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Exercise therapy intervention for children and young adults with cerebral palsy

Submission date
18/04/2017

Recruitment status
No longer recruiting

Registration date
21/04/2017

Overall study status
Completed

Last Edited
01/05/2025

Condition category
Nervous System Diseases

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

Plain English summary of protocol

Background and study aims
Cerebral palsy (CP) is a term for a number of conditions that affect movement, posture and coordination. It occurs due to abnormal development or damage in the brain before, during or after the birth in the areas responsible for controlling muscles. CP leads to a range of symptoms, including muscle weakness, decrease in joint flexibility and coordination problems. These secondary symptoms hinder the person's ability to perform everyday activities such as walking or negotiating steps. It has been shown that children and adults with CP are less physically active than those who have developed normally. Sedentarism leads to lower physical fitness, and elevates the risk of developing a range of health conditions. Since CP has no cure, it is of upmost importance to develop interventions to increase function, health and participation in everyday activities. The aim of this study is to evaluate the effects of an individualized exercise programme consisting of strength, flexibility and gait training for children and young adults with CP.

Who can participate?
People with spastic CP aged 9 to 24 years old, and age and sex-matched typically developing controls.

What does the study involve?
The study is divided into three parts. The first part consists of a three-month "control period", in which participants are tested while continuing their normal living. In the second part, participants go through the three-month EXECP intervention period, in which The last part is a three-month "maintenance period" during which participants continue their normal living and choose if they want to keep following the training programe or not. The CP group take part in all three parts, and typically developing group take part only in the control period. The exercise programme involves two to three supervised exercise sessions per week for 12 weeks. These sessions involve strength and flexibility training for the legs and trunk muscles and inclined-treadmill walking. Before and after the control period (Pre-tests 1 and 2 respectively) and before and after the maintenance period (Post-tests 1 and 2), participants complete a range of assessments and questionnaires to measure their physical capacities, functionality, cardiometabolic health and factors influencing participation in physical activities. Also, families will be involved in this study by answering a questionnaire exploring motivational factors

towards their children's physical activity participation. In addition, for one week during each study part (i.e. control, intervention and maintenance), participants wear an accelerometer to record their physical activity levels.

In addition to this, a sub-study called I-SENS involving new data collection will be performed in Jyväskylä to complement the study on musculoskeletal properties, gait analysis, and behavioral proprioception. From the participants within EXECP-study, 10 children with CP and 10 TD children will be re-called and asked to participate in 3D freehand ultrasound data collection and behavioral proprioception testing.

What are the possible benefits and risks of participating?
Participants may benefit from an improvement to their physical abilities, which could help them exercise more and decrease their risk of developing health problems. Participants will receive a comprehensive neuromuscular evaluation with the possibility to personalize their treatments. There are no notable risks involved with taking part other than the general risks associated with exercising such as muscle soreness, tiredness or risk of falling.

Where is the study run from?
University of Jyväskylä (Finland)

When is the study starting and how long is it expected to run for?
September 2016 to January 2023

Who is funding the study?
1. University of Jyväskylä (Finland)
2. Olvi Foundation (Finland)
3. Ellen and Artturi Nyyssönen Foundation (Finland)
4. Academy of Finland (Finland)
5. Jane and Aatos Erkko Foundation (Finland)
6. European Commission, via its Marie Skłodowska-Curie Actions (MSCA) Postdoctoral Fellowships program

Who is the main contact?
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
8U/2017

Study information

Scientific Title
Effects of a tailored exercise therapy intervention on physical capacities and function, neuromuscular mechanisms and cardiometabolic risk factors of children and young adults with cerebral palsy

Acronym
EXECP and sub-study I-SENS

Study objectives
Current study hypothesis as of 26/11/2021:
The primary hypothesis to be tested is gait performance:
1. The EXECP intervention will enhance gait performance by: a) increasing walking distance in the 6 minutes walking test; b) increasing ankle dorsiflexion during the swing and stance phase of gait; c) increasing maximal walking velocity, joint net moments and ranges of motion in the lower limb joints.
The secondary hypotheses to be tested are:
2. Physical activity (PA) level will remain constant throughout the study. Furthermore, PA is expected to be inversely correlated with the cardiometabolic risk factors in the control period and positively correlated with the retention of the adaptations during the maintenance period.
3. The EXECP intervention will: a) increase maximal isometric and concentric torque for plantarflexors, dorsiflexors, knee extensors and flexors; b) increase torque-angle curve width (Reid et al.2010) for all four muscle actions; c) increase torque steadiness during submaximal isometric dorsiflexion; d) increase gross motor function measure (GMFM; Russel et al. 2000) score; e) not affect cardiometabolic risk factors such as arterial stiffness, sedentarism-related blood biomarkers and body adiposity.
4. The EXECP intervention will: a) increase lower limb joint flexibility (i.e. range of motion) of the trained muscle groups; b) increase triceps surae muscle passive resistance, average joint stiffness and energy (i.e. area under the torque-angle curve) during slow passive stretching.
5. The EXECP intervention will: a) decrease antagonist muscle electromyography (EMG) during maximal voluntary isometric and concentric plantarflexion and dorsiflexion; b) not change the tonic stretch reflex threshold angle); c) not change soleus post-activation depression; d) not change the H-reflex normalized by the maximum M-wave of soleus muscle; d) increase the passive-movement evoked fields in the primary somatosensory cortex (i.e. cortical proprioceptive responses); e) increase cortico-muscular and intramuscular coherence in tibialis anterior during a submaximal isometric dorsiflexion; f) increase tibialis anterior intramuscular coherence during the swing phase of the gait cycle.
No changes in any of the studied variables are expected during the 3-month control period, except if the participant is going through the growth spurt. After the 3-month maintenance period, the studied variables values are expected to be in between the control and post intervention values. All study variables are hypothesized to be different between the TD and CP groups.
6. Within the I-SENS study, the extent to which ankle joint proprioception at the cortical level is impaired in children with CP will be associated with the level of ankle joint spasticity. We hypothesize to find such an association between spasticity and cortical proprioception.
7. Within the I-SENS study, musculoskeletal properties will be quantified both in passive and active conditions, and relate to gait performance. We intend to find the relationship that explains how the altered passive muscle-tendon properties influence their active behavior during gait.
8. Within the I-SENS study, we examined spasticity, musculoskeletal properties, cortical and

behavioural proprioception. We hypothesize that musculoskeletal properties will have the predominant effect on altering (reducing) the stimulation on load-sensitive afferents during gait.

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Previous study hypothesis as of 20/06/2019:
The primary hypothesis to be tested is gait performance:
1. The EXECP intervention will enhance gait performance by: a) increasing walking distance in the 6 minutes walking test; b) increasing ankle dorsiflexion during the swing and stance phase of gait; c) increasing maximal walking velocity, joint net moments and ranges of motion in the lower limb joints.
The secondary hypotheses to be tested are:
2. Physical activity (PA) level will remain constant throughout the study. Furthermore, PA is expected to be inversely correlated with the cardiometabolic risk factors in the control period and positively correlated with the retention of the adaptations during the maintenance period.
3. The EXECP intervention will: a) increase maximal isometric and concentric torque for plantarflexors, dorsiflexors, knee extensors and flexors; b) increase torque-angle curve width (Reid et al.2010) for all four muscle actions; c) increase torque steadiness during submaximal isometric dorsiflexion; d) increase gross motor function measure (GMFM; Russel et al. 2000) score; e) not affect cardiometabolic risk factors such as arterial stiffness, sedentarism-related blood biomarkers and body adiposity.
4. The EXECP intervention will: a) increase lower limb joint flexibility (i.e. range of motion) of the trained muscle groups; b) increase triceps surae muscle passive resistance, average joint stiffness and energy (i.e. area under the torque-angle curve) during slow passive stretching.
5. The EXECP intervention will: a) decrease antagonist muscle electromyography (EMG) during maximal voluntary isometric and concentric plantarflexion and dorsiflexion; b) not change the tonic stretch reflex threshold angle); c) not change soleus post-activation depression; d) not change the H-reflex normalized by the maximum M-wave of soleus muscle; d) increase the passive-movement evoked fields in the primary somatosensory cortex (i.e. cortical proprioceptive responses); e) increase cortico-muscular and intramuscular coherence in tibialis anterior during a submaximal isometric dorsiflexion; f) increase tibialis anterior intramuscular coherence during the swing phase of the gait cycle.
No changes in any of the studied variables are expected during the 3-months control period, except if the participant is going through the growth spurt. After the 3-months maintenance period, the studied variables values are expected to be in between the control and post intervention values. All study variables are hypothesized to be different between the TD and CP groups.

Previous study hypothesis:
1. The intervention will enhance gait performance, increase muscle strength, neuromuscular coordination and joint range of motion.
2. The intervention will increase daily physical activity levels and improve cardiometabolic risk factors

Ethics approval required
Old ethics approval format

Ethics approval(s)

1. Approved 13/04/2017, Ethics Committee of Central Finland Health Care District, ref: 8u/2017.
2. Amendment approved 17/04/2018
3. Amendment approved 11/04/2019 (added 23/07/2020)
4. Amendment approved 21/09/2021 (added 26/11/2021)

Study design
Single-centre non-randomized study with multiple baseline design

Primary study design
Interventional

Study type(s)
Quality of life

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

Interventions
Current intervention as of 26/11/2021:
The EXECP exercise therapy intervention will have two to three supervised sessions per week during 12 weeks. The intervention will be tailored to address deficits identified by instrumented gait analysis, strength and flexibility tests. The intervention will include:
1. Strength training for the lower limb and trunk muscles (ankle plantar flexors and dorsiflexors, knee, hip and trunk flexors and extensors).
2. Flexibility training for lower limb muscles diagnosed short (e.g. hip and knee flexors, hip adductors)
3. Inclined treadmill walking
All sessions will have 90 minutes of duration and will be interspaced by a minimum of 48 hours.

For participants with CP, the study starts with a familiarization session, then 1 week later the pre-test 1. After the control period (3 months), the pre-test 2 is done and the intervention period (three months) starts. At the end of the intervention period, post-test 1 is done, and after the end of the maintenance period (3 months) the study is finalized with post-test 2. There is no intervention on the control and maintenance periods. Pre-tests 1 and 2, and Post-tests 1 and 2 are similar, consisting of three testing sessions in which most research variables will be collected (only exception is Post-test 2, in which there will be no magnetoencephalography measurements). Physical activity data will be collected in each of the three periods, during normal daily living.

For control participants, only the control period will be performed, meaning one familiarization session, and two testing sessions three month apart (Pre-tests 1 and 2). Physical activity data will be collected during this period.

During the I-SENS sub-study, both CP and control participants will be invited for an additional visit to the laboratory where musculoskeletal properties, gait analysis, and behavioral proprioception will be assessed.

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Previous intervention as of 20/06/2019:
The EXECP exercise therapy intervention will have two to three supervised sessions per week during 12 weeks. The intervention will be tailored to address deficits identified by instrumented gait analysis, strength and flexibility tests. The intervention will include:
1. Strength training for the lower limb and trunk muscles (ankle plantar flexors and dorsiflexors, knee, hip and trunk flexors and extensors).
2. Flexibility training for lower limb muscles diagnosed short (e.g. hip and knee flexors, hip adductors)
3. Inclined treadmill walking
All sessions will have 90 minutes of duration and will be interspaced by a minimum of 48 hours.

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Previous intervention:
For participants with Cerebral Palsy (CP), there is a three month control period, followed by a three month intervention period, followed by a three month maintenance period. For participants in the control group (typically developing participants), there is a three month control period only (at the same time as those in the CP group undergo their control period.

The exercise therapy intervention will have two to three supervised sessions per week during 12 weeks. The intervention will be tailored to address deficits identified by instrumented gait analysis, strength and flexibility tests. The intervention will include:
1. Strength and flexibility training for the main lower limb muscles (quadriceps, hamstrings, triceps surae, tibialis anterior, hip flexors, extensors and abductors)
2. Skill and functional training (e.g. balancing and force matching exercises, climbing stairs)
3. Treadmill walking
4. Various sport activities (e.g. swimming, football, volleyball)
All sessions will have 60 to 90 minutes of duration and will be interspaced by a minimum of 48 hours

For participants with CP, the study starts with a familiarization session, then 1 week later the pre-test 1. After the control period (3 months), the pre-test 2 is done and the intervention period (three months) starts. At the end of the intervention period, post-test 1 is done, and after the end of the maintenance period (3 months) the study is finalized with post-test 2. There is no intervention on the control and maintenance periods. Pre-tests 1 and 2, and Post-tests 1 and 2 are similar, consisting of three testing sessions in which most research variables will be collected (only exception is Post-test 2, in which there will be no magnetoencephalography measurements). Physical activity data will be collected in each of the three periods, during normal daily living.

For control participants, only the control period will be performed, meaning one familiarization session, and two testing sessions three month apart (Pre-tests 1 and 2). Physical activity data will be collected during this period.

Intervention Type
Other

Primary outcome(s)
Current primary outcome measure as of 20/06/2019:
Gait performance is assessed using a six minute walking test. Gait kinetics/kinematics

/mechanical efficiency is assessed using Vicon cameras, force plates and a heart rate monitor at pre-tests 1 and 2, and post-tests 1 and 2 for the CP group and pre-tests 1 and 2 for the control group.

Previous primary outcome measure:
Gait performance is assessed using a 6 minutes walking test at baseline (pre-test 1), 3 (pre-test 2), 6 (post-test 1) and 9 (post-test 2) months for participants with CP and at baseline and 3 months for control participants.

Key secondary outcome(s))

Current secondary outcome measures as of 29/11/2021:
1. Physical activity levels are measured using electromyography and accelerometry during 7 days of normal daily living at all three periods (control, intervention and maintenance)
2. Muscle strength is assessed using Isokinetic dynamometry at pre-tests 1 and 2, and post-tests 1 and 2 for the CP group and pre-tests 1 and 2 for the control group
3. Body composition is assessed using Inbody at pre-tests 1 and 2, and post-test for the CP group and pre-tests 1 and 2 for the control group
4. Blood biomarkers, arterial stiffness is assessed through blood sampling and arteriography at pre-tests 1 and 2, and post-test 1 for the CP group and pre-tests 1 and 2 for the control group
5. H-reflex and, Post-activation depression is assessed through nerve stimulation and Electromyography at pre-tests 1 and 2, and post-tests 1 and 2 for the CP group and pre-tests 1 and 2 for the control group
6. Proprioceptive responses and corticomuscular coherence is assessed through Magnetoencephalography at pre-tests 1 and 2, and post-test 1 for the CP group and pre-tests 1 and 2 for the control group
7. Spasticity is assessed using the tonic stretch reflex threshold at pre-tests 1 and 2, and post-tests 1 and 2 for the CP group and pre-tests 1 and 2 for the control group
8. Joint Flexibility is assessed using an Isokinetic dynamometer coupled with a linear potentiometer at pre-tests 1 and 2, and post-tests 1 and 2 for the CP group and pre-tests 1 and 2 for the control group
9. Motor Function is assessed using the Gross Motor Function Measure (GMFM-66) at pre-test 2 and post-test 1 for the CP group
10. Motivational factors influencing physical activity in the intervention will be assessed using a questionnaire at the familiarization session
11. Motivational factors influencing physical activity participation will be assessed using a questionnaire at 6 and 9 months
12. Parents' motivational factors towards their children's physical activity participation will be explored using a questionnaire at the familiarization session and 6 months
13. Passive musculoskeletal properties (from medial and lateral gastrocnemius, soleus and Achilles tendon) are measured using 3D freehand ultrasonography (2D ultrasound system and motion tracking system are synchronized and spatially calibrated for implementing this technique) and shear wave elastography, in static ankle joint positions at a single timepoint between January 2022 and December 2022
14. Active musculoskeletal properties (from belly and fascicles of medial gastrocnemius, and Achilles tendon) are measured with 2D ultrasound imaging recorded simultaneously during 3D gait analysis at a single timepoint between January 2022 and December 2022
15. Behavioural proprioception is measured using a silent and motorized ankle-movement actuator to slightly move the joint with different angular velocities at a single timepoint between January 2022 and December 2022. The subjects will be asked to push a button when the movement is perceived.

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Previous secondary outcome measures as of 26/11/2021:
1. Physical activity levels are measured using electromyography and accelerometry during 7 days of normal daily living at all three periods (control, intervention and maintenance)
2. Muscle strength is assessed using Isokinetic dynamometry at pre-tests 1 and 2, and post-tests 1 and 2 for the CP group and pre-tests 1 and 2 for the control group
3. Body composition is assessed using Inbody at pre-tests 1 and 2, and post-test for the CP group and pre-tests 1 and 2 for the control group
4. Blood biomarkers, arterial stiffness is assessed through blood sampling and arteriography at pre-tests 1 and 2, and post-test 1 for the CP group and pre-tests 1 and 2 for the control group
5. H-reflex and, Post-activation depression is assessed through nerve stimulation and Electromyography at pre-tests 1 and 2, and post-tests 1 and 2 for the CP group and pre-tests 1 and 2 for the control group
6. Proprioceptive responses and corticomuscular coherence is assessed through Magnetoencephalography at pre-tests 1 and 2, and post-test 1 for the CP group and pre-tests 1 and 2 for the control group
7. Spasticity is assessed using the tonic stretch reflex threshold at pre-tests 1 and 2, and post-tests 1 and 2 for the CP group and pre-tests 1 and 2 for the control group
8. Joint Flexibility is assessed using an Isokinetic dynamometer coupled with a linear potentiometer at pre-tests 1 and 2, and post-tests 1 and 2 for the CP group and pre-tests 1 and 2 for the control group
9. Motor Function is assessed using the Gross Motor Function Measure (GMFM-66) at pre-test 2 and post-test 1 for the CP group
10. Motivational factors influencing physical activity in the intervention will be assessed using a questionnaire at the familiarization session
11. Motivational factors influencing physical activity participation will be assessed using a questionnaire at 6 and 9 months
12. Parents' motivational factors towards their children's physical activity participation will be explored using a questionnaire at the familiarization session and 6 months
13. Passive musculoskeletal properties (from medial and lateral gastrocnemius, soleus and Achilles tendon) are measured using 3D freehand ultrasonography (2D ultrasound system and motion tracking system are synchronized and spatially calibrated for implementing this technique) and shear wave elastography, in static ankle joint positions
14. Active musculoskeletal properties (from belly and fascicles of medial gastrocnemius, and Achilles tendon) are measured with 2D ultrasound imaging recorded simultaneously during 3D gait analysis
15. Behavioural proprioception is measured using a silent and motorized ankle-movement actuator to slightly move the joint with different angular velocities. The subjects will be asked to push a button when the movement is perceived.

Previous secondary outcome measures as of 20/06/2019:
1. Physical activity levels are measured using electromyography and accelerometry during 7 days of normal daily living at all three periods (control, intervention and maintenance)
2. Muscle strength is assessed using Isokinetic dynamometry at pre-tests 1 and 2, and post-tests 1 and 2 for the CP group and pre-tests 1 and 2 for the control group
3. Body composition is assessed using Inbody at pre-tests 1 and 2, and post-test for the CP group and pre-tests 1 and 2 for the control group
4. Blood biomarkers, arterial stiffness is assessed through blood sampling and arteriography at pre-tests 1 and 2, and post-test 1 for the CP group and pre-tests 1 and 2 for the control group
5. H-reflex and, Post-activation depression is assessed through nerve stimulation and Electromyography at pre-tests 1 and 2, and post-tests 1 and 2 for the CP group and pre-tests 1

and 2 for the control group
6. Proprioceptive responses and corticomuscular coherence is assessed through Magnetoencephalography at pre-tests 1 and 2, and post-test 1 for the CP group and pre-tests 1 and 2 for the control group
7. Spasticity is assessed using the tonic stretch reflex threshold at pre-tests 1 and 2, and post-tests 1 and 2 for the CP group and pre-tests 1 and 2 for the control group
8. Joint Flexibility is assessed using an Isokinetic dynamometer coupled with a linear potentiometer at pre-tests 1 and 2, and post-tests 1 and 2 for the CP group and pre-tests 1 and 2 for the control group
9. Motor Function is assessed using the Gross Motor Function Measure (GMFM-66) at pre-test 2 and post-test 1 for the CP group

Previous secondary outcome measures:
1. Physical activity levels are measured using electromyography and accelerometry during 7 days of normal daily living at all three periods (control, intervention and maintenance)
2. Muscle strength is assessed using Isokinetic dynamometry at baseline (pre-test 1), 3 (pre-test 2), 6 (post-test 1) and 9 (post-test 2) months for participants with CP and at baseline and 3 months for control participants
3. Gait kinetics/kinematics/mechanical efficiency is assessed using Vicon cameras, force plates and a heart rate monitor at baseline (pre-test 1), 3 (pre-test 2), 6 (post-test 1) and 9 (post-test 2) months for participants with CP and at baseline and 3 months for control participants
4. Body composition is assessed using Inbody at baseline, 3, 6 and 9 months for participants with CP and at baseline and 3 months for control participants
5. Blood biomarkers, arterial stiffness is assessed through blood sampling and arteriography at baseline, 3, 6 and 9 months for participants with CP and at baseline and 3 months for control participants
6. H-reflex, Post-activation depression is assessed through nerve stimulation and Electromyography at baseline, 3, 6 and 9 months for participants with CP and at baseline and 3 months for control participants
7. Proprioceptive responses and corticomuscular coherence is assessed through Magnetoencephalography at baseline, 3, 6 and 9 months for participants with CP and at baseline and 3 months for control participants
8. Spasticity is assessed using the tonic stretch reflex threshold at baseline, 3, 6 and 9 months for participants with CP and at baseline and 3 months for control participants
9. Joint Flexibility is assessed using a Isokinetic dynamometer coupled with a linear potentiometer at baseline, 3, 6 and 9 months for participants with CP and at baseline and 3 months for control participants
10. Motor Function is assessed using the Gross Motor Function Measure (GMFM-66) at baseline, 3, 6 and 9 months for participants with CP
11. Perceived competence, relatedness and autonomy are assessed using questionnaires at the familiarization session, 6 and 9 months
12. Parent's intentions and attitudes towards physical activity of their children are assessed using a questionnaire at the familiarization session and 6 months

Completion date
31/01/2023

Eligibility

Key inclusion criteria

Current participant inclusion criteria as of 20/06/2019:
Experimental group:
1. Spastic CP (diplegic or hemiplegic)
2. Male and Female
3. Age range of 9 to 24 years old
4. Gross Motor Function Classification System (Palisano et al. 2008) levels 1 to 3

Control group:
1. Typically developing
2. Male and Female
3. Age range of 9 to 24 years old

Previous participant inclusion criteria:
Experimental group:
1. Spastic CP (diplegic or hemiplegic)
2. Male and Female
3. Age range of 10 to 23 years old
4. Gross Motor Function Classification System (Palisano et al. 2008) levels 1 to 3

Control group:
1. Typically developing
2. Male and Female
3. Age range of 10 to 23 years old

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
9 years

Upper age limit
24 years

Sex
All

Total final enrolment
36

Key exclusion criteria
1. Pharmacological treatments (e.g. intrathecal baclofen, botullinum toxin) in the last 6 months
2. Surgical procedures in the last 6 months
3. Selective dorsal rhyzotomy
4. Dystonia
5. Inability to understand basic instructions
6. Current utilization of serial casting
7. Inability to stand with the sole of the foot flat on the floor
8. Participation in the past 3 months in a structured physical training program

*Exclusion criteria 1 to 3 may be accepted as a case study (added 20/06/2019).

Date of first enrolment
24/04/2017

Date of final enrolment
15/12/2020

Locations

Countries of recruitment
Finland

Study participating centre
University of Jyväskylä
Neuromuscular Research Center
Faculty of Sport and Health Sciences
Jyväskylä
Finland
40014

Sponsor information

Organisation
University of Jyväskylä

ROR
https://ror.org/05n3dz165

Funder(s)

Funder type
University/education

Funder Name
Jyväskylän Yliopisto

Alternative Name(s)
University of Jyväskylä, Jyväskylä University, University of Jyväskylä - Finland, University of Jyväskylä, Finland, JYU

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Finland

Funder Name
OLVI-Säätiö

Alternative Name(s)
Olvi Foundation

Funding Body Type
Private sector organisation

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

Location
Finland

Funder Name
Ellen ja Artturi Nyyssösen Säätiö

Alternative Name(s)
Ellen and Artturi Nyyssönen Foundation

Funding Body Type
Private sector organisation

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

Location
Finland

Funder Name
Academy of Finland

Alternative Name(s)
Academy of Finland, Suomen Akatemia, Finlands Akademi, AKA

Funding Body Type
Government organisation

Funding Body Subtype
Research institutes and centers

Location
Finland

Funder Name
Jane ja Aatos Erkon Säätiö

Alternative Name(s)
Jane and Aatos Erkko Foundation, Jane och Aatos Erkkos stiftelse, J&AE

Funding Body Type
Private sector organisation

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

Location
Finland

Funder Name
H2020 Marie Skłodowska-Curie Actions

Results and Publications

Individual participant data (IPD) sharing plan
Current IPD sharing plan:
The datasets generated during and/or analysed during the current study will be stored in a publicly available repository at https://doi.org/10.17605/OSF.IO/4KBJH or https://osf.io/4kbjh/. The type of data stored: raw data (spike files .smr), processed files (matlab .mat files), analysis code in matlab (.mlx or .m).
Data was fully anonymized by destroying the only document that had personal information and subject research ID (consent form).

Previous IPD sharing plan:
Participant-level data contains sensible information and according to the Finnish Data Protection Act cannot be shared. All data files will be stored on the server of the University of Jyväskylä and protected by individual usernames and passwords.

IPD sharing plan summary

Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		07/08/2023	18/09/2023	Yes	No
Results article		23/11/2022	18/09/2023	Yes	No
Results article	Cardiometabolic risk factors	21/10/2024	24/10/2024	Yes	No
Results article	Physical activity	01/05/2025	01/05/2025	Yes	No
Protocol article	protocol	26/02/2021	01/03/2021	Yes	No
Dataset			18/09/2023	No	No
Interim results article		23/11/2022	12/12/2022	Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes