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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
06/03/2025

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 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 2023 to September 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

Study website
https://robust-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
325313

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 57227, IRAS 325313

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

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

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

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

Secondary outcome measures
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

Overall study start date
01/01/2023

Completion date
01/09/2027

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

Age group
Child

Lower age limit
12 Years

Upper age limit
18 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 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
01/03/2026

Locations

Countries of recruitment
England

United Kingdom

Wales

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
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

Study participating centre
Whittington Health NHS Trust
Northern Health Centre, 580 Holloway Road
London
United Kingdom
N7 6LB

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

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

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

Sponsor information

Organisation
University of Oxford

Sponsor details
Research Governance, Ethics & Assurance Team
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Sponsor type
University/education

Website

http://www.ox.ac.uk/

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

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 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?
Protocol file	version 1.0	15/06/2023	05/09/2023	No	No
Participant information sheet			10/12/2024	No	Yes
Protocol file	version 2.0	21/11/2023	10/12/2024	No	No