UNIVERSITY OF ABERDEEN
The Rowett Institute

PARTICIPANT INFORMATION SHEET

1. Study Title and Chief Investigator

Study Title and number: Diabetes and Health Study (Study 805)
Chief Investigator: Dr Alex Johnstone

2. Invitation Paragraph

You are invited to take part in a research study. Before you decide whether to volunteer, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully. Talk to others about the study if you wish.

Please do not hesitate to contact us (see below) if there is anything that is not clear or if you would like more information.

3. What is the purpose of this study?

Our previous work identified changes in the gut microbiota when Molkosan®, a prebiotic liquid supplement was consumed over 6 weeks. There were significant changes in fasting metabolic parameters observed following the intervention period. A reduction in Total Cholesterol, Glucose, Triglycerides and Insulin was also observed. This study will assess if the consumption of the prebiotic over a longer period (12 weeks) will improve metabolic health by altering gut microbiota profile in subjects with Type 2 diabetes.

4. Why have I been chosen?

- You have expressed an interest in taking part after seeing the study advertised either on the Rowett Institute website, on social media, in local press, by letter, newsletter, on a public poster or by GP doctors
- You have Impaired Glucose Tolerance (IGT) or Type 2 Diabetes (managed by diet or intake metformin)
- You are aged 18-75years
- Your BMI is within the range 18-40kg/m^2

You will not be suitable for the study if you …

- Are aged under 18 or over 75years
- Anyone with a BMI (in kg/m^2) under 18 or over 40
- Females who are planning to be pregnant, are pregnant or breastfeeding
- Anyone who has used any antibiotics within the last 3 months, including proscribed and prescribed use
- Anyone who currently uses a probiotic or prebiotic
- Anyone who uses medication for glucose regulation
- Anyone with Type 1 Diabetes
- Anyone with an eating disorder
- Anyone with a severe gastrointestinal disorder, kidney disease, liver disease, thromboembolic or coagulation disease, gout
- Anyone suffering from a psychiatric disorder or any type of alcohol or substance abuse

- Anyone suffering from unregulated thyroid disease

5. Do I have to take part?

Taking part in this study is voluntary. As a volunteer, you are under no obligation to take part or continue with the study if you do not wish to do so. Therefore, you can withdraw at any time without giving a reason.

6. What does the study involve?

You will be asked to attend the Rowett Human Nutrition Unit (HNU) on six occasions include screening visit.

We will provide all the supplements you require for the study duration.
A diagram for the study protocol can be found at the end of this information sheet

7. What measurements will be conducted if I take part?

Visit 1 - Screening (HNU, ~1hr):

- Consent paperwork
- Complete and return a 'health' questionnaire to confirm inclusion criteria are met
- Height and Body weight
- A small blood sample will be collected for analysis of HbA1C to confirm impaired glucose tolerance
- Collection of food diary 1 & pot for faecal sample 1

Washout Period (at Home):

- Complete 3day food diary
- Record gastro-intestinal symptoms
- Provide faecal sample (collected in pot <16hours before Baseline visit)

Visit 2 – Baseline (HNU, Week 0, ~3½ hrs): 2days before visit 3, Oral Glucose Tolerance Test (OGTT) will be measured- Blood samples will be collected over 3hours (0, 30, 60, 90, 120 and 180 min; a total of blood sample per visit ~40ml or two tablespoons).
Breath sample - will be collected every 30 min in special breath bags for up to 3 hr.

Visit 3 – Baseline (HNU, Week 0, ~3½ hrs):

- Bring faecal sample 1 in collection pot
- Give completed food diary 1 to study team
- Body weight
- Blood pressure measurement

- Oral Glucose Tolerance Test (OGTT) - Blood samples will be collected over 3 hours (at 0, 30, 60, 90, 120 and 180 min, total volume for the blood samples are ~40ml, or two tablespoons). Analysis of fasted glucose, insulin, lipid profile and gut hormone profile will be conducted from the samples
- Breath sample - will be collected every 30 min in special breath bags for up to 3 hr.
- Collection of new food diary (diary 2) & pot for faecal sample 2
- Collection of sufficient supplements for 6weeks with advice on consumption

Intake Period 1 (at Home):

- Consume 1 x 20ml supplement daily. Keep all empty bottles (to be returned to HNU)
- Complete 3day food diary (include record of any supplements or change in medications)
- Record gastro-intestinal symptoms
- Provide faecal sample 2 (collected in pot <16hours before Visit 3)

Visit 4 (HNU, Week 6, 45mins):

- Bring faecal sample 2 in collection pot
- Give completed food diary 2 to study team
- Body weight
- Blood pressure measurement
- Blood sample (~7ml will be taken, or one teaspoon)
- Collection of new food diary (diary 3) & pot for faecal sample 3
- Collection of sufficient supplements for 6weeks

Intake Period 2 (at Home):

- Consume 1 x 20ml supplement daily. Keep all empty bottles (to be returned to HNU)
- Complete 3day food diary (include record of any supplements or change in medications)
- Record gastro-intestinal symptoms
- Provide faecal sample 3 (collected in pot <16hours before Visit 4)

Visit 5 – (HNU, Week 12, ~3½ hrs): 2days before visit 6, Oral Glucose Tolerance Test (OGTT) will be measured- Blood samples will be collected over 3hours (0, 30, 60, 90, 120 and 180 min; a total of blood samples per visit ~40ml, or two tablespoons)

Breath sample - will be collected every 30 min in special breath bags for up to 3 hr.

Visit 6 – (HNU, Week 12, ~3½ hrs):

- Bring faecal sample 3 in collection pot
- Give completed food diary 3 to study team
- Body weight
- Blood pressure measurement
- Oral Glucose Tolerance Test (OGTT) - Blood samples will be collected Blood samples will be collected over 3hours (0, 30, 60, 90, 120 and 180 min; a total of blood samples per visit ~40ml, or two tablespoons)
- Breath sample - will be collected every 30 min in special breath bags for up to 3 hr.
- Analysis of fasted glucose, insulin, lipid profile and gut hormone profile will be conducted from the samples
- A small blood sample will be collected for analysis of HbA1C

8. What if you find something in my samples?

If we find a blood, or other result, that is out with normal ranges we will inform you and your GP

9. What will happen to the samples I give?

All the samples will be coded to maintain confidentiality. We will store your samples until the study has been completed and then for a further 5 years.

10. Expenses and payments

All of the prebiotic supplements will be provided and we are able to offer a small gratuity (£50) as financial reimbursement for travel expenses related to participation in this study.

11. What are the possible disadvantage and risk of taking part in the study?

This study uses a commercially available product, therefore we do not expect any serious adverse effects. However any time during the study, if you have a complaint or unwell, you can contact to the research team or Human Nutrition Unit Manager, Ms Sylvia Stephen. The research team will also closely monitor how you are feeling during the study, and you can be withdraw the study anytime you wish.

12. What are the possible benefits of taking part in the study?

We would hope that by taking part your metabolic health will improve (e.g. a reduction in blood cholesterol or glucose). On completion of the study you will receive a report detailing the results from your measurements: weight, height, blood pressure and blood results, which you may find interesting and useful.

13. What if there is a problem?

At any time during the study, if you have a complaint or a concern that you have been unable to resolve with the Principal Investigator or Human Nutrition Unit Manager, Ms Sylvia Stephen you may contact Dr Baukje de Roos (Chair of the Human Studies Management Committee). You can be assured that Dr de Roos will be a sympathetic listener and that your concerns will be treated

seriously. She can be contacted on 01224 438636 or by email b.deroos@abdn.ac.uk. The University carries indemnity insurance for any harm or adverse event and Dr de Roos can be contacted for more information about this.

14. Who has reviewed this study?

This study has been reviewed and approved by the Human Studies Management Committee of the Rowett Institute of Nutrition and Health and the Rowett Institute Ethics Panel.

15. Who is organising and funding the research?

The study is funded by the Scottish Government as part of the 'Healthy, Safe Diets' research theme

16. Will my taking part be kept confidential?

All data collected from you will be coded to ensure your anonymity in any publication from this study. Only your screening paperwork will have record of your name and will be stored separately to the rest of the documents containing your data. All of the data will be held in locked cabinets, in locked offices and/or on password protected computers/memory sticks. All data will be stored for a maximum of 5 years, after which they will be destroyed.

17. What will happen to the results of the research study?

You will be received a short report on their own data such as height, weight, blood composition results. We will use only average data for publishing the results and non-identifiable data.

18. Contact for the this study

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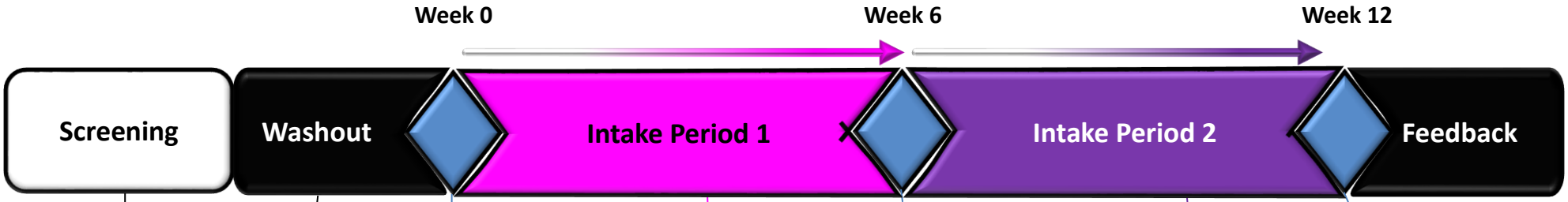
Thank you for having taken the time to read this information sheet and for your interest in the study.

If you do decide to take part, you will be given a signed consent form for you to keep.

Study Diagram:



Visit 1 Screening (at HNU)
- Consent Paperwork
- Health Questionnaire
- Height & Weight
- Finger prick Sample for HbA1c
- Collection of Food Diary & pot for faecal sample 1

Washout Period (at Home)
- **No** probiotics or prebiotics to be consumed
- Record 3day Food Diary & gastro-intestinal (GI) symptoms questionnaire
- Provide faecal sample 1 (collected in pot <16hours before Baseline visit)

Visit 2 (~3½ hrs) - Baseline
- Visit 2 day before Visit 3 for OGTT & breath test –HNU (~3½ hrs)

Visit 3 (~3½ hrs) - Baseline
- Bring faecal sample 1
- Return completed food diary & GI questionnaire
- Body Weight
- Blood Pressure
- OGTT Blood Samples
- Breath Samples
- Collect new food diary, pot for faecal sample 2 & supplements for 6 week intake period 1

Intake period 1 (at Home)
- Consume 1x20ml supplement daily
- Record 3day Food Diary & GI symptoms questionnaire
- Provide faecal sample 2 (collected in pot <16hours before Visit 3)

Visit 4 (~45 mins) – week 6
- Bring faecal sample 2
- Return completed food diary & GI questionnaire
- Body Weight
- Blood Pressure
- Collect new food diary & pot for faecal sample 3 & supplements for 6 week intake period 2

Intake Period 2 (at Home)
- Consume 1 x 20ml supplement daily
- Record 3day Food Diary & GI symptoms questionnaire
- Provide faecal sample 3 (collected in pot <16hours before Visit 4)

Visit 5 (~3½ hrs) – week 12
- Visit 2 day before Visit 6 for OGTT & breath test – HNU (~3½ hrs)

Visit 6 (~3½ hrs) – week 12
- Bring faecal sample 3
- Return completed food diary
- Body Weight
- Blood Pressure
- OGTT Blood Samples
- Breath Samples
- Finger prick blood samples for HbA1c