

# Dynamic stretching programme for children with cerebral palsy

<b>Submission date</b> 05/07/2023	<b>Recruitment status</b> Recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 01/08/2023	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 21/01/2026	<b>Condition category</b> Nervous System Diseases	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Cerebral palsy (CP) is caused when babies suffer brain injury from a lack of oxygen in the brain. Children with CP often develop stiff muscles. They often have difficulty walking and moving and that makes it difficult for them to join in many different activities. Exercises prescribed by Physiotherapists become a big part of their lives and aim to train their muscles, stop them from becoming stiff and help children participate in activities. Exercises to stretch tight muscles to maintain or improve movement are often used by physiotherapists in children with CP. However, there is wide variability in the stretching exercise programmes used. Therefore, professional groups have highlighted the need for evidence-based physiotherapy exercise programmes in children with CP. The aim of this study is to assess the effectiveness of a stretching programme compared to usual care in children with CP.

### Who can participate?

Children aged 4 to 11 years with spastic cerebral palsy

### What does the study involve?

Participants will be randomly allocated to either the intervention (exercise programme) group or the usual NHS physiotherapy group. The intervention arm will involve six sessions with the physiotherapist over 16 weeks. Children will receive an exercise programme, which includes specific dynamic muscle stretching exercises. The usual care group will receive the usual NHS physiotherapy treatment, involving one session to receive advice and guidance on their usual exercise and activity programme but does not include specific muscle dynamic stretches. Children or their parents/guardians in both groups will be required to fill out a questionnaire when entering the study and again at 6 and 12 months. Participants will also receive a clinical assessment upon entering the study and again at 6 months.

### What are the possible benefits and risks of participating?

As with any form of exercise, children may experience delayed muscle soreness on movement and/or mild altered walking (limping) for a few days after completing some of the exercises suggested by the physiotherapist. The benefit of participating is that the information from this study will be used to help treat other children with CP more effectively.

Where is the study run from?

The study will be centrally managed by the Surgical Intervention Trials Unit (SITU), in collaboration with the Oxford Clinical Trials Unit (OCTRU) (UK)

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

January 2023 to September 2026

Who is funding the study?

National Institute for Health and Care Research (NIHR), Health Technology Assessment (HTA) Programme (UK)

Who is the main contact?

1. Tim Theologis, tim.theologis@msd.ox.ac.uk
2. Debbie Jewell, debbie.jewell@ndorms.ox.ac.uk

## Contact information

### Type(s)

Scientific

### Contact name

Ms Debbie Jewell

### Contact details

Surgical Intervention Trials Unit  
The Botnar Research Centre  
Windmill Road  
Oxford  
United Kingdom  
OX3 7LD  
+44 (0)1865 613763  
debbie.jewell@ndorms.ox.ac.uk

### Type(s)

Principal investigator

### Contact name

Prof Tim Theologis

### ORCID ID

<https://orcid.org/0000-0002-4758-9081>

### Contact details

University of Oxford  
Botnar Institute for Musculoskeletal Sciences  
Windmill Road  
Oxford  
United Kingdom  
OX3 7LD  
+44 (0)7770901483  
tim.theologis@msd.ox.ac.uk

# Additional identifiers

## Clinical Trials Information System (CTIS)

Nil known

## Integrated Research Application System (IRAS)

326645

## ClinicalTrials.gov (NCT)

Nil known

## Protocol serial number

CPMS 57141, IRAS 326645

# Study information

## Scientific Title

Clinical effectiveness of a child-specific dynamic stretching programme, compared to usual care, for ambulant children with spastic cerebral palsy (SPELL trial): a parallel group randomised controlled trial

## Acronym

SPELL

## Study objectives

A child-specific dynamic stretching programme has superior clinical effectiveness compared to usual care for ambulant children with spastic cerebral palsy.

## Ethics approval required

Ethics approval required

## Ethics approval(s)

approved 11/07/2023, East of England - Essex Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)207 104 8106; essex.rec@hra.nhs.uk), ref: 23/EE/0153

## Study design

Randomized controlled trial

## Primary study design

Interventional

## Study type(s)

Treatment

## Health condition(s) or problem(s) studied

Cerebral palsy

## Interventions

SPELL is a randomised controlled trial with 1:1 allocation. Follow-up assessors will be blinded to the randomisation allocation.

Participants will be identified through the Cerebral Palsy Integrated Pathway (CPIP) Network and recruited from NHS Trusts, providing care for children and young people with CP, where they will be assessed for eligibility by the clinical team, both supported by the local PI and research team in case of uncertainty.

Children and their parent(s) will be approached as part of their annual community physiotherapy CPIP review or other routine CP clinical care attendance and/or will be sent letters with study information. They will have the opportunity at their appointment to ask any questions they have about the study.

Screening forms will be completed at each site. These will include demographic questions for eligible patients and detail any reasons given for exclusion and non-participation.

Participants will be asked to sign an assent form whilst the parent/carer will be asked to sign a consent form on behalf of their child.

Randomisation will take place once informed consent has been given, eligibility has been confirmed and baseline assessments have been made. During the baseline assessment participants, with the support of their parent/carer will be asked to complete a baseline assessment questionnaire, which will include baseline measurements for the primary and secondary outcomes.

Clinician-assessed outcomes (ie passive range of lower limb joint motion and motor function) at baseline will be recorded electronically by a physiotherapist at site and before learning the outcome of the randomisation. All data will be entered into the study database (REDCap).

Those randomly allocated to the dynamic stretching exercise programme will receive six physiotherapy sessions over 16 weeks and will be requested to complete follow-up questionnaires via a link in an email or by paper through the post at 6 and 12 months. Clinician-assessed outcomes will be assessed at a face-to-face clinic appointment at 6 months by a blinded physiotherapist/assistant practitioner who is blind to the treatment allocation and has not been involved in the delivery of the intervention or usual care.

Those randomly allocated to the usual NHS care will receive one session of usual care advice, with a physiotherapist/assistant practitioner. Participants allocated to this group will also be sent a link via email or a paper copy of the questionnaire to complete at 6 months and 12 months. They will also receive a blinded clinician assessment at the 6-month timepoint.

## **Intervention Type**

Behavioural

## **Primary outcome(s)**

Functional mobility measured using the patient/parent-reported Gait Outcomes Assessment List (GOAL) questionnaire at 6 months

## **Key secondary outcome(s)**

1. Passive joint range of motion measured using the CPIP protocol of lower limb joint range of motion at 6 months
2. Motor function measured using the Timed Up and Go (TUG) test at 6 months

3. Functional mobility measured using the patient/parent-reported Gait Outcomes Assessment List (GOAL) questionnaire at 12 months
4. Independence measured using GOAL subdomain A at 6 and 12 months
5. Balance measured using GOAL subdomains A, B, D at 6 and 12 months
6. Pain and discomfort measured using GOAL subdomain C at 6 and 12 months
7. Health-related quality of life measured using EQ-5D-Y at 6 and 12 months
8. Educational outcomes measured using educational attendance records (days) at 6 and 12 months
9. Patient/parent exercise adherence self-reported at 6 and 12 months
10. Additional physiotherapy treatment self-reported at 6 and 12 months

**Completion date**

01/09/2026

## Eligibility

**Key inclusion criteria**

1. Children 4-11 years (i.e. from their 4th birthday to the day before their 12th birthday)
2. Diagnosis of spastic CP (bilateral or unilateral) GMFCS levels I–III
3. Willing for their community physiotherapy service and GP to be informed of their participation in the trial

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Child

**Lower age limit**

4 years

**Upper age limit**

11 years

**Sex**

All

**Total final enrolment**

0

**Key exclusion criteria**

1. Patient has had orthopaedic surgery of the lower limbs or selective dorsal rhizotomy in the past 12 months or planned (i.e. date confirmed) in the next 6 months
2. Patient has had lower limb botulinum toxin injections or serial casting in the past 4 months or planned (i.e. date confirmed) in the next 6 months
3. Patient is regularly performing a structured dynamic exercise programme focused on dynamic stretching as part of their usual physiotherapy routine

4. Patient is unable to comply with the assessment procedures and exercise programme with or without support by their parent/guardian

**Date of first enrolment**

28/11/2023

**Date of final enrolment**

28/02/2026

## **Locations**

**Countries of recruitment**

United Kingdom

England

**Study participating centre**

**University Hospitals Dorset NHS Foundation Trust**

Management Offices

Poole Hospital

Longfleet Road

Poole

England

BH15 2JB

**Study participating centre**

**Derbyshire Healthcare NHS Foundation Trust**

Trust Headquarters

Kingsway Hospital

Kingsway

Derby

England

DE22 3LZ

**Study participating centre**

**Gloucestershire Health and Care NHS Foundation Trust**

Edward Jenner Court

1010 Pioneer Avenue

Gloucester Business Park

Gloucester

England

GL3 4AW

**Study participating centre**

**Alder Hey Children's NHS Foundation Trust**

Alder Hey Hospital  
Eaton Road  
West Derby  
Liverpool  
England  
L12 2AP

**Study participating centre**

**Solent NHS Trust**

Solent NHS Trust Headquarters  
Highpoint Venue  
Bursledon Road  
Southampton  
England  
SO19 8BR

**Study participating centre**

**Isle of Wight NHS - Hq**

St Mary's Hospital  
Parkhurst Road  
Newport  
England  
PO30 5TG

**Study participating centre**

**Barts Health NHS Trust**

The Royal London Hospital  
80 Newark Street  
London  
England  
E1 2ES

**Study participating centre**

**Coventry and Warwickshire Partnership NHS Trust**

Wayside House  
Wilsons Lane  
Coventry  
England  
CV6 6NY

**Study participating centre**  
**St George's University Hospitals NHS Foundation Trust**  
St George's Hospital  
Blackshaw Road  
Tooting  
London  
England  
SW17 0QT

**Study participating centre**  
**Leeds Community Healthcare NHS Trust**  
3 White Rose Office Park  
Millshaw Park Lane  
Leeds  
England  
LS11 0DL

**Study participating centre**  
**West Suffolk NHS Foundation Trust**  
West Suffolk Hospital  
Hardwick Lane  
Bury St. Edmunds  
England  
IP33 2QZ

**Study participating centre**  
**The Royal Wolverhampton NHS Trust**  
New Cross Hospital  
Wolverhampton Road  
Heath Town  
Wolverhampton  
England  
WV10 0QP

**Study participating centre**  
**Northern Care Alliance NHS Foundation Trust**  
Salford Royal  
Stott Lane  
Salford  
England  
M6 8HD



**Study participating centre**  
**Torbay and South Devon NHS Foundation Trust**  
Torbay Hospital  
Newton Road  
Torquay  
England  
TQ2 7AA

**Study participating centre**  
**Mid Cheshire Hospitals NHS Foundation Trust**  
Leighton Hospital  
Leighton  
Crewe  
England  
CW1 4QJ

**Study participating centre**  
**Bedfordshire Hospitals NHS Foundation Trust**  
Lewsey Road  
Luton  
England  
LU4 0DZ

**Study participating centre**  
**Betsi Cadwaladr University Health Board**  
Ysbyty Gwynedd, Bangor  
Gwynedd  
Wales  
LL57 2PW

**Study participating centre**  
**Hertfordshire Community NHS Trust**  
Unit 1a Howard Court  
14 Tewin Road  
Welwyn Garden City  
England  
AL7 1BW

**Study participating centre**

**Kingston and Richmond NHS Foundation Trust**  
Galsworthy Road  
Kingston upon Thames  
England  
KT2 7QB

**Study participating centre**  
**Leicestershire Partnership NHS Trust (university Hospitals)**  
George Hine House  
Gipsy Lane  
Humberstone  
Leicester  
England  
LE5 0TD

**Study participating centre**  
**Maidstone and Tunbridge Wells NHS Trust**  
The Maidstone Hospital  
Hermitage Lane  
Maidstone  
England  
ME16 9QQ

**Study participating centre**  
**North London NHS Foundation Trust**  
4th Floor, East Wing  
St. Pancras Hospital  
4 St. Pancras Way  
London  
England  
NW1 0PE

**Study participating centre**  
**Northampton General Hospital NHS Trust**  
Cliftonville  
Northampton  
England  
NN1 5BD

**Study participating centre**

**Oxford Health NHS Foundation Trust**

Littlemore Mental Health Centre  
Sandford Road  
Littlemore  
Oxford  
England  
OX4 4XN

**Study participating centre**

**Powys Teaching Local Health Board**

Bronllys Hospital  
Brecon  
Wales  
LD3 0LY

**Study participating centre**

**Robert Jones & Agnes Hunt Orthopaedic Hospital**

Gobowen  
Oswestry  
England  
SY10 7AG

**Study participating centre**

**Royal Free London NHS Foundation Trust**

Royal Free Hospital  
Pond Street  
London  
England  
NW3 2QG

**Study participating centre**

**Shropshire Community Health NHS Trust**

Mount Mckinley  
Anchorage Avenue  
Shrewsbury Business Park  
Shrewsbury  
England  
SY2 6FG

**Study participating centre**

**Whittington Health NHS Trust**  
The Whittington Hospital  
Magdala Avenue  
London  
England  
N19 5NF

## Sponsor information

### Organisation

University of Oxford

### ROR

<https://ror.org/052gg0110>

## Funder(s)

### Funder type

Government

### Funder Name

NIHR Evaluation, Trials and Studies Co-ordinating Centre (NETSCC); Grant Codes: NIHR135131

## Results and Publications

### Individual participant data (IPD) sharing plan

Upon completion of the trial, and with appropriate participant consent, anonymised research data will be shared with other organisations on request to the Chief Investigator Tim Theologis and in accordance with the data sharing policies of OCTRU, the Sponsor and funder. Requests for data (anonymised trial participant level data) will be provided at the end of the trial to external researchers who provide a methodologically sound proposal to the trial team (and who will be required to sign a data sharing access agreement with the Sponsor) and in accordance with the NIHR guidance. After the end of the trial an anonymised trial dataset will be created and stored, and may be shared with other researchers upon request. Participant consent for this is included in the informed consent form for the trial.

### IPD sharing plan summary

Available on request

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Participant information sheet</a>			10/12/2024	No	Yes

<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes
<a href="#">Protocol file</a>	version 1.0	06/06/2023	05/09/2023	No	No
<a href="#">Protocol file</a>	version 2.0	27/09/2023	10/12/2024	No	No
<a href="#">Protocol file</a>	version 3.0	07/02/2025	15/01/2026	No	No
<a href="#">Protocol file</a>	version 4.0	09/06/2025	15/01/2026	No	No
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes