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Brain health in very old people, long-term time trends and associated social and health-related factors – the Gerontological Database study

Submission date 23/04/2025	**Recruitment status** Recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 28/04/2025	**Overall study status** Ongoing	
Last Edited 25/04/2025	**Condition category** Other	

Plain English summary of protocol

Background and study aims
As people live longer, dementia and depression are affecting an increasing number of those aged 85 years and older. The risk of brain-related health conditions, such as dementia and depression, rises with age, posing a threat to overall health and well-being while also placing significant strain on societal and healthcare systems. However, most research has focused on younger, healthier groups, leaving many questions about brain health among the oldest adults unanswered. This project aims to study brain health in very old adults living in Västerbotten (Sweden), Österbotten (Finland), and Åland (Finland). This project will investigate cognitive function (how one thinks and remembers things) and mental well-being (how one feels emotionally), as well as various factors that might affect these aspects of health.

Who can participate?
People aged 85, 90, and 95 years and older living in Umeå, Malå, Sorsele, Storuman, Vilhelmina and Dorotea in Sweden, and those aged 85, 90 or 95 years and older living in Vaasa, Korsholm, Malax, Korsnäs or the Åland islands in Finland.

What does the study involve?
A trained assessor will visit participants at home, including aged care facilities, to conduct structured interviews and assessments. The interview consists of questions pertaining to social relationships, health and mood, and the assessments include, but are not limited to, cognitive tests, vision and hearing tests, gait speed evaluations and physical assessments such as blood pressure measurements and capillary blood tests.

What are the possible benefits and risks of participating?
The benefits of participating in the study include contributing towards research aiming to promote the health and quality of life of very old adults, as well as potentially gaining increased insight into one’s own health status. As the study population consists of older adults, many of whom may be vulnerable, there is a risk of psychological distress when participating in the study. This risk has been minimized by providing contact details to the research team, including medical doctors, who will provide support and referrals as necessary.

Where is the study run from?
Umeå University (Sweden)

When is the study starting and how long is it expected to run for?
Sepetember 2023 to December 2030

Who is funding the study?
1. Demensfonden (Sweden)
2. BAS-ALF medel (Region Västerbotten) (Sweden)

Who is the main contact?
Prof.r Birgitta Olofsson, birgitta.olofsson@umu.se

Contact information

Type(s)
Public, Scientific, Principal investigator

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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
Biopsychosocial correlates, regional variations and long-term trends of brain health in very old adults, the BRAIN HEALTH project

Acronym
GERDA= GERontological DAtabase

Study objectives
Explore brain health by investigating cognitive functioning and mental well-being in very old adults (aged 85-, 90-, and ≥95-year) including prevalence, interconnections, long-term temporal trends, associated social and health-related factors and blood biomarkers, in three Nordic regions (Västerbotten, Sweden; Österbotten, Finland and Åland, Finland).

Ethics approval required
Ethics approval required

Ethics approval(s)
1. approved 19/03/2025, Swedish Ethical Review Authority (Box 2110, Uppsala, 750 02, Sweden; +46 (0)10 475 08 00; registrator@etikprovning.se), ref: Dnr 2025-01089-01

2. notYetSubmitted, Ethics committee name not provided (Address not provided, Wasa, Zip /postal code not provided, Finland; Telephone number not provided; Email not provided), ref: Reference number not provided

3. notYetSubmitted, Ethics committee name not provided (Address not provided, Mariehamn, Zip /postal code not provided, Åland Islands; Telephone number not provided; Email not provided), ref: Reference number not provided

Study design
Observational study (longitudinal and cross-sectional)

Primary study design
Observational

Study type(s)
Diagnostic, Other, Prevention, Quality of life, Screening, Treatment, Safety, Efficacy

Health condition(s) or problem(s) studied
Participants' health and well-being, living conditions, etc, are studied in relation to brain health (cognitive function and mental well-being)

Interventions
Home visits will be conducted using structured interviews with validated assessments in 2025-2027 in Umeå and five rural municipalities in Västerbotten, in Vasa and three rural municipalities in Osterbotten and Åland. Assessors will receive comprehensive training and supervision to ensure consistency and data quality. Interviews will take place at participants’ homes, residential care facilities, or, if preferred, in a clinic or hospital. Additional interviews with next of kin and caregivers, along with medical record reviews (when approved), will complement the assessments. This approach ensures participation regardless of physical or cognitive impairments and maintains high data quality.

Intervention Type
Other

Primary outcome(s)
1. Dementia disorders measured using the Mini Mental State Examination (MMSE), the Frontal Assessment Battery (FAB), and the Organic Brain Scale (OBS) during the home visits
2. Depressive disorders measured using the Geriatric Depression Scale 15-item version (GDS-15),

the Life Orientation Scale (LOS), the Philadelphia Geriatric Center Morale Scale (PGCMS), the Hospital Anxiety and Depression Scale (HAD) and the Organic Brain Syndrome Scale (OBS) during the home visits

Measured at home visits in 2000/2002 and every 5 years (except in 2020/2022 due to the COVID-19 pandemic) until 2025/2027

Key secondary outcome(s))
1. Health-related factors measured using self-rated health, the Mini Nutritional Assessment (MNA), the Global Leadership Initiative on Malnutrition (GLIM) criteria, the Katz Activities of Daily Living (KATZ-ADL) staircase (Personal and Instrumental ADL), the BARTHEL ADL index, the International Physical Activity Questionnaire Expanded Version (IPAQE-80+), the Frändin Grimby activity scale (summer/winter), and by collecting data on diseases, medications, hospitalization, vision, hearing, pain, sleep, tobacco, alcohol, dizziness, biomarkers and immunomarkers, different aids, outdoor activities, 30 sec chair stand test, gait speed, handgrip (isometric handgrip strength), body composition, height, weight, blood pressure, pulse, oral health, dental status, falls and fear of falling during the home visits
2. Psychosocial factors measured by collecting data on leisure activities, social interactions, loneliness, number of contacts, informal caregiving, pets, inner strength, life crises, ageism, safety, and digital technology use during the home visits

Measured at home visits in 2000/2002 and every 5 years (except in 2020/2022 due to the COVID-19 pandemic) until 2025/2027

Completion date
31/12/2030

Eligibility

Key inclusion criteria
1. Being 85 years old, 90 years old or 95 years or older
2. Living in the municipality of Umeå (Sweden 2025-2026), Vasa (+ three municipalities in Österbotten) and Åland (Finland 2025-2026) and five rural municipalities in Sweden (Sorsele, Malå, Storuman, Vilhelmina and Dorotea) in 2027

Participant type(s)
Population, Other

Healthy volunteers allowed
No

Age group
Senior

Lower age limit
85 years

Upper age limit
120 years

Sex

All

Key exclusion criteria
Does not meet the inclusion criteria

Date of first enrolment
30/04/2025

Date of final enrolment
31/12/2027

Locations

Countries of recruitment
Åland Islands

Finland

Sweden

Study participating centre
Department of Nursing
Umeå Universitet
Umeå
Sweden
901 87

Study participating centre
Ab Yrkeshögskolan vid Åbo Akademi/Yrkeshögskolan Novia
Wolffskavägen 33
Vasa
Finland
652 00

Study participating centre
Högskolan på Åland
PB 1010
Mariehamn
Åland Islands
221 11

Sponsor information

Organisation
Umeå University

ROR
https://ror.org/05kb8h459

Funder(s)

Funder type
Charity

Funder Name
Demensfonden

Alternative Name(s)
Dementia Fund, Stiftelsen Demensfonden

Funding Body Type
Private sector organisation

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

Location
Sweden

Funder Name
BAS ALF-medel (Region Västerbotten)

Results and Publications

Individual participant data (IPD) sharing plan
The project involves sensitive data from the Gerontological Regional Database (GERDA) and newly collected datasets. In compliance with legal and ethical standards, including the GDPR and Biobank Act, all data will be pseudonymized, encrypted, and stored in access-controlled environments. Personal identifiers will be removed before data access is granted. Pseudonymized data will only be shared upon request and under strict protocols, ensuring that only authorized researchers can access it. All reported findings will be presented in aggregate form to prevent individual identification. Metadata will be published at researchdata.se according to FAIR principles through the Swedish National Data Service (SND), enabling future research and ensuring transparency.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Study website	Study website	11/11/2025	11/11/2025	No	Yes