

# Investigating the use of taping for children with cerebral palsy

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		<input type="checkbox"/> Protocol
<b>Registration date</b> 18/02/2020	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 20/09/2023	<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

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 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

samantha.payne@plymouth.ac.uk

## Contact information

### Type(s)

Scientific

### Contact name

Mrs Samantha Jane Payne

### ORCID ID

<https://orcid.org/0000-0002-7137-6748>

### Contact details

School of Health Professions

Faculty of Health and Human Sciences

Derriford Road

Plymouth

United Kingdom

PL6 8BH

+44 (0)1823 690470

samantha.payne@plymouth.ac.uk

## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

**ClinicalTrials.gov (NCT)**

Nil known

**Protocol serial number**

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

## **Study type(s)**

Treatment

## **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 previously (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(s)

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

#### Key secondary outcome(s)

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

#### 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

#### Healthy volunteers allowed

No

**Age group**

Child

**Lower age limit**

6 years

**Upper age limit**

16 years

**Sex**

All

**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**

United Kingdom

England

**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**

## 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

### 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?
<a href="#">HRA research summary</a>			20/09/2023	No	No
<a href="#">Participant information sheet</a>	version V2	06/07/2018	18/02/2020	No	Yes
<a href="#">Participant information sheet</a>	version V6	26/04/2019	18/02/2020	No	Yes
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes



