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A pilot study investigating a probiotic strain for health and well-being

Submission date
09/04/2025

Recruitment status
No longer recruiting

Registration date
22/04/2025

Overall study status
Completed

Last Edited
23/04/2026

Condition category
Nutritional, Metabolic, Endocrine

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
This study is investigating whether a probiotic strain called Levilactobacillus brevis can help improve blood glucose levels and metabolic health. This study aims to determine if this dietary supplement might help regulate blood sugar levels by comparing the effects of high-dose probiotic, low-dose probiotic, and placebo on glucose variability in people with slightly elevated blood sugar levels.

Who can participate?
Men aged 25-50 years or pre-menopausal women aged 25-45 years who have a recent HbA1c result between 5.7% and 6.9%, have a BMI between 20-45 kg/m², are willing to wear a glucose monitor and maintain their usual lifestyle, and are not currently taking diabetes medication or dietary supplements

What does the trial involve?
Participants will be randomly assigned to receive either a high-dose probiotic, a low-dose probiotic, or a placebo for 6 weeks, followed by a 2-week washout period. Throughout the 10-week study, participants will wear a continuous glucose monitor for certain periods, provide blood and stool samples, and complete online questionnaires about their diet, physical activity, sleep quality, and quality of life.

What are the possible benefits and risks of participating?
Benefits may include information about your metabolic health and potential improvements in blood glucose regulation. Risks are minimal but may include temporary digestive discomfort (bloating, gas), minor discomfort during glucose monitor application, and minor pain or bruising from blood draws.

Where is the trial run from?
The trial is coordinated by Lindus Health (UK) on behalf of IFF, with remote participation from home.

When is the trial starting and how long is it expected to run for?
December 2024 to April 2026

Who is funding the trial?
Danisco Sweeteners Oy, a subsidiary of International Flavors & Fragrances Inc. (IFF) (Finland)

Who is the main contact?
gsquared@lindushealth.com
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Contact information

Type(s)
Scientific, Principal investigator

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Type(s)
Public

Contact name
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London
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Additional identifiers

Integrated Research Application System (IRAS)
354296

Protocol serial number
CT01693

Study information

Scientific Title
A probiotic strain for metabolic health and well-being: a randomised placebo-controlled pilot trial

Acronym
G Squared

Study objectives
To compare glucose variability (GV), via the percentage time in range (TIR), of participants taking an encapsulated placebo, a low-dose probiotic strain or a high-dose probiotic strain.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 15/05/2025, Newcastle & North Tyneside 2 Research Ethics Committee (NHS BT Blood Donor Centre Holland Drive, Newcastle upon Tyne, NE2 4NQ, United Kingdom; +44 (0)207 104 8086; newcastlenorthtyneside2.rec@hra.nhs.uk), ref: 25/NE/0031

Primary study design
Interventional

Study design
Double-blind hybrid parallel three-arm randomized placebo-controlled pilot trial

Study type(s)
Other

Health condition(s) or problem(s) studied
Individuals with HbA1c levels between 39.0 mmol/mol and 51.9 mmol/mol (5.7% to 6.9%)

Interventions
Eligible participants will be randomised into one of three arms as below taken by mouth once daily for 6 weeks, followed by a 2-week washout period:
Arm 1: Placebo (microcrystalline cellulose)
Arm 2: Low-dose probiotic strain (Levilactobacillus brevis)
Arm 3: High-dose probiotic strain (Levilactobacillus brevis)

Web-based randomisation with 1:1:1 allocation ratio using random permuted blocks

Intervention Type
Supplement

Primary outcome(s)
Glucose percentage time in range measured via continuous glucose monitor (CGM) during the baseline 14-day period and week 5-6

Key secondary outcome(s)
Current secondary outcome measures as of 22/10/2025:

1. Glucose variability measured via CGM during the baseline 14-day period and week 7 and 8
2. Serum cholesterol triglycerides (total cholesterol, HDL cholesterol, LDL cholesterol, triglycerides) measured using a blood test at baseline, week 6 and week 8
3. Glycaemic variability percentage measured via CGM during the baseline 14-day period and week 5-6 and week 7-8
4. Frequency of hypoglycaemia measured via CGM during the baseline 14-day period and week 5-6 and week 7-8
5. Frequency of hyperglycaemia measured via CGM during the baseline 14-day period and week 5-6 and week 7-8
6. HbA1c measured using a blood test at baseline and week 6
7. Fasting insulin and glucose levels measured using a blood test at baseline, week 6 and week 8
8. Gut proteins (GLP-1, GIP, PYY, ghrelin, and leptin) measured using a blood test at baseline, week 6 and week 8
9. Estimated glomerular filtration rate (eGFR) measured using a blood test at baseline, week 6 and week 8
10. Sleep quality measured via the Pittsburgh Sleep Quality Index (PSQI) at baseline, week 6 and week 8
11. Quality of life measured via the EQ-5D-5L at baseline, week 6 and week 8
12. Insulin sensitivity measured using the Homeostatic Model Assessment of Insulin Resistance (HOMA-IR) measured at baseline, week 6 and week 8
13. Insulin resistance measured using the Triglycerides-Glucose Index (TyG) measured at baseline, week 6 and week 8
14. hs-CRP measured using blood test at baseline, week 6 and week 8

Previous secondary outcome measures:

1. Serum cholesterol triglycerides (total cholesterol, HDL cholesterol, LDL cholesterol, triglycerides) measured using a blood test at baseline, week 6 and week 8
2. Glycaemic variability percentage measured via CGM during the baseline 14-day period and week 5-6
3. Frequency of hypoglycaemia measured via CGM during the baseline 14-day period and week 5-6
4. HbA1c measured using a blood test at baseline and week 6
5. Fasting insulin and glucose levels measured using a blood test at baseline, week 6 and week 8
6. Gut proteins (GLP-1, GIP, PYY, ghrelin, and leptin) measured using a blood test at baseline, week 6 and week 8
7. Estimated glomerular filtration rate (eGFR) measured using a blood test at baseline, week 6 and week 8
8. Sleep quality measured via the Pittsburgh Sleep Quality Index (PSQI) at baseline, week 6 and week 8
9. Quality of life measured via the EQ-5D-5L at baseline, week 6 and week 8
10. Stool quality measured via the Bristol Stool Scale (BSS) at baseline, week 6 and week 8
11. Insulin sensitivity measured using the Homeostatic Model Assessment of Insulin Resistance (HOMA-IR) measured at baseline, week 6 and week 8
12. Insulin resistance measured using the Triglycerides-Glucose Index (TyG) measured at baseline, week 6 and week 8
13. hs-CRP measured using blood test at baseline, week 6 and week 8

Completion date
01/04/2026

Eligibility

Key inclusion criteria

Current key inclusion criteria as of 04/02/2026:
1. Pre-menopausal female aged 25-45 years old, or male aged 25-50 years old
2. Evidence of HbA1c value between 39.0 mmol/mol and 51.9mmol/mol (5.7% to 6.9%) within the past 12 months
3. Weight stable over the last 12 months (±5%)
4. Current BMI between 20-45 kg/m2
5. Have access to a smartphone, tablet or laptop/computer
6. Able and willing to give consent to the trial prior to participation.
7. In the Investigator's opinion, is able and willing to comply with all trial requirements.
8. Able and willing to use a continuous glucose monitor (CGM) device for up to six weeks.
9. Willing to maintain their usual lifestyle throughout the trial, i.e., agrees not to change their dietary habits and level of exercise etc. during the trial and does not currently utilise an extreme diet or exercise plan.
10. Willing to allow their General Practitioner, if appropriate, to be notified of participation in the trial.
11. Females of child-bearing potential must agree to use medically approved methods for birth control including condoms with or without spermicides, hormonal contraceptives (oestrogen and /or progestin products; either oral, intrauterine, or epidermal) or intrauterine device with copper. The contraceptive method should have been in place for at least 3 cycles before the beginning of the trial and should not be modified during the trial.

Previous key inclusion criteria as of 04/09/2025:
1. Pre-menopausal female aged 25-45 years old, or male aged 25-50 years old
2. Evidence of HbA1c value between 42.1 mmol/mol and 51.9mmol/mol (6.0% to 6.9%) within the past 12 months
3. Weight stable over the last 12 months (±5%)
4. Current BMI between 20-45 kg/m2
5. Have access to a smartphone, tablet or laptop/computer
6. Able and willing to give consent to the trial prior to participation.
7. In the Investigator's opinion, is able and willing to comply with all trial requirements.
8. Able and willing to use a continuous glucose monitor (CGM) device for up to six weeks.
9. Willing to maintain their usual lifestyle throughout the trial, i.e., agrees not to change their dietary habits and level of exercise etc. during the trial and does not currently utilise an extreme diet or exercise plan.
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Previous key inclusion criteria:
1. Pre-menopausal female aged 25-45 years old, or male aged 25-50 years old
2. Evidence of HbA1c value between 42.1 mmol/mol and 51.9mmol/mol (6.0% to 6.9%) within the past 6 months
3. Weight stable over the last 6 months (±5%)

4. Current BMI between 20-45 kg/m2
5. Have access to a smartphone, tablet or laptop/computer
6. Able and willing to give consent to the trial prior to participation.
7. In the Investigator's opinion, is able and willing to comply with all trial requirements.
8. Able and willing to use a continuous glucose monitor (CGM) device for up to six weeks.
9. Willing to maintain their usual lifestyle throughout the trial, i.e., agrees not to change their dietary habits and level of exercise etc. during the trial and does not currently utilise an extreme diet or exercise plan.
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Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
25 Years

Upper age limit
50 Years

Sex
All

Total final enrolment
60

Key exclusion criteria
Current key exclusion criteria as of 04/02/2026:
1. Participants with self-reported current or prior diagnosis of:
1.1. Hypersensitivity, allergy or intolerance to any ingredient in the investigational products
1.2. Gastrointestinal conditions including lactose intolerance, coeliac disease, gastroesophageal reflux disease, irritable bowel syndrome (IBS), and inflammatory bowel disease (IBD)
1.3. Recent gastrointestinal infection within 4 weeks prior to enrolment
1.4. Gastrointestinal surgery (except for appendicitis or hernia surgery)
1.5. Type 1 diabetes
1.6. Pituitary dysfunction
1.7. Significant psychiatric disorder, including any eating disorder
1.8. Severe hepatic (liver) disease including severe derangement of LFTs as defined by any of the below:
1.8.1 ALT > 3x ULN

1.8.2 AST > 3x ULN
1.8.3 Bilirubin > 3x ULN
1.8.4 Albumin < 30g/L (15% below normal)
1.9. Severe organic diseases, including cancer, coronary heart disease, heart failure, recent myocardial infarction (within the past 12 months), autoimmune disease, severe kidney disease, cerebral apoplexy or terminal illness
1.10. Infectious diseases, including pulmonary tuberculosis and AIDS
1.11. Severe hypertension (>160/100)
1.12. Significant dyslipidaemia (>3 months use of low-dose statins permitted*) as defined by any of the below:
1.12.1 Triglycerides >5.6 mmol/L (>500 mg/dL)
1.12.2 LDL cholesterol >5.0 mmol/L (>190 mg/dL) (67% above normal)
1.12.3 Total cholesterol >8.0 mmol/L (>310 mg/dL) (54% above normal)
1.12.4 HDL cholesterol <0.5 mmol/L (<20 mg/dL) (50-60% below normal)
1.13Severe derangement of FBC as defined by any of the below:
1.13.1 Platelets $<90 \times 10^9$/L
1.13.2 Neutrophils $<1 \times 10^9$/L
1.13.3 Hemoglobin <10 g/dL
1.13.4 WBC $<2.0 \times 10^9$/L (50% below normal) or $>30 \times 10^9$/L (170% above normal)
2. Any self-declared clinically significant alcohol misuse (more than 14 units of alcohol per week) at screening that may impact the safety of the participant or the trial data.
3. Any self-declared use of illicit drugsat screening that may impact the safety of the participant or the trial data
4. Currently taking diabetes-specific medication
5. Antibiotic course of any duration within 3 months before screening or any active infection during the screening period or ongoing chronic infection for the duration of the trial.
6. Receiving drug therapy to treat cholecystitis, peptic ulcers, urinary tract infection, acute pyelonephritis, or urocystitis
7. Continuous use of weight-loss drug within 3 months of trial entry
8. Steroid use (except for topical steroids and inhalers)
9. Paracetamol use during the period of trial participation
10. Currently taking Hydroxyurea
11. Current or recent (within 3 weeks prior to enrolment) use of any dietary supplements, such as probiotics, prebiotics, synbiotics, vitamins (except vitamin D), fermented milk, and/or yogurt containing probiotics, omega-3 fatty acids, plant stanols/sterols), including the use of food supplements for blood glucose control (e.g. chromium picolinate)
12. Current consumption of vitamin D supplement exceeding 10 µg per day
13. Pregnant or breastfeeding, or planning to become pregnant during the planned period of trial participation
14. Current participation in a weight loss program or planned during the planned period of trial participation
15. Participation in another interventional clinical trial in the last 30 days.
16. Longer-term absence planned during the planned period of trial participation
17. Any other significant disease or disorder which, in the opinion of the Investigator, may put the participants at risk because of participation in the trial, or may influence the result of the trial, or the participant's ability to participate in the trial.

Previous key exclusion criteria as of 04/09/2025:
1. Participants with self-reported current or prior diagnosis of:
1.1. Hypersensitivity, allergy or intolerance to any ingredient in the investigational products
1.2. Gastrointestinal conditions including lactose intolerance, coeliac disease, gastroesophageal reflux disease, irritable bowel syndrome (IBS), and inflammatory bowel disease (IBD)

1.3. Recent gastrointestinal infection within 4 weeks prior to enrolment
1.4. Gastrointestinal surgery (except for appendicitis or hernia surgery)
1.5. Type 1 diabetes
1.6. Pituitary dysfunction
1.7. Significant psychiatric disorder, including any eating disorder
1.8. Severe hepatic (liver) disease
1.9. Severe organic diseases, including cancer, coronary heart disease, heart failure, myocardial infarction, autoimmune disease, kidney disease, cerebral apoplexy or terminal illness
1.10. Infectious diseases, including pulmonary tuberculosis and AIDS
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*NICE Guidelines will be used to define low doses of statins.

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1.11. Severe hypertension (>160/100)
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3. Any self-declared use of illicit drugsat screening that may impact the safety of the participant or the trial data
4. Currently taking diabetes-specific medication
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Date of first enrolment
23/05/2025

Date of final enrolment
02/02/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre

Lindus Health
The Harlequin Building, 65 Southwark Street
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SE1 0HR

Sponsor information

Organisation
Danisco Sweeteners Oy, a wholly owned subsidiary of International Flavors & Fragrances Inc. (IFF)

Funder(s)

Funder type
Industry

Funder Name
Danisco Sweeteners Oy, a wholly owned subsidiary of International Flavors & Fragrances Inc, (IFF)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Data sharing statement to be made available at a later date