

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 10/06/2020	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 08/08/2024	Condition category Neonatal Diseases	<input type="checkbox"/> 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 have 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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Study website

<https://www.ntnu.edu/ikom/lbw#/view/about> <http://thl.fi/hesva>

Contact information

Type(s)

Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design

Cohort study

Study setting(s)

Community

Study type(s)

Other

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet.

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 measure

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 vigorous-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)

Secondary outcome measures

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 by Grooved 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

Overall study start date

01/01/2018

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

Age group

Adult

Sex

Both

Target number of participants

400

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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Helsinki
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Study participating centre
Norwegian University of Science and Technology (NTNU)
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Sponsor information

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Sponsor type
Government

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Sponsor type
University/education

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<http://www.ntnu.edu>

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)
Suomen Akatemia, Finlands Akademi, Academy of Finland, AKA

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

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

Publication and dissemination plan

The results will be published on the primary and secondary outcome measures in international peer-reviewed open access journals and presented at international conferences. The results will be published on a group level - for example those born preterm are compared on average with those born at term - such that it will not be possible to recognise individuals from the publications.

Health authorities and the general public will be reached through media, popular science webpages, webpages of our NTNU LBW Life research group (www.ntnu.no/ikom/langtidsoppfolging) and webpages of HeSVA (<http://thl.fi/hesva>) and NTNU LBW Life research groups (<https://www.ntnu.edu/ikom/lbw#/view/about>).

Intention to publish date

01/06/2021

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