

Participant Information Sheet

Health benefits of fermented foods

You are being invited to take part in a research study. Before you decide whether or not to take part, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully

The purpose of the study:

The aim of the study is to investigate the health benefits of fermented foods, both the physiological and the psychological effects. Fermented foods can comprise up to 40% of the human diet, many people consume such products daily, and their effects on human health can be assessed by their influence at the gut microbiota level. We know that fermented food consumed in our diet modulates the bacteria that live in our gut, and the functions of these bacteria influence a great number of systems in the human body, including the brain.

In this study, we will measure emotional wellbeing, general mood, anxiety, stress and cognitive function; we will also measure biomarkers that indicate the health and function of the gastrointestinal system by utilising stool samples.

Many researchers are suggesting that fermented foods should become part of National Dietary Guidelines. This information will help towards identifying personalised nutritional solutions for a healthy brain and gut.

The study will run from August 2019 – March 2020.

Why have I been invited to participate?

You are invited to participate because you may be interested in the topic of the study as you are interested in fermented foods and the human microbiota. To be eligible for the study you must be healthy, aged between 18 and 55, a BMI between 18.5 and 29.9, not presently taking antibiotics (or within the last 2 weeks), not diagnosed with an inflammatory bowel disease, not have a known allergy to histamine, not have a history of migraines or cancer, and not allergic to cow's milk.

In total, we will be recruiting 50 people to participate in our study.

The voluntary nature of participation

It is up to you to decide whether or not to take part. If you do decide to take part, you will be given this information sheet to keep and you will be asked to sign a consent form. You will be free to withdraw at any time during participation and up to one week following participation. Choosing not to participate will not have any negative consequences for you.

What will happen to me if I take part?

You will be randomly assigned to be in either the fermented food group or the control group. If you are in the fermented food group, you will be required to eat the fermented foods given to you every day for 30 days and visit London South Bank University (LSBU) 3 - 4 times to undertake several different testing protocols that will take around an hour (visit 2 and 4), or half an hour (visit 1 and 3) of your time. The fermented foods will comprise of a normal portion that would usually be expected to be consumed. For example 125ml, or 250ml, or 125g (one heaped, or two level table spoons). You will also need to take stool samples at home 2 times with a special kit that will be provided to you. If you are in the control group, you will not be given fermented foods during the trial, but you will receive a selection of the fermented foods at the end of the trial. You will be required to undertake the same testing protocols as all the other participants. Participation in the study involves the following: If you decide to participate, you will return the signed consent form. You will then receive a Health Screening Questionnaire that you must complete. This determines your eligibility to participate in the study.

If you are eligible, you will be invited to come to the LSBU for the first study session. You will be asked before the study starts, to write down every plant food you eat for 7 days. On the first study session day, we will collect general diet and lifestyle information from you. We will measure your height, weight, waist and hip, and you will complete a series of paper and computer-based assessments. This will take around 60 minutes of your time. We will describe how to use the stool sampling kit and how to make arrangements with the courier company to collect your completed sample kit. The stool collection kit comprises of special collection containers, gloves and plastic tubes with an attached spoon in the lid to put the stool samples in.

If you are in the fermented food group, you will be given a 15-day supply of the fermented food.

Everyone taking part in the study will receive their first stool sample kit. It takes 3 consecutive days to complete the stool sampling. Once you have done this, you start your 15-day fermented foods.

Everyone taking part in the study will be asked to come back after 15-days to repeat the series of paper and computer-based assessments. Those who are in the fermented food groups, will receive the next 15-day supply of fermented foods.

Everyone taking part will be asked to come back at the end of the 30-day trial to repeat the same assessments that we took at the first session. Everyone taking part will receive their second stool sample kit.

If you are interested in taking part in this study, please contact Adri Bester (contact information is provided below).

Are there any possible disadvantages to participation?

You may experience changes in your bowel movements, such as an increase in the number of movements and a change in stool consistency. You may experience increased intestinal gas.

Results from the stool sample test may indicate an underlying health condition that you may not be aware of and this could cause you distress. We will discuss all the results with you in private and recommend you show the results to your Health Care Provider, such as your Dr for further discussion.

Some of the paper assessments asks you to rate your psychological state, such as anger, anxiety and how you are feeling. This may cause you distress.

During taking your measurements, the female researcher will have to touch your body around your waist and hips in order to put the measuring tape in the appropriate area. The researcher will explain the procedure beforehand, be professional at all times and wear sterile gloves. Some people do not like to be touched. If you prefer a male researcher to take these measurements, one will be on hand. You are reminded that you may withdraw from the study at any time without giving any reason, or suffering any consequences.

Possible benefits to participation

By taking part in this study, you will gain understanding of the health of your gastrointestinal system, and you may improve your general health. If you are interested in receiving the data report from the Gastrointestinal Health Biomarker screen, you need to consent to being contacted after the study to receive these results. You will also receive a £30 Amazon voucher for completing the study.

Will the data collected in this study be kept confidential?

All the information collected about you and other participants will be kept strictly confidential and will only be shared with members of the research team at London South Bank University. Your identity or personal details, such as your name, e-mail

address and phone number) will not be linked to the information you provide, and the data collected from you. You will be given an anonymised identification number at the first study session. Your personal details will be kept separately and only the research team will have access to this information.

We will need to keep personal data for the duration of the study in order to contact you to remind you about your appointments and when your results have been received from the laboratory and you have chosen to receive these results. It can take approximately 3 weeks to receive the results. After the study has finished and you have received your results, we will destroy your personal details.

The final anonymised dataset will be kept indefinitely.

What will happen to the results of the research study on completion

The data from the research study will be analysed by the research team at London South Bank University. The data from all participants will be analysed together so individual data is kept confidential. We will publish the findings via open access journals and conferences.

Who is organising and funding the research?

The research study is being organised by Adri Bester from London South Bank University and is in charge of the day-to-day running of the project. The study is funded through LSBU's London Agri Food Innovation Clinic.

Who has reviewed the study?

This study has been approved by the School of Applied Science's Ethics Committee.

Who to contact for further information?

If you have any questions regarding this project, please contact the lead researcher Adri Bester.

Please note if you have any concerns about the way in which the study has been conducted, you should contact the School of Applied Science Ethics Panel on sasec@lsbu.ac.uk

Research Team:

Adri Bester Email: bestera@lsbu.ac.uk

Professor Katya Mileva Email: milevagn@lsbu.ac.uk

Dr Nadia Gaoua Email: gaouan@lsbu.ac.uk

Thank you for taking the time to read the information sheet.

Adri Bester

Date:

Research Project Consent Form

Full title of Project: Integrated multi-omics of the gut microbiome: assessing the beneficial effects of fermented foods to human health.

Ethics approval registration Number: ETH1819-0142

Name: Adri Bester

Researcher Position: Senior Food Technologist

Contact details of Researcher: bestera@lsbu.ac.uk

Taking part (please tick the box that applies)	Yes	No
I confirm that I have read and understood the information sheet and the researcher has explained the above study. I have had the opportunity to ask questions.	<input type="checkbox"/>	<input type="checkbox"/>
I understand that my participation is voluntary and that I am free to withdraw at any time, up to one week following my participation, without providing a reason.	<input type="checkbox"/>	<input type="checkbox"/>
I agree for my stool samples to be sent to an external laboratory for analyses and I understand that my personal details will not be shared with this laboratory.	<input type="checkbox"/>	<input type="checkbox"/>
I agree to take part in the above study.	<input type="checkbox"/>	<input type="checkbox"/>

Use of my information (please tick the box that applies)	Yes	No
I understand my personal details such as phone number and address will not be revealed to people outside the project.	<input type="checkbox"/>	<input type="checkbox"/>
I agree to being informed if my results indicate that further investigation with my Health Care Provider may be required.	<input type="checkbox"/>	<input type="checkbox"/>
I understand that my data/words may be quoted in publications, reports, posters, web pages, and other research outputs.	<input type="checkbox"/>	<input type="checkbox"/>
I would like to receive my Gastro Intestinal Health Biomarker test results and consent to being contacted by e-mail to receive these results.	<input type="checkbox"/>	<input type="checkbox"/>

 Name of Participant

 Date

 Signature

 Name of Researcher

 Date

 Signature

Project contact details for further information:

Professor Katya Mileva milevakn@lsbu.ac.uk

Adri Bester bestera@lsbu.ac.uk