1495 UNIVERSITY OF ABERDEEN
The Rowett Institute

PARTICIPANT INFORMATION SHEET

Name of Investigator:	Nigel Hoggard

Name of Study:	The Fruit Bar Study (2019/ROW_Berry/3)

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 (our contact details are at the end of this sheet) 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 determine if the consumption of a fruit bar containing a concentrated bilberry or apple extract can reduce the amount of sugar crossing over into the blood when eaten with a standardised meal. The main measurements will be changes in blood glucose and insulin.

Why have I been chosen?

Healthy men or post-menopausal women aged 40-70 years with a BMI greater than 25 kg/m^2 are eligible to participate Anyone who fulfils all the criteria listed below are qualified to be included in the study. We will confirm eligibility at the study screening session.

You have none of the conditions below:

Chronic illness, including:

- thromboembolic or coagulation disease
- unregulated thyroid disease
- kidney disease
- hepatic disease
- severe gastrointestinal disorders
- pulmonary disease (e.g. chronic bronchitis, COPD, pacemaker implant)
- Allergic/intolerant to foods provided in the study (Nut or date allergy)
- Eating disorders
- Women who are lactating or breastfeeding, pregnant
- Alcohol and/or other substance abuse
- Smoking and the use of e-cigarettes
- Physically active at a competitive level (exercising strenuously on a daily basis for long periods of time)

You are not taking any of the following medication:

- Oral steroids
- Tricyclic antidepressants, neuroleptics
- Anticoagulants
- Digoxin and anti-arrhythmics
- Insulin
- Sulphonylureas,
- Thiazolidinediones (glitazones),
- metformin.
- Chronic use of anti-inflammatories (e.g. greater than 200mg doses of aspirin, ibuprofen),

If you are interested in participating, then we will invite you to the Human Nutrition Unit (HNU) at the Rowett Institute (RI) (AB25 2ZD) for a screening visit which will last approximately one hour. During this visit we will go through the participant information sheet with you and provide all details of the study. We will give you the opportunity to ask questions and make any clarifications. Following this if you are interested in continuing then we will give you a consent form to sign. We will then do a screening to assess if you meet all the required criteria. We will ask you to complete a health questionnaire and record your height and weight. Furthermore, we will collect a finger prick blood sample (5ul) for measuring HbA1c to confirm it is below <6.5%

If you meet the criteria, then we will invite you to take part in the study.

Do I have to take part?

No, it is up to you to decide whether or not 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 at any time, tell us and we will withdraw you from the study immediately. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive.

What will happen to me if I take part

All study activities will take place at the HNU. Figures 1A and 1B below illustrate the study protocol;

Figure 1A: Study protocol

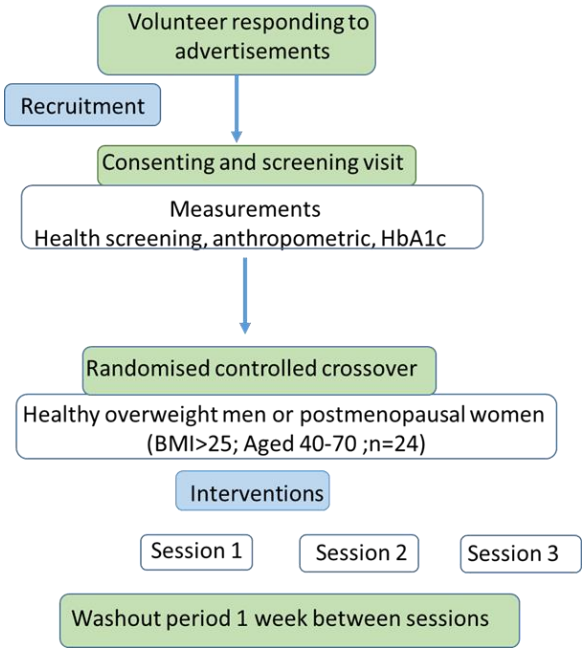
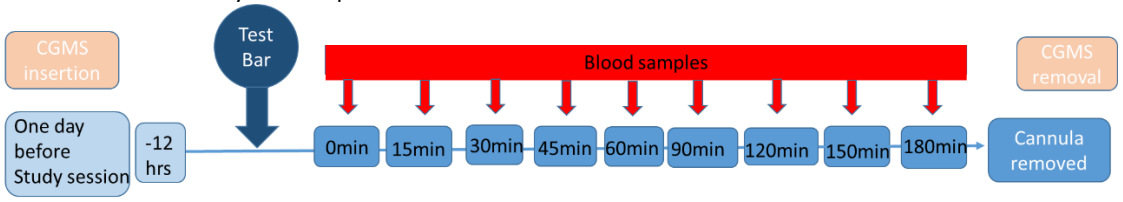


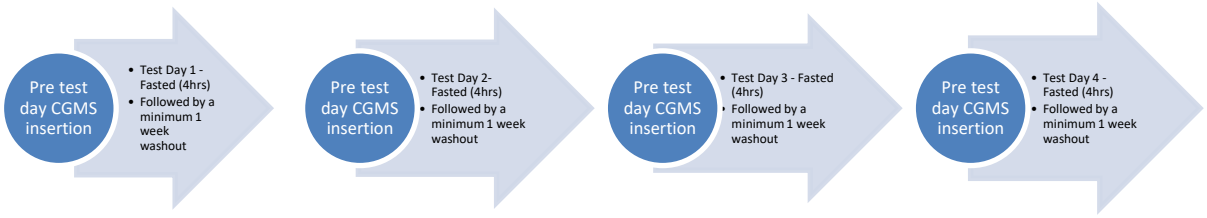
Figure 1B: Details of study session protocol



CGMS- Continuous blood glucose monitoring sensor

Figure 1C: Details of the visits you would have to make during the study

Figure 1D: Intervention Test Days



You would have to take part in four of these intervention sessions each with two visits to the HNU. These would have to be separated by at least one week (Figure 1C &D).

OGTT and Intervention sessions (study sessions 1-3)

The protocol for the intervention sessions is illustrated in Figure 1B. At each session you will be asked visit the HNU on two occasions. The OGTT and interventions sessions are the same except on the intervention session days you will be asked to eat a fruit bar. We will ask you to restrict your intake of certain foods and drink rich in phenolics three days prior to each session. A list of which foods and drink will be provided.

Visit 1: Pre - Study Session Day

On the day before each intervention session, you will have to come to the HNU for the insertion of a continuous blood glucose monitoring sensor (CGMS). This visit will last just over an hour. Upon arrival your weight, waist circumference and body fat composition using bio-impedance will be also be measured. We will insert a sensor (which is like a little piece of string about 4mm long) just under your skin in the abdomen area. The insertion is rapid and causes minimal discomfort and will be carried out by a trained phlebotomist/nurse. We will ask you to wear the CGMS device for less than 24 hours. Wearing the sensor, which is about the size of a £2 coin, causes minimum interference with your daily activities (including sleeping and having baths). The CGMS is commonly used by diabetics to track their blood glucose levels daily. Therefore it is designed for daily use and for minimal discomfort. If the sensor causes you any pain, tenderness or undue discomfort then it will be removed. After insertion you will have to remain in the HNU for one hour in order to take a finger prick blood sample to calibrate the sensor. We will provide you with instructions and give you a blood glucose meter to take home to carry out further calibrations. Before leaving, we will provide you with dinner suggestions to consume and will ask that you consume that same meal before each of the 4 test days. You will be asked to complete a simple food diary over three days before each visit.

Visit 2: study session day

You will be asked to return to the HNU the following morning after a 10-12 hour overnight fast for a visit lasting approximately 4 hours. we will insert a cannula in one of your arms and take a blood sample

We will give you a breakfast meal consisting of bread and jam along with a fruit bar on three of the intervention visits to consume within 10 minutes. The fruit bar will be un-cooked vegan bars made from the base ingredients of dates and cashew nuts. Either plain or with the addition of bilberry or bilberry and apple concentrated powder. Further blood samples will be taken at 15min, 30min, 45min, 1h, 1.5h, 2h, 2.5h, and 3h after the breakfast consumption (please see figure 1B above). In total, 9 blood samples will be taken during each of these intervention visits; the amount of blood sampled will be approximately 5 tablespoons (8mls). After 3h we will provide lunch, after which we will remove the CGM sensor and you would be free to leave the HNU.

During the intervention days after the insertion of the CGM sensor you will be advised to avoid intense physical activity. You will be asked to also carry out up to three finger prick blood glucose tests per day to calibrate the CGMS. We will provide guidance on how to do this.

What will happen to the samples I give?

The blood samples you provide will be used to measure levels of metabolites related to glucose metabolism. Each participant will be assigned a unique anonymising code that will be used to label all samples, and no names will be used. All data will be treated confidentially. All data and study information will be stored in password protected university computers in a locked office. Hard copies will be stored in locked drawers. These samples and data may be looked at by responsible individuals from the Rowett Institute, from regulatory authorities or from Aberdeen University where it is relevant to this study.

Expenses and payments

We will give £50 on your last study visit as a small gesture of our gratitude for your participation.

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

At the end of the study, we will give you a profile of your health status based on the measurements we obtained from your visits. This study may not help you personally but the information you provide will help us understand the health benefits of eating apples and bilberries how it could contribute to improving human health. The information will be used to develop public health strategies for improving the health status of our population, and the sustainability of Scottish agriculture. In addition, the data once published will be useful also to the wider research community and policymakers.

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

There are no significant risks of taking part in this study as it is a food-based intervention. To minimise risks of reactions to the study foods we will exclude all those having known allergies/intolerances to any foods. While you are in the study you will be closely monitored by the research team, research nurse and HNU doctor.

What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to the researchers (contact details below) who will do their best to answer your questions. Alternatively, you could contact the Chair of the Human Studies Management Committee, Professor Baukje 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 Rowett Ethics Committee.

Who is organising and funding the research?

The study is being organised by the Rowett Institute, University of Aberdeen. It is funded by the Scottish government (RESAS) and the University of Aberdeen.

Will my taking part be kept confidential?
Yes, your participation in the study will be kept confidential.

CONTACTS FOR STUDY

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Name of Participant *(Please Print)*	Date	Signature

Name of researcher taking consent	Date	Signature