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# Adults born preterm at very low birth weight entering middle age: a two-country birth cohort study

**Submission date**
09/06/2020

**Recruitment status**
No longer recruiting

**Registration date**
10/06/2020

**Overall study status**
Completed

**Last Edited**
08/08/2024

**Condition category**
Neonatal Diseases

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

## Plain English summary of protocol

Background and study aims
Research by us and others has shown that most adults born prematurely at very low birth weight (less than 1500 g) live healthy lives. The same applies to most individuals who were born at term but with a lower birth weight than would have been expected based on the duration of pregnancy (term small for gestational age, SGA). However, both groups have on average have higher levels of many risk factors of cardiovascular disease and adverse mental health, including higher blood pressure, lower levels of physical activity and more often depressive or anxiety symptoms. Many of those born preterm at very low birth weight also have various challenges in social development and relationships.
Our groups in Helsinki, Finland, and Trondheim, Norway, (NTNU) have previously followed up people born preterm at very low birth weight, together with comparison individuals born at term. The Trondheim group have also followed up a group of now adults who were born at term SGA.
By doing so we will learn how the factors related to health and well-being develop with increasing age and the transition from young adulthood to midlife.
Performing the study with similar methods in Helsinki and Trondheim increases the accuracy and reproducibility of the findings.
The project represents novel research with potential benefits for individuals born with low birth weight, health care providers and society. It involves multi-disciplinary and clinically relevant patient-centered research of international significance and quality.

Who can participate?
Adults belonging to the original birth cohorts born 1978-85 (Helsinki) and 1986-88 (Trondheim).

What does the study involve?
The Helsinki and Trondheim groups have now joined their forces. In 2019-2020, when the study participants are approximately 32 to 42 years of age, we conduct new follow-up visits in which repeats many of the assessments of physical and mental health and well-being performed

before. The study will also include assessments of eye health and motor function which wave not been previously studied. The study will be performed during 1 or 2 visits, which together take approximately 5 to 7 hours.

What are the possible benefits and risks of participating?
Participants are offered a thorough clinical examination, receive medically relevant feedback and are referred to appropriate health services if needed. All methods are non-invasive and entail very low risk for injury or adverse events.

Where is the study run from?
1. Finnish Institute for Health and Welfare
2. Norwegian University of Science and Technology

When is the study starting and how long is it expected to run for?
January 2018 to December 2020

Who is funding the study?
1. The joint research committee of St. Olavs hospital HF and the Faculty of Medicine, NTNU (Finland/Norway)
2. Academy of Finland
3. Horizon 2020
4. Lastentautien Tutkimussäätiö (Foundation for Pediatric Research) (Finland)
5. Sigrid Juséliuksen Säätiö (Sigrid Jusélius Foundation) (Finland)
6. Signe och Ane Gyllenbergs stiftelse (Signe and Ane Gyllenberg Foundation) (Finland)
7. Helsinki University Hospital Governmental Special Subsidiary (VTR) (Finland)
8. Silmätautien tutkimussäätiö (Ophthalmology Research Foundation) (Finland)

Who is the main contact?
Prof. Kari Anne I. Evensen, karianne.i.evensen@ntnu.no
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# Contact information

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Scientific


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## Additional identifiers

### Clinical Trials Information System (CTIS)
Nil known

### ClinicalTrials.gov (NCT)
Nil known

### Protocol serial number
Nil known

## Study information

### Scientific Title
Adults born preterm at very low birth weight entering middle age: a follow-up of the Helsinki Study of Very Low Birth Weight Adults and the NTNU Low Birth Weight in a Lifetime Perspective birth cohort studies

### Acronym
HeSVA-NTNU LBW Life

### Study objectives
Adults born preterm with very low birth weight have lower physical activity and fitness levels, a higher body fat percentage, lower expiratory airflow, lower cardiac parasympathetic function, slower speed in manual dexterity and gross motor tasks, functional and anatomical visual challenges, higher levels of internalising traits and that they report lower scores in a quality of life assessment, as compared with term-born controls.

### Ethics approval required
Old ethics approval format

## Ethics approval(s)
1. Approved 04/10/2019, Helsinki and Uusimaa Hospital District, Ethics Committee IV (Helsingin ja Uudenmaan sairaanhoitopiiri, Stenbäckinkatu 9, PL 100, 00029 HUS, Finland; +358 40 359 4618; eettiset.toimikunnat@hus.fi), ref: HUS/1157/2019 (HeSVA)
2. Approved 30/01/2019, Regional Committee for Medical and Health Research Ethics Central Norway (NTNU/REC Central, Faculty of Medicine and Health Sciences, P.O. Box 8905, NO-7491 Trondheim, Norway; +47 73597511; rek-midt@mh.ntnu.no), ref: REC Central 2013/ 636 (NTNU LBW Life)

## Study design
Cross-sectional assessment of two longitudinal birth cohort studies.

## Primary study design
Observational

## Study type(s)
Other

## Health condition(s) or problem(s) studied
Health and well-being in adults born preterm with very low birth weight or at term, small for gestational age.

## Interventions
The study involves a clinical follow-up at age 32-42 years with objective measurements of physical activity (for seven days), fitness, body composition, respiratory, motor and visual function, and questionnaires for measuring mental health and quality of life. The study is performed during 1 or 2 visits, which together take approximately 5 to 7 hours. Data collection started in September 2019 and will end in December 2020.

Key measurements include:
Physical activity: two AX3 accelerometers and self-report.
Physical fitness: hand grip test, 40 sec modified push-up test and the Åstrand-Ryhming step test.
Respiratory function: spirometry
Body size and composition: standard anthropometry and bioelectrical impedance (Seca mBCA 515).
Motor function: Trail Making Test 1-5, Grooved Pegboard Test, the Bruininks Motor Ability Test, the High-Level Mobility Assessment Tool.
Visual function: visual acuity, optical computerised tomography scans, visual fields, strabismus, fundoscopy, electroretinogram and visual evoked potentials.
Questionnaires: ASEBA - Adult Self-Report, Behavior Rating Inventory of Executive Function and Short form 36 Health Survey.
Glucose tolerance (HeSVA only): oral glucose tolerance test.

## Intervention Type
Other

## Primary outcome(s)
The assessments consist of multiple substudies carried out during 1 or 2 study visits between September 2019 and December 2020 when participants are 32-42 years of age:
1. Physical activity: Time spent in vigourous-moderate physical activity measured by two accelerometers

2. Physical fitness: handgrip strength measured by dynamometer; heart rate measured by heart rate monitor belt after a 4 min step test
3. Motor function: fine and gross motor tasks measured by Bruininks Motor Ability Test
4. Lung function: expiratory airflow, FEV1 and FEV1/FVC measured by spirometry
5. Cardiac autonomic function: parasympathetic function as indicated by heart rate variability high-frequency power and mean root mean square of successive differences measured by heart rate monitor belt
6. Body composition: body fat percentage measured by bioimpedance
7. Ophthalmic: ETDRS visual acuity measured by ETDRS chart and macular anatomical status measured by optical coherence tomography
8. Health-related quality of life: Mental and physical health-related quality of life measured by SF-36 component summary scores
9. Impaired glucose tolerance or type 2 diabetes: 75 g oral glucose tolerance test (HeSVA only)

### Key secondary outcome(s))
As above:
1. Body size and composition: lean body mass measured by bioimpedance, waist circumference measured by a tape measure
2. Lung health: history of obstructive airways disease diagnosis, wheezing or persistent cough measured by questionnaire
3. Motor function: manual dexterity measured byGrooved Pegboard Test, gross motor performance measured by High-level mobility Assessment Tool
4. Ophthalmic: contrast sensitivity measured by functional acuity contrast test (HeSVA) and Vistech chart (NTNU), visual fields measured by Octopus (HeSVA) and Humphrey field analyser (NTNU), anatomical papillae status measured by optical coherence tomography, (NTNU only: visual processing measured by visual evoked potentials and EEG)
5. Psychiatric symptoms: internalising and externalising problem scores measured by ASEBA questionnaire, depressive and anxiety symptoms measured by Beck Depression Inventory and Beck Anxiety Inventory, (HeSVA only: MINI structured psychiatric interview)
6. Cardiac autonomic function: time and frequency domain heart rate variability indices, office blood pressure measured by automated blood pressure monitor
7. Executive function: BRIEF-A questionnaire

### Completion date
31/12/2020

## Eligibility

### Key inclusion criteria
Adults belonging to the original birth cohorts born 1978-85 (Helsinki) and 1986-88 (Trondheim).

### Participant type(s)
Other

### Healthy volunteers allowed
No

### Age group
Adult

### Sex

All

### Total final enrolment
351

### Key exclusion criteria
Congenital syndromes and anomalies (NTNU), severe disability that makes testing or providing consent impossible

### Date of first enrolment
01/09/2019

### Date of final enrolment
31/12/2020

## Locations

### Countries of recruitment
Finland

Norway

### Study participating centre
**Finnish Institute for Health and Welfare (THL)**
Finnish Institute for Health and Welfare
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### Study participating centre
**Norwegian University of Science and Technology (NTNU)**
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## Sponsor information

### Organisation
National Institute for Health and Welfare

**ROR**
https://ror.org/03tf0c761

**Organisation**
Norwegian University of Science and Technology

**ROR**
https://ror.org/05xg72x27

# Funder(s)

**Funder type**
Hospital/treatment centre

**Funder Name**
The joint research committee of St. Olavs hospital HF and the Faculty of Medicine, NTNU

**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**
Horizon 2020

**Alternative Name(s)**
EU Framework Programme for Research and Innovation, Horizon 2020 - Research and Innovation Framework Programme, European Union Framework Programme for Research and Innovation

**Funding Body Type**
Government organisation

**Funding Body Subtype**
National government

**Location**

**Funder Name**
Lastentautien Tutkimussäätiö

**Alternative Name(s)**
Foundation for Pediatric Research, Stiftelsen för Pediatrisk Forskning

**Funding Body Type**
Private sector organisation

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

**Location**
Finland

**Funder Name**
Sigrid Juséliuksen Säätiö

**Alternative Name(s)**
Sigrid Jusélius Foundation, Sigrid Jusélius Stiftelse

**Funding Body Type**
Private sector organisation

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

**Location**
Finland

**Funder Name**
Signe och Ane Gyllenbergs stiftelse

**Funder Name**
Helsinki University Hospital Governmental Special Subsidiary (VTR)

**Funder Name**
Silmätautien tutkimussäätiö

# Results and Publications

## Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request. Researchers interested in analysing participant-level data are requested to contact the principal investigators. All sharing of individual data must be consistent with the consent the participants have signed.

## IPD sharing plan summary

Available on request

## Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | | 12/05/2023 | 06/06/2023 | Yes | No |
| Results article | | 01/03/2023 | 06/06/2023 | Yes | No |
| Results article | | 14/09/2022 | 06/06/2023 | Yes | No |
| Results article | | 24/03/2022 | 06/06/2023 | Yes | No |
| Results article | Body composition | 16/11/2023 | 08/08/2024 | Yes | No |
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |
| Study website | Study website | 11/11/2025 | 11/11/2025 | No | Yes |