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How can Lycra® sleeves improve upper limb functioning in hemiplegic cerebral palsy?

Submission date
18/06/2019

Recruitment status
No longer recruiting

Registration date
25/06/2019

Overall study status
Completed

Last Edited
26/06/2019

Condition category
Nervous System Diseases

[X] 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 (CP) occurs as a result of damage to the developing brain and the symptoms in any individual is affected by the location, time and size of the brain damage. In this study, we will focus on children who have hemiplegia (i.e. brain damage affecting one side of the body) as a result of CP. Children with hemiplegia will have a combination of paralysis and spasticity (a condition where some muscle are overactive). In addition, sensations can also be affected (i.e. this either be increased or decreased) making them unable to feel things or tell what things are by using touch. Besides touch, their ability to describe the position of their body in space is also affected. As a result of these problems, the child will not be able to control body movement effectively and efficiently. Normal development can also be affected.
Children with CP receive different types of treatments (e.g. medical, surgical, rehabilitation, and orthotics) to help with improving motor control and improve their independence. One of the orthotics that are being used with children is pressure garments or Lycra® garments. However, there is little scientific understanding related to the true therapeutic effects of pressure garments because studies are limited in number and the quality of existing research is weak.
This research project aims to investigate the effect of using a pressure garment on upper limb sensation, the ability to move and factors that can interfere with functional movements.

Who can participate?
Participants with hemiplegic CP, between ages 5 and 16 years, who will normally require this treatment

What does the study involve?
Each participant is expected to wear a custom-made lycra sleeve for the duration of the study (approximately 4 months).
The study would involve 3 visits to meet the researcher throughout the study period.
Finally, each participant and/or guardians are expected to record daily wear time in a compliance diary.

What are the possible benefits and risks of participating?
There may be no real benefits directly to participants, but we hope that their participation will help us see if this sleeve really works, which might make it more commonly available to others

NHS service users. A custom-made Lycra sleeve will be given to your child at no cost.
Lycra sleeve is a type of compression garment. Pressure and resistance to normal movement are expected effects. However, treatment using Lycra sleeve may have some unwanted effects, that may be related to wearing the Lycra sleeve.

Where is the study run from?
Robert Jones and Agnes Hunt Orthopaedic Hospital, UK

When is the study starting and how long is it expected to run for?
August 2019 to March 2020

Who is funding the study?
Keele University, UK

Who is the main contact?
Prof. Anand Pandyan
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
246566

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 246566

Study information

Scientific Title
How can soft dynamic pressure orthoses (Lycra®) influence upper limb functioning in children with spastic hemiplegic cerebral palsy?

Study objectives
1. Do pressure garments for arms improve impairments of:
a. Motor control
i. Spasticity or Hyperactive muscle responses
ii. Ability to move elbow, forearm and wrist
b. Sensations
i. Touch
ii. Identify objects by only touch
iii. Match arm position in space
2. Do pressure garments for arms improve:
a. Child’s ability to use his affected arm in various activities
b. Child's participation in daily life

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 17/05/2019, West Midlands - Coventry & Warwickshire Research Ethics Committee (Nettle Hill Conference Centre; 0207 104 8056; NRESCommittee.WestMidlands-CoventryandWarwick@nhs.net), ref: 19/WM/0122, IRAS Reference Number: 246566

Study design
Cohort observational study with repeated-measure design

Primary study design
Observational

Secondary study design
Cohort study

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

Spastic hemiplegic cerebral palsy

Interventions
Treatment provided: Lycra made-to-measure sleeve
Sleeve Wear Protocol: The recommended wear protocol is 7 days/week for a maximum duration of 6 hours/day. This wear routine will be followed for 5 months by each participant (depending on manufacturing time & each participant's habituation period to the sleeve). However, we understand that not every participant will be able to comply with recommended protocol. Therefore, each participant will be issued a Compliance Diary to record their daily use.

Methodology:
-Study design is a cohort observational study design with repeated measures
-Each participant will have to undergo three visits, for a total duration of about 5 months:
-1st visit: to take baseline measurements of: (1) Participation & Quality of life, (2) Activity Capacity of affected limb, and (3) Measure the affect upper limb for Lycra to be manufactured
-2nd visit (2-4 weeks after 1st visit): to take baseline measurements for Impairments: (1) Motor and (2) sensory impairments. In addition, the Lycra Sleeve will be issued to participants, will be asked to start using it as instructed.
-3rd visit: re-measure (4 months after 2nd visit): re-measure all three domains: (1) Participation, (2) Activity level, and (3) impairments (Motor & Sensory).

Intervention Type
Other

Primary outcome measure
1. Shriner's Hospital Upper Extremity Evaluation (SHUEE) will measure changes in activity-related use of the affected arm at first and third visits
2. Cerebral Palsy Quality of Life Questionnaire (CPQOL) will measure the satisfaction level of a participant in utilising the affected arm in daily living activities at first and third visits
3. Active/Passive Range of movement (at elbow, forearm, and wrist) measured using biometric electrogoniometer at second and third visits
4. Spasticity electrophysiological measures (at elbow and wrist) measured using neurophysiological measures using biometrics wireless kit (goniometer, myometer & electromyography) at second and third visits
5. Stiffness measure (at elbow and wrist) measured using modified Ashworth scale at second and third visits
6. Tactile Threshold (monofilament test) measured using Semmen Weinstein monofilament (20-piece set) at second and third visits
7. Stereognosis test measured using 10-item kit at second and third visits
8. Proprioception test (at elbow and wrist) measured using biometric electrogoniometer at second and third visits

Secondary outcome measures
none

Overall study start date
24/10/2016

Completion date
14/08/2020

Eligibility

Key inclusion criteria
1. Diagnosis of Cerebral Palsy (Spastic Hemiplegic), as confirmed by a referring professional
2. Age between 5-18
3. Able to sit independently on a chair without armrests
4. Able to understand and follow instructions

Participant type(s)
Patient

Age group
Child

Lower age limit
5 Years

Upper age limit
18 Years

Sex
Both

Target number of participants
35

Key exclusion criteria
1. Botulinum Toxin Injection within the past six months
2. Previous orthopaedic surgery for upper limb
3. Use of Soft Dynamic Pressure Orthosis or similar compression garment treatment in the past two years
4. No significant decrease in PROM due to musculoskeletal contracture or deformities at the elbow and/or wrist.

Date of first enrolment
15/07/2019

Date of final enrolment
14/03/2020

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

Robert Jones and Agnes Hunt Orthopaedic Hospital
Oswestry
United Kingdom
SY10 7AG

Sponsor information

Organisation
Keele University Directorate of Research, Innovation and Engagement

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Sponsor type
University/education

Website
https://www.keele.ac.uk/research/raise/governanceintegrityandethics/researchintegrity

ROR
https://ror.org/00340yn33

Funder(s)

Funder type
University/education

Funder Name
Keele University

Alternative Name(s)
La Universidad de Keele

Funding Body Type
Private sector organisation

Funding Body Subtype

Universities (academic only)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
This project is part of my PhD at the School of Health & Rehabilitation, which means a PhD thesis will be developed out of this study. In addition, findings will be disseminated and reported as part of the body of evidence for uses of Lycra®.

Intention to publish date
14/08/2021

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a non-publically available repository.

Repository Name/Link
-All data generated by this study will be stored and safeguarded at RJAH hospital trust servers. As the study sponsor, Keele University is the owner of all the research data produced by this study and shares control over these data with RJAH. Members of staff from the sponsor and/or regulatory bodies may also require access to study participants' data in order to carry out audits. All these staff work to robust data security procedures.
Type of Data to be shared
-All study related data will be stored in hard copy form in an anonymised section of the Case Report Form. This data will also be stored in a secondary anonymised electronic form, on an NHS-secured laptop with two-factor authentication procedure. Paper-based forms will be kept and stored on-site throughout the study.
-Primary anonymised data could be accessed by research team/regulatory authorities for the purpose of auditing and checking the integrity of data.
When data will be available? for how long?
-both paper-based/electronic Data will be available at RJAH location/servers. However, secondary anonymised data will be reported in the following repositories:
-Keele University (http://eprints.keele.ac.uk/)
-RJAH (https://www.rjah.nhs.uk/Our-Services/For-health-professionals/Health-Library-(Francis-Costello-Library)/Using-the-Library/Staff-publications.aspx)
-Data will be kept for 10 years then will be destroyed by the Data Custodian on-site (ORLAU manager - Dr. Caroline Stewart).
Access criteria/by whom
-Data access will only be granted for one of two purposes: either to re-check the secondary anonymised data integrity, and/or to audit the study by regulatory bodies/research team.
For what type of analysis? by what mechanism
-Analysis will only be carried-out for secondary anonymised data.
-Each outcome measure will be analysed differently, and it is discussed in the Data Analysis section (2.9) in the methodology/protocol of this study. In short, a mixture of parametric/non-parametric statistical tests will be performed.

IPD sharing plan summary

Stored in repository

Study outputs

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