

## **Information for Research Participants**

We would like to ask whether you would like to participate in a research project. This document provides information about the project and what participation would involve.

### **What is this project and why do we want you to participate?**

Today, more and more people are recommended to eat more plant-based foods in order to benefit both health and the environment. Plant-based protein sources, such as legumes and cereals, often contain a great deal of dietary fibre and other substances that are not completely broken down in the small intestine. Instead, they reach the colon, where they influence the gut bacteria and the substances these bacteria produce. These substances may in turn affect, for example, metabolism, immune function and gastrointestinal health.

However, we still know relatively little about how the specific combination of plant protein and dietary fibre is broken down in the gastrointestinal tract in different individuals, and how this relates to health. The aim of the study is to gain a better understanding of how plant-based proteins and dietary fibres are broken down in the gastrointestinal tract, how this affects the gut bacteria, and which breakdown products are formed (for example short-chain fatty acids and other small molecules). We also want to investigate how these processes differ between individuals depending, for example, on gut function, the gut environment (pH), the composition of the gut bacteria, and usual dietary habits.

In the longer term, this knowledge may contribute to better recommendations regarding plant-based diets and protein intake, adapted to the individual's circumstances. You are being asked to participate because you are an adult, live in the region, and meet the study criteria (for example age and otherwise good general health). We obtained access to your contact details because you yourself expressed an interest in the study after receiving our information (for example via an advertisement, poster or mailing), and we are contacting you solely for this purpose. Your participation is entirely voluntary.

Örebro University is the research principal for the project. By research principal we mean the organisation responsible for the project. The research has been approved by the Swedish Ethical Review Authority. The diary number for the ethical review is Dnr 2026-00147-01.

### **How will the project be carried out?**

The research will be conducted during 2026. All visits will take place at Örebro University.

The "screening visit" will take place at X-huset, on campus USÖ, Örebro University (Södra Grev Rosengatan 30, 703 82 Örebro). The visit will take approximately 45 minutes. During this meeting you will receive verbal information about the study and all related activities, schedules and procedures.

At the screening visit you will also complete a questionnaire about your general health background, medication use, weight and height. The health background questionnaire will be used to assess whether you are eligible to participate in the study according to the inclusion and exclusion criteria. If you meet the study's inclusion and exclusion criteria and still wish to participate in the study, you must sign a consent form.

If you take part in the study, you will attend four visits to the study centre (X-huset, campus USÖ). The visits will be at least one week apart. Before each visit you will fast overnight (10-12 hours), complete questionnaires about diet, physical activity, gastrointestinal symptoms and your bowel habits, and collect stool samples at home using a special collection kit (EasySampler). At each visit you will hand in the samples and eat a standardised breakfast consisting of a protein-rich drink (with oat protein) and a

muffin containing blue food colouring, either with or without extra dietary fibre. You will eat the breakfast under supervision within approximately 15 minutes and will then receive instructions on when you may start drinking (after 2 hours) and eating (after 4 hours) for the rest of the day.

During the study you will also collect additional stool samples after the breakfast. You will use the same collection kit at home or at the hospital and take small subsamples (up to approximately four small containers on each occasion). Samples are collected until you see blue colour in the stool, which shows when the eaten meal has passed through the gut. The total amount of stool stored on each occasion is at most about 40 grams (roughly a couple of tablespoons). During the study period you will also wear a small glucose sensor on the skin that measures blood glucose continuously (for a total of up to 28 days, not necessarily consecutively).

Some participants will also swallow small medical device capsules in connection with the breakfast at at least two of the visits. One capsule measures pH (acidity) in the gastrointestinal tract, another measures internal body temperature, and one capsule collects small amounts of fluid from the small intestine. The capsules are approximately the same size as ordinary medicinal capsules, are powered by a small battery, and pass naturally through the body in the stool. You will receive clear instructions on how to collect the capsules from the stool, store them in a cool place, and hand them in to the study team. While the capsules are still inside the body, you may wear a simple wristband reminding you that you must not undergo an MRI examination before the capsules have passed out of the body.

All of these procedures - the standardised breakfast, the repeated stool samples and the swallowable capsules - are carried out solely for research purposes and are not part of routine healthcare or treatment. Participation in the study does not replace ordinary medical assessment or care, and no clinical decisions will be made on the basis of your samples. The purpose is to collect research data on how plant-based protein and dietary fibre are broken down in the gastrointestinal tract, how this affects gut bacteria, and which substances are formed. Your participation is entirely voluntary, and you may stop participating at any time without giving a reason.

### **Possible consequences and risks of participating in the project**

The foods used in the study (muffin and protein drink) are ordinary food ingredients that are approved as food and used in regular products. The fibres come from wheat- and oat-based ingredients, and blue food colouring is used to track passage through the gut. People with known allergy or intolerance to, for example, wheat, oats, milk, egg, gluten, vegetable oil or the colouring agent will not be included in the study. Stool samples are collected using special collection kits and containers, and these procedures are not expected to involve pain or physical injury, but may be experienced as uncomfortable or sensitive from a privacy perspective by some individuals. In some cases the glucose sensor may cause mild skin irritation where it is attached.

Some participants will swallow small medical device capsules that measure pH (acidity) and body temperature and collect small amounts of fluid from the small intestine. The capsules are about the same size as a normal medicinal capsule that you can swallow with a glass of water. They follow the same route as food through the stomach and intestines and then leave the body naturally in the stool. The capsules are approved medical devices within the EU (CE-marked), and the material they are made of is adapted to remain in the body without damaging tissue. Similar capsules have been used in several clinical studies, and when safety procedures are followed no serious adverse effects have been observed. There is nevertheless a small risk that a capsule may remain in the intestine (so-called retention) or cause discomfort. For this reason, people with increased risk - for example swallowing difficulties, known narrowings or obstructions in the gastrointestinal tract, pregnancy, or a need for MRI

during the measurement period - will not be included in the study. While the capsules are inside the body, you must not undergo MRI, and you will wear a wristband to remind you of this.

You will receive clear instructions on how to collect the capsules from the stool and what to watch out for. If you experience abdominal pain, or if the capsules have not passed after the second bowel movement in which you see blue colour in the stool, you must contact the study team using the telephone numbers you will receive at inclusion. If there is suspicion that a capsule has not passed, a medical assessment will be arranged and, if necessary, the capsule can be located by X-ray or other imaging and removed endoscopically according to ordinary healthcare routines. All side effects or discomfort that arise during the study will be recorded, and the responsible physician will ensure that you receive the necessary medical assessment and care.

### **What happens to your data?**

The project involves collecting and registering information about you, for example your questionnaire responses, measurement data from the glucose sensor and capsules, and results from the samples and examinations carried out in the study. The data are collected directly from you in connection with the study visits. Your identity is protected by marking all data with a specific study code (pseudonymisation) and storing them without your name. The code key is kept locked by the person responsible for the study. The code key is handled so that unauthorised persons cannot access it. Results will always be reported at group level in reports and scientific articles, so that no individual participants can be identified. The data will be stored during the conduct of the study and thereafter for at least ten years after the study has ended, or for as long as required under applicable laws and regulations for research and archiving at Örebro University.

The information collected about you in this study (for example your questionnaire responses and the results from the stool samples) will therefore be stored in coded form. To promote open and secure research, we plan to make parts of the study data available to other researchers in the future. The project has been granted ethical review approval, which is a prerequisite for conducting research on the kind of information collected from you in this study. We want to be able to make the results and data generated by this research project available so that more people can use them. For you, this means that data collected from questionnaires and samples may, upon request, be shared with researchers or others who are interested in the material underlying the results we have reached in the study. The parts that contain information requiring ethical approval will only be disclosed for research purposes after review and confirmation of the necessary permits.

If an individual requests access to data as an official public document, this may result in data being disclosed unless there is legal support for refusing disclosure. All data shared externally will be in de-identified form, which means that recipients will not know who you are and will not have access to the code key. The data may be made available through secure research databases or shared with researchers in Sweden or abroad, when this is compatible with Swedish law, the General Data Protection Regulation (GDPR) and the relevant ethical approval. If data are transferred to a country outside the EU/EEA (a third country), this will only take place if that country is covered by an adequacy decision or if other appropriate safeguards, for example standard contractual clauses, are used. Information about such safeguards can be obtained from Örebro University. Results will also in these contexts always be reported at group level.

You may stop participating in the study at any time and request that your stored coded data and samples not be used in new analyses. However, data that have already been anonymised or that are included in completed analyses or published results normally cannot be deleted afterwards.

Your responses and your results will be handled so that unauthorised persons cannot access them.

Örebro University is responsible for your personal data. Under the EU General Data Protection Regulation, you have the right, free of charge, to access the data about you that are processed in the project and, where necessary, to have any errors corrected. You may also request that data about you be erased and that the processing of your personal data be restricted. However, the right to erasure and the right to restriction of processing do not apply when the data are necessary for the research in question. If you wish to access the data, please contact Robert Brummer (robert.brummer@oru.se; +46 019 303731). The data protection officer can be contacted at dataskyddombud@oru.se. If you are dissatisfied with how your personal data are processed, you have the right to lodge a complaint with the Swedish Authority for Privacy Protection, which is the supervisory authority.

### **What happens to your samples?**

The samples taken in the project will be stored in coded form in a so-called biobank. The name of the biobank is Örebro Biobank (number 454 assigned by the Health and Social Care Inspectorate, IVO), and it is located at Örebro University Hospital (USÖ). The principal (the body responsible) for the biobank is Region Örebro County. All samples will be coded (pseudonymised), which means that they cannot be linked directly to you as a person. The code key is kept locked by the person responsible for the study and handled so that unauthorised persons cannot access it.

The samples will be analysed at Örebro University and Örebro University Hospital (USÖ). In some cases, coded (pseudonymised) samples may be sent to collaborating laboratories within Sweden or in EU/EEA countries for specific analyses. No samples will be sent to countries outside Sweden, that is, not to other EU/EEA countries or to so-called third countries. After analysis is complete, any remaining sample material will be destroyed at the receiving laboratory or sent back to the biobank. The samples will be stored in the biobank for as long as they are needed for the current study and any future research to which you have consented, but for at least ten years after the end of the project or for as long as required by applicable laws and regulations.

You have the right, without giving a reason, to say no to the storage of your samples. If you consent to storage of the samples, you have the right later, and without giving a reason, to withdraw that consent. In that case your samples will be destroyed or de-identified. De-identification means that all links between the sample and you as a person are permanently removed, so that the sample can no longer be traced back to you. If you wish to withdraw consent, please contact Robert Brummer (robert.brummer@oru.se; 019-30 37 31).

The samples may only be used for the purposes to which you have consented. If you agree that we may preserve and use your samples for future research purposes, you must consent specifically to this. If further research is planned that has not yet been described in more detail, the Swedish Ethical Review Authority will assess that project, and it may then decide whether you need to be asked again.

### **How will you receive information about the results of the project?**

In order to gain knowledge from the results, the collected data will be compiled and processed by the principal investigator of the study, Robert Jan Brummer, together with the other persons responsible for the study. A summary of the project results will be published on [www.oru.se/ngbi](http://www.oru.se/ngbi), under the "research projects" tab and by clicking on the name of the study. If you would like to receive your individual analysis results, you may contact the principal investigator of the study, Robert Jan Brummer. If review of the material reveals any abnormal findings, the study-responsible senior consultant Robert Jan Brummer will be contacted by the responsible researchers and reviewing physician, after which you as a study participant will be contacted by Robert Jan Brummer. The study-responsible senior consultant

Robert Brummer is responsible for referring you onwards for further investigation, in agreement with you, should any abnormal findings be identified during review.

### **Insurance and compensation**

If you were to suffer injury during the study, you are insured through the patient insurance scheme (USÖ). Based on the research centre's established reimbursement for study participants, you will receive 800 Swedish kronor (taxable income) for time and inconvenience after completion of the study. Travel costs to and from the study centre will not be reimbursed.

### **Participation is voluntary**

Your participation is voluntary and you may choose to stop participating at any time. If you choose not to participate, or if you want to withdraw your participation, you do not need to state why, and this will not affect your future care or treatment. However, data collected up to the time of withdrawal will be analysed in the study.

If you wish to withdraw your participation, please contact the person responsible for the project (see below).

### **Persons responsible for the project**

Responsible for the project:

#### **Professor Robert Brummer, senior consultant physician**

Department of Medical Sciences  
Nutrition-Gut-Brain Interactions Research Centre  
Örebro University  
Tel: 019-303731  
Email: robert.brummer@oru.se

#### **Samira Prado, researcher**

Department of Medical Sciences  
School of Science and Technology  
Nutrition-Gut-Brain Interactions Research Centre  
Örebro University  
Tel: 019-303470  
Email: samira.prado@oru.se

#### **Victor Castro-Alves, researcher**

School of Science and Technology  
Örebro University  
Tel: 019-302385  
Email: victor.castro-alves@oru.se