

Feasibility study of the ExTraChild-project

Submission date 05/06/2025	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol <input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results <input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year
Registration date 09/06/2025	Overall study status Completed	
Last Edited 09/06/2025	Condition category Nervous System Diseases	

Plain English summary of protocol

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?

Dr Åsa Tornberg, asa.tornberg@med.lu.se

Contact information

Type(s)

Public, Scientific, Principal investigator

Contact name

Dr Åsa Tornberg

ORCID ID

<https://orcid.org/0000-0001-5617-0728>

Contact details

Sölvergatan 19

Lund

Sweden

223 62

+46-46-222 97 64

asa.tornberg@med.lu.se

Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

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 objectives

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

Study type(s)

Other, Treatment, Safety, Efficacy

Health condition(s) or problem(s) studied

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(s)

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

Key secondary outcome(s)

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. Spasticity 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-structred interviews about the experiences of participating in the testing and exercise sessions

Completion date

31/12/2025

Eligibility

Key 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

Healthy volunteers allowed

No

Age group

Child

Lower age limit

10 years

Upper age limit

16 years

Sex

All

Total final enrolment

4

Key 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.

Date of first enrolment

01/03/2024

Date of final enrolment

01/08/2024

Locations

Countries of recruitment

Sweden

Study participating centre

Gerdahallen
Helgonavägen 8
Lund
Sweden
221 62

Sponsor information

Organisation

Lund University

ROR

<https://ror.org/012a77v79>

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

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