

# **VIPVIZA Visualization of asymptomatic Atherosclerotic disease for optimum cardiovascular prevention – a randomized controlled trial nested in the Västerbotten Intervention Program - Psychological factors and reactions to the VIPVIZA intervention (Problem management), 3 years**

**SND-ID:** 2020-204-9.

## **Alternative title**

VIPVIZA

## **Creator/Principal investigator(s)**

[Margareta Norberg](#) - Umeå University, Department of Epidemiology and Global Health

Steven Nordin - Umeå University, Department of Psychology

Bernt Lindahl - Umeå University, Department of Public Health and Clinical Medicine

Umeå University, Department of Public Health and Clinical Medicine

## **Research principal**

[Umeå University](#) - Department of Public Health and Clinical Medicine

## **Description**

The aim of the project is to develop better methods for prevention of cardiovascular diseases (CVD). It is based on the hypothesis that image-based information on subclinical atherosclerosis (i) increases the precision in the assessment of risk of CVD, (ii) improves communication and understanding of the risk, and as a consequence (iii) the motivation for and adherence to evidence-based pharmacological treatment and lifestyle modification will increase. In addition to conventional risk factor assessment and CVD prevention within the framework of Västerbotten Intervention Program.

3500 healthy participants with low/moderate risk of CVD underwent ultrasound examination of the carotid arteries and were randomized to two groups. In the intervention group, the participants and their doctors received pictorial and graphic information in color about the participant's subclinical atherosclerosis. No information about the ultrasound results was given to the control group. Follow-up after 1, 3 and 6.5 years includes sampling regarding clinical risk factors, blood for biomarker analyses, extensive questionnaires and interviews.

At 3 and 6.5 years the ultrasound examination was repeated and all participants and their doctors were informed about the results. The database also includes register data regarding prescriptions of preventive medication, exposure data for air pollutants, data from health examinations within the VIP 10 and 20 years before VIPVIZA, and for men conscription data.

After 10 years, registry data on endpoints, CVD morbidity and mortality will be collected.

Access to VIPVIZA's data portal and research data from VIPVIZA is possible in collaboration with researchers within the VIPVIZA project. For further information, contact PI Ulf Näslund

[ulf.naslund@umu.se](mailto:ulf.naslund@umu.se)

Validated questionnaires on psychological factors of importance for the development of CVD.  
Examples: Health literacy, anxiety/depression, coping mechanisms, general self efficacy, stress/burnout, optimism/pessimism, self-rated risk of CVD, Burnout.  
Self-rated risk of CVD, specific self efficacy, attitudes to life style habits  
Intervention group: Reactions to and impact of the ultrasound report

**Data contains personal data**

Yes

**Sensitive personal data**

Yes

**Type of personal data**

Medical data at individual level

**Code key exists**

Yes

**Language**

[English](#)

**Unit of analysis**

[Individual/Patient](#)

**Population**

Healthy subjects aged 40-60 years at low/moderate risk of cardiovascular disease

**Study design**

Randomised controlled trial (RCT)

**Description of study design**

Pagmatic open-label, randomised controlled trial with masked evaluators (PROBE)

**Sampling procedure**

[Other](#)

Subjects having at least one cardiovascular risk factor at the occasion of participation in the Västerbotten INtervention Programme: 1) age 40 years and a first-degree relative with a history of cardiovascular disease at an age younger than 60 years, abdominal obesity, hypertension, diabetes, LDL-cholesterol  $\geq 4.5$  mmol/l, smoking. 3) Age 60 years.

Exclusion criterion: More than 50% narrowing of the lumen of carotid arteries

**Time period(s) investigated**

2013-04-29 - Ongoing

**Biobank is connected to the study**

Yes

## Data format / data structure

[Numeric](#)

[Text](#)

## Data collection 1

- Mode of collection: Self-administered questionnaire
- Time period(s) for data collection: 2016-09-05 – 2019-05-28
- Instrument: GSE General Self Efficacy Scale - Self-report measure of general self-efficacy, an individual's belief in his or her capacity to execute behaviors necessary to produce performance attainments
- Instrument: LOT-R Life Orientation Test - Revised - Self-report instrument that assesses one's dispositional level of optimism/pessimism
- Instrument: Brief Cope - Self-report questionnaire designed to measure effective and ineffective ways to cope with a stressful life event
- Instrument: Specific VIPVIZA questionnaire - Self-rated risk of CVDm Specific self-efficacy, attitudes and norms related to life style habits. To the intervention group: Emotional and cognitive reactions and impact of the intervention
- Instrument: BHLS Brief Health Literacy Screen - Three questions on self-rated health literacy, according to Chew
- Instrument: HADS Hospital Anxiety Depression Scale - Self-assessment form for anxiety (subscale HADS-anxiety, 7 questions) and depression (subscale HADS-depression, 7 questions)
- Instrument: SMBQ Shirom-Melamed Burnout Questionnaire - Questionnaire to evaluate burnout

## Geographic spread

Geographic location: [Västerbotten County](#)

Geographic description: Region Västerbotten

## Highest geographic unit

Region

## Responsible department/unit

Department of Public Health and Clinical Medicine

## Contributor(s)

Wolfgang Lohr - Umeå University, Department of Epidemiology and Global Health

## Funding 1

- Funding agency: The Swedish Research Council
- Funding agency's reference number: Dnr 521-2013-2708, 2016-01891, 2017-02246

## Funding 2

- Funding agency: Region Västerbotten
- Funding agency's reference number: ALFVLL-298001, ALFVLL-643391

## Funding 3

- Funding agency: The Heart and Lung Foundation
- Funding agency's reference number: Dnr 20150369, 20170481)

#### **Funding 4**

- Funding agency: SKANDIA Risk & Health

#### **Funding 5**

- Funding agency: Swedish Society of Medicine
- Funding agency's reference number: 405351, 503111

#### **Funding 6**

- Funding agency: Carl Bennet Ltd, Sweden

#### **Funding 7**

- Funding agency: Visare Norr (the four Northern Regions)
- Funding agency's reference number: 465621, 561591, 741711, 931135

#### **Funding 8**

- Funding agency: The Heart Foundation in Northern Sweden

#### **Funding 9**

- Funding agency: The Swedish Insurance Society

#### **Ethics Review**

Swedish Ethical Review Authority - Ref. Dnr 2011-441-31M. Amendments: Dnr 2012-463-32M, Dnr 2013-373-32M, Dnr 2016-245-32M, Dnr 2017-95-32M, Dnr 2018-182-32, Dnr 2018-482-32M, Dnr 2019-0691, Dnr Ö 23-2020/3.1

#### **Research area**

[Cardiac and cardiovascular systems](#) (Standard för svensk indelning av forskningsämnen 2011)

[Radiology, nuclear medicine and medical imaging](#) (Standard för svensk indelning av forskningsämnen 2011)

[Clinical laboratory medicine](#) (Standard för svensk indelning av forskningsämnen 2011)

[General practice](#) (Standard för svensk indelning av forskningsämnen 2011)

[Public health, global health, social medicine and epidemiology](#) (Standard för svensk indelning av forskningsämnen 2011)

[Medical biotechnology \(focus on cell biology \(incl. stem cell biology\), molecular biology, microbiology, biochemistry or biopharmacy\)](#) (Standard för svensk indelning av forskningsämnen 2011)

[Psychology](#) (Standard för svensk indelning av forskningsämnen 2011)

#### **Keywords**

[Cardiovascular diseases](#), [Primary prevention](#), [Randomized controlled trial](#), [Risk assessment](#), [Risk reduction behavior](#), [Plaque](#), [Arteriosclerosis](#)

#### **Publications**

Bengtsson, A., Norberg, M., Ng, N., Carlberg, B., Grönlund, C., Hultdin, J., ... & Näslund, U. (2021). The beneficial effect over 3 years by pictorial information to patients and their physician about subclinical atherosclerosis and cardiovascular risk: Results from the VIPVIZA randomized clinical trial. American

Journal of Preventive Cardiology, 7, 100199.

**DOI:** <https://doi.org/10.1016/j.ajpc.2021.100199>

Vanoli, D. (2017). Vascular ultrasound for the assessment of carotid atherosclerosis [PhD dissertation, Umeå University]. <http://urn.kb.se/resolve?urn=urn:nbn:se:umu:diva-139538>

**ISBN:** 978-91-7601-748-7

**URN:** <urn:nbn:se:umu:diva-139538>

Vanoli, D., Lindqvist, P., Wiklund, U., Henein, M., & Näslund, U. (2013). Fully automated on-screen carotid intima-media thickness measurement : a screening tool for subclinical atherosclerosis. *Journal of Clinical Ultrasound*, 41(6), 333–339. <https://doi.org/10.1002/jcu.22041>

**URN:** <urn:nbn:se:umu:diva-78429>

**DOI:** <https://doi.org/10.1002/jcu.22041>

Bengtsson, A., Lindvall, K., Norberg, M., & Fhärm, E. (2021). Increased knowledge makes a difference!—general practitioners' experiences of pictorial information about subclinical atherosclerosis for primary prevention: an interview study from the VIPVIZA trial. *Scandinavian Journal of Primary Health Care*, 39(1), 77-84.

**DOI:** <https://doi.org/10.1080/02813432.2021.1882083>.

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Vanoli, D., Wiklund, U., Lindqvist, P., Henein, M., & Näslund, U. (2014). Successful novice's training in obtaining accurate assessment of carotid IMT using an automated ultrasound system. *European Heart Journal Cardiovascular Imaging*, 15(6), 637–642. <https://doi.org/10.1093/ehjci/jet254>

**DOI:** <https://doi.org/10.1093/ehjci/jet254>

**URN:** <urn:nbn:se:umu:diva-91057>

Lindahl, B., Norberg, M., Johansson, H., Lindvall, K., Ng, N., Nordin, M., Nordin, S., Näslund, U., Persson, A., Vanoli, D., & Schulz, P. J. (2020). Health literacy is independently and inversely associated with carotid artery plaques and cardiovascular risk. *European Journal of Preventive Cardiology*, 27(2), 209–215. <https://doi.org/10.1177/2047487319882821>

**DOI:** <https://doi.org/10.1177/2047487319882821>

**URN:** <urn:nbn:se:umu:diva-165791>

Nyman, E., Vanoli, D., Näslund, U., & Grönlund, C. (2020). Inter-sonographer reproducibility of carotid ultrasound plaque detection using Mannheim consensus in subclinical atherosclerosis. *Clinical Physiology and Functional Imaging*, 40(1), 46–51. <https://doi.org/10.1111/cpf.12602>

**DOI:** <https://doi.org/10.1111/cpf.12602>

**URN:** <urn:nbn:se:umu:diva-165443>

Näslund, U., Ng, N., Lundgren, A., Fhärm, E., Grönlund, C., Johansson, H., Lindahl, B., Lindahl, B., Lindvall, K., Nilsson, S. K., Nordin, M., Nordin, S., Nyman, E., Rocklöv, J., Vanoli, D., Weinehall, L., Wennberg, P., Wester, P., & Norberg, M. (2019). Visualization of asymptomatic atherosclerotic disease for optimum cardiovascular prevention (VIPVIZA) : a pragmatic, open-label, randomised controlled trial. *The Lancet*, 393(10167), 133–142. [https://doi.org/10.1016/S0140-6736\(18\)32818-6](https://doi.org/10.1016/S0140-6736(18)32818-6)

**DOI:** [https://doi.org/10.1016/S0140-6736\(18\)32818-6](https://doi.org/10.1016/S0140-6736(18)32818-6)

**URN:** <urn:nbn:se:umu:diva-154318>

Nyman, E., Lindqvist, P., Näslund, U., & Grönlund, C. (2018). Risk Marker Variability in Subclinical Carotid Plaques Based on Ultrasound is Influenced by Cardiac Phase, Echogenicity and Size. *Ultrasound in medicine & biology*, 44(8), 1742–1750.

**DOI:** <https://doi.org/10.1016/j.ultrasmedbio.2018.03.013>

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### **Accessibility level**

Access to data through an external actor  
Access to data is restricted

### **Homepage**

[VIPVIZA](#)

### **Contact for questions about the data**

Ulf Näslund

[ulf.naslund@umu.se](mailto:ulf.naslund@umu.se)

### **Related research data in SND's catalogue**

[Northern Sweden Diet Database \(NSDD\)](#)

[NSHDS-VIP](#)

[VIPVIZA VisualiZation of asymptomatic Atherosclerotic disease for optimum cardiovascular prevention – a randomized controlled trial nested in the Västerbotten Intervention Program - VIPVIZA - Included study participants](#)

[VIPVIZA VisualiZation of asymptomatic Atherosclerotic disease for optimum cardiovascular prevention – a randomized controlled trial nested in the Västerbotten Intervention Program - VIP baseline \(lifestyle\)](#)

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[VIPVIZA VisualiZation of asymptomatic Atherosclerotic disease for optimum cardiovascular prevention – a randomized controlled trial nested in the Västerbotten Intervention Program - Clinical CVD risk factors and lifestyle habits 3 year](#)

[VIPVIZA VisualiZation of asymptomatic Atherosclerotic disease for optimum cardiovascular prevention – a randomized controlled trial nested in the Västerbotten Intervention Program - Ultrasound baseline](#)

[VIPVIZA VisualiZation of asymptomatic Atherosclerotic disease for optimum cardiovascular prevention – a randomized controlled trial nested in the Västerbotten Intervention Program - Ultrasound 3 year](#)

[VIPVIZA VisualiZation of asymptomatic Atherosclerotic disease for optimum cardiovascular prevention – a randomized controlled trial nested in the Västerbotten Intervention Program - Psychological \(Problem management\) , baseline](#)

[VIPVIZA VisualiZation of asymptomatic Atherosclerotic disease for optimum cardiovascular prevention – a randomized controlled trial nested in the Västerbotten Intervention Program - The Swedish Prescribed Drug Register](#)

[VIPVIZA VisualiZation of asymptomatic Atherosclerotic disease for optimum cardiovascular prevention – a randomized controlled trial nested in the Västerbotten Intervention Program - VIP Historical data 10 years before baseline](#)

[VIPVIZA VisualiZation of asymptomatic Atherosclerotic disease for optimum cardiovascular prevention](#)

[– a randomized controlled trial nested in the Västerbotten Intervention Program - VIP historical data 20 years before baseline](#)

[VIPVIZA VisualiZation of asymptomatic Atherosclerotic disease for optimum cardiovascular prevention – a randomized controlled trial nested in the Västerbotten Intervention Program - Military service mustering register](#)

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