Participant Information Sheet

V3.0 August 2021

The title of the research project:

Investigating the potential health benefits of ergothioneine supplementation in people with metabolic syndrome (ErgMS)

You are invited to take part in a research project at the University of Leeds. Before you decide to take part, it is important for you to understand the purpose of the study and what it will involve. Please take time to read the following information carefully. If you have any questions or would like more information, please feel free to ask us.

What is the purpose of the study?

The aim of our study is to investigate the effects of 12 weeks ergothioneine supplementation in people with metabolic syndrome. We will assess changes in indicators of metabolic syndrome, oxidative stress, inflammation and liver function.

Why have I been chosen?

You have been invited to take part in the study because we are looking for adults with risks of metabolic syndrome. Metabolic syndrome is defined as a cluster of risk factors for cardiometabolic disease. To be diagnosed with metabolic syndrome, you must have at least 2 of the 6 following risk factors:

- Overweight or obesity
- Increased waist circumference (abdominal obesity)
- Increased triglycerides or receiving treatment for elevated triglycerides
- Increased blood pressure or receiving treatment for elevated blood pressure
- Increased fasting glucose or receiving treatment for elevated blood glucose
- Decreased high density lipoprotein cholesterol (HDL-C) or receiving treatment for low HDL-C

Do I have to take part?

It is up to you to decide whether to take part in this study. If after reading this information sheet, you do decide to take part, you will be asked to sign a consent form. You may withdraw from the study at any time without giving a reason. Your choice will not affect the care that you receive from your general practitioner (GP), doctor or nurse.

What will happen to me if I take part?

At an initial screening for eligibility, you will be contacted by telephone or email to answer some questions to establish if you are likely to be eligible to take part. These questions will include general information about your health. If you are eligible and decide to take part, you will be invited to come to the University of Leeds for a baseline examination.

For the baseline examination, you will be asked to come to the University of Leeds fasted. Your last meal should before 10pm the night before coming to the University. You will be asked not to drink alcohol the night before or do any strenuous exercise the night before or the morning of screening examination. You will need to have signed the research study consent form before the exam. You will receive a copy of the signed consent form and this information sheet. You will have your height, weight, waist circumference and blood pressure measured, and be asked do a finger prick blood test to test your blood fasting glucose, high density lipoprotein cholesterol (HDL-C, 'good cholesterol') and triglycerides in your blood. These measurements will help us to confirm that you have metabolic syndrome. You will be instantly informed of your results and if eligible, you will be invited to take part in the intervention study. Once confirmed you are eligible, we will draw blood from your arm, for analysis of indicators of oxidative stress, inflammation, liver function and other metabolites. This will be done by a trained specialist—a phlebotomist— and only a small amount of blood will be taken (15 ml). At the end, you will then be given a total amount of supplements for 6 weeks. Then you will be informed with a date to come to the University after 6 weeks. At the following visit, you will again have your weight, waist circumference and blood pressure measured, and have a finger prick blood test for fasting glucose, triglycerides and HDL tests. We also will draw blood from your arm.

The supplementation period will last for 12 weeks. You will collect your supplements twice – once at the beginning of the period (or baseline), once at 6 weeks. During the 12-week supplementation period, you will be asked to take one capsule daily at approximately the same time daily (e.g. before you brush your teeth in the morning to help remember). We will ask you to come back to the University at 6 weeks and the end of study (12 weeks) bringing the supplement package and any untaken capsules with you. We will repeat the measurements: height, weight, waist circumference, blood pressure, fasting glucose, triglycerides and HDL-C, and the blood draw from your arm at 6 weeks and 12 weeks. You will be asked to avoid high mushroom intake during the supplementation period.

Due to the current COVID-19 epidemic, you are required to wear a face covering during the visit. You are required to inform us and cancel the visit if you have any of the covid

symptoms (fever, coughing, short of breath, loss of taste and/or smell), and/or if you have tested positive for COVID-19, and/or if you live with anyone who has tested positive for COVID-19. We will phone you at least 1 hour before you come to the University to confirm your health on the day. If you can come to the University, before we start sample collection, your body temperature will be taken with a non-contact temperature monitor at the entrance to the Chemistry building on Woodhouse Lane. Once normal body temperature is confirmed, you will be provided hand sanitiser to clean your hands and be escorted through the building following a designated one way system. You will also be escorted back out of the building. You are required to inform us if you develop any of the covid symptoms within the 48 hours (2 days) after the visit.

What are the possible disadvantages and risks of taking part?

We believe the risks to taking part are very low. Ergothioneine is an amino acid normally found in food (it is found in high amounts in mushrooms) and the doses of ergothioneine being tested (5 or 30 mg/day) are well below the safety limit (800 mg/kg bodyweight per day—e.g. if you weigh 70kg, you could safely consume up to a total of 56,000mg per day). Ergothioneine has minimal allergy risk determined by European Food Safety Authority. While there might be a small discomfort when having your blood drawn, this will be only momentary.

Due to the close contact requirements for obtaining blood samples and the current COVID-19 epidemic in circulation, there is risk of potential COVID transmission. All of our researchers will wear appropriate PPEs, including a face mask along with a face shield, single use gloves and a single use apron. All researchers will have their body temperature measured each day (being normal) and will be regularly tested for covid-19 (negative results)to reduce risk to of COVID transmission. The study desks and chairs will be cleaned down before and after the visit. There will be minimum of 1 hour between participants and the room will be aired. The window will also be opened during the visit. Should a participant report COVID-19 symptoms within 48 hours of visiting the University, the researchers who met them will immediately self-isolate and any other participants who interacted with the researchers within that timespan will be notified.

What are the possible benefits of taking part?

Ergothioneine may be beneficial to people with metabolic syndrome. The information from this study will help us to learn if taking ergothioneine as a supplement can reduce risks and/or symptoms of metabolic syndrome, oxidative damage, inflammation and liver function. Your risk factors will be measured several times and the results shared with you. If our study does

conclude a benefit to taking ergothioneine we will recommend all participants to take it at the end of the study.

You will receive a voucher from amazon or on your request at the end of the study. It will cover your travel fees to the University of Leeds (3 times) and an additional £10 for a small thank you.

Will the information be kept confidential?

Yes, all the collected information will be kept confidential. The personal information collected from participants will be coded and cannot be identified by any other people apart from research team members. All the data about participants' personal information will be encrypted or locked at the University of Leeds.

What will happen to the results of the study?

All the contact information that we collect about you during the study will be kept strictly confidential and will stored separately from the research data. Only anonymised data will be used in the data analysis and publications.

The results will be used in PhD dissertation, and may also be used in academic journal publications and academic conference presentation.

Who is organising/ funding the research?

This study is organised and funded by the University of Leeds.

Who has reviewed this study?

This study has been approved by the Faculty Research Ethics Committee at The University of Leeds (**MEEC 20-007**).

Thank you for taking the time to read this information.

If you have any questions or would like more information, please contact our research team:

Researcher: Ms Xiaoying Tian 07938500527 ErgMS@leeds.ac.uk

Research supervisor: Dr Bernadette Moore J.B.Moore@leeds.ac.uk

School of Food Science and Nutrition, Faculty of Environment, University of Leeds, LS2 9JT