Non-invasive monitoring methods to explore gastrointestinal tract dynamics during the breakdown of dietary fibre and protein

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 involves.

What kind of project is this and why do we want you to participate?

Today, more and more people are recommended to eat more plant-based foods to benefit both health and the environment. Plant-based protein sources, such as legumes and cereals, often contain large amounts of dietary fibre and other substances that are not fully broken down in the small intestine. Instead, they reach the large intestine, where they affect the gut bacteria and the substances that these bacteria produce. These substances may, in turn, affect metabolism, the immune system and gastrointestinal health, among other things. However, we still know relatively little about how the combination of plant protein and dietary fibre is broken down in the stomach and intestine in different people, and how this is linked to health. The aim of the study is to better understand how plant-based proteins and dietary fibres are broken down in the gastrointestinal tract, how this affects the gut bacteria and which breakdown products (for example short-chain fatty acids and other small molecules) are formed. We also want to investigate how these processes differ between individuals depending on, for example, 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 on plant-based diets and protein intake, adapted to individual 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 have obtained your contact details because you have personally expressed 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. The research principal for the project is Örebro University. The research principal is the organisation responsible for the project. The research has been approved by the Swedish Ethical Review Authority. The case number for the review at the Swedish Ethical Review Authority 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 meeting for the "screening visit" will take place at X-huset, Campus USÖ, Örebro University (Södra Grev Rosengatan 30, 703 82 Örebro). The meeting 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 background health, medication use, weight and height. The background health 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 inclusion and exclusion criteria and still wish to participate in the study, you must sign a consent form.

If you participate in the study, you will make 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 toilet habits, and collect stool samples at home using a special collection kit (EasySampler or similar). At each visit, you will hand in the samples and eat a standardised breakfast consisting of a protein-rich drink (with oat protein) and muffins with blue food coloring, either with or without added dietary fibre. The breakfast is fully vegan. You will eat the breakfast under supervision within approximately 15 minutes and will then receive instructions about when you may start drinking (after 2 hours) and eating (after 4 hours) during the rest of the day.

During the study, you will collect additional stool samples after the breakfast (one to three times). You will use the same collection kit at home or at the hospital and take small subsamples (up to approximately four small containers per occasion). Samples are collected until you see blue colour in the stool, which shows when the consumed meal has passed through the intestine. During the study period, you will also wear a small glucose sensor on your skin that continuously measures blood glucose (for a total of up to 28 days, not necessarily consecutively).

Some participants will also swallow small medical device capsules one hour after breakfast at at least two of the visits. One capsule measures pH (acidity) in the gastrointestinal tract, another measures body temperature from inside the body, 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 through the body naturally via 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 inside the body, you will wear a simple wristband reminding you (and medical staff) not to undergo an MRI examination until the capsules have passed out of the body.

All 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 any routine healthcare or treatment. Participation in the study does not replace ordinary medical investigation 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 fibres 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 withdraw your participation 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 common products. The fibres come from wheat- and oat-based ingredients, and blue food coloring is used to follow passage through the intestine. People with known allergies or intolerances to, for example, wheat, oats, gluten, almond, vegetable oil or blue food coloring will not be included in the study. Stool samples are collected using special collection kits and containers. These procedures are not expected to cause pain or physical harm, but some people may find them uncomfortable or sensitive from an integrity/privacy perspective. 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 approximately the same size as an ordinary 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 pass out naturally with the stool. The pH and temperature capsules are approved medical devices within the EU (CE-marked), and the material they are made of is designed to remain in the body without damaging tissue. Similar capsules have been used in several clinical studies, and when safety routines are followed, no serious side effects have been observed. Nevertheless, there is a small risk that a capsule may remain in the intestine (so-called retention) or cause discomfort. Therefore, people at increased risk, for example those with swallowing difficulties, known narrowing or obstruction in the gastrointestinal tract, pregnancy, or a need for magnetic resonance imaging (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 reminding you (and medical staff) of this. You will receive clear instructions on how to collect the capsules from the stool and what to pay attention to. If you experience stomach pain, or if the capsules have not passed out after the second bowel movement in which you see blue colour in the stool, you should contact the study team using the telephone numbers you receive at enrolment. If it is suspected that a capsule has not passed out, a medical assessment will be arranged. If necessary, the capsule can be located using X-ray or other imaging diagnostics 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 recording 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 labelling all data with a special study code (pseudonymisation) and storing them without your name. The code key is kept locked by the study lead. 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 safe 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 type of information collected from you in this study. We want the results and data generated by this research project to be made 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 on which the results of the study are based. The parts that contain information requiring ethical review will only be disclosed for research purposes after review and confirmation of the necessary permits.

If an individual requests access to data as a public document, this may lead to data being disclosed if there is no legal basis for refusing disclosure. All data shared externally will be in de-identified form, which means that the 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 current ethical approval. If data are transferred to a country outside the EU/EEA (a third country), this will only take place if the country is covered by an adequacy decision or if other appropriate safeguards, such as standard contractual clauses, are used. Information about such safeguards can be obtained from Örebro University. In these contexts too, results will always be reported at group level.

You may withdraw your participation in the study at any time and request that your stored coded data and samples are not used in new analyses. However, data that have already been anonymised or that are included in completed analyses or published results can normally not 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 to access, free of charge, the data about you that are processed in the project and, if necessary, to have any errors corrected. You can also request that data about you be erased and that the processing of your personal data be restricted. However, the right to erasure and to restriction of processing of personal data does not apply when the data are necessary for the current research. If you want to access the data, you should contact Robert Brummer (robert.brummer@oru.se; +46 019 303731). The Data Protection Officer can be reached at dataskyddsombud@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 are stored in coded form in a biobank. The name of the biobank is Örebro Biobank (number 454, assigned by the Swedish Health and Social Care Inspectorate, IVO), and it is located at Örebro University Hospital (USÖ). The principal (responsible organisation) for the biobank is Region Örebro County. All samples will be coded (pseudonymised), which means that they cannot be directly linked to you as a person. The code key is kept locked by the study lead and is handled so that unauthorised persons cannot access it. The code key and sample-related information are handled by the responsible researcher, but may also be shared with other participating researchers in the project and with the responsible biobank.

The samples will be analysed at Örebro University and Örebro University Hospital (USÖ). Coded samples may be analysed by laboratories or other collaborating partners and companies in Sweden and/or within the EU/EEA. After the analysis has been completed, your samples will be destroyed.

The samples will be stored in the biobank for as long as they are needed for the current study, but no longer than until 2036. All laboratory analyses in Sweden and abroad will be completed no later than 2036. If any samples remain after that, they will be destroyed.
You have the right, without giving a reason, to say no to the samples being stored. If you consent to the samples being stored, you have the right to withdraw (revoke) that consent later, without giving a reason. In that case, your samples will be discarded or, in exceptional cases, de-identified if it is not possible to discard the sample without destroying other samples. 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, you should 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 approve that we may store and use your samples for future research purposes, you must give specific consent to this. If further research is planned that has not yet been described in more detail, the Swedish Ethical Review Authority will review the project, and it may decide that you need to be asked again.

How will you receive information about the results of the project?
To obtain knowledge about the results, the collected data will be compiled and processed by the principal investigator for the study, Robert Jan Brummer, together with the other people responsible for the study. A summary of the project results will be published at www.oru.se/ngbi, under the "research projects" tab and by clicking on the study name. If you wish to access your individual analysis results, you can contact the principal investigator for the study, Robert Jan Brummer. If abnormal findings emerge during review, the responsible senior consultant physician for the study, 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 responsible senior consultant physician for the study, Robert Brummer, is responsible for referring you onward for investigation, with your consent, if abnormal findings are identified during review.

Insurance and compensation
If you suffer harm during the study, you are insured under the patient insurance scheme (USÖ). Based on the research centre's established compensation for study participants, you will receive SEK 800 (taxable income) for your time and inconvenience after completing the study. Travel costs to and from the study centre are not reimbursed.

Participation is voluntary
Your participation is voluntary and you may choose to withdraw your participation at any time. If you choose not to participate or wish 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, you should contact the person responsible for the project (see below).

People responsible for the project
The person responsible for the project is:
Professor Robert Brummer, Senior Consultant Physician
School of Medical Sciences
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