ISRCTN15808719 https://doi.org/10.1186/ISRCTN15808719

Dynamic stretching programme for children with cerebral palsy

Submission date
05/07/2023

Recruitment status
Recruiting

Registration date
01/08/2023

Overall study status
Ongoing

Last Edited
07/03/2025

Condition category
Nervous System Diseases

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] 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. Megan Stone, megan.stone@ndorms.ox.ac.uk

Study website
https://spell-study.org/

Contact information

Type(s)
Scientific

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Type(s)
Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
326645

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)

Other

Study type(s)
Treatment

Participant information sheet
https://spell-info.digitrial.com/

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

Secondary outcome measures
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

Overall study start date
01/01/2023

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

Age group
Child

Lower age limit
4 Years

Upper age limit
11 Years

Sex
Both

Target number of participants
Planned Sample Size: 334; UK Sample Size: 334

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
England

United Kingdom

Study participating centre
University Hospitals Dorset NHS Foundation Trust
Management Offices
Poole Hospital
Longfleet Road
Poole
United Kingdom
BH15 2JB

Study participating centre
Derbyshire Healthcare NHS Foundation Trust
Trust Headquarters
Kingsway Hospital
Kingsway
Derby

United Kingdom
DE22 3LZ

Study participating centre
Gloucestershire Health and Care NHS Foundation Trust
Edward Jenner Court
1010 Pioneer Avenue
Gloucester Business Park
Gloucester
United Kingdom
GL3 4AW

Study participating centre
Alder Hey Children's NHS Foundation Trust
Alder Hey Hospital
Eaton Road
West Derby
Liverpool
United Kingdom
L12 2AP

Study participating centre
Solent NHS Trust
Solent NHS Trust Headquarters
Highpoint Venue
Bursledon Road
Southampton
United Kingdom
SO19 8BR

Study participating centre
Isle of Wight NHS - Hq
St Mary's Hospital
Parkhurst Road
Newport
United Kingdom
PO30 5TG

Study participating centre
Barts Health NHS Trust
The Royal London Hospital

80 Newark Street
London
United Kingdom
E1 2ES

Study participating centre
Coventry and Warwickshire Partnership NHS Trust
Wayside House
Wilsons Lane
Coventry
United Kingdom
CV6 6NY

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

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

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

Study participating centre
The Royal Wolverhampton NHS Trust
New Cross Hospital

Wolverhampton Road
Heath Town
Wolverhampton
United Kingdom
WV10 0QP

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

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

Study participating centre
Mid Cheshire Hospitals NHS Foundation Trust
Leighton Hospital
Leighton
Crewe
United Kingdom
CW1 4QJ

Sponsor information

Organisation
University of Oxford

Sponsor details
Research Governance, Ethics & Assurance Team
Boundary Brook House
Churchill Drive
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United Kingdom
OX3 7GB
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Sponsor type
Hospital/treatment centre

Website
http://www.ouh.nhs.uk/

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

Publication and dissemination plan
Publication and dissemination of trial results and associated trial publications (e.g. the trial protocol, statistical analysis plan (SAP) will be in accordance with OCTRU Standard Operating Procedures and irrespective of trial findings. The findings from the trial will inform NHS clinical practice for the management of ambulant children with spastic CP. The trial protocol will be available via the NIHR HTA website and published in an open-access peer-reviewed journal in accordance with the SPIRIT Statement (https://www.spirit-statement.org/). The trial results will be published in a high-impact open-access journal, in accordance with the NIHR's policy on open-access research and reported following the CONSORT guideline (https://www.consort-statement.org)All trial materials, including the physiotherapist training materials and high-quality patient advice materials, will be made freely available via the trial website.

Prior to formal publication, the researchers will inform the children and their parent(s)/guardian (s) of the trial results using explainer videos and infographics to support written information. The participants will be asked how they would like to be informed of the trial results as part of their original consent process. Patient and Public Involvement representatives will help inform how best to disseminate the trial results to other young people with CP and to the wider public. The researchers will also host an Investigator Day to feed the trial results back to the physiotherapists and other members of the team at the trial sites. They will link with the CPIP

network, the British Society for Children's Orthopaedic Surgery, the British Academy of Childhood Disability, and the Association of Paediatric Chartered Physiotherapists to ensure the results are communicated to all relevant professionals.

Intention to publish date
01/09/2027

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?
Protocol file	version 1.0	06/06/2023	05/09/2023	No	No
Participant information sheet			10/12/2024	No	Yes
Protocol file	version 2.0	27/09/2023	10/12/2024	No	No