UNIVERSITY OF ABERDEEN
The Rowett Institute

PARTICIPANT INFORMATION SHEET

Name of Study:	Assessing the effects of a purple corn and yacon on gut microbiota composition and glucose metabolism of healthy individuals (**Purple food study**)

Principal investigator: Dr Madi Neacsu

Thank you for expressing an interest in participating 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.

What is the purpose of this study?

The purpose of this study is to understand potential benefits of consuming foods prepared from Peruvian crops like purple corn and yacon, on gut and metabolic health.

Why have I been chosen?

You have been chosen because you:

- Are a healthy male or female aged between 18 and 70 years
- Have a Body Mass Index (BMI) between 18 and 35
- Eat a mixed (omnivorous) diet
- Have regular bowel movements and do not suffer from constipation
- Are able to attend the Rowett Institute to give consent
- Can arrange for a faecal sample to be delivered to the Rowett Institute
- Can read and understand English and the study documents

You cannot take part if you:

- Have taken antibiotics in the last 3 months
- Are currently taking medication for high blood pressure
- Are receiving treatment for severe inflammatory bowel disease (IBD) or irritable bowel syndrome (IBS)
- Have an autoimmune condition
- Are currently living with cancer or receiving cancer treatment
- Have active ulcerative colitis or Crohn's disease
- Are directly managed or supervised by the study's Principal Investigator (PI)
- Have any known food allergies

You will be asked about inclusion/exclusion criteria during your recruitment meeting.

Do I have to take part?

No. It is up to you to decide whether or not you would like to take part.

You will have a minimum of 48 hours to decide. If you do decide to take part, you will be given this information sheet to keep and be asked to sign a consent form.

You can withdraw at any time, without giving a reason. If you do withdraw from the study, any data collected up to this point may still be used (unless you ask for samples and data to be destroyed).

What will happen to me if I take part?

If you agree to take part, an initial screening meeting will then take place, at least 48 hours after you received this Participant information sheet, during which you will meet with a member of the research team.

After you sign a consent form, you will be asked to complete a questionnaire detailing your age, availability, height and weight (if not accurately known, will be measured) and details of any relevant health conditions and regular medication to ensure you meet the inclusion/exclusion criteria for the study.

If you meet the study eligibility criteria then you will be given a unique identification number that will be used at all times during the study to keep your identity anonymous and you will be invited to participate in a randomised crossover design human dietary intervention. We will recruit 20 eligible volunteers.

This will involve four short visits to the Human Intervention Studies Unit (HISU) at the Rowett Institute like described in the study diagram (Figure 1).

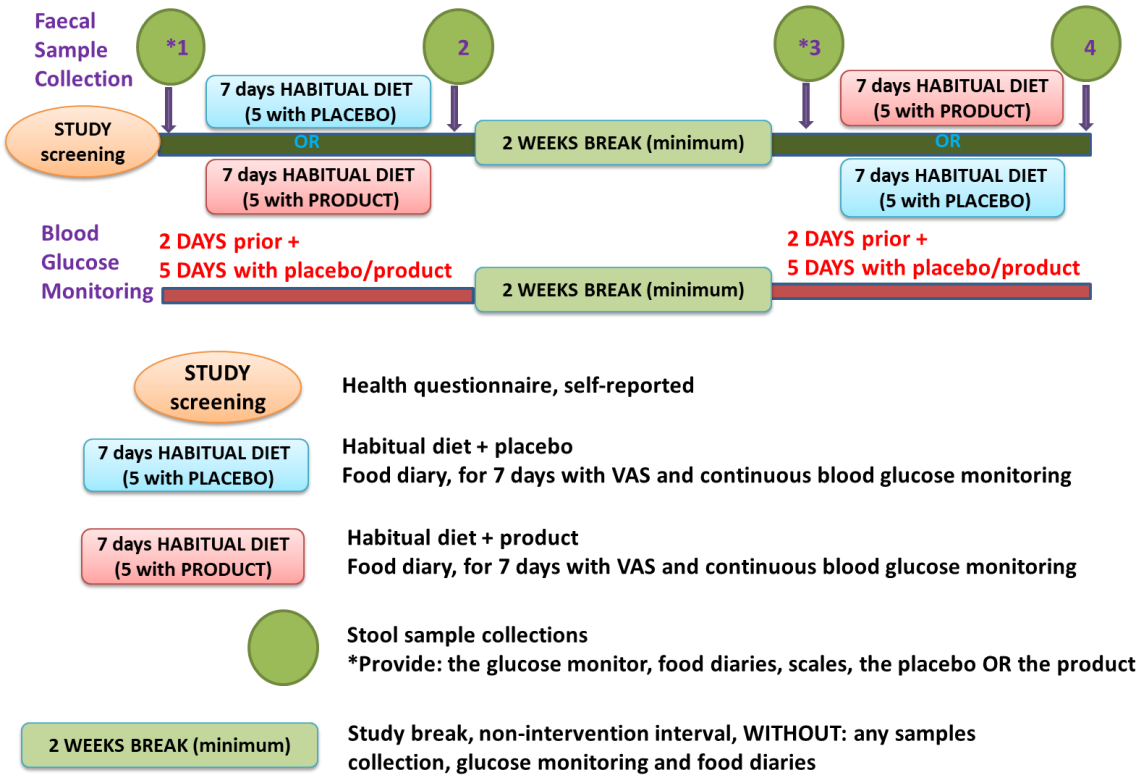

Figure 1: Study diagram

The screening: Comprises measurements of body weight, height and the completion of a self-reported medical questionnaire.

Habitual diet: Comprises of a 7-day weighed dietary intake of your normal diet. You will follow your habitual diet and record all details into a food diary (provided), combined with measurement of appetite during usual waking hours.

You will be asked to consume a purple corn and yacon beverage (or a placebo beverage) three times a day with your main meals for five consecutive days. You will be told which beverage you need to take and when and you will be able to distinguish between the beverages. The beverages will be provided in powder form, and you will be advised best way to incorporate them as part of your main meals. You will receive a questionnaire to assess any potential gastrointestinal discomfort the beverage might produce during the intervention. This questionnaire will be filled for seven days (2 days prior plus 5 days intervention) for each of the two interventions periods.

You will be asked to provide four faecal samples in total (Figure 1). The Bristol Stool Chart will be also provided, which is a simple tool that helps you describe the shape and consistency of your poop. This chart will be filled for seven days (2 days prior plus 5 days intervention) for each of the two interventions periods.

Prior the first faecal collection you will be provided with the study beverage (in powder form) and placebo product, the food diaries, glucose monitors and all the study collection faecal kits.

Your blood glucose will be recorded for 14 days using a portable device starting two days prior the 5-days administration of the placebo or beverage product (Figure 1). For this we will use a continuous glucose monitor (CGM), which you will be supplied with (one for each intervention period, two interventions in total).This require the access to a smart phone, if you do not have one, this will be provided for the duration of the study.

A continuous glucose monitor (CGM) is a small device that tracks your blood sugar levels throughout the day and night. It works by using a tiny sensor placed just under the skin, usually on your arm or stomach, which measures glucose levels in the fluid between your cells. The sensor sends this information to a small device on your phone via an app, so you can see how your levels change in real time. This helps us better understand how your body responds to the food we give you to trial (beverage) and means we do not need to collect blood to measure this.

A bit more info about CGM: When it is fitted, a very small needle is briefly inserted just under the skin to place the sensor. This needle is then removed, leaving the sensor in place. The sensor continuously measures glucose levels in the fluid under your skin and sends the data to a small reader or app.
Most people find the CGM comfortable to wear and experience no problems. However, some may notice mild skin irritation, redness, or discomfort at the site. Serious side effects are very rare.
If you have any concerns or questions about wearing the CGM, please speak to a member of the study team.

The test beverage consists in a purple corn beverage sweetened with yacon. This type of non-alcoholic drink produced from purple corn is a very popular (national drink) of Peru. To produce the purple corn beverage for this study, has been used a simplified recipe similar to “chicha morada” without adding any extra sugar, spices or aromas only yacon as sweetener. The ingredients used comprised purple corn water and citric acid (instead of lemon juice) and yacon syrup.

For convenience, the beverage will be provided in powder form. One portion of beverage is 10 g containing 5 g of dietary fibre.

The placebo beverage will consist of cellulose (specifically carboxymethyl cellulose), dyed with a natural, beetroot-based edible colorant. It will be matched to the test beverage in both fibre sugar content and appearance.

You will be asked to consume the beverage and/or placebo three times per day with/as part of your main meals for five days (Figure 1). You have the option to incorporate it in your drinks, shakes, yogurts, cereals, main meals and consume it along with your food.

During the two intervention periods, you will keep a food diary containing questionnaires assessing your hunger and appetite during your normal waking hours.

What will happen to the samples I give? What happens to my results?

Data will be collected using questionnaires, forms, glucose monitoring data and food diaries and will be stored in secure electronic files on study-specific shared drives or locked cupboards and filing cabinets until and after the analysis. This data and the data collected during the measurements performed on the collected biological samples will be recorded in laboratory notebooks and secure electronic files on study-specific shared drives. All samples will be collected and stored in an anonymised form.

The biological samples collected will be link-anonymised and measured using specialised techniques for several metabolites (carbohydrates). The bacterial DNA will be extracted from faecal samples to understand how the diet we provide will affect your gut microbiota composition.

We will inform your GP about your participation in the study only in case of out of clinical range parameters measured or the presence of blood in your stool. We will therefore ask for your consent to do this and ask you to provide your GP name and address at the time of recruitment.

All electronic data will be stored for 10 years after the end of the study in a secure University of Aberdeen Shared Drive. Archiving will only occur once all relevant paper data has been published, we estimate this will be for five years. The paper data will be archived for 10 years following publication of the project, in line with the institutional retention schedule.

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

The study may not help you personally but the information we collect should help identify if these crops are worth considering for developing novel prebiotics and for inclusion in human diet. You can also learn how your body responds (in terms of blood glucose levels) consuming your normal diet and also learn about the composition of your gut microbiota.

Will any genetic testing be done?

No genetic testing of human DNA will be carried out on your samples at any time. We will only study the microbes that are present in the donated faecal samples.

What are the possible disadvantages and risks of taking part?

The inconvenience will be the time spent bringing the samples at the Rowett Institute; potentially if you will dislike the food product (beverage) provided.

What if something goes wrong?

Potentially for you the purple corn and yacon based beverage is a new culinary experience. These crops are not listed allergens, and the drink is containing very low amounts of protein, which means it is well-tolerated by most people and not likely to cause an allergic reaction. However, people can develop an allergy to any food at any time.

If you notice potential side-effects (listed below) when consuming the products, stop taking the products and to contact your GP or A&E department:
Irritation: itchiness, swelling, and puffiness of the eyes, and the skin in general.
Hives: in the forms of skin rash, plaques, or pale red bumps.
Allergic Rhinitis: sneezing, running nose, and nasal congestion.
Asthma: difficulty in breathing, tightness in the chest, and abnormal lung function.
Conjunctivitis: pink and/or red bloodshot eyes.
Anaphylaxis: skin rash, nausea, vomiting, difficulty in breathing, and shock. If you're having an allergic reaction with signs of anaphylaxis, you should immediately call 999 or your local medical emergency number.

At any time during the study, if you have a complaint or concern that you have been unable to resolve with the Chief or Principal Investigator, you can contact the Deputy Director Professor Frank Thies who is Head of the Human Studies Management Committee and independent of the study. You can be assured that Professor Thies will treat your concerns sympathetically and confidentially. He can be contacted by phone on 01224 437954, and email to: f.thies@abdn.ac.uk. Alternatively you can file a formal complaint to researchgovernance@abdn.ac.uk

Expenses and payments

You will not receive any payment for your participation in this study. The test products during this study will be free.

Will my taking part in this study be kept confidential?

All information which is collected about you during the course of the research will be kept strictly confidential. Any information about you which leaves the Institute will have your name and address removed so that you cannot be recognised from it. All data will be stored for a maximum of 10 years from the end of the study, after which time it will be destroyed. Please refer to the University of Aberdeen privacy statement: https://www.abdn.ac.uk/about/privacy/research-participants-938.php

What will happen to the results of this research study

We will present our findings at conferences and the data may form part of published scientific paper(s). You will not be identified in any report/publication.

How will we use information about you?

We will need to use information from you for this research project.
This information will include your name/contact details. People will use this information to do the research or to check your records to make sure that the research is being done properly. 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.

Once we have finished the study, 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 study.
We will keep your study data for a maximum of 10 years. The study data will then be fully anonymized and securely archived.

What are your choices about how your information is used?

You can stop being part of the study 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 study. 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.
More information you can find from University of Aberdeen data protection team. Phone: 01224 272596 Email address: dpa@abdn.ac.uk

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

You can find out more about how we use your information, including the specific mechanism used by us when transferring your personal data out of the UK.
• by asking one of the research team
• by sending an email to [email], or
• at www.abdn.ac.uk/about/privacy/

Who is organising and funding the research?

The study is being run by the University of Aberdeen and is funded by Biotechnology and Biological Sciences Research Council. The research team involved will not be paid for including you in this study.

Who has reviewed this study?

This study has been reviewed by the University of Aberdeen, Rowett Institute's Human Studies Management Committee and ethically approved by their Ethical Review Panel.

Who do I contact about this study?

If you have any further questions about the study or your involvement, please contact any of the study team members mentioned below or the study PI: Dr Madi Neacsu (m.neacsu@abdn.ac.uk)

CONTACTS FOR 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 IN THE STUDY, YOU WILL BE GIVEN A COPY OF THIS INFORMATION SHEET AND A CONSENT FORM TO SIGN AND DATE.