1495 UNIVERSITY OF ABERDEEN
The Rowett Institute

PARTICIPANT INFORMATION SHEET

Name of Investigator:	Fiona Campbell

Name of Study:	The Scottish fruit study **(2022_01/ROW-Honeyberry)**

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 new varieties of fruits grown in Scotland which can adapt better to climate change namely, honeyberries and cherries, have the same health benefits as established fruits such as raspberries. To do this we will investigate the effects of consuming honeyberries, cherries, and raspberries on short term changes in blood glucose, and on short term memory.

Why have I been chosen?

Healthy men or post-menopausal* women aged 40-70 years with a BMI between 18.5 kg/m^2 and 39.9kg/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 (fruit allergy)
- eating disorders
- 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 daily for long periods of time)
- HbA1c >6.5%
- Self-report of prior diagnosis of dementia, probable dementia, or mild cognitive impairment
- history of stroke, severe head injury or other neurological condition which may adversely affect cognition
- history of anxiety and depression

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),
- psycho-active drugs
- chlorphenamine

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

**Postmenopausal is defined as not having experienced a period for over a year.*

Do I have to take part?

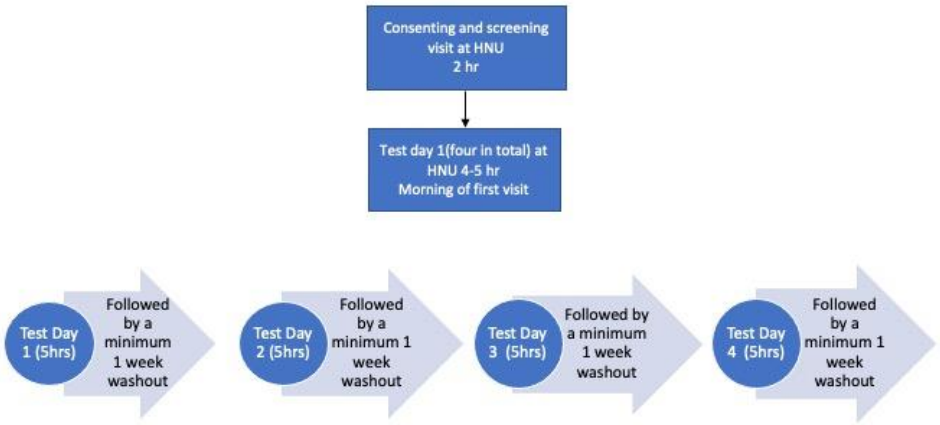
No, it is up to you to decide whether or not to take part. If you do decide to take part, you will be asked to sign a consent form**.** If you initially think you would like to participate but change your mind at any time, tell us and we will withdraw you from the study immediately. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive. All samples collected up to the point of withdrawal will be destroyed and the data will not be used in this study.

What will happen to me if I take part

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 2 hours. 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 health screening to assess if you meet all the required criteria. Record your height and weight. Furthermore, we will collect a finger prick blood sample (5 µl) for measuring HbA1c to confirm it is below <6.5% which is a marker used to determine long term sugar metabolism and diabetic status. It gives a picture of the average level of glucose in your blood over a three-month period.

All study activities will take place at the Human Nutrition Unit (HNU) at the Rowett Institute. Figure 1 illustrates the visits you would make to the HNU and consists of four intervention sessions which each last approximately 4 to 5 hours. These would have to be separated by at least one week.

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



	Test day/session 1	Test day/session 2	Test day/session 3	Test day/session 4
Intervention/ Meal	Breakfast meal	Breakfast meal plus Honeyberry (240g)	Breakfast meal plus Cherry (240g)	Breakfast meal plus Raspberry (240g)

Study visits 1-4

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) and arrive at the HNU after an overnight fast from 10pm the night before, for a visit lasting approximately 5 hours. You will be asked to complete a short food diary over the three days. Upon arrival your weight, waist circumference and body fat composition using bio-impedance will be measured. We will insert a cannula into your arm and a blood sample will be taken (a canula allows repeated blood sampling).

Then we will give you a breakfast consisting of a standardised high carbohydrate meal with a portion of fruit (240g of either honeyberries, cherries, or raspberries) to consume within 15 minutes. Blood samples (around a tablespoonful in total at each time point) will be taken immediately before the breakfast and again after 15, 30, 45, 60, 90, 120, 150 and 180 and 240 min. In total, 10 blood samples (10ml each) will be taken during each of these intervention visits. Computer based memory tests will be carried out at 0, 30 and 90 and 240 minutes – there are no right answers to these tests. After the sampling we will provide lunch, you are welcome to eat at HNU dining room or take away if more convenient, after which you would be free to leave the HNU.

We will ask you to provide an optional urine sample at the beginning and end of each study visit.

What will happen to the samples I give?

The blood and urine samples you provide will be analysed for glucose, lipids and 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. Any samples collected during the study will be kept for a maximum of 5 years after completion of the study.

Results from the memory tests will be kept in an anonymised format on password protected University of Aberdeen computers. The University of Aberdeen treats data in accordance with the General Data Protection Regulation (UK GDPR) and the requirements of the Data Protection Act 2018, (https://www.abdn.ac.uk/staffnet/governance/data-protection-6958.php#panel8634). All data will be treated confidentially. All data and study information will be stored in password protected university computers. Hard copies will be stored in locked drawers in a locked room. Following the completion of the study, documents will be kept for 10 years. All 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 and to supplement travel expenses.

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 soft fruit 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, 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, Dr Frank Thies, University of Aberdeen, Rowett Institute, Foresterhill, Aberdeen AB25 2ZD (f.thies@abdn.ac.uk, 01224 437954) or the Director of the Rowett Institute, Professor Jules Griffin (Jules.griffin@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. All laboratory specimens, evaluation forms, reports, and other records will be identified in a manner designed to maintain participant confidentiality. All your data will be coded and stored in lockable cabinets or on password-protected computers. The code that can link the data to you will be kept separately. Any publications or presentations arising from these data will not identify you as a participant. Any individualised questions or responses will be referred to using minimal non-identifiable characteristics such as age and gender only.

CONTACTS FOR STUDY

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