

Participant Information Leaflet

Fermented Milk Powder to Aid Gut Health

1. Introductory Statement:

Thank you for your interest in this study. Researchers at University College Dublin (UCD) and University College Cork (UCC) are conducting a study on fermented milk products, and their potential to ease symptoms of gut discomfort. This study is led by Dr. Emma Feeney at UCD's School of Agriculture and Food Science, and Dr. Alice Lucey at UCC's School of Food and Nutritional Sciences. The researcher conducting the day-to-day activity on the study at University College Dublin (UCD) is Ms. Éimear Gregory, and you can contact Éimear on Eimear.gregory@ucd.ie.

2. What is this research about?

This study aims to test the effects of a fermented skimmed milk product in improving digestive health in adults who report recurrent mild to moderate digestive issues or discomfort. We hope the study may help to improve these issues as self-reported Irritable Bowel Syndrome (IBS) is associated with having an impact on health care utilization, quality of life and absence from work.

3. Why are we doing this research?

With this study, we hope to gain a better understanding around digestive health in adults and the role that fermented milk can play in this.

4. Why have you been invited to take part?

You have been invited to take part as you are a man/woman aged 20-45 years who has self-reported digestive discomfort or transit issues. These age cut-offs are applied to avoid those experiencing pre-menopause symptoms, which could affect the study outcomes. Participants experiencing mild-moderate digestive discomfort are sought for this study. Anyone suffering with diagnosed IBS or IBD will not be eligible for the study, and the severity of symptoms will be assessed via a Digestive Discomfort series of questions in the screening questionnaire. Your screening has indicated that you fall within this range.

5. How will your data be used?

Your data will be used to assess how, potentially, fermented milk products may improve digestive health and quality of life in adults who have self-reported

recurrent mild to moderate digestive issues.

6. What will happen if you decide to take part in this research study?

If you decide to take part, in brief, you will be asked to fill out a series of web-based questionnaires, and different measures will be taken at certain time points throughout the study, which lasts for a total of 16 weeks, and you will give a number of stool samples (done at your home using a home fecal collection kit that is provided for you).

There will be a total of 5 study visits throughout the duration of the 16 weeks.

There is a 4 week 'baseline' period where your usual gut health and transit will be monitored. Then the intervention period (adding the fermented skimmed milk to your diet, or a control which may be either maltodextrin or a skimmed milk powder) will be from weeks 4-12. You will be asked to consume a small amount (20g) of a fermented skimmed milk product or a control, provided in powdered form to your daily diet.

There will be a 4 week follow up after this 8 week intervention period, where we assess the effect of the treatment on your gut health.

The questionnaires you will be asked to complete are as follows:

The Perceived stress Scale questionnaire (PSS) will be used to assess daily stressors in the participants daily life.

Question example: You fear you may not manage to attain your goals. Answers: 'Almost', 'sometimes', 'often' or 'usually'.

The Functional Digestive Disorders Quality-of-Life questionnaire (FDDQoL) will be used to assess the impact of functional digestive disorders on the participant.

Question example: Have you had any difficulties carrying out your daily activities?

Answers: 'not at all', 'a little bit', 'moderately', 'quite a bit' or 'extremely'.

The Patient assessment of Constipation (PAC-QoL) will be used to assess the impacts of constipation on your daily life

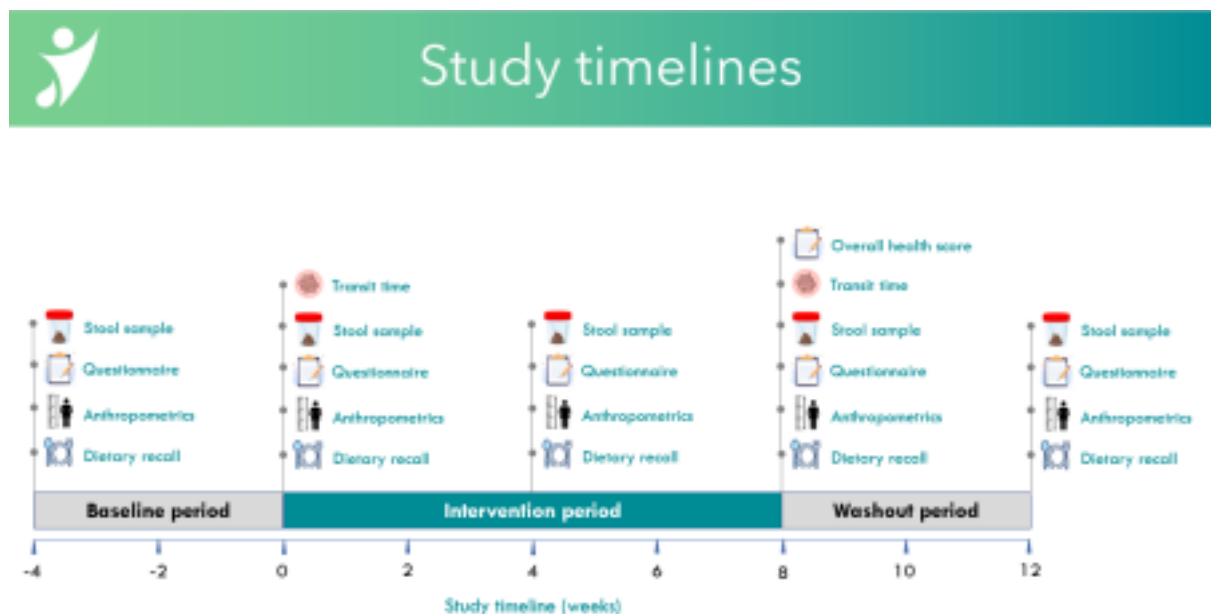
Question example: To what extent or intensity have you felt bloated to the point of bursting?

Answers: 'not at all', 'a little bit', 'moderately', 'quite a bit' or 'extremely'.

Stool samples will be collected during each visit. You will be provided with home faecal collection kits and given instructions on collecting stool samples at home

and delivering stool samples to University College Dublin (UCD) or University College Cork (UCC). Anthropometrics will be measured at each study visit using a weighing scales and stadiometer. Body Mass Index (BMI) will also be calculated at this time. Daily gas evacuation will be measured by participants carrying a tally event marker and recording each time they pass gas for 1 week before each visit. A periodic dietary recall will be carried out at each study visit throughout the duration of the study. Gut transit time will be measured using the 'blue dye method'. This will involve participants consuming a muffin made with blue dye which will be provided to them. They will consume the muffin and record their transit time themselves. Gut transit time refers to how long it takes for your food to move from your mouth to the end of your intestine (anus).

The below overview diagram of the timepoints of the study may help to show what we will be asking you at each time point:



7. How will your privacy be protected?

Your data will not be disclosed to any third parties. Any data that is generated will be stored in a password-protected computer database.

8. What are the benefits of taking part in this research study?

There are no known benefits to taking part in this study. However, the fermented skimmed milk product may potentially benefit your gut health. You will be involved in research that may help us to understand gut health to a further extent.

9. What are the risks of taking part in this research study?

There are no known risks to taking part in this study. There is a small risk, as with any addition to the diet for those who experience occasional digestive discomfort, that you may experience *increased* digestive discomfort. **Your participation is**

voluntary and you are free to withdraw at any stage from this study, for any reason, or indeed for no reason.

10. Can you change your mind at any stage and withdraw from the research study?

Yes of course. Your participation is entirely voluntary. You may withdraw from the study at any stage or time throughout the study without any penalty or consequence to you. You may let any of the researchers know at any time, either verbally, or via email that you no longer wish to take part, and we will remove you from the study.

11. How will you find out what happens with this project?

If you wish to find out what happens after the study, please feel free to request that we keep your name and contact details and we can share the results with you when the study is complete. You can also contact the investigators, Dr Emma Feeney or Dr Alice Lucey.

12. Contact details for further information.

Please feel free to contact me at any time if you have any questions/queries regarding the study through email at eimear.gregory@ucd.ie.

Support and Health related Links:

Aware:

<https://www.aware.ie/>

Pieta House:

<https://www.pieta.ie/>

Samaritans:

<https://www.samaritans.org/ireland/samaritans-ireland/>

Mental Health Ireland:

<https://www.mentalhealthireland.ie/get-support/>

HSE Mental Health Services:

<https://www2.hse.ie/mental-health/services-support/supports-services/>