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Feasibility and efficacy of resistance training in cerebral palsy (CP)

Submission date
26/08/2015

Recruitment status
No longer recruiting

Registration date
27/08/2015

Overall study status
Completed

Last Edited
09/05/2023

Condition category
Nervous System Diseases

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Cerebral palsy (CP) is the medical term used to describe a number of neurological conditions that affect movement and co-ordination. It is caused by a damage to the parts of the brain responsible for controlling muscles. This can be due to a number of reasons including infections caught by the mother during pregnancy, a difficult birth, bleeding in the baby's brain and mutations in the genes that affect brain development. Symptoms of CP include muscle stiffness or floppiness, muscle weakness, random and uncontrolled body movements and balance and co-ordination problems. Being able to walk and function independently becomes especially important as children enter adolescence and want to take part in activities outside family life. Just as young adults with CP are becoming more independent, they can experience deterioration in their walking ability making it difficult for them to participate in everyday life. One reason for this deterioration is that it takes more effort for people with CP to walk than people without CP. The increased effort is possibly due to people with CP having less control over their muscles and because the mechanical characteristics of their muscles and tendons are different from people without CP. Resistance training can be used to treat people with CP. Improved muscle strength and altered mechanical properties of muscle and tendons as a result of resistance training could reduce the effort of walking. This in turn could prevent deterioration in walking function and encourage physical activity. The aim of this study is to investigate the effectiveness and acceptability of resistance training in adolescents with CP.

Who can participate?
Adolescents (aged 10-19) with cerebral palsy that are able to walk independently.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in group 1 carry out a set of specific exercises including resistance training. Those in group 2 continue with their usual care, provided that this does not include resistance training. The researchers then make assessments in order to answer three important questions: Firstly, is resistance training feasible and acceptable in adolescents with CP? Secondly, does it make walking easier and increase physical activity and participation in everyday life?

What are the possible benefits and risks of participating?
The information collected may help in deciding on the best treatment to provide teenagers with cerebral palsy. Participants in the resistance training group may find that their muscles get stronger and they may find it easier to walk. Possible risks include muscle soreness after the assessments or after the exercises. It may also be painful when the sticky tape used to attach sensors to the participants legs and feet to record their movement, video their muscles and measure how much their muscles are working is removed.

Where is the study run from?
Brunel University London (UK)

When is the study starting and how long is it expected to run for?
August 2015 to July 2018

Who is funding the study?
1. Action Medical Research (UK)
2. Chartered Society of Physiotherapy Charitable Trust (UK)

Who is the main contact?
Dr Jennifer Ryan

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
19112

Study information

Scientific Title
An evaluation of the feasibility, acceptability and efficacy of resistance training in adolescents with cerebral palsy: a randomised controlled trial

Study objectives
The aim of this study is to investigate the effectiveness and acceptability of resistance training in adolescents with cerebral palsy (CP)

Ethics approval required
Old ethics approval format

Ethics approval(s)
Brunel University London's Department of Clinical Sciences' Research Ethics Committee and the NRES Committee London – Surrey Borders, ref: 15/LO/0843

Study design
Randomised; Interventional; Design type: Screening

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Topic: Children, Musculoskeletal disorders; Subtopic: All Diagnoses, Musculoskeletal (all Subtopics); Disease: Musculoskeletal, All Diseases

Interventions
Progressive resistance training will be performed three times per week for 10 weeks; two sessions will be carried out at participants' homes and one will be a group session carried out in participants' local physiotherapy departments or gyms. Single-joint plantarflexor exercises will be based on individual strength capacities, to ensure the participant can perform a minimum of eight and a maximum of 12 repetitions, which equates to approximately 65-80% of 1-repetition maximum. To minimise injury risk in adolescents unaccustomed to strength training, the number of repetitions completed during the first training session will depend on their rating of perceived exertion recorded in a familiarisation session. Each group session will be managed by a physiotherapist and will include a 5-10 minute aerobic warm-up of aerobic activity and a 5-10 minute cool-down consisting of aerobic activity and plantarflexor stretches. Adolescents will perform two circuits of four stations: two stations of plantarflexor exercises and two stations of unrelated activities such as basketball shooting or throwing and catching a ball with a partner, to help maintain participant motivation. Plantarflexor exercises will include standing heel raises with or without added resistance from a weighted vest, plantarflexor contractions against the footplate of a recumbent calf-raise machine, and plantarflexor contractions against a Thera-Band resistance band in long-sitting. Home exercises will consist of four sets of 8-12 repetitions of single-leg heel raises with or without a weighted vest, or plantarflexor exercises using a Thera-Band resistance band, at the intensity prescribed in the class. Participants will record the number of reps and sets they perform of each exercise, their rate of perceived exertion on a scale of 0-10, their level of pain on a scale of 0-10, and any potentially related or unrelated adverse effects after each session using a patient support tool. This information will be transmitted directly to the research team. Attendance at the group sessions will also be recorded. All participants, including those in the control group, will be instructed to continue their normal activities. All participants will also be instructed to continue with their usual physiotherapy programme, provided it does not include progressive resistance training.

Intervention Type
Behavioural

Primary outcome(s)
Gait efficiency measured using indirect calorimetry at 0, 10 and 22 weeks

Key secondary outcome(s))
1. Physical activity measured using accelerometry
2. Participation measured using Assessment of Life Habits questionnaire (Life-H)
3. Gross Motor Function measured using components D and E of Gross Motor Function Measure (GMFM) and 10m walking trial
4. Muscle strength measured using isokinetic dynamometry
5. Muscle activity during dynamometry and treadmill walking measured using EMG
6. Muscle and tendon force measured using isokinetic dynamometry and ultrasonography
7. Muscle and tendon length measured using ultrasonography and motion analysis
8. Muscle and tendon stiffness measured using ultrasonography and motion analysis
9. Muscle, tendon and fascicle strain measured using ultrasonography
10. Muscle and tendon cross-sectional area measured using ultrasonography
11. Quality of life measured using EQ-5D-Y and CHU 9D
All measured at 0, 10 and 22 weeks

Deleted 04/08/2016:
Movement quality measured using Quality Function Measure

Completion date
31/12/2018

Eligibility

Key inclusion criteria
1. Adolescents with cerebral palsy aged 10-19 years (amended from 12-19 years on 12/07/2016)
2. The ability to walk independently with or without a mobility aid
3. The ability to activate the ankle plantarflexors

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
64

Key exclusion criteria

1. Orthopaedic surgery in the past year
2. Botulinum toxin type A (Botox) injections or serial casting in the past 6 months
3. Receiving intrathecal baclofen
4. Unable to comply with the protocol

Date of first enrolment
21/09/2015

Date of final enrolment
01/07/2018

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Brunel University
Clinical Sciences
Mary Seacole Building
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UB8 3PH

Sponsor information

Organisation
Brunel University (UK)

ROR
https://ror.org/00dn4t376

Funder(s)

Funder type
Charity

Funder Name
Action Medical Research

Alternative Name(s)
action medical research for children, actionmedres, The National Fund for Research into Crippling Diseases, AMR

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Funder Name
Chartered Society of Physiotherapy Charitable Trust

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available publicly, as consent was not obtained to publish the anonymised data.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/11/2020	30/06/2020	Yes	No
Results article	Qualitative results	08/05/2023	09/05/2023	Yes	No
Protocol article	protocol	04/10/2016		Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes