

## PARTICIPANT INFORMATION SHEET



The Functional Gut Clinic  
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**Project Title: The effect of enzyme-rich malt extract on symptoms of chronic constipation.**

**IRAS Reference: 291064**

**Chief Investigator:** Dr Anthony Hobson ([Anthony@thefunctionalgutclinic.com](mailto:Anthony@thefunctionalgutclinic.com))

**Study co-ordinator:** Jordan Haworth ([jordan@functionalgutdiagnostics.com](mailto:jordan@functionalgutdiagnostics.com))

### **Section A: The Research Project**

#### **Why might I be suitable to participate?**

We would like to invite you to take part in our research study. Joining the study is entirely up to you, but before you decide we would like you to understand why the research is being done and what it would involve for you.

You may be suitable to participate if you have a history of chronic constipation and are willing to take a food supplement, enzyme-rich malt extract, to compare the symptoms of constipation after 28 days of oral supplementation.

We suggest this should take at least 24 hours to consider the information about the study. Please feel free to talk to others about the study if you wish. The first part of the Participant Information Sheet tells you the purpose of the study and what will happen to you if you take part. Then we give you more detailed information about the conduct of the study and how your data is handled.

#### **Summary of research:**

Constipation is a common condition, but there may be one or multiple causes, including age, diet, medications, and the gut microbiome i.e. types of bacteria living in the gut.

Enzyme-rich malt extract (ERME) is a by-product of the malting process in which the cereal grain barley is dried. The ingredients are 100% barley malt extract. It smells and tastes sweet, with a runny jam-like texture. Malt extract has been used as a food stuff in baking and cookery for many years, ERME is the same ingredients but uses a method which retains more active enzymes, such as amylase, which are able to break down carbohydrates.

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Undigested carbohydrates can be fermented by the gut bacteria to produce gases and contribute to constipation. The effects of enzyme-rich malt extract on constipation are unknown, therefore, the aim of this study is to look at the effects of enzyme-rich malt extract on symptoms of chronic constipation.

### **How many people will be asked to participate?**

This study has been designed to enrol 20 participants.

### **What are the likely benefits of taking part?**

This project will evaluate the effect of enzyme-rich malt extract on the symptoms of chronic constipation.

Taking part may or may not have any direct benefit to yourself, but taking part will help to understand the effects of this food supplement on constipation.

### **Can I refuse to take part?**

At any point of the study, you can refuse to take part without giving a reason.

### **Has the study got ethical approval?**

This study has been approved by *the London Queen Square Research Ethics Committee*.

### **Has the organisation where you are carrying out the research given permission?**

Yes.

### **Source of funding for the research project:**

Functional Gut Diagnostics Limited and Ateria Health Limited.

### **What will happen to the results of the study?**

The data collected will be aggregated and results of the research project will be published in journals and presented at conferences.

**Contact for further information**

If you require any further information, or have any questions about this research project then please contact Jordan Haworth at [jordan@functionalgutdiagnostics.com](mailto:jordan@functionalgutdiagnostics.com)

**Section B: Your Participation in the Research Project**

**What will I be asked to do?**

Once you have read through the participant information sheet, you will be sent a screening questionnaire and constipation questionnaire by email. If anything doesn't make sense or you would like to speak to someone, please contact [jordan@functionalgutdiagnostics.com](mailto:jordan@functionalgutdiagnostics.com). You can either complete the screening/health questionnaires and send it back to the study co-ordinator or relay your answers over the phone to the study co-ordinator.

If you meet all the criteria and are happy to go ahead with the study, you will then be asked to complete a consent form.

You will be first asked to complete a consent form and then you will have been fully enrolled into the study. You will then be asked to give a fasted breath sample and complete a questionnaire. Then you will be asked to fill in a 7-day diary of your bowel habit e.g. how many times you went that day and what the stool consistency was like.

After these 7 days, you will begin 4 weeks or 28 days (+/- 2 days) of enzyme-rich malt extract. The questionnaire will ask questions about your quality of life and should take approximately 10 – 20 minutes to complete. The breath samples and questionnaire will be returned by freepost. You will keep the diary and continue to fill it in daily whilst taking the enzyme-rich malt extract.

Taking the enzyme-malt extract will begin after 7 days of completing the bowel habit diary. A member of the research team will contact you to make sure that you have started correctly.

Half-way through the study,(14 days, +/- 2 days), a member of the research team will contact you to make sure everything is going well and to check if you have been taking the supplement as instructed, answer any questions you have and check to see if you have had any side effects from the supplement. This call will take approximately 5 minutes.

After 28 days (+/- 2 days) of enzyme-rich malt extract you will be asked to provide a fasted breath sample and complete two questionnaires on symptoms of constipation and quality of life, as well as a questionnaire asking if you have experienced any side effects from the enzyme-rich malt extract. The breath samples questionnaires and diary that you have been filling in throughout will be returned by freepost.

**Summary of study visits/calls**

Eligibility screening – (verification of health status with health and constipation questionnaire) – these questionnaires will take ~10 minutes to complete.

5 weeks (35 days):

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- Day 0 - **Enrolment:** Breath sample collection + quality of life questionnaire – this is performed at home and should take around 30 minutes. Complete the daily bowel habit diary for the next 7 days, but DO NOT take the enzyme-rich malt extract.
- Day 7 – Start taking enzyme-rich malt extract and continue to fill in the daily bowel habit diary
- Day 21 – **Phone call:** Side effects questionnaire + monitoring of adherence to the protocol + Q&A – this phone call will last approximately 5 minutes
- Day 35 – **End of study:** Breath sample collection + constipation questionnaire + quality of life questionnaire + side effects questionnaire + compliance verification – this is performed at home and should take around 30 minutes.

### Giving a fasted breath sample

For the study you will need to provide a total of 4 fasted breath samples. These will be performed on two days 5 weeks apart i.e. 2 fasted breath samples at the start of the study and 2 fasted breath samples at the end of the study.

For the 4 weeks before the baseline breath sample you should have not taken any antibiotics.

A fasted breath sample requires you not to eat or drink anything except water for 12 hours before giving a breath sample. The fasted breath samples should be given in the morning.

For example, if you want to give your breath sample at 9:00 am you would stop eating and drinking at 9:00 pm the night before. In addition, please allow one hour after waking before giving your sample, you may brush your teeth (do not swallow any toothpaste) and have one cup of water within this time.

DO NOT EAT, DRINK (except water) or SMOKE before giving the breath sample. Please try to avoid any vigorous exercise and taking any medications until after providing the breath sample.

Fasted breath samples will be performed at home and returned by freepost along with any questionnaires.

Daily bowel habit diary

Once you have completed the breath samples, you will complete a daily bowel habit diary for 7 days, but DO NOT take the enzyme-rich malt extract during this time.

### Enzyme-rich malt extract

Once you have given the breath samples and completed 7-days of the bowel habit diary, you can begin your enzyme-rich malt extract.

28 days of enzyme-rich malt extract will be given from day 7 after completion of the 7-day bowel diary. You will continue to complete the bowel habit diary whilst taking enzyme-rich malt extract.

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You will receive a dose of 15 ml given twice a day before meals i.e. before morning meal (1 tablespoon) and evening meal (1 tablespoon). Participants will be given the product in the post and compliance will be determined by measuring the remaining liquid at the end of the study.

At 14 days (+/- 2 days) from the date your enzyme-rich malt extract was commenced, a member of the research team will arrange a follow up phone call with you to answer any questions you may have and complete a questionnaire to check if you have experienced any side effects from the enzyme-rich malt extract.

At 28 days (4 weeks +/- 2 days) from the date your enzyme-rich malt extract was commenced, the procedure to provide a fasted breath sample should be repeated. The questionnaires for constipation, quality of life and side-effects will also be completed again at this point.

### **Will my participation in the study be kept confidential?**

Participation in the study will be kept completely confidential and only members of the research team conducting the study will have access to the information you provide. Although, your GP will need to be informed that you are taking part. You will be assigned a unique study ID number that will be used as an identifier during the study with all breath samples and questionnaires being labelled with this number.

Only members of the study team at the Functional Gut Clinic will have access to the information linking you to this study ID number. All members of the study team at the Functional Gut Clinic are trained and certified in general data protection, and your data will be handled according to the Data Protection Act 2018.

The results will be written up in an anonymised format. Participant's personal data will not be included in the dissemination of the findings.

### **Will I be paid for my participation?**

£25 compensation will be given for full participation within the trial, to cover time and travel expenses. However, no travelling is required since all samples and questionnaires will be posted to you with a pre-paid return envelope. Compensation will be given following completion of the final breath samples and confirmation of compliance to the study.

### **Are there any possible disadvantages or risks to taking part?**

Enzyme-rich malt extract is a tested product available on the market currently as a food supplement for equines. ERME is taken in liquid form so there is almost no risk of choking. For the study, one tablespoon (15ml) will be given twice daily before meals i.e. breakfast and dinner.

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Enzyme-rich malt extract has been tested in human and animals with no adverse events. However, potential side-effects may include gastrointestinal symptoms such as diarrhoea, constipation, bloating and/or abdominal pain. Any noted side-effects will be communicated with by a designated, experienced clinician, Dr Philip Woodland. In the unlikely event of a serious adverse effect, such as requiring hospitalisation, these will be reported appropriately to the Sponsor and MHRA.

There are no other known risks or disadvantages with taking part in this study. The agreement to participate in the study does not affect participant's legal rights.

### **Can I withdraw at any time, and how?**

Participants can withdraw from the study at any time and without giving a reason by emailing [jordan@functionalgutdiagnostics.com](mailto:jordan@functionalgutdiagnostics.com). Participants that withdraw from the study will be asked if they are happy for anonymised data collected up to that point to be used or if they would like to have their data removed.

The last approximate time it will be possible to withdraw their data will be fourteen (14) days after the completion of the last breath sample since breath samples are valid for fourteen days. After this point data will have been anonymised and amalgamated and in certain cannot then be excluded

### **Are there any special precautions that must be taken before, during or after taking part in the study?**

Participants should fast overnight before giving their breath samples the following morning.

Participants should not take a prokinetic, unless already taking one at the start of the study. Rescue laxatives are allowed in cases of persisting constipation.

Participants should not take antibiotics or opioid-based medications (e.g. codeine) during the study without addressing the study co-ordinator [jordan@functionalgutdiagnostics.com](mailto:jordan@functionalgutdiagnostics.com)

There are no other special precautions that must be taken before, during or after taking part in the study. Participants should try to minimise changes to their diet and lifestyle throughout the study.

### **What will happen to the information and samples that are collected from you?**

Information collected from participants will be securely held until 3 years after the end of the project to allow time for analysis and publication, after which it will be destroyed.

### **Summary of research findings**

Research findings will be published in journal articles and presented at conferences.

All participants will receive a copy of any published journal article, if an email address is provided.

### Contact details for complaints

Participants that have any complaints about the study should contact [jordan@functionalgutdiagnostics.com](mailto:jordan@functionalgutdiagnostics.com) or [anthony@thefunctionalgutclinic.com](mailto:anthony@thefunctionalgutclinic.com) in the first instance.

### Contact details for adverse effects

All participants with health and safety concerns will be communicated with *by* an independent clinician, Dr Philip Wood. [philipjwoodland@me.com](mailto:philipjwoodland@me.com) for advice and report these concerns to [jordan@functionalgutdiagnostics.com](mailto:jordan@functionalgutdiagnostics.com)

## Section 3: Protecting your data

### How will we use information about you?

We will need to use information from you for this research project.

This information will include your:

- Name
- Contact details
- Date of Birth
- Medical history

We will use this information to do the research and make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

We will keep all information about you safe and secure.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

**What are your choices about how your information is used?**

- You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.
- We need to manage your records in specific ways for the research to be reliable. This means that we will not be able to let you see or change the data we hold about you.

**Where can you find out more about how your information is used?**

You can find out more about how we use your information

- by asking one of the research team
- by sending an email to [jordan@functionalgutdiagnostics.com](mailto:jordan@functionalgutdiagnostics.com)
- by ringing us on 0161 302 7777.