PARTICIPANT INFORMATION SHEET

Name of Chief Investigator (CI): Madalina Neacsu

Name of Study: BUCKFOOD study: Assessing the effects of a buckwheat beverage on postprandial glucose metabolism on healthy and T2D individuals

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.

What is the purpose of this study?

A constant high glucose level in blood after meal consumption is an independent risk factor for cardiovascular complications and death. In order to prevent Type 2 Diabetes Mellitus (T2D) and/or its complications it is important to have a strict control of the blood glucose levels after a meal. There are known therapies for the control of the high glucose blood levels such as agents that act on intestinal digestion of carbohydrates and therapeutic agents that mimic the insulin response after a meal. The combination of these type of agents was commonly prescribed in the treatment of T2D.

Buckwheat is a unique crop because is naturally rich in compounds that have shown beneficial effects on glucose metabolism.

The aim of the study is to assess the effect of a buckwheat beverage on glucose metabolism after meals consumption in healthy individuals and those with T2D controlled by medication and diet.

Why have I been chosen?

We are looking for healthy and T2D (controlled by diet and lifestyle or metformin) volunteers; Age 18+; males and females.

The exclusion criteria for this study are as follows

For the healthy group,
Taking prescribed medication which affect the study outcomes. These include medication treating any digestive and gastro-intestinal disorders which interfere with the glucose metabolism.
Have HbA1c above 48mmol/mol (or 6.5%). This will be determined at the screening visit.
Pregnant or breastfeeding
Have given a blood donation in the last three months
Are unable to give written informed consent
Have eating disorders such as anorexia, bulimia, binge eating or night eating syndrome.
Report any significant health issue
Subjects are taking vitamin or mineral supplements (unless they agree to discontinue supplementation 2 weeks or more before the start of the study)
Food allergies/intolerances

Buckfood study, PIS, Version 3 25/04/2019
For the T2D groups,
Having T2D controlled by medication other than metformin
Pregnant or breastfeeding
Have given a blood donation in the last three months
Are unable to give written informed consent
Have eating disorders such as anorexia, bulimia, binge eating or night eating syndrome.
Report any other significant health issue other than T2D such as any digestive and gastro-intestinal disorders which affect the study outcomes (the glucose metabolism).
Subjects are taking vitamin or mineral supplements (unless they agree to discontinue supplementation 2wk before the start of the study)
Food allergies/intolerances

Do I have to take part?
No, it is up to you to decide whether to take part. If you do decide to take part, you will be asked to sign a consent form. If you initially think you would like to participate but change your mind, you are free to withdraw at any time, without providing a reason. A decision to withdraw will not affect the standard of care you receive.

What will happen to me if I take part?
Before you are enrolled in the actual study, we will need to establish whether you are eligible. To do that, you will be invited to take part in the screening session at the Rowett Institute Human Nutrition Unit.

At this visit you will be asked to complete a study consent form, self-health questionnaire and we will measure your sugar in blood (as glycated haemoglobin) by finger spot blood. We will follow the NHS guideline to establish these values. A normal target is below 48 mmol/mol (or 6.5%). Additionally, for T2D volunteers, as part of the screening visit, an NHS consultant will access their medical notes to ensure their eligibility. Specifically, the consultant will check the type of medication you are taking. We will ask for your permission to do so in the study consent form.

If eligible, you will be enrolled in the study consisting of two morning visits at the Rowett Institute which last approximately six hours each visit (including lunch after the sampling period). You will receive a study number and will be allocated to one of the three study groups (healthy, T2D on metformin and T2D on diet and lifestyle) and start with one (of two) intervention visits in a random order (see Study diagram below).

Study Diagram

Buckfood study, PIS, Version 3 25/04/2019
For each of the intervention visits, you will be asked to come fasted. You will be asked to not consume any food and drink apart from water for minimum 10 hours prior the study visit. For one visit, you will undergo an oral glucose tolerance (OGTT) test, consisting in drinking 75 g glucose dissolved in 300 ml water, followed by another 100 ml water.

For the other visit, you will consume 100 g buckwheat food and the 75 g glucose dissolved in 300 ml water followed by 100 ml water. The intervention drinks (test meals) will need to be consumed within 5 minutes. The second visit will take place a minimum of two weeks after the first visit.

If you are a T2D volunteer, you will be advised to take their medication (metformin) as normal. We will record the dose.

Before and after consumption of the intervention products, we will collect blood and urine samples following the intervention day diagram described below. For the duration of the blood sampling (300 min), you will be advised to reduce to a minimum your movements. You will be asked to stay in a resting and comfortable position and relaxed for the entire (300 min) sampling period and to not leave the HNU.

**Intervention Day Diagram**

As described in the diagram above, we will take blood samples at 0, 15, 30, 45, 60, 75, 90, 105, 120, 150, 180 and 300 min with the help of a very thin tube (cannula) which will be inserted into the vein. The intervention foods will be served once the cannula has been inserted in your arm and the 0 hour sample collected. A total amount of approximate five table spoons of blood will be taken for each intervention. Additionally urine samples will be collected before the intervention and at half way (150 minutes) and at the end (300 minutes) after the removal of cannula and before the lunch is served. If you prefer for the baseline sample, you can bring a urine sample (collection kit will be provided).

In the blood samples we will measure the glucose and insulin levels. In the plasma and urine we will measure the concentration of some key bioactive molecules present in the study test beverage. Additionally, in the urine we will measure the glucose levels as well.

The buckwheat food product consists of a fermented sprouted buckwheat beverage prepared from sprouted buckwheat flour. This type of non-alcoholic beverage, prepared from cereals, like wheat
b  

bran, barley, rye is very popular in Eastern Europe and Balkans. To produce the buckwheat beverage for this study, has been used a simplified recipe similar to “boza”, “bors” and “braga” without adding any extra sugar, spices or aromas. The ingredients used consist in sprouted buckwheat flour, yeast and water. After the beverage is produced it is dried and is dissolved in water on the intervention day.

After five hours once all the blood samples have been collected the cannula will be extracted from your arm and lunch will be provided.

Withdrawal - If you decide to withdraw then with your permission we will retain the data collected up until the point of withdrawal.

If, after you have given informed consent, you lose capacity to consent during the study, you will be withdrawn from the study. Identifiable data or tissue already collected with consent will be retained and used in the study. No further data or tissue will be collected or any other research procedures carried out on or in relation to you.

What will happen to the samples I give?

The University complies with the Data Protection Act and each participant will be assigned a unique anonymising code. All information will be treated with the strictest confidence. The University monitors research projects, so individual (anonymised) data may be accessed for this purpose. Your anonymised samples may be kept for up to ten years after the study is completed to be used for further investigations. After this period we will destroy your samples.

Expenses and payments

We will reimburse your travel costs to and from the Rowett Institute, up to a total maximum of £50.

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

Participating in this study it might not benefit to you directly, however you will contribute on understanding on how certain dietary components, in this case buckwheat could be integrated in the diet for prevention or maintenance of metabolically imbalances such T2D. If proved successful the buckwheat beverage will be incorporated into a wide range of specialised foods as part of nutritional therapies.

You will receive copies of any scientific publications arising from the study if requested. You will be offered advice on their dietary habits and provided with recommendations for a healthy and balanced diet if you wish.

What are the possible disadvantages and risks of taking part?

The safety of the participants will be ensured at all times during the study through following strict standard operating procedures, which have been established in our Human Nutrition Unit.

Blood collection may cause bruising or mild discomfort, and there is a risk of infection after the cannula is removed, precautions to minimise this will be taken by the highly trained phlebotomists which will take the blood during the study visits.

Since this study involves an OGTT test, in case of high or low blood glucose level event we will follow Diabetes Scotland Think Check Act protocols, and we will have a HypoBox on site. Also if
necessary we will ask for help from the Diabetes on call team at Aberdeen Royal Infirmary on the Foresterhill site where a clinician is available 24/7.

You and your GP will be notified of any of incidental findings or any out of range results during the study. You will be given a written consent for doing this when signing the study consent form.

**What will happen to the results of the study?**

A report will be generated from the study, which may result in publications; there will be no information in this which will identify you.

**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, Mrs Sylvia Stephen (01224 438607, sylvia.stephen@abdn.ac.uk), you may contact the Head of the Human Studies Management Committee, Professor Baukte de Roos, University of Aberdeen, Rowett Institute, Foresterhill, Aberdeen AB25 2ZD (01224 438636, b.deroos@abdn.ac.uk) or the Director of the Rowett Institute, Professor Peter Morgan (p.morgan@abdn.ac.uk, 01224 438642).

**Who has reviewed this study?**

This study has been reviewed and approved by the Human Studies Management Committee of the Rowett Institute, and received ethical approval from the North of Scotland Research Ethical Committee.

**Who is organising and funding the research?**

The study is funded by a grant from the RESAS (Rural and Environment Science and Analytical Services), sponsored by the University of Aberdeen and run by the Rowett Institute in collaboration with NHS.

**Will my taking part be kept confidential?**

Your participation in the study will be kept confidential. All laboratory specimens, evaluation forms, reports, and other records will be identified in a manner designed to maintain participant confidentiality. All records will be kept in a secure storage area with limited access to study staff only. Subject data will be anonymised with a study and subject code. Codes will be kept in separate files from volunteers’ names and information. Paper data will be stored in a locked filing cabinet with restricted access. The subjects’ data will be accessed only by authorized members of the research team. Once the data is published the electronic data will be stored on the Rowett Institute secure server accessed only by a password protected mechanism; the paper will be stored in an allocated, secure data archiving facility, on site. Permission will be granted to allow University monitors and other relevant regulatory authorities access to information for audit.

Clinical information will not be released without the written permission of the participant, except as necessary for monitoring and auditing by the Sponsor (University of Aberdeen) or its designee. The chief investigator and study staff involved with this study will not disclose or use for any purpose other than performance of the study, any data, record, or other unpublished, confidential information disclosed to those individuals for the purpose of the study. Prior written agreement from the Sponsor or its designee will be obtained for the disclosure of any said confidential information to other parties.
Rowett Institute site will keep your name, and contact details confidential and will not pass this information to Sponsor (University of Aberdeen). Rowett Institute will use this information as needed, to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Certain individuals from University of Aberdeen and regulatory organisations may look at your medical and research records to check the accuracy of the research study. University of Aberdeen will only receive information without any identifying information. The people who analyse the information will not be able to identify you and will not be able to find out your name, or contact details. Rowett Institute will keep identifiable information about you from this study for 10 years.

This information will not identify you and will not be combined with other information in a way that could identify you. The information will only be used for the purpose of health and care research, and cannot be used to contact you or to affect your care. It will not be used to make decisions about future services available to you, such as insurance.

The University of Aberdeen is the sponsor for this study based in the United Kingdom. We will be using information from you and your medical records in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. University of Aberdeen will keep identifiable information about you from this study for 10 years.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

You can find out more about how we use your information at http://www.abdn.ac.uk/privacy

**CONTACTS FOR STUDY**

Name: Madalina Neacsu  
Rowett Institute, University of Aberdeen  
Foresterhill, AB25 2ZD  
Tel: 01224 438760  
Email: m.neacsu@abdn.ac.uk

Name: Phillip Morrice  
Rowett Institute, University of Aberdeen  
Foresterhill, AB25 2ZD  
Tel: 01224 438758  
Email: p.morrice@abdn.ac.uk