# The Good Health Retrospective Data Analysis

Submission date	Recruitment status	<ul><li>Prospectively registered</li></ul>
25/06/2025	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
21/07/2025	Ongoing	Results
Last Edited	Condition category	Individual participant data
23/07/2025	Other	[X] Record updated in last year

#### Plain English summary of protocol

Background and study aims

Health is a complex area of research involving various areas and the network of interactions between physical, mental, and social well-being domains. Micronutrient status appears to be closely tied to health. Every 4 to 5 years, Austrian nutrition reports publish an assessment of the nutritional status of the population, which also analyzes the supply of essential micronutrients. These reports generally form a basis in the food and nutrition sector, not only on a national level, but also on a European and international level. Continuous publication of the nutrition reports in Austria ensures regular monitoring and access to the nutritional status of the population. However, the initial situation of the individual respondent, including personal metabolism, cannot be taken into account when making mathematical conclusions about the supply status, as the previous nutritional reports have done thus far. For example, using food tables, random error ranges from 2 to 20 % for individual estimates of iron and calcium have been reported. Additionally, food estimations based on frequency reports involve errors up to 90 %, and are typically in the 20-50 % range. Therefore, this study aims to retrospectively analyze the micronutrient status of a large sample of healthy Austrian adults, and to identify possible differences in the micronutrient status based on various factors, solely based on retrospective data analyses in 2025 of an already existing data set.

### Who can participate?

Adults 20 to 65 years of age and residing in Austria. Participants are enrolled on a voluntary basis via direct contact with registered physicians in primary care offices. The region for involvement is Austria, nationwide and voluntary in all cases.

#### What does the study involve?

Analysis of sociodemographic-anthropometric variables: region of residence in Austria, sex, age, body weight, calculated body mass index (BMI), including a questionnaire with self-reported measures for diet pattern; physical activity levels; alcohol and nicotine consumption; supplement intake; medication intake (based on sex, age, substance prevalence); and a blood sample.

What are the possible benefits and risks of participating? As this is a retrospective study, there is no direct involvement or risk for the patients.

Where is the study run from? University of Innsbruck (Austria)

When is the study starting and how long is it expected to run for? The study began in March 2023 and will end in December 2025.

Who is funding the study? BIOGENA GmbH & Co KG (Austria)

Who is the main contact? Prof. Dr. rer. nat. Katharina Wirnitzer, katharina.wirnitzer@uibk.ac.at

# Contact information

#### Type(s)

Public, Scientific, Principal Investigator

#### Contact name

Prof Katharina Wirnitzer

#### Contact details

Fürstenweg 185 Innsbruck Austria 6020 +43 (512)507-0 katharina.wirnitzer@uibk.ac.at

# Additional identifiers

## EudraCT/CTIS number

Nil known

**IRAS** number

# ClinicalTrials.gov number

Nil known

# Secondary identifying numbers

P6210-045-011

# Study information

#### Scientific Title

Retrospective data analysis of the micronutrient status of healthy adults in Austria and the relationship with health variables

#### **Acronym**

**GHRDA** 

# **Study objectives**

This research hypothesized that there are distinct associations between blood micronutrient levels and health indicators in adulthood, including blood lipids and body composition.

#### Ethics approval required

Ethics approval not required

#### Ethics approval(s)

Due to the retrospective design, no ethics approval is applicable for the present project. The new medical methods involve treatments after existing conventional medical treatment methods have been exhausted (Section 30 of the Salzburg Hospitals Act). This situation, in combination with the lack of intervention, blood sampling via registered doctors as standardized medical check-up, anonymization of the data and the fact that no ethics vote would have been legally required for an Austrian project with a similar structure - the Austrian Nutrition Report 2012 - and that this was obtained purely on a voluntary basis, leads to the conclusion that no ethics vote was required for the aforementioned research project.

#### Study design

Retrospective data analysis

#### Primary study design

Observational

#### Secondary study design

Cross sectional study

#### Study setting(s)

Laboratory, Workplace

#### Study type(s)

Prevention

#### 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

Micronutrient status of healthy adults in Austria and the relationship with health variables

#### Interventions

This project is retrospective, includes no intervention, and utilizes data from an online questionnaire on sociodemographic characteristics as well as a previous blood collection for micronutrient laboratory analysis.

Sociodemographic-anthropometric variables: region of residence in Austria, sex, age, body weight, calculated body mass index (BMI), including a questionnaire with self-reported measures for diet pattern, physical activity levels, alcohol and nicotine consumption, supplement intake, and medication intake (based on sex, age, substance prevalence).

Blood sample: omega-3-index, cholesterol corrected coenzyme q10, folic acid, ferritin, vitamin B12, vitamin D, vitamin B6, molybdenum, manganese, selenium, zinc, copper, magnesium,

calcium, potassium, iron, soluble transferrin-receptor, hemoglobin, wrCRP, apolipoprotein A, triglycerides, HDL-C, LDL-C, total cholesterol, homocysteine, leukocytes, erythrocytes, hematocrit, mean corpuscular volume, mean corpuscular hemoglobin, mean corpuscular hemoglobin concentration, thrombocytes, and mean platelet volume.

#### **Intervention Type**

Other

#### Primary outcome measure

- 1. Body weight (kg) reported by questionnaire, single cross-sectional assessment
- 2. Body mass index (BMI; kg/m2) calculated from questionnaire, single cross-sectional assessment
- 3. Region of residence in Austria reported by questionnaire, single cross-sectional assessment
- 4. Omega-3-index measured by blood test (% of total Fatty Acids), single cross-sectional assessment
- 5. Cholesterol measured by blood test (mg/dl), single cross-sectional assessment
- 6. Adjusted coenzyme q10 (µmol/mmol Chol) measured by blood test, single cross-sectional assessment
- 7. Folic acid measured by blood test (ng/ml), single cross-sectional assessment
- 8. Ferritin measured by blood test (ng/ml), single cross-sectional assessment
- 9. Vitamin B 12 measured by blood test (pg/ml), single cross-sectional assessment
- 10. Vitamin D measured by blood test (nmol/l), single cross-sectional assessment
- 11. Vitamin B 6 measured by blood test (µg/l), single cross-sectional assessment
- 12. Molybdenum measured by blood test  $(\mu/l)$ , single cross-sectional assessment
- 13. Manganese measured by blood test  $(\mu/l)$ , single cross-sectional assessment
- 14. Selenium measured by blood test  $(\mu/l)$ , single cross-sectional assessment
- 15. Zinc measured by blood test (mg/l), single cross-sectional assessment
- 16. Copper measured by blood test (mg/l), single cross-sectional assessment
- 17. Magnesium measured by blood test (mg/l), single cross-sectional assessment
- 18. Calcium measured by blood test (mg/l), single cross-sectional assessment
- 19. Potassium measured by blood test (mg/l), single cross-sectional assessment
- 20. Iron measured by blood test (mg/l), single cross-sectional assessment
- 21. Soluble transferrin-receptor measured by blood test (mg/l), single cross-sectional assessment
- 22. Hemoglobin measured by blood test (q/dl), single cross-sectional assessment
- 23. wrCRP measured by blood test (mg/l), single cross-sectional assessment
- 24. Apolipoprotein A measured by blood test (q/l), single cross-sectional assessment
- 25. Triglycerides measured by blood test (mg/dl), single cross-sectional assessment
- 26. HDL-C measured by blood test (mg/dl), single cross-sectional assessment
- 27. LDL-C measured by blood test (mg/dl), single cross-sectional assessment
- 28. Homocysteine measured by blood test (µmol/l), single cross-sectional assessment
- 29. Leukocytes measured by blood test (cells/nl), single cross-sectional assessment
- 30. Erythrocytes measured by blood test (cells/pl), single cross-sectional assessment
- 31. Hematocrit measured by blood test (V%), single cross-sectional assessment
- 32. Mean corpuscular volume measured by blood test (fl), single cross-sectional assessment
- 33. Mean corpuscular hemoglobin measured by blood test (pg), single cross-sectional assessment
- 34. Mean corpuscular hemoglobin concentration measured by blood test (g/dl Ery), single cross-sectional assessment
- 35. Thrombocytes measured by blood test (cells/nl), single cross-sectional assessment
- 36. Mean platelet volume measured by blood test (fl), single cross-sectional assessment

#### Secondary outcome measures

- 1. Physical activity levels reported by questionnaire (WHO PA guidelines 150-300 min/week), single cross-sectional assessment
- 2. Dietary pattern reported by questionnaire, single cross-sectional assessment
- 3. Diastolic blood pressure assessed during medical check-up examination (mmHg), single cross-sectional assessment
- 4. Alcohol consumption reported by questionnaire, single cross-sectional assessment
- 5. Smoking prevalence reported by questionnaire, single cross-sectional assessment
- 6. Supplement intake reported by questionnaire, single cross-sectional assessment
- 7. Medication intake reported by questionnaire, single cross-sectional assessment

#### Overall study start date

01/03/2023

#### Completion date

31/12/2025

# Eligibility

#### Key inclusion criteria

- 1. Reside in Austria
- 2. Aged at least 20 years
- 3. No severe health ailments

#### Participant type(s)

Healthy volunteer

#### Age group

Adult

#### Lower age limit

20 Years

#### Upper age limit

65 Years

#### Sex

Both

#### Target number of participants

488 (based on power analysis, estimated 94% power)

#### Total final enrolment

1377

#### Key exclusion criteria

- 1. Failing to provide written informed consent
- 2. Being younger than 20 years or older than 65 years
- 3. Lactating or pregnant
- 4. Being diagnosed with a severe health condition (such as diabetes, cardiovascular disease, hypertension, specific allergies, chronic lung disease, liver disease, musculoskeletal disorders,

cancer, mental illness, chronic pain, or COVID-19)

- 5. Taking medications for severe illnesses (whether prescribed or self-administered)
- 6. Incomplete questionnaires or lacking responses to key questions

#### Date of first enrolment

25/03/2021

#### Date of final enrolment

27/04/2021

# Locations

#### Countries of recruitment

Austria

# Study participating centre University of Innsbruck

Fürstenweg 185 Innsbruck Austria 6020

# Sponsor information

#### Organisation

BIOGENA GmbH & Co KG

#### Sponsor details

Strubergasse 24
Salzburg
Austria
5020
+43 (0)662 23 11 11-0
info@biogena.com

#### Sponsor type

Industry

#### Website

https://www.biogena.com

# Funder(s)

# Funder type

Industry

#### Funder Name

BIOGENA GmbH & Co KG

# **Results and Publications**

#### Publication and dissemination plan

Planned publication in a peer-reviewed journal

#### Intention to publish date

31/12/2026

### Individual participant data (IPD) sharing plan

Data will be used and analyzed exclusively and only in the context of the study. The datasets generated and/or analyzed during the current study are not expected to be made available due to data security laws and protection.

## IPD sharing plan summary

Not expected to be made available