PARTICIPANT INFORMATION SHEET

Name of Investigator: Viren Ranawana

Name of Study: Bean Good study

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 the health properties of broad bean hull. The UK is a major producer of broad beans (*Vicia faba*) in the world, and it is a pulse crop that contributes significantly to our economy, land fertility and nutrition. Broad beans are eaten in many parts of the world including the UK. During milling of broad beans the seed coat (hull) is removed as this is believed to improve cooking and eating quality of the beans. Therefore, the hull is a secondary product of milling that is currently underutilised. Our research shows that broad bean hull (BBH) is rich in fibre and phytonutrients with antidiabetic properties. We also found that it has physical characteristics similar to wheat bran but with more superior nutritional properties. These findings indicate that BBH could be a valuable functional food for humans for improving health. Its rich fibre and phytonutrient profiles suggest BBH can be particularly beneficial for reducing diabetes risk, and for improving gut health through promoting the growth of good bacteria. The objective of this study is to determine the effects of eating BBH on blood glucose control and gut health. We will be testing this using bread fortified with BBH, and the study will help us establish the health potential of this novel locally-produced functional food.

Why have I been chosen?

Healthy men and women between the ages of 18-75 years with a BMI between 23-35 kg/m² 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.

- No known illnesses
- Do not have polycystic ovary syndrome (PCOS)
- Do not have favism or Glucose-6-Phosphate Dehydrogenase (G6PD) deficiency
- Not pregnant or breastfeeding
- Not taking prescription medications including hormonal contraceptives
- Not smoking
- Do not habitually consume large amounts of fruits and vegetables
- Not allergic/intolerant to foods provided in the study
- Not physically active at the competitive level
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 blood sample (5 mL) for measuring blood lipids, glycosylated haemoglobin and G6PD deficiency status. If you meet all the inclusion and exclusion 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;
You would have to take part in two intervention sessions (arms), each lasting three days. These would have to be separated by at least one week. Each intervention session will involve three visits to the HNU, and possibly a fourth (Figure 1C).

Visit 1 (day 1 of the intervention session): On the day before each intervention session, you would 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. 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 researcher/nurse. We will ask you to wear the CGMS device for three days. 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. We will also provide a container for you to collect a faecal sample and provide instructions on how to use it. You would be asked to bring with you the faecal sample when you come the following morning, and we will ask you to complete a short questionnaire on bowel function. Before leaving, we will provide you with dinner to take home and consume and a food diary to complete.

Visit 2: You will be asked to return to the HNU the following morning after a 10-12 hour overnight fast for a visit lasting approximately 5 hours. Upon arrival you will be asked to complete three questionnaires on physical activity, hunger and stress, and your weight will be recorded. We will also measure your body fat percentage using the BodPod at one of the two intervention sessions. Following these measurements, we will insert a cannula in one of your arms and take a blood sample. We will also ask you to provide a breath sample, which will involve blowing into a tube using a straw. We will be taking this measurement to see how long it takes the food to empty from your stomach. Following these...
samples, we will give you one of two breakfast meals to consume within 10 minutes. This will consist of either plain bread or bread fortified with broad bean hull. Further blood samples will be taken at 15, 30, 45, 60, 90, 120, 180 and 240 min 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 3 tablespoons. In addition to the blood samples, we will ask you to provide breath samples every 15 min. We will also ask you to complete a questionnaire on your hunger levels every 30 min. After 240 min we will provide lunch, after which you would be free to leave the HNU. We will provide all the meals for the remainder of the day for you to take home.

We will also provide all your meals for the next two days, these will be packed and provided for you to eat at home or elsewhere. They could be collected from the HNU or we can drop them at your home. The meals will consist of breakfast, lunch, dinner, and snacks. The meals will be standardised for meeting your daily energy and nutrient requirements. We will provide you a list of the meals at the screening visit for your comments and feedback. We will use your feedback to finalise menu choices to ensure the meals meet your approval and comply with any allergies and intolerance you may have. The meals will consist of two portions of bread per day which would be either plain bread or bread fortified with broad bean hull. You will be asked to eat only the foods provided and nothing else. However you would be allowed to drink as much water as you would like and up to three hot beverages (tea and/or coffee). You would have to also refrain from consuming any alcoholic beverages. We will encourage you to try and consume all the foods provided, and particularly the breads. You will be asked to bring back any leftovers to the HNU for us to record.

During the intervention days 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.

Visit 3: You will be asked to return to the HNU in the morning of the fourth day following an overnight fast. We will obtain one blood sample and provide breakfast before removing the CGMS. We will also ask you to produce a faecal sample or bring with you a sample produced the day before and ask you to record the time it was produced. We will ask you to complete a short questionnaire on bowel function. We may also ask you to provide one more faecal sample between days 5-7 from the start of the intervention session. This is to ensure we obtain a faecal sample that is representative of the intervention period.

In total we will collect a maximum of 7 tablespoons (125 mL) of blood during the entire study.

What will happen to the samples I give?

The blood and faecal samples you provide will be used to measure levels of metabolites related to diabetes and gut health. The breath samples will be used to measure how long it takes for food to empty from your stomach. Each participant will be assigned a unique anonymising code that will be used to label all samples, and no names will be used. Only the research team will have access to your samples. 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 with access only to research staff.

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 at your screening visit. This study may not help you personally but the information you provide will help us understand the health benefits of eating broad bean hull, and 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. Since the intervention is a high fibre food some may experience transient gastrointestinal discomfort. However, we foresee this to be minimal as the study does not provide excessive fibre amounts but only what is recommended in UK dietary guidelines. 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, Prof. 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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