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Feasibility study of the ExTraChild-project

Submission date
05/06/2025

Recruitment status
No longer recruiting

Registration date
09/06/2025

Overall study status
Ongoing

Last Edited
09/06/2025

Condition category
Nervous System Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] Record updated in last year

Plain English Summary
Background and study aims
The ExTraChild research project is looking at how exercise can help children with cerebral palsy (CP). The goal is to find the best ways to create personalised exercise plans that are both effective and practical. Researchers want to understand how exercise affects the body in the short and long term, and how to make these exercise programs easier for children with CP to take part in.

Who can participate?
The study involves three groups of children:
-Children with CP who cannot walk (non-ambulant)
-Children with CP who can walk (ambulant)
-Children who do not have CP and can walk (typically developing)

What does the study involve?
Children will take part in two types of exercise programs: moderate-intensity continuous training (MICT) and high-intensity interval training (HIIT). The study will look at how their bodies respond to exercise by measuring things like breathing, blood samples, and small muscle samples.
Some children will help test how well the study methods work before the full study begins. Feedback from children and their exercise supervisors will be collected regularly to improve the program.

What are the possible benefits and risks of participating?
Taking part may help children with CP improve their health and fitness. The study could also lead to better exercise programs for other children with CP in the future.
There are some small risks, such as discomfort from blood tests or muscle samples, but these will be carefully managed by trained professionals.

Where is the study run from?
The study is being run by Lund University in Sweden.

When is the study starting and how long is it expected to run for?
The study began in March 2024 and is expected to continue until December 2025.

Who is funding the study?
The study is funded by several organisations, including:
-The Swedish Research Council (Vetenskapsrådet)
-Promobilia Foundation
-Linnea and Josef Carlsson Foundation
-Norrbacka-Eugenia Foundation
-The Foundation for Assistance to the Disabled in Skåne

Who is the main contact?
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Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
2023-05806-01

Study information

Scientific Title
Feasibility study of exercise training among children with cerebral palsy to increase health and wellbeing (ExTraChild-project a sub-study of the LEER-project

Acronym

ExTraChild

Study hypothesis
The overarching hypothesis is that the strongest exercise training effects will be for those who manage to be persistent, and that children may have individual preferences for types of exercise training. Two different exercise regimes, Moderate Intensity Continuous Training (MICT) and High Intensity Interval Training (HIIT) will be used to determine the most effective exercise regime on an individual level. Furthermore, environmental and behavioral facilitators and barriers to participate in exercise will be identified for stakeholders. The specific aims of this feasibility study are:

Aim 1: To study the feasibility of the tests performed to assess the immediate effects from a single exercise training session on cardiopulmonary and metabolic biomarkers, neural and vascular growth factors in blood, and transcriptomic biomarkers in skeletal muscle in ambulant children with cerebral palsy (CP) and ambulant children who are typically developed (TD).
Aim 2: To study the feasibility of the interventions performed to compare the additive effects from multiple exercise training session during 16 weeks of two types of structured exercise training regimes (HIIT vs. MICT) on cardiopulmonary and metabolic parameters and neural growth factors, in ambulant children with CP and with ambulant children who are TD as controls.
Aim 3: To study the feasibility of the method used to identify environmental and behavioral facilitators and barriers considering the child and family caregivers, healthcare professionals, fitness center professionals, that may affect the participation in exercise among ambulant children with CP and ambulant children who are TD.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 06/11/2023, The Swedish Ethical Review Authority (Box 2110, Uppsala, 750 02, Sweden; +46-10-475 08 00; regostrator@etikprovning.se), ref: 2023-05806-01

Study design
Interventional crossover study

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Fitness/sport facility, Laboratory

Study type(s)
Other, Treatment, Safety, Efficacy

Participant information sheet

Condition
Exercise training among children with cerebral palsy to increase health and well-being

Interventions
Two different exercise regimes on spinning-bikes, Moderate Intensity Continuous Training (MICT) and High Intensity Interval Training (HIIT), will be performed three times per week for 16-weeks with 16-weeks washout period in-between.

Since children are non-autonomous, the common point of departure for our research is the family; lifestyle changes as well as interventions must be implemented through the family. Feasibility testing aims to analyze clinical, procedural, and methodological uncertainties of the exercise testing and the exercise training interventions of HIIT and MICT in the controlled intervention trial. The feasibility period will convey of exercise testing before the intervention the first 16 weeks of exercise training.

If no major changes are made to the study design and/or the intervention these children will be included into the evaluation phase.

Intervention Type
Behavioural

Primary outcome measure
Number of completed exercise sessions measured using patient records at end of study

Secondary outcome measures
1. Number of completed tests measured using patient records at end of study
2. Exercise test VO2, VCO2, VE, RER, BF, VO2/kg adn HR before and after exercise period.
3. Body composition by bio impedance before and after exercise period.
4. Range of motion according to CPUP before and after exercise period.
5. Spaticity according to CPUP before and after exercise period.
6. Variance i watt during each exercise session.
7. Variance in HR during each exercise session.
8. Physical activity assessed by accelerometry before and after exercise period.
9. Quality of life (EQ5D) before and after exercise period.
10. Bowl function assessed by the Bristol scale before and after exercise period.
11. Changes in blood biomarkers BDNF, VEGF, ACTH, GH, CRP, IL-6, IGF-1, IGFBP-3, TNF-a and insulin, assessed in plasma collected from venues blood sampling before and after each exercise test performed before and after the exercise period
12. Capillary blood glucose and lactate collected before and after each exercise test performed before and after the exercise period.
13. Semi-structed interviews about the experiences of participating in the testing and exercise sessions

Overall study start date
01/03/2024

Overall study end date
31/12/2025

Eligibility

Participant inclusion criteria

1. Ambulant children with CP defined as GMFCS-E&R I-II
2. Healthy controls: ambulant children who are TD and not participating in any regular and planned leisure time physical exercise will be included in the study.

Participant type(s)
Population

Age group
Child

Lower age limit
10 Years

Upper age limit
16 Years

Sex
Both

Target number of participants
8

Total final enrolment
4

Participant exclusion criteria
1. Ambulant children with CP walking with a walking aid (GMFCS-E&R III)
2. Ambulant children who are TD with other neurological diagnoses, metabolic diagnoses, orthopaedic disabilities, asthma, heart diseases, cognitive impairment, or indigestion of regular medication.

Recruitment start date
01/03/2024

Recruitment end date
01/08/2024

Locations

Countries of recruitment
Sweden

Study participating centre
Gerdahallen
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Sponsor information

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University/education

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Funder(s)

Funder type
Government

Funder Name
Vetenskapsrådet

Alternative Name(s)
Swedish Research Council, VR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Sweden

Funder Name
Promobilia

Funder Name
Linnea och Josef Carlssons stiftelse

Funder Name
Norrbacka-Eugenia stiftelsen

Funder Name
Stiftelsen för bistånd åt rörelsehindrade i Skåne

Results and Publications

Publication and dissemination plan
The overall goal is to disseminate the result to all relevant stakeholders, i.e. children and their families, user organizations, health care and school professionals, sport clubs including parasport associations, healthcare professionals, and policy makers on local, regional and national level. Dissemination needs to occur in structured manner with tools appropriate for each stakeholder's individual setting. Tools have different strengths and to reach all targets groups and we will use tools that complement one another. The main dissemination tools will be magazines and newsletters, user meetings, seminars/webinars and presentations at conferences, social media, research reports and both non-peer-reviewed and peer-reviewed journals. Policy-briefs will be used to present the findings to a non-specialized, busy audience, e. g. policymakers. We will also disseminate the results of the research study to the research community by publication in peer-reviewed scientific international journals and present at conferences.

Intention to publish date
31/12/2025

Individual participant data (IPD) sharing plan
The datasets generated during and/or analyzed during the current study are not expected to be made available due to the low number of participants with identifiable disabilities.

IPD sharing plan summary
Not expected to be made available