# Can taping improve hand posture and use in infants with brain lesions?

Submission date	Recruitment status  No longer recruiting	[X] Prospectively registered		
04/07/2012		☐ Protocol		
Registration date 16/08/2012	Overall study status Completed	Statistical analysis plan		
		[X] Results		
Last Edited	Condition category	Individual participant data		
28/01/2019	Nervous System Diseases			

#### Plain English summary of protocol

Background and study aims

Children who sustain damage to the developing brain often develop contractures (a permanent shortening of a muscle or joint) leading to thumb and wrist deformity. Early intervention with elastic taping prior to the development of contractures may help to improve thumb and wrist position, and hopefully have beneficial effects on function. However, this approach has not been well evaluated although it has begun to be used in clinical practice. The aim of this study is to determine the feasibility and acceptability of using elastic taping for this purpose in infants and young children, and to look for effects on hand and wrist posture and function.

#### Who can participate?

Infants and young children aged 6 months to 3 years who have difficulties with hand and wrist posture and use, worse on one side than the other, following an injury to the developing brain

#### What does the study involve?

Children are randomly allocated to one of two groups. One group receives routine care for 2 weeks then taping for 2 weeks. The other group receives taping for the 4-week period of the study. Videotaped assessments of hand and wrist posture and function are undertaken at baseline, 2 and 4 weeks with tape on and tape off. Families also complete a home diary and questionnaire to provide feedback regarding the experience.

What are the possible benefits and risks of participating?

Taping is noninvasive and safe. The trialists check for skin sensitivity to the tape. It is not known at this stage whether taping is beneficial. However, if taping is felt to help a participant, treatment is continued after the study within the clinical service.

Where is the study run from?

Child Development Centre, Newcastle upon Tyne NHS Hospitals Foundation Trust (UK)

When is the study starting and how long is it expected to run for? September 2012 to September 2014

Who is funding the study?
British Academy of Childhood Disability/Royal College of Paediatrics and Child Health (UK)

Who is the main contact?

- 1. Dr Anna Basu (anna.basu@ncl.ac.uk)
- 2. Dr Jill Kisler (jill.kisler@nuth.nhs.uk)

#### Contact information

#### Type(s)

Scientific

#### Contact name

Dr Jill Cadwgan

#### Contact details

Evelina London Children's Hospital St Thomas' Hospital Westminster Bridge Road London United Kingdom SE1 7EH

## Additional identifiers

**EudraCT/CTIS** number

**IRAS** number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

## Study information

#### Scientific Title

Can taping improve hand posture and use in infants with brain lesions? A feasibility study

#### **Study objectives**

The aim of this pilot study is to determine, in infants and young children with asymmetric brain injury affecting hand posture and function:

- 1. The feasibility and acceptability of using elastic tape applied to the thumb, wrist and arm
- 2. Whether the elastic tape has a beneficial effect on hand and wrist posture and function both immediately when applied and in the longer term.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Not provided at time of registration

#### Study design

Pilot randomised single-blinded (assessor) single-centre study. Based on a randomised crossover design except that in the second time interval both groups will receive the intervention.

#### Primary study design

Interventional

#### Secondary study design

Randomised cross over 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

Elastic tape as intervention for hand and wrist posture and function after early brain damage

#### **Interventions**

Application of elastic tape with intent to improve thumb and wrist posture and function.

Children are randomised to one of two groups, one receiving routine care for 2 weeks then taping for 2 weeks. The other group receive taping for the 4 week period of the study. Videotaped assessments of hand and wrist posture and function are undertaken at baseline, 2 and 4 weeks with tape on and tape off. Families also complete a home diary and questionnaire to provide feedback regarding the experience.

#### Intervention Type

Other

#### Phase

Not Applicable

#### Primary outcome measure

- 1. Feasibility and acceptability of the intervention
- 2. Change in score on Assisting Hand Assessment (AHA)

#### Secondary outcome measures

- 1. Thumb position, measured using the House Thumb classification
- 2. Hand and wrist position, measured using the Zancolli classification

## Overall study start date

03/09/2012

#### Completion date

03/09/2014

## **Eligibility**

#### Key inclusion criteria

- 1. Infants and young children age 6 months to 3 years
- 2. Asymmetric abnormalities of hand and wrist posture and function secondary to non-progressive brain lesions and including acquired brain injury

#### Participant type(s)

**Patient** 

#### Age group

Child

#### Lower age limit

6 Months

#### Upper age limit

3 Years

#### Sex

Both

## Target number of participants

20

#### Key exclusion criteria

- 1. Known allergy to tape adhesive
- 2. Known progressive or degenerative disorder
- 3. Already recruited to another trial
- 4. Other splinting already in use

#### Date of first enrolment

03/09/2012

#### Date of final enrolment

03/09/2014

## Locations

#### Countries of recruitment

England

**United Kingdom** 

#### Study participating centre

#### **Royal Victoria Infirmary**

Newcastle upon Tyne United Kingdom NE14LP

## Sponsor information

#### Organisation

Newcastle upon Tyne NHS Hospitals Foundation Trust (UK)

#### Sponsor details

Joint Research Office Leazes Wing Royal Victoria Infirmary Queen Victoria Road Newcastle upon Tyne England United Kingdom NE1 4LP

#### Sponsor type

Hospital/treatment centre

#### Website

http://www.newcastle-hospitals.org.uk/

#### **ROR**

https://ror.org/05p40t847

## Funder(s)

#### Funder type

Charity

#### **Funder Name**

British Academy of Childhood Disability (UK) - Paul Polani Research Fund

## **Results and Publications**

#### Publication and dissemination plan

The results were presented orally at the Annual Conference of the British Academy of Childhood Disability in March 2014. The results paper is in preparation with an aim to submit by March 2017.

## Intention to publish date 16/03/2017

## 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?
Results article	results	01/01/2020	28/01/2019	Yes	No