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Investigating the use of taping for children with cerebral palsy

Submission date	Recruitment status	[ ] Prospectively registered
12/11/2018	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
18/02/2020	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
20/09/2023	Nervous System Diseases	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Elastic therapeutic taping (the most recognised brand name is Kinesio taping) has become increasingly popular within the world of athletics as well as with treatment of conditions such as Cerebral Palsy. Yet there is limited research to support the use of taping. Researchers are carrying out research into the immediate impact of applying elastic therapeutic taping to the thigh in children with Cerebral Palsy, spastic hemiplegia or diplegia. The study consists of two phases and children can take part in phase 1, phase 2 or both phases. Phase 1 will assess how tape changes the response to stretching the hamstring muscles (the muscle at the back of the thigh). Phase 2 will assess how tape changes the length of the hamstrings, stiffness in the muscle and walking and standing pattern and ability.

Who can participate?
Patients aged 6 to 16 years old with cerebral palsy

What does the study involve?
In Phase 1 the hamstring muscle of the most affected or dominant leg will be stretched at different speeds using a motor. The stretch will be in the child's current range of movement and there are motor safety features to prevent over-stretching the muscle. Muscle activity will be measured via using pads attached to the muscles. This will assess whether the stretch gives rise to a contraction of the muscle and how this is affected by tape applied to the back or front of the thigh. The order of these tests will vary and there will be a 5-minute rest between each taping application. It will take about 60 minutes to the complete the whole process.

In Phase 2 measures will be taken before or after tape is applied to the back of the leg or in two "control" conditions when no tape is applied to the leg. The researchers will cover the thigh in an elasticated stocking so the person taking the measures does not know whether tape has been applied or not. The researchers will take the following measures:
1. Myotonometer. The device applies a small tap to the back of the leg three times and measures how much the muscle moves (this looks at muscle stiffness)
2. Clinical measure muscle stiffness - with the child lying on their front the shin will be raised and allowed to drop with gravity three times; sensors attached to the leg will record how quickly the leg drops

3. Muscle length will be assessed using sensors attached to the legs after stretching the leg slowly
4. Time stand up and down from sitting five times
5. Speed, quality and movement of the knee while walking over 5 meters, this will be recorded on video

What are the possible benefits and risks of participating?
There are no direct benefits or risks of taking part in this study, but it is hoped that the study will inform researchers whether taping can affect muscle tone and function and help them to understand how this may occur. The results will help inform a larger clinical trial into the effects of taping in children with cerebral palsy.

Where is the study run from?
Plymouth University (UK)

When is the study starting and how long is it expected to run for?
June 2018 to August 2022

Who is funding the study?
Chartered Society of Physiotherapy Charitable Trust (UK)

Who is the main contact?
Samantha Jane Payne
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Study website
https://www.plymouth.ac.uk/schools/school-of-health-professions/ett4cp

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 39161

Study information

Scientific Title
Elastic therapeutic taping (ETT) of the thigh in children with Cerebral Palsy and spastic hemiplegia or diplegia: a phase 1 trial investigating mechanisms of action and a phase 2 proof of concept cross over trial investigating the effects of ETT on neuromuscular impairment and walking

Acronym
ETT4CP

Study objectives
Approximately 67% of children with Cerebral Palsy (CP) are able to walk with 70% having a presentation characterised by excessive stretch reflex activation (spasticity) and weakness. This increases energy expenditure and reduces participation in activities. Elastic therapeutic taping (ETT) is a potential adjunct to physiotherapy management that may reduce spasticity and improve muscle extensibility (length) in keeping with work in healthy adults. However, research investigating its effectiveness in CP is limited and lacks a theoretical basis. It is hypothesised that ETT alters somatosensory inputs which reduces stretch reflex size and thus the resistance to movements.

Following MRC guidelines for developing and evaluating complex interventions, the researchers will investigate firstly the theoretical underpinnings of ETT and then investigate the immediate effects of ETT on impairment and function. In children with CP (n=15), the effects of 3 conditions (ventral thigh ETT; dorsal thigh ETT; no taping) on hamstring stretch reflex amplitude and latency elicited by stereotyped motor-driven stretches will be investigated. Secondly, the researchers will undertake a proof of concept trial with 20 children with CP. ETT will be compared to no-taping. The immediate effects of ETT on hamstring extensibility, limb stiffness, the speed of knee bending and straightening while walking and ability to stand up from sitting will be assessed. This project will provide a theoretical basis for ETT and inform future clinical trials aimed at assessing the long term impact of ETT on ability and participation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 11/09/2018, South West - Cornwall & Plymouth Research Ethics Committee (Level 3, Block B, Whitefriars, Lewins Mead, Bristol, BS1 2NT, UK; Tel: +44 (0)207 104 8017; Email: nrescommittee.southwest-cornwall-plymouth@nhs.net), REC ref: 18/SW/0180EC

Study design
Randomised; Both; Design type: Treatment, Device, Physical, Rehabilitation, Cross-sectional

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Cerebral palsy

Interventions
Target Population: Ambulant children with spastic hemiplegic or diplegic cerebral palsy (Gross Motor Classification I-III) will be recruited through two routes:
1. Participants will be recruited via child development centres within South Devon and Somerset (n=4) and gait lab clinics based at the University of the West of England and Plymouth University. Children and families who fulfil the inclusion criteria will be approached by their treating therapist to explain the study and provide an information sheet. People who are interested in being contacted will fill out their preferred contact details on a contact form which will be sent to the PI.
2. Children will be recruited via CP Sport. Children and families will be contacted via a named gatekeeper at CP Sport. They will send out information sheets and contact forms. In addition, we will arrange a short presentation and put up posters about the study at CP Sport activity days. Families who are interested in the study will contact the research team. In both cases, once contact has been made with the research team, the PI will then contact the family to discuss the study further. If people are willing, an appointment will be made and informed consent and assent obtained.

Phase 1:

Study Site: This study takes place at the Peninsula Allied Health Centre in Plymouth.

Study Design: It is a cross-sectional design where the child attends on one occasion and their response to taping or not taping the thigh on stretch reflex activation is assessed.
Participant characteristics:

The following data would be gathered:
(a) Demographics
(b) Gross motor function classification scale and classification of CP (diplegia vs hemiplegia)
(c) Tardieu test for the hamstrings which is reliable following training. This is a clinical test of muscle tone that involves rating the resistance to movement when the leg is moved at fast and

slow speeds
(d) Hamstring extensibility using a goniometer whose reliability has been assessed previous (IntraClassCorrelation coefficient=0.71)
(e) Usual falls rate per week (to allow monitoring of potential adverse events)

Method of measuring stretch reflexes in the hamstrings:
The participant will lay on their back with a small block under the bottom and a strap across their pelvis to stabilise them. The test leg will rest on a padded part of a machine which will be moved by a customised motor to stretch the hamstring muscles through a comfortable range. Initially, this range will be 105° to 90° and then through a range specific to the participant, and nearer the end of their range. Although no part of the assessment should cause pain, participants are supplied with a safety cut off switch and there are mechanical stops and software-induced breaks to prevent overstretching. Pads to measure muscle activity will be placed on the Hamstring and Quadriceps muscles (front and back of thigh). We will test the response of the muscles to stretching (with slow and fast movements) when there is no tape applied over the muscles, when there is tape applied to the quadriceps muscle at the front of the thigh and when there is tape applied to the hamstring muscle at the back of the thigh. The order of these tests will vary and there will be a 5-minute rest between each taping application. It will take approximately 60 minutes to complete the whole process. At the end of the study, we will remove any tape that has been applied.

Phase 2:

Study Site:
This phase can occur at a convenient location for the child and family. This can be the laboratory at the Peninsula Allied Health Centre, child development units (subject to available space) or the child's home.

Study Design:
A crossover design will be used. Children will be seen on one occasion and act as their own controls. They will be tested with tape on the hamstrings and no tape. There will be two "no tape" conditions (control/placebo) and the order of the conditions (tape, no tape 1 and no tape 2 or no tape 1, tape and no tape 2) will be randomised between participants.

Procedure:
There will be 5 measures for each condition. Between conditions there will be a rest period. The choice of leg will be that assessed as the tighter leg, if both legs have the same hamstring length the dominant leg (the leg the participant would choose to kick a ball with) will be the test leg.

Intervention:
The thigh of the test leg will be covered with a tubigrip bandage so the assessor does not know if tape is attached. The taping techniques will be a treatment application of 10x2.5cm of Kinesiotape and placed under 10% tension as per ETT training recommendations and the tape will be rubbed four times. The second condition is a control "placebo taping" where the tape is laid over the same area, but is not stuck on, the tape will be rubbed four times and then removed.
The set of tests will take 10 minutes to perform and they will be repeated 4 times with or without tape attached depending on which group the participant has been allocated to. The order of conditions will vary. Between conditions participants will have a minimum of a 5-minute rest, therefore it will take ~60 minutes for the whole process.

At the end of the study, any tape that has been applied will be removed and the participant and family are asked to complete a short questionnaire about their experience in the study. This can be completed while at the location or returned by post in the stamped envelope provided.

Intervention Type
Other

Primary outcome measure
Measures taken within 1 session, T=0 baseline, T1= post intervention:

Phase 1:
Stretch reflex size: surface electromyography will measure medial hamstrings and rectus femoris activity. Stretch reflex amplitude will be determined as the mean between the onset and offset of the muscle activation (defined as the point when the rectified EMG signal falls above/below a target indicated by the mean pre-stretch baseline period + 2 standard deviations for at least 10 ms)

Phase 2:
Hamstring extensibility, measured with a goniometer: the test leg will be moved to 90° hip flexion and then popliteal angle will be measured

Secondary outcome measures
Measures taken within 1 session, T=0 baseline, T1= post intervention:

Phase 1:
1. Stretch reflex latency, measured using the same EMG data as for the primary outcome, the analysis for the stretch reflex onset will be determined by the time the EMG rises above/below a level (baseline mean + 2 standard deviations) for at least 10 ms
2. Passive stiffness, measured using the data from the customised motor, this measures the torque (by an in series torque transducer) and motor position. Passive stiffness will be determined as the change in torque/change in position over a 300 ms window immediately before and after the stretch, so the change in resistance from before and during the passive movement will show the passive stiffness

Phase 2:
1. Clinical measure of stiffness (modified Wartenburg's test). The participant will be lying on their front with the lower leg over the edge of the bed. The leg will be raised and allowed to drop with gravity. The researchers will record how quickly the leg drops using sensors that are placed above and below the knee and attached using Velcro straps. They will record three drops and the test should take 3 minutes
2. Time to sit to stand: how quickly the child can stand up from sitting 5 times. The use of arms and any aids to help push up are allowed if needed. There will be a two-minute maximum time allowance.
3. Knee velocity while walking: the speed of knee movement as the child walks 5 m and the time they take to walk over the distance. The child should use any walking aids typically used.
4. Quality during walking, measured using the Quality FM during the 5-meter walkthrough video analysis

Overall study start date
01/06/2018

Completion date
31/08/2022

Eligibility

Key inclusion criteria
1. 6 to 16 years old
2. Diagnosis of cerebral palsy
3. Gross Motor Classification Scale (GMFCS I to III)
4. Able to stand up and walk without adult assistance
5. Increased muscle tone

Participant type(s)
Patient

Age group
Child

Lower age limit
6 Years

Upper age limit
16 Years

Sex
Both

Target number of participants
Planned Sample Size: 35; UK Sample Size: 35

Key exclusion criteria
1. Surgery or Botulinum Toxin Injections in the last 3 months
2. Medical advice to limit weight bearing or leg movement
3. Popliteal angle > 80o

Date of first enrolment
02/01/2019

Date of final enrolment
30/06/2022

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Plymouth University
School of Health Professions
Peninsula Allied Health Centre
Derriford Road
Faculty of Health and Human Sciences
Plymouth
United Kingdom
PL6 8BH

Sponsor information

Organisation
Plymouth University

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Sponsor type
University/education

Funder(s)

Funder type
Charity

Funder Name
Chartered Society of Physiotherapy Charitable Trust; Grant Codes: NP/17/01

Alternative Name(s)
CSP Charitable Trust, The Chartered Society of Physiotherapy Charitable Trust, The CSP Charitable Trust, Chartered Society of Physiotherapy, The Chartered Society of Physiotherapy, CSPCT

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
1. Study protocol will be available on the rehabilitation research group, Plymouth University website
2. Planned publication in peer-reviewed journal
3. Publication of summary of results on research rehabilitation group website

Intention to publish date
01/08/2023

Individual participant data (IPD) sharing plan
The datasets generated and analysed during the current study will be available upon request from J. Marsden (jonathan.marsden@plymouth.ac.uk). The computer-generated raw data information will be available from 02/01/2023 until 01/12/2024. Data which can be shared without risk of identifying the participant will be available.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version V2	06/07/2018	18/02/2020	No	Yes
Participant information sheet	version V6	26/04/2019	18/02/2020	No	Yes
HRA research summary			20/09/2023	No	No