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Strengthening programme for ambulant adolescents with cerebral palsy

Submission date
12/07/2023

Recruitment status
Recruiting

Registration date
01/08/2023

Overall study status
Ongoing

Last Edited
20/03/2026

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 around birth from a lack of oxygen in the brain. Children with CP develop stiff and weak muscles. They often have difficulty walking and moving and that makes it difficult for them to join in activities. Exercises prescribed by physiotherapists become a big part of their lives as it tries to train their muscles and help them participate in activities. When they reach adolescence and their body grows, weakness of muscles in the legs becomes more of a problem.
Exercises to strengthen muscles to maintain or improve movement are often used by physiotherapists in adolescents with CP. However, there is wide variability in the strengthening exercise programmes used. Therefore, professional groups have highlighted the need for evidence-based physiotherapy exercise programmes in adolescents with CP. The aim of this study is to assess the effectiveness of a strengthening programme compared to usual care in adolescents with CP.

Who can participate?
Adolescents aged 12-18 years with spastic cerebral palsy

What does the study involve?
Participants will be randomly allocated into either the intervention (exercise programme) group or the usual NHS physiotherapy group. The intervention will involve six sessions with the physiotherapist over 16 weeks. Adolescents will receive an exercise programme which includes specific individually tailored strengthening 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 strengthening exercises. Adolescents 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, adolescents 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 adolescents 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 2024 to August 2027

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. Sally Hopewell, sally.hopewell@csm.ox.ac.uk
2. Joanna O'Mahoney, joanna.omahoney@ndorms.ox.ac.uk

Contact information

Type(s)
Scientific

Contact name
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Type(s)
Principal investigator

Contact name
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Additional identifiers

Integrated Research Application System (IRAS)
325313

Central Portfolio Management System (CPMS)
57227

Study information

Scientific Title
Clinical effectiveness of an adolescent-specific strengthening programme, compared to usual care, for ambulant adolescents with spastic cerebral palsy (ROBUST trial): a parallel group randomized controlled trial

Acronym
ROBUST

Study objectives
An adolescent-specific muscle strengthening programme has superior clinical effectiveness compared to usual care for ambulant adolescents with spastic cerebral palsy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 30/08/2023, South Central - Hampshire A Research Ethics Committee (Health Research Authority, 2 Redman Place, Stratford, London, E20 1JQ, UK; +44 (0)207 104 8388; hampshirea.rec@hra.nhs.uk), ref: 23/SC/0231

Study design
Randomized; Interventional; Design type: Treatment, Physical, Rehabilitation

Primary study design
Interventional

Study type(s)
Treatment

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

Interventions
ROBUST 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.

Adolescents and their parent(s) will be approached as part of their annual community physiotherapy CPIP review or other routine CP clinical care attendance. 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 questions on patient demographics and detail any reasons given for exclusion and non-participation.

Participants will be asked to sign an assent form (for adolescents aged 12-15 years) whilst the parent/guardian will be asked to sign a consent form on behalf of their child. For those aged 16-18 years when entering the study, the young person will either be asked to sign a consent form or, if the clinician assesses the young person to be unable to provide informed consent, their parent/guardian (or other relative/friend, if applicable) will be asked to complete a consultee declaration on their behalf.

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/guardians will be asked to complete a baseline assessment questionnaire, which will include baseline measurements for the primary and secondary outcomes.

Clinician-assessed outcomes (i.e. muscle strength 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 progressive resistance 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 arm 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 questionnaires 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. Muscle strength measured using the five time sit-to-stand test for adolescents with CP 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
31/08/2027

Eligibility

Key inclusion criteria
1. Adolescents aged 12-18 years (i.e. from their 12th to their 18th birthday)
2. Diagnosis of spastic CP (bilateral or unilateral) Gross Motor Function Classification System (GMFCS) levels I–III
3. Willing for their community physiotherapy service and GP to be informed of their participation in the trial
4. Under 16 years of age: Participant is willing to take part in the study and has a parent /guardian who is willing and able to give informed consent for the child’s participation in the study.
5. Over 16 years of age: Participant is willing and able to give informed consent or a nominated Consultee can advise on behalf of the participant (Outside Scotland)/legal representative can consent on the participant's behalf (Scotland)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
12 years

Upper age limit
18 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 resistance exercise programme focused on resistance training as part of their usual physiotherapy routine
4. Patient is unable to comply with the assessment procedures and exercise programme with or without support from their carer

Date of first enrolment
29/01/2024

Date of final enrolment
28/02/2027

Locations

Countries of recruitment
United Kingdom

England

Wales

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
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
Whittington Health NHS Trust
Northern Health Centre, 580 Holloway Road
London
England
N7 6LB

Study participating centre
Oxford Health NHS Foundation Trust
NIHR Oxford Cognitive Health Clinical Research Facility, Warneford Hospital, Warneford Lane, Headington
Oxford
England
OX3 7JX

Study participating centre
Bedfordshire Hospitals NHS Trust
Child Development Centre, Hill Rise
Kempston
England
MK42 7EB

Study participating centre
Betsi Cadwaladr University Health Board
Ysbyty Glan Clwyd, Rhuddlan Road
Rhyl
Wales
LL18 3RF

Study participating centre
Cambridgeshire and Peterborough NHS Foundation Trust
Elizabeth House
Fulbourn Hospital
Fulbourn
Cambridge
England
CB21 5EF

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
Room 100/110 Pen Lloyd Building
County Hall
Leicester Road
Leicester
England
LE3 8RA

Study participating centre

Maidstone and Tunbridge Wells NHS Trust
The Maidstone Hospital
Hermitage Lane
Maidstone
England
ME16 9QQ

Study participating centre
North East London NHS Foundation Trust
West Wing
C E M E Centre
Marsh Way
Rainham
England
RM13 8GQ

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

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
The Newcastle upon Tyne Hospitals NHS Foundation Trust
Freeman Hospital
Freeman Road
High Heaton
Newcastle upon Tyne
England
NE7 7DN

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: NIHR135150

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 Sally Hopewell (sally.hopewell@csm.ox.ac.uk) 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?
Participant information sheet			10/12/2024	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file	version 1.0	15/06/2023	05/09/2023	No	No
Protocol file	version 2.0	21/11/2023	10/12/2024	No	No
Protocol file	version 3.0	12/12/2024	15/01/2026	No	No
Protocol file	version 4.0	09/06/2025	15/01/2026	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes