Participant Information Sheet

The IFF *G Squared* Trial Summary Sheet

G Squared: A Probiotic Strain for Metabolic Health and Well Being: A randomised placebo-controlled pilot trial

We are inviting you to join this trial because we understand that you have been identified as someone with a recent HbA1c test result of 39.0 mmol/mol to 51.9 mmol/mol inclusive (5.7% to 6.9%). HbA1c test results indicate your average blood glucose (sugar) level over 2–3 months, providing a snapshot of long-term blood glucose control.

WHAT YOU NEED TO KNOW

- The aim of the trial is to find out the potential impact of a probiotic strain (*Levilactobacillus brevis*) on blood glucose levels and supporting well-being and metabolic health (how the body processes sugar and fats) when taken as a daily dietary supplement.
- We are aiming to recruit 60 people to take part in this research.
- Participation in the trial will last approximately 10 weeks.
- Taking part is voluntary.

REQUIREMENTS TO TAKE PART

- Male aged 25-50 years (inclusive) or pre-menopausal female aged 25-45 years (inclusive)
- Evidence of HbA1c test result between 39.0 mmol/mol and 51.9 mmol/mol inclusive (5.7% to 6.9%) within the past 12 months
- Have access to a smartphone, tablet or laptop/computer
- Current BMI between 20-45 kg/m^2
- Able and willing to use a continuous glucose monitor (CGM) sensor for up to 6 weeks
- Stable weight over the last 12 months (±5%) and **not** currently:
    - Participating in a weight loss program or plan to during the duration of the trial
    - Taking a weight-loss drug for the previous 3 months
    - Taking (or within 3 weeks prior to enrolment) 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)
    - Consuming more than 10 µg (400 IU) per day of a vitamin D supplement
- Willing to maintain your usual lifestyle throughout the trial, i.e., agree not to change your dietary habits and level of exercise etc., during the trial and do not currently utilise an extreme diet or exercise plan.
- Not currently taking any diabetes-specific medication (e.g. Insulin, Metformin, Gliclazide, SGLT-2, GLP-1)
- Not participated in another interventional clinical trial within the last 30 days.
- No long-term absence planned during the planned period of trial participation (if you have any absence or holiday planned, please let the trial team know during the first video call)

- Not pregnant or breastfeeding, or planning to become pregnant during the planned period of trial participation
- Agree to use medically approved methods for birth control including abstinence, condoms with or without spermicides, hormonal contraceptives (oestrogen and/or progestin products; either oral, intrauterine, or epidermal) or intrauterine sensor 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.
- No current or prior diagnosis of the following:
    - Gastrointestinal condition, recent gastrointestinal infection (within 4 weeks) or gastrointestinal surgery (except for appendicitis or hernia surgery)
    - Type 1 diabetes
    - Pituitary dysfunction (this occurs when the pituitary gland produces too much or too little of a hormone)
    - Significant psychiatric disorder, including any eating disorder
    - Severe hepatic (liver) disease
    - Severe diseases including cancer, coronary heart disease, heart failure, recent heart attack, autoimmune disease, severe kidney disease, cerebral apoplexy (stroke) or terminal illness
    - Infectious diseases, including pulmonary tuberculosis and AIDS
    - Severe hypertension (high blood pressure >160/100)
    - Significant dyslipidaemia (abnormal levels of cholesterol)
    - Recent/current significantly abnormal blood test results

Not currently taking/receiving/using:

- Course of antibiotics within 3 months or any active infection or ongoing chronic infection
- Steroids (except for topical (skin) steroids and inhalers)
- Drug therapy to treat cholecystitis (gall bladder infection), peptic ulcers, urinary tract infection, acute pyelonephritis (kidney infection) or urocystitis (bladder infection)
- Illicit drugs
- Significant alcohol misuse (more than 14 units of alcohol per week)
- Paracetamol, and agree to not take paracetamol during the period of trial participation (however NSAIDs (nonsteroidal anti-inflammatory drugs) such as ibuprofen are allowed)
- Hydroxyurea

WHAT DOES TAKING PART IN THE TRIAL MEAN?

- You will receive one of the following to take as a daily capsule each morning for 6 weeks: high dose probiotic strain, low dose probiotic strain or placebo
- The selection is random with an equal chance (i.e. like rolling a dice) of receiving the high dose probiotic, low dose probiotic or placebo. You will not know what you receive until the end of the trial
- You will visit a clinic in Marylebone (London) to provide blood samples at the beginning of the trial (baseline) and during week 6 and week 8
- You will take at-home stool samples, using a kit sent to your home address, at baseline and

during week 6 and week 8

- You will wear a Continuous Glucose Monitor (GCM) shipped to your home address, for up to 6 weeks
- You will be asked to complete questionnaires online to record
  i) Weekly whether you have taken the trial product
  ii) Weekly any side-effects you may experience
  iii) Weekly food diary
  iiii) Surveys about your sleep quality, quality of life, physical activity, and stool samples at 3 timepoints

CONFIDENTIALITY & DATA PROTECTION

Your information will only be gathered to the extent necessary to conduct the research trial. People with access to your health information will be limited, to include the trial team at Lindus Health, the trial sponsor Danisco Sweeteners Oy (a wholly owned subsidiary of International Flavors & Fragrances Inc.) ("IFF" or "Sponsor"), and the regulatory authorities who check that the trial is being carried out correctly.

Everyone involved in the trial will keep your data safe and secure. We will also follow all privacy rules, such as the Data Protection Act (2018) in the UK. At the end of the trial, the information obtained from you during the course of the trial will be anonymised, and your personal information will not be a part of the reports written with respect to the trial. Further, we will make sure no-one can work out who you are from the reports we write.

TO TAKE PART:

- ❑ Fill in a short form on the trial website to check that you are eligible - this includes uploading evidence of a recent HbA1c reading (if you have been directed to this study by your GP, you may not need to do this).
- ❑ Read and consider the information provided to you on this Participant Information Sheet in full, and talk to other people about the trial if you wish.
- ❑ Book a call with the G Squared trial team to discuss the trial with you.
- ❑ Complete a consent form to confirm you agree to take part in the trial.

Need more information?

If you would like to speak to a member of the G Squared trial team, please feel free to get in touch:
Freephone: 0800 0584496
Email address: gsquared@lindushealth.com

Trial Name: The *G Squared* Trial

A Probiotic Strain for Metabolic Health and Well Being: A randomised placebo-controlled pilot trial

PARTICIPANT INFORMATION LEAFLET

The G Squared Trial, Sponsored by Danisco Sweeteners Oy (a wholly owned subsidiary of International Flavors & Fragrances Inc.) ("IFF" or "Sponsor"), is trying to find out the potential impact of a probiotic strain (*Levilactobacillus brevis*) on blood glucose levels when consumed daily as a dietary supplement.

We are inviting you to join this trial because you have been identified as someone with a recent HbA1c test result of 39.0 mmol/mol to 51.9 mmol/mol inclusive (5.7% to 6.9%). HbA1c test results indicate your average blood glucose (sugar) level over the past 2–3 months, providing a snapshot of long-term blood glucose control.

This leaflet provides information about the trial, including its aims, and tells you about the risks and benefits of taking part.

Study Overview

What is the purpose of the trial?

Metabolic syndrome is the name for a group of health problems that may put you at risk of Type 2 Diabetes or conditions that affect your heart or blood vessels. People are seeking new tools to support their metabolic health journey, specifically solutions that support their blood glucose regulation. Probiotics are live bacteria and yeasts promoted as having various health benefits. A growing body of evidence suggests probiotics may have beneficial effects on metabolic health.

The aim of the trial is to find out the potential impact of a probiotic strain (*Levilactobacillus brevis*) on blood glucose levels and supporting well-being and metabolic health (how the body processes sugar and fats) when taken as a daily dietary supplement.

Participants will be randomly allocated to receive either the high dose probiotic, low dose probiotic or placebo. The placebo is a substance which has no effect and is used as a control to compare the effects of the probiotics to. We will monitor changes in blood glucose levels in all participants during the trial via a Continuous Glucose Monitoring (CGM) sensor. A CGM is a small, wearable sensor that measures your blood sugar levels in real time. The sensor consists of a very small needle which is inserted under the skin and a transmitter which sits on the surface that sends data to a reader. CGMs are primarily used by people with diabetes to help them manage their blood sugar levels.

Can I take part?

To take part, you need to be male (aged 25-50 years) or a pre-menopausal female (aged 25-45 years) with a recent HbA1c test result of 39.0 mmol/mol to 51.9 mmol/mol inclusive (5.7% to 6.9%).

You will also need to:

- Upload evidence of a recent (within the last 12 months) HbA1c test result (if you have been directed to this trial through your GP you may not need to do this)
- Have a current BMI between 20-45 kg/m^2 with stable weight over the last 12 months (±5%)
- Be willing to wear and replace a CGM for up to 6 weeks
- Be willing to complete at-clinic blood tests (taken by an appropriately trained staff member), collect at-home stool samples and complete online participant trial surveys
- Be willing to maintain your usual lifestyle throughout the trial, i.e., agree not to change your dietary habits and level of exercise etc. during the trial and do not currently utilise an extreme diet or exercise plan.
- Have access to a smartphone, tablet or laptop/computer

Do I have to take part?

No, taking part is entirely your choice and voluntary. It is up to you to decide whether to take part in the trial or not. A decision not to take part will not affect the standard of care you receive from the NHS in any way, now or in the future.

Participation

What will happen to me if I take part?

The trial will last for 10 weeks, and you will take the trial product (high dose probiotic, low dose probiotic or placebo) via a daily capsule each morning for 6 weeks of this time. You will attend a clinic in Marylebone (London) on 3 occasions, at the start of the trial (baseline) and on weeks 6 and 8 for fasting blood samples. You will be asked to fast from midnight the night prior to your blood sample appointment.

At baseline and on weeks 6 and 8, you will also be asked to collect at-home stool samples. This is so the composition of your gut bacteria and metabolites produced can be analysed. You will be sent stool sample collection kits to your home address and asked to follow the instructions provided to collect the stool samples within 24 hours of each clinic appointment, and you will need to bring the samples with you to each appointment. You will also complete online surveys on your sleep quality, quality of life, physical activity and stool samples at 3 timepoints during the trial.

You will also be asked to wear and replace a CGM sensor sent to your home address for up to 6 weeks, following instructions provided, where data on your blood glucose levels will be collected. While wearing the sensor, you will not have access to view your glucose readings, as this is necessary to maintain the scientific validity of the trial.

Lastly, on a weekly basis, you will be asked to complete an online survey to record whether you have

taken the trial product, complete a food diary and you will also be asked about any side-effects you have experienced since starting the trial.

The information below provides further details.

Initial Online Survey

After reading this information sheet and if you are interested in taking part, we will ask you to complete a short online form to see if you may be eligible. If eligible, you will be asked to complete a short Informed Consent Form (ICF), agreeing to share your relevant medical information with the trial team.

Evidence Upload

If you complete the short ICF, you will be directed to upload evidence online of your recent HbA1c test result (within the last 12 months), either via your GP record or a screenshot of your recent HbA1c test. Guidance on acceptable evidence will be included on the upload page. Your evidence uploaded will then be reviewed by the trial team to confirm your suitability for the trial.

If you have been directed to this trial through your GP, you may not need to do this step.

If your HbA1c test result meets the criteria for the trial, you will be invited to book a video call with a member of the trial team, at a time that is suitable for you, using an online booking system.

Informed Consent

During the video consent call, you will be asked to confirm your identity by showing a government issued ID i.e. Passport or Driving License. You will be asked to complete a consent form electronically online to show your consent for taking part in the trial. You will be able to discuss, with a member of the trial team, the risks, benefits, and what you need to do to take part, and ask any questions. Instructions on how to fill out the form will be provided, so you will know what to do. Your consent form will be counter-signed by a member of the trial team. You will be sent a copy of your consent form to keep.

As an optional part of the informed consent process, you will be asked if you are willing to be contacted about providing additional stool samples after the completion of the trial for the purposes of further research. If you do not wish to consent to this contact it will not impact your ability to participate in the main trial.

Telephone/Video call with the Trial Team and Eligibility Assessment

During the call, you will be able to ask the trial team member any questions you have. If you have signed the Informed Consent Form, you will then be asked about your medical history to check that you are suitable for the trial and your home address will be confirmed for correct shipment of the trial equipment. Once confirmed, the trial team member will help to arrange your first blood test at the clinic.

Baseline Measurements

You will receive a shipment to your home address with the following equipment for initial trial procedures and will be asked to confirm receipt via an online survey sent to you via text/email:

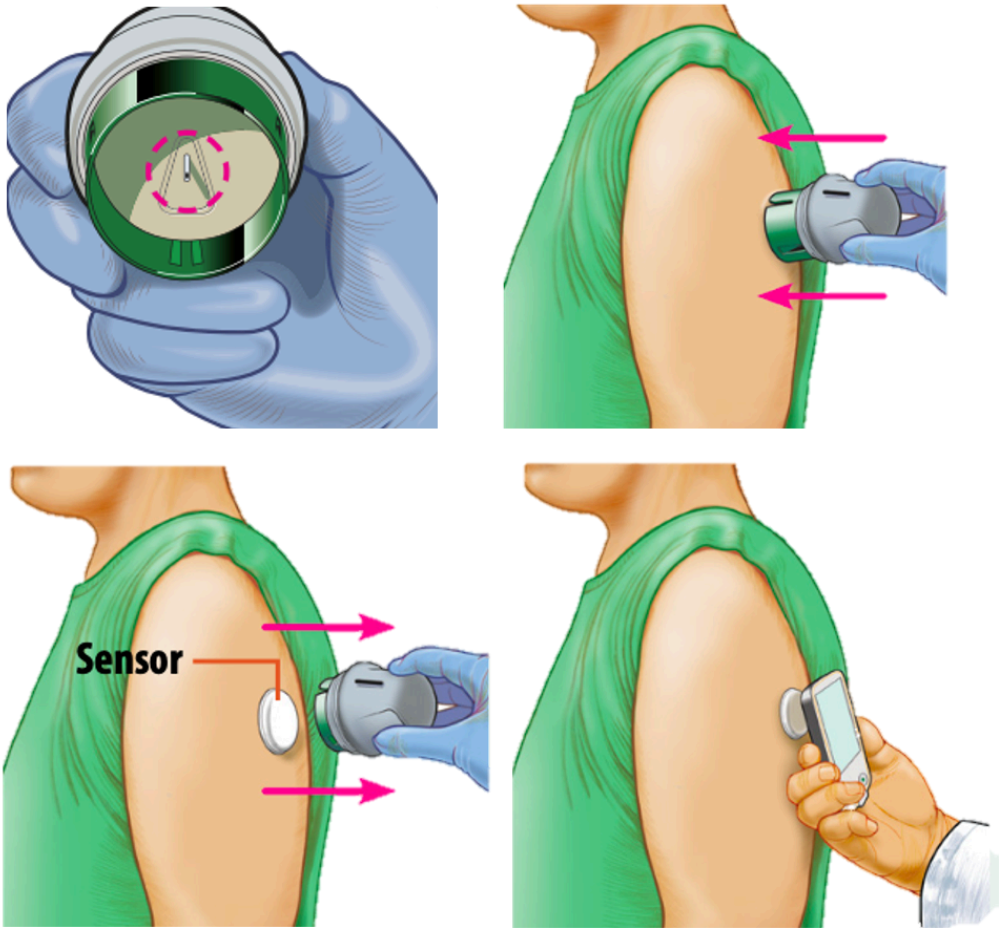
- Continuous Glucose Monitoring (CGM) sensors and reader kits (including instructions for use)
- Pre-paid packaging to post the CGM reader and used sensors back to the trial team as required
- Stool sample collection kits (including sample collection instructions)
    - OMNIgene-Gut OM-200 (this is the specific name of the testing kit)
    - OMNImet-Gut ME-200 (this is the specific name of the testing kit)
    - Stool sample collection aid

If you require further supplies during the course of your participation, you can contact the central trial team via phone or email using the contact details at the bottom of this document.

Before you start taking the trial product, you will complete the following at-home and at-clinic assessments outlined below.

CGM monitoring (at-home)

You will be asked to apply the CGM sensor following the manufacturer's instructions provided in the shipment and via email. As outlined in the images below, this will involve placing the CGM applicator onto the prepared skin area, and pushing down to insert the small sensor needle which sits under the skin. The provided CGM reader will then be used to activate the sensor.



The CGM sensor can be worn while bathing, showering, swimming or exercising. The sensor should not be taken below 1 meter of water (3 feet) and should not be submerged in water for more than 30 minutes.

You will have a video call with the trial team, scheduled via a booking link, for additional guidance on this process. You will be instructed to continuously wear the CGM sensor for the baseline assessment period of 14 days. This is to establish your normal glucose patterns before you start taking the intervention. After the baseline period, you will stop wearing the CGM for a period and then start wearing the CGM sensor again during weeks 5-8. This will allow us to compare your glucose patterns after taking the intervention for several weeks, and then see how this may change once you stop taking the intervention.

You will also be instructed to:

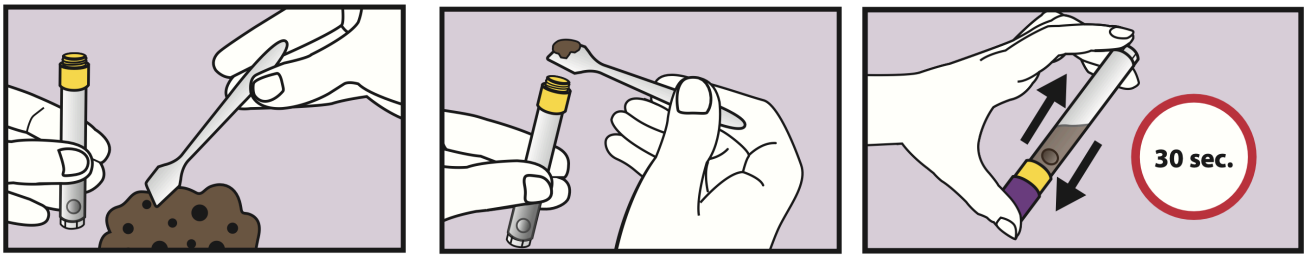
- Return the CGM reader, using the pre-paid packaging, once the CGM sensor has been activated
- Return the used CGM sensor, using the pre-paid packaging, at the end of each 14-day period via a pre-paid envelope in order for its data to be downloaded
- Confirm you have returned the CGM reader and CGM sensor via online surveys sent via text/email

Call with the trial team

Both at the beginning and towards the end of the baseline period you will have a call with a member of the trial team to check in on your progress with baseline assessments and you can ask any questions you may have. These calls will also be used to guide you through the application, activation, removal and return of the CGM sensor.

Stool sample (at-home)

You will be asked to take two stool samples using the collection kits sent to your home address, following the instructions provided in the shipment and via email. This will involve collecting a small amount of fecal sample with a spatula, transferring this into the top yellow section of the tube and then shaking the tube to mix it with the liquid inside the tube, as demonstrated in the images below.



You will be instructed to collect the stool samples within 24 hours of your scheduled clinic appointment and take the collected stool samples to the appointment. You will also receive a survey via email asking

you to complete the date and time that you collected your stool sample. The stool samples will be analysed to measure the following:

- Faecal microbiota structure (refers to the makeup and balance of the trillions of bacteria and other tiny organisms living in your gut)
- Faecal metabolites (faecal microbiome produced metabolites)

Surveys (at-home)

You will receive an email and text with a link to surveys during the trial at baseline, 6 weeks and 8 weeks, asking questions about your sleep quality, quality of life, physical activity, and stool sample survey. You will also receive a weekly food diary. These surveys should take around 10-15 minutes to complete.

Blood test (at-clinic)

Towards the end of the baseline period, you will attend a clinic, where a blood sample will be collected by a trained member of staff. You will be asked to fast from midnight the night prior to your blood test appointment. This visit will approximately take 30 minutes. The blood samples will be analysed to measure the following:

- HbA1c (to measure your average blood sugar levels over the past two to three months)
- Serum cholesterol triglycerides (to measure the amount of cholesterol and fats in your blood)
- Fasting insulin and glucose (to measure your prediabetes status)
- Gut proteins (to measure the levels of these in your blood as they can impact things such as appetite and energy levels)
- Estimated glomerular filtration rate (eGFR) (measures how well your kidneys filter waste from your blood)
- Complete blood count (measures the number and size of different cells in your blood)
- Liver function (to assess the health of your liver)

You will also be asked to bring your at-home collected stool samples to your clinic appointment. You will receive a reminder via text and email 2 days and 1 day prior to your scheduled appointment.

Randomisation

After completing all baseline assessments (for a period of 14 days), you will be randomly put into one of the following trial groups by our computer system:

- High dose probiotic
- Low dose probiotic
- Placebo

Neither you, your GP, nor the Trial Team can decide which group you will be in, it will be decided purely by chance. You will be informed via phone call/email that you have been randomised into the trial. The trial is double-blinded, which means that both you as the participant and the Trial Team will not know whether you are taking the high dose probiotic, low dose probiotic, or placebo until the end of the trial. The reason the trial is blinded is to prevent bias, to make sure that any effects we see are most likely to be due to the probiotic alone and not any other factors.

We will tell you at the end of the trial what you have received. This information will only be provided to you after all participants have completed the trial and the final data has been collected and verified (database lock). At this point, you will be informed which treatment group you were assigned to.

Trial Intervention and Placebo

Trial Intervention

There are 3 treatment groups with different trial products (trial interventions).

If allocated to the low dose probiotic, you will be asked to consume a capsule once a day by mouth each morning for 6 weeks containing:

- Low dose probiotic (*L. brevis*)

If allocated to the high dose probiotic, you will be asked to consume a capsule once a day by mouth each morning for 6 weeks containing:

- High dose probiotic (*L. brevis*)

If allocated to placebo, you will be asked to consume a capsule once a day by mouth each morning for 6 weeks containing 'Microcrystalline cellulose'.

Receiving your Intervention

Arrangements will be made for your allocated trial intervention (high dose probiotic, low dose probiotic or placebo) to be delivered to your home, with instructions on how to take it and for how long.

You should start the allocated product the first available morning after you receive it. You will be instructed to consume 1 capsule once a day by mouth each morning, preferably at least 30 minutes before breakfast time (e.g. 7am) with still water (not sparkling) at room temperature, and record this in your weekly survey. You will be asked to confirm receipt of the product via an online survey received via text and email.

Follow-Up

Weekly Online Survey

On a weekly basis, you will receive an online survey via text and email and be asked to record whether you have consumed the trial product, and any new symptoms, medications or any contacts you have had with healthcare services (e.g. visited your GP or A&E). You can report side-effects to the trial team at any stage of the trial, using the contact details at the end of this document.

If you do not respond to the weekly assessment, a member of the trial team may contact you via phone or email to check whether there are any problems.

CGM sensor

- You will be instructed to start wearing the CGM sensor again at week 5, where glucose measurements will be continuously recorded. You will be instructed to replace the CGM sensor after 14 days following the instructions provided in your initial shipment. CGM sensors have to be replaced regularly to maintain the accuracy of your blood sugar readings. You will be instructed to: Return the reader after CGM sensor activation via a pre-paid envelope
- Remove and return the CGM sensor after the 14-day baseline period via a pre-paid envelope
- Confirm you have returned the reader and the CGM sensor via online surveys sent via text/email

Week 6 Assessments (Including Clinic visit)

The same measurements taken at baseline, at the start of the trial, will also be measured at Week 6. At Week 6, you will:

- Provide stool (at-home) samples
- Provide blood (at-clinic) samples
- Complete an online survey on your sleep quality, quality of life, diet quality, physical activity, and stool samples
- Continue to wear the CGM sensor

At the end of Week 6, you will take your final capsule of your allocated product (high dose probiotic, low dose probiotic, or placebo).

You will be asked to fast from midnight the night prior to your blood test appointment and you will also be asked to bring your stool samples that you collected at home to your clinic appointment. You will receive a reminder via text and email 2 days and 1 day before your scheduled appointment.

Weeks 7-8 Assessments (Including Clinic visit)

At the end of Week 6 you will **stop taking** the probiotic or placebo (this is called a washout period) and any remaining trial product should be disposed of at home. The same measurements taken at baseline and Week 6, will also be measured at Week 8.

At the end of Week 8, you will stop wearing the CGM sensor.

Telephone/Video Calls

The trial team will call you throughout the trial. In particular, at the beginning of weeks 5 and 7 participants you will have a phone/video call with a member of the trial team to check in on your progress with trial assessments and remind you of the need to apply/reapply your CGM sensor. You will also have the opportunity to ask any questions you may have. During the week 7 call, you will be reminded about the washout period in weeks 7-8.

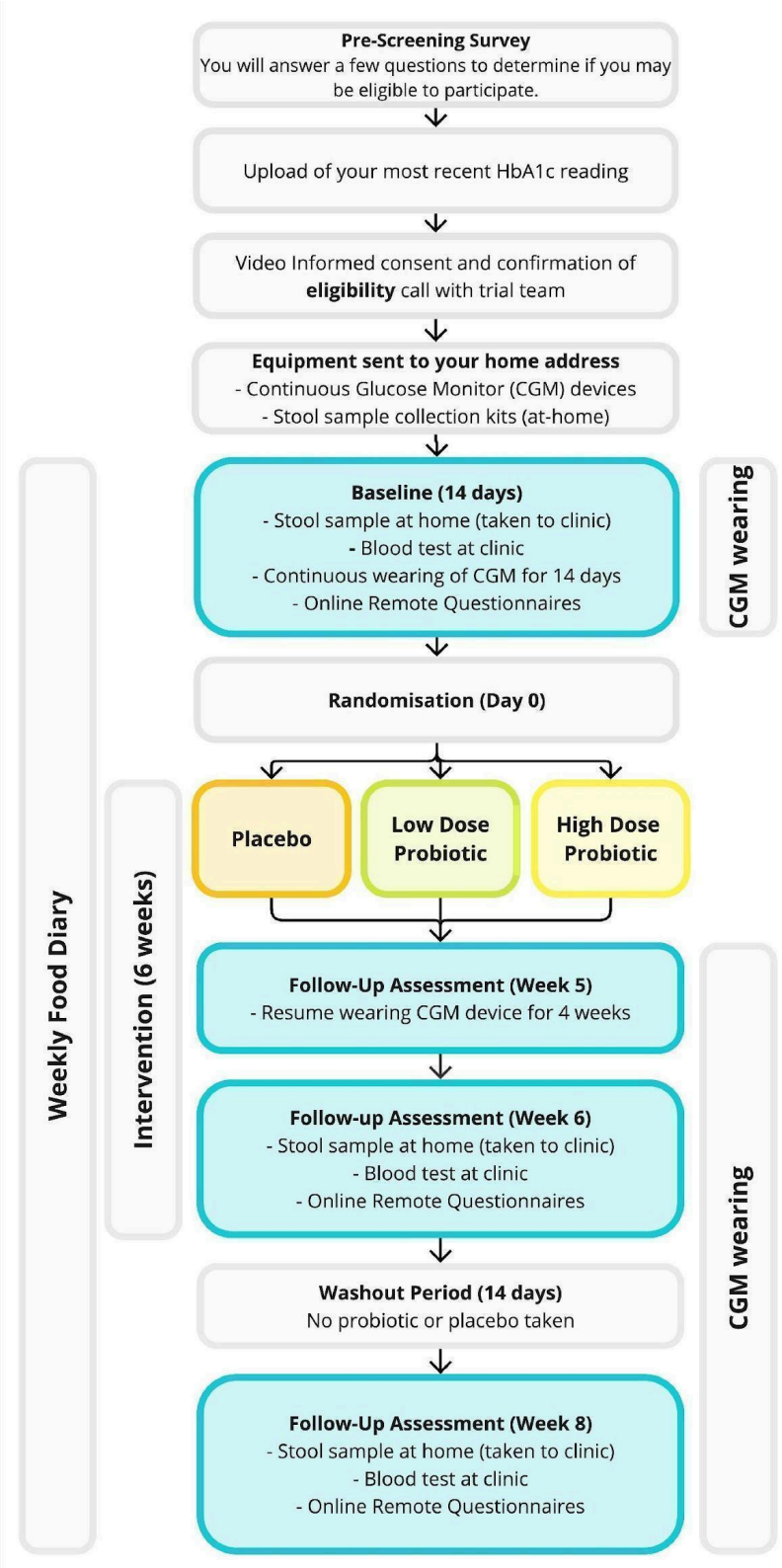


Table 1 – Overview of Trial Assessments

Assessment	Baseline	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8

	(period of 14 days)	(Days 1-7)	(Days 8-14)	(Days 15-21)	(Days 22-28)	(Days 29-35)	(Days 36-42)	(Days 43-49)	(Days 50-56)
CGM sensor monitoring	✓	X	X	X	X	✓	✓	✓	✓
At-home stool samples	✓	X	X	X	X	X	✓	X	✓
At-clinic blood samples	✓	X	X	X	X	X	✓	X	✓
Surveys on Sleep Quality, Quality of Life, Physical Activity and Stool Samples	✓	X	X	X	X	X	✓	X	✓
Weekly online surveys asking about Diet Quality, whether you have taken the product (week 1 to end of week 6) and asking about any side-effects and new medications	✓	✓	✓	✓	✓	✓	✓	✓	✓

Risk, Benefits and Compensation

What are the possible disadvantages or side effects of taking part?

With any intervention there is a risk of side effects. There are a number of known side-effects that commonly occur with probiotic intake as listed below:

- *Bloating*
- *Gas*
- *Mild flatulence*

We will ask you to tell us about any side-effects, which you think may be related to taking the probiotic/placebo, in your weekly online surveys. These side-effects will be monitored by a clinical member of the team.

You may experience some pain or discomfort during the application of the CGM sensor, and in some cases bleeding may occur. If there is any ongoing pain or the bleeding does not stop, you should contact the trial team using the details at the bottom of this document.

You will need to provide blood samples at 3 time-points. This is usually straightforward with no significant side effects. It may cause pain, bruising, light-headedness, fainting, and extremely rarely a skin infection. However, to reduce these risks we will be using experienced phlebotomists to take these samples.

Please note that no further trial product will be provided after you have completed participation in the trial.

What are the possible benefits of taking part?

We do not know if the intervention being tested will have any benefits. The probiotic may, or may not, help you personally, but we hope the evidence gathered in this trial will help future people with higher HbA1c levels.

At the end of the trial, you have the option to receive summary reports of your individual CGM data and laboratory test results, including blood markers such as HbA1c measured throughout the trial.

What will happen to any samples I give?

All of your samples and data will be linked to each other through your unique participant identification code. The samples you provide will be de-identified, labelled with your participant identification only, and stored securely and in compliance with the Human Tissue Act (2004). All of your faecal samples and some of your blood samples will be sent to a Sponsor lab outside UK (Finland and Denmark) for analysis and will also be destroyed at the end of the trial.

You will receive no financial benefits and may not receive any health-related benefits from such

developments.

No genetic testing will be conducted as part of this trial.

The Sponsor will be studying the DNA of the bacteria from your stool samples (i.e. **not your DNA**, only the DNA of the bacteria found in your stool). The samples in these cases would be destroyed once they have been analysed.

What will happen if I do not want to continue with the trial or lose capacity to consent during the trial?

If you decide to take part, you can still withdraw at any time without giving a reason. If you decide to withdraw or lose the capacity to consent during the trial, information collected up to that point will still be used. The blood and stool samples that you provide will still be processed and destroyed once analysed.

If you wish to withdraw from the trial, please contact the Trial Team using the contact details at the end of this document. The decision to withdraw will not affect the standard of care you receive from the NHS in any way, now or in the future.

Expenses and Payments

You will be compensated up to £350 in cash via PayPal or e-vouchers for your time taken to collect samples and complete surveys for the trial. This will also cover expenses for your travel to the clinic for your blood tests. Your email address will be provided to the vendor responsible for organising trial payments. You will receive a one-off payment at the end of the trial based on the assessments you have completed during the trial.

Please see below the breakdown for compensation:

- £110 upon completion of all baseline assessments (at-home stool samples, at-clinic blood samples, online surveys, wearing of CGM monitor)
- £110 upon completion of all week 6 assessments (at-home stool samples, at-clinic blood samples, online surveys, wearing of CGM monitor)
- £130 upon completion of all week 8 assessments (at-home stool samples, at-clinic blood samples, online surveys, wearing of CGM monitor)

What if there are any problems?

If you have any questions about this trial, please contact the Trial Team (see the last page for contact details).

IFF, as Sponsor, has appropriate insurance in place in the unlikely event that you suffer any harm as a direct consequence of your participation in this trial. The Sponsor will provide compensation for any

injury caused by taking part in this trial in accordance with guidelines of the Association of the British Pharmaceutical Industries (ABPI). The Sponsor will pay compensation where the injury has resulted from:

- A product being administered as part of the trial protocol; or
- Any test or procedure you received as part of the trial.

Any payment would be without legal commitment (please ask if you wish more information on this). The Sponsor will not be bound by these guidelines to pay compensation where the injury resulted from a medication or procedure outside the trial protocol or where the protocol and/or instructions of the trial Doctor and trial staff were not followed.

If you wish to complain about any aspect of the way in which you have been approached or treated, or how your information is handled during the course of this trial, you should contact the trial team on gsquared@lindushealth.com or 0800 058 4496**.**

If you remain unhappy and wish to complain formally to someone independent of the trial team, please contact support@lindushealth.com. They will be able to provide you with support for any formal complaints or problems you have, completely separately from the trial team. Your concern will be acknowledged within 2 working days.

What will happen to the results of the trial?

Results will be shared with trial participants by the Sponsor through appropriate channels, which may include written reports or electronic communications through the trial website. Results may also be published in scientific journals, presented at scientific conferences, published on the Sponsor and/or Lindus Health websites, or reported in the media. It will not be possible to identify you in any report, publication or presentation.

Confidentiality

How will we use information about you?

We will need to use information from you, from your medical records and, in some cases, your GP for this research project. 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 trial, 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 trial.

IFF is the sponsor of this research (i.e. they have overall responsibility for the initiation, financing and management of the trial) and is responsible for looking after your information. Lindus Health will be processing your data on IFF's behalf, to conduct the trial.

We will keep all information about you safe and secure by:

- Storing your trial information safely on a database on a secure computer system. Only approved staff members can access this information using their personal login details
- Following relevant rules on data protection, e.g. the Data Protection Act (2018) in the UK
- Following international standards for information security management
- Encryption of any identifiable participant data (encryption is a mathematical process that scrambles data into a secret code, making it unreadable to anyone without the key)
- Ensuring data transfers are encrypted
- Ensuring other organisations processing your data have appropriate security measures to protect your data which are consistent with the data security and confidentiality obligations we have. This includes having appropriate measures to protect your data against accidental loss and unauthorised access, use, changes or sharing
- Ensuring there are procedures in place to deal with any suspected personal data breach. We will tell you and applicable regulators when there has been a breach of your personal data when we legally have to. For further details about UK breach reporting rules visit the Information Commissioner's Office (ICO) website

What are your choices about how your information is used?

You can stop being part of the trial at any time, without giving a reason, but we will keep information about you that we already have.

You have the right to ask us to remove, change or delete data we hold about you for the purposes of the trial. We might not always be able to do this if it means we cannot use your data to do the research. If so, we will tell you why we cannot do this.

If you agree to take part in this trial, you will have the option to take part in future research. As an optional part of the informed consent process, you will be asked if you are willing to be contacted about providing additional stool samples after the completion of the trial for the purposes of further research that may result in microbial isolates to be used to design a commercial strategy or product. If you do not wish to consent to this contact it will not impact your ability to participate in the main trial.

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

You can find out more about how we use your information

- at www.hra.nhs.uk/information-about-patients/
- our leaflet available from https://www.lindushealth.com/privacy-policy
- by asking one of the trial team
- by sending an email to data@lindushealth.com

Other Information about your data

Our procedures for handling, processing, storage and destruction of data comply with the Data Protection Act of 2018 and GDPR. We will keep identifiable information about you for up to twelve

months after the trial has finished. This excludes any research documents with personal information, such as consent forms, which will be held securely for 10 years after the end of the trial.

Lindus Health may also retain personal data for business improvement purposes. For example, use of behavioural data to make feature improvements to the Electronic Data Capture platform.

All samples taken and sent to a laboratory for processing will contain your unique participant ID and no personally identifiable information. Further information about your rights with respect to your data is available at: TDL Privacy Policy. Some samples taken during the trial will be sent to the EU for analysis, these samples will contain your unique participant ID and no personally identifiable information.

As part of this clinical trial, your CGM data will be collected. Please note that your CGM data will be shared with the following parties: The third-party vendor responsible for processing your CGM data, Lindus Health (CRO) and IFF (Sponsor). The data will contain your unique participant ID and no personally identifiable information.

With your consent, your GP will be informed about your participation in the trial.

Further information about your rights with respect to your personal data is available at: Lindus Health Privacy Policy. You can find out more about how we use your information by contacting gsquared@lindushealth.com.

What if relevant new information becomes available during the trial?

Sometimes during the course of a research project, new information becomes available about the intervention that is studied. **If this happens, the trial team will tell you about it and discuss with you to confirm whether you want to continue in the trial or not.** If you decide to continue you may be asked to sign an updated consent form.

Trial Team Oversight & Contact Details

Who is organising and funding the research?

Funding has been provided by IFF, who is the trial Sponsor. The trial is being organised by Lindus Health, who are a Contract Research Organisation (CRO).

Who has reviewed the trial?

All research in the NHS is looked at by an independent group of people called a Research Ethics Committee (REC). The REC is there to protect your safety, rights, wellbeing and dignity. This trial has been ethically reviewed and favourable opinion issued by the Newcastle & North Tyneside 2 Research Ethics Committee (REC Reference: 25/NE/0031).

Thank you for considering taking part in this trial. For further details, please contact the trial team:

Trial Team Contact Details

Telephone: 0800 0584496

Email Address:
gsquared@lindushealth.com