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The effect of fermented milk powder on gut health in healthy individuals with mild to moderate symptoms

Submission date 04/10/2023	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 17/10/2023	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 13/12/2024	**Condition category** Digestive System	[_] Individual participant data [X] Record updated in last year

Plain English summary of protocol

Background and study aims
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. The researcher conducting the day-to-day activity on the study at University College Cork (UCC) is Ms. Bernadette Finnerty. You can contact Bernadette on BFinnerty@ucc.ie

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.

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.

Who can participate?
A potential participant will be invited to take part if they are aged 20-45 years and have 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. The screening will indicate if they fall within this range.

What does the study involve?
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.
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).

What are the possible benefits and risks of participating?
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.

Where is the study run from?
University College Dublin (Ireland)
University College Cork (Ireland)

When is the study starting and how long is it expected to run for?
May 2023 to July 2024

Who is funding the study?
This research is funded by Food for Health Ireland, via Enterprise Ireland TC. Grant number TC20180025.

Who is the main contact?
Dr Alice Lucey, a.lucey@ucc.ie
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Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Fermented milk powder to aid gut health and quality of life in healthy inidividuals with mild to moderate gastrointestinal symptoms compared with placebo, and non-fermented milk control

Acronym
FHI3

Study objectives
Consumption of fermented skimmed milk powder will improve gut health symptoms and quality of life outcomes compared with placebo and non-fermented skimmed milk

Ethics approval required
Ethics approval required

Ethics approval(s)
1. Approved 22/05/2023, UCD Health Research Ethics Committee (University College Dublin, Belfield, Dublin, D04 V1W8, Ireland; +353 1 716 7777; research.ethics@ucd.ie), ref: LS-23-20-Feeney

2. Approved 09/08/2023, Clinical Research Ethics Committee of the Cork Teaching Hospitals (University College Cork, Lancaster Hall, 6 Little Hanover street, Cork, T12 CY82, Ireland; +353 214903000; crec@ucc.ie), ref: ECM 3 (i) 12/09/2023

Study design
Dual-centre parallel 3 arm interventional double blind randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Home, Laboratory, University/medical school/dental school

Study type(s)
Quality of life, Treatment

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Healthy individuals experiencing mild to moderate gastrointestinal symptoms

Interventions
A total of n=120 participants (total across both sites) will be recruited to this single-blinded study with a parallel design that will involve a 4-week baseline phase before participants are randomised to either the intervention arm (consumption of 20g of fermented skimmed milk product daily) or one of the two control arms (maltodextrin 20g daily) or (skimmed milk powder 20g daily) at a ratio of 3:1:1, respectively.

Intervention arm (consumption of 20g of fermented skimmed milk powder product daily)
Control arm 1 (20g maltodextrin powder)
Control arm 2 (20g skimmed milk powder)

The overall duration of the study will be 16 weeks, conducted in 3 phases:
Phase 1 A 4-week baseline period will be conducted (to establish patterns of gut comfort / discomfort).
Phase 2 The 8-week intervention phase, where participants will be randomised to one of 3 treatment arms, where they will consume their assigned treatment for 8 consecutive weeks.
Phase 3 A 4-week ‘washout’ period will then be conducted for 4-weeks after intervention has been completed.

For randomisation, an external independent entity was used to perform randomisation and assign study codes to participant IDs.

Intervention Type
Supplement

Pharmaceutical study type(s)
Pharmacokinetic

Primary outcome measure
The Functional Digestive Disorders Quality-of-Life questionnaire (FDDQoL) measured once per week each week for 16 weeks

Secondary outcome measures
1. Gut Transit Time measured using the blue dye method at week 0 and week 8
2. Constipation measured using The Patient Assessment of Constipation Quality of Life Questionnaire (PAC-QoL) & Bristol Stool Chart at weeks -4, 0, 4, 8 & 12
3. Microbial diversity measured using stool samples provided by participants which will be analysed in an external lab at weeks -4, 0, 4, 8 & 12
4. Faecal Calprotectin levels measured using stool samples provided by participants which will be analysed in an external lab at weeks -4, 4 & 12
5. Flatulence measured using a tally counter (day time anal gas evacuation) on the previous week before each study visit.

Overall study start date
22/05/2023

Completion date
31/07/2024

Eligibility

Key inclusion criteria
1. Respondents aged 20-45 years old.
2. Respondents who have self-reported mild to moderate digestive issues as per the Structured Assessment of Gastrointestinal Symptoms (Koloski et. al) / Hospital Anxiety and Depression Scale (Zigmond et. al, 1983) questionnaires.

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
20 Years

Upper age limit
45 Years

Sex
Both

Target number of participants
120

Total final enrolment
146

Key exclusion criteria
1. Respondents who report lactose intolerance
2. Respondents who report either very mild or very severe gastrointestinal issues.
3. Post-menopausal women or those experiencing menopause.
4. Respondents who report self-medication with probiotics or similar products for gastrointestinal issues will be excluded or will have to undergo a washout period before recruitment.
5. Respondents who report medical issues that affect gut transit/digestion.
6. Respondents who report living situations where they are not independently living, or require care.
7. Respondents who report regular taking antacids.
8. Respondents who report that they are smokers.
9. Respondents who report they are pregnant or lactating.
10. Respondents who have been prescribed antibiotics in the last 3 months.
11. Respondents who report having Type-1 Diabetes.

Date of first enrolment
01/09/2023

Date of final enrolment
30/04/2024

Locations

Countries of recruitment
Ireland

Study participating centre
University College Dublin, Institute of Food and Health, Human Intervention Suites.
Belfield
Dublin
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D04C1P1

Study participating centre
Human Nutrition Studies Unit, School of Food & Nutritional Sciences, University College Cork
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Sponsor type
University/education

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ROR
https://ror.org/03265fv13

Funder(s)

Funder type
Government

Funder Name
Enterprise Ireland

Alternative Name(s)

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Ireland

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed journal.

Intention to publish date
31/12/2025

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request.

The data will consist of that retained from fully consenting adults. (Quality of life questionnaires, stool samples, gut transit time, anthropometric data). This data will be stored in a de-identified manner.

A link list, in the form of a spreadsheet, will be used to link the study codes to the individuals on recruitment. This will not be shared and will be kept in a password-protected file by the principal investigators. The data will not be kept any longer than is required.

The data shared will be in de-identified form only.

The data agreement covers the following:
• Why the data is being used?
This will allow both the principal and co-investigators to analyse the collected data; to examine the effects of a fermented dairy product on digestive issues in adults who have self-reported recurrent mild to moderate digestive issues.

• Who is using the data?
The principal investigators Dr. Emma Feeney and Dr. Alice Lucey.
• Where is the data being used?
The de-identified data will be used in the researchers' work settings. This may be in the researcher's home.
• What data is appropriate?
The de-identified data is appropriate for sharing and required for the planned analysis.
• How are the results of the project used?
The results of this study will be used to contribute to future research in gastrointestinal health.

IPD sharing plan summary

Available on request, Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			05/10/2023	No	Yes