitation hospital over the course of 6 months and invited to participate in the study. The intervention consists of the use of hand orthoses, commonly known as splinting, for 4 months. The randomization process will be carried out through the online system www.randomization.com. The intervention group A will receive 3D-scanned-and-printed hand orthotics. The intervention group B will receive conventional orthoses hand-made by an orthopedist. In addition, both groups will receive reminder phone-calls of the proper use of the orthoses. Hand orthoses should be used permanently, even when sleeping, in one or both hands if necessary. Both groups will receive this information. The orthosis can only be removed during the activities of cleaning, dress and during the rehabilitation sessions. Participants will receive the orthotics and maintenance service free of cost. In case of adverse events, such as the developments of blisters, all treatment costs will be covered by the researchers. After 4 months, improvements in hand range of movement from baseline will be compared between users of 3D-printed orthoses and conventional orthoses.

Intervention Type
Device

Primary outcome measure

Wrist passive range of movement, measured in angles using a goniometer at baseline and after four months

Secondary outcome measures
1. Spasticity degree, measured using the Ashworth modified scale at baseline and after 4 months
2. Hand function, measured using the Manual Ability Classification System (MACS) in its Spanish version at baseline and after 4 months
3. Acceptability and usability of the 3D orthotics, assessed through interviews with parents after four months

Overall study start date
01/05/2017

Completion date
07/02/2018

Eligibility

Key inclusion criteria
This study will include children younger than 12 years with a diagnosis of spastic cerebral palsy who have a score of >1+ on the Ashworth scale. These criteria are applied because, at that age, children with cerebral palsy are at an age where there is a greater risk of suffering from deformities but also, they are preventable. Parents of children who meet the inclusion criteria should be able to understand the study objectives and not intend to move in the next 6 months. These criteria are applied as part of the information in the study will be obtained from the parents. If they are not able to understand the objectives of the study or plan to move, this will not allow adequate measurements or allow them to be attended in a timely manner in case of an emergency or adverse event.

Participant type(s)
Patient

Age group
Child

Upper age limit
12 Years

Sex
Both

Target number of participants
The total number of participants to recruit will be 130 participants in total

Key exclusion criteria
This study will not include children who have undergone surgical intervention for the treatment of spasticity or who have indication for surgery to correct hand deformities. Neither will children who are currently receiving botulinum toxin for the treatment of spasticity or any other treatment for spasticity, including prior use of orthoses. The presence of allergic reactions to

contact with orthotic material will also be considered as an exclusion criterion. These criteria are to be applied in order to ensure the orthoses effectiveness. If participants are already receiving some others treatments for spasticity, they will not require the use of orthoses. If during the study the participants require surgery or are prescribed the use of Botox, it will also be considered an exclusion criterion for the analysis of the study.

Date of first enrolment
01/08/2017

Date of final enrolment
01/09/2018

Locations

Countries of recruitment
Peru

Study participating centre
Hospital de Rehabilitacion del Callao
Vigil 591, Bellavista, Callao
Lima
Peru
07016

Sponsor information

Organisation
Consejo Nacional de Ciencia, Tecnologia e Innovacion Tecnologica - CONCYTEC

Sponsor details
Schell 459, Miraflores
Lima
Peru
Lima 18

Sponsor type
Government

Website
http://www.cienciactiva.gob.pe/

ROR
https://ror.org/05c7j7r25

Funder(s)

Funder type
Government

Funder Name
Consejo Nacional de Ciencia, Tecnología e Innovación Tecnológica - Perú

Results and Publications

Publication and dissemination plan
The Protocol and Results from this trial and other relevant results (interview extractions regarding usability) will be submitted to indexed peer-review journals. Locally, results from the trial will be disseminated to relatives and health personnel in the trial recruitment site only after its conclusion.

Intention to publish date
30/12/2018

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Miguel Moscoso-Porras (miguel.moscoso.p@upch.pe). Type of data: dataset in .dta format . Other results will be publicly available in a research article. When data will become available: 1 year after publication of results in a peer-reviewed journal. For how long: undefined. A de-identified dataset will be available permanently on figshare.com. Criteria for access: To obtain the dataset, researchers must state this data will only be used for academic purposes (research, verification of results, teaching statistics), and provide credit to the original research and its authors.

IPD sharing plan summary
Available on request