PARTICIPANT INFORMATION SHEET

Name of Investigator: Wendy Russell

Name of Study: Barley Benefits

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?

There is lots of scientific evidence that eating wholegrain cereals such as barley can protect against disorders such as type 2 diabetes, obesity and cardiovascular disease. In this study we will try to find out which compounds in barley could be responsible for these benefits. Cereals can also contain mycotoxins, which can be harmful. We have tested our intervention foods to be sure that they are below current EU levels and are therefore safe. However, we will also measure the compounds to which they converted to in the blood so that we can develop methods to ensure that safe consumption of healthy foods such as cereals can be appropriately monitored.

Who can take part?

You can take part in this study if you are a healthy male or female (18-65 years) with a normal weight to overweight (BMI less than 35 kgm²) and you do not smoke, have a food allergy or intolerance and are not taking any medication or nutritional supplements.

Do we have to take part?

No, it is up to you to decide if you would like to take part or not. You are also free to withdraw at any time, without giving a reason; it will not affect the standard of care you receive. Should you choose to withdraw from our study; we will ask you if samples can possibly be retained or we will destroy any samples collected up until that point.

What will happen to us if we take part?

If you take part in the study all the information collected during the course of the study will be kept strictly confidential. Before the study starts you will be invited to the Rowett Institute, where we will discuss the study and collect your consent to participate. We will then assess whether you are eligible for the study. The study consists of two intervention sessions where you will come to the Human Nutrition Unit at the Rowett Institute. Before you come to take part in the intervention session, we will ask you to eat a diet which does not contain some plant-based foods (information provided) for three days prior to the intervention. The night before the intervention session, we...
will ask you to not eat any food after 10 pm, although you will be able to drink water. When you arrive at HNU on the morning of the intervention we will collect a blood and urine sample. The blood samples will be collected by cannulation and each sample will be 12 mL; slightly less than one tablespoon. You will then be asked to consume porridge made from barley and water and we will collect blood and urine samples 1, 3 and 5 hours after you have eaten the porridge. Each of these blood samples will be 12 mL. You will be provided with a lunch and then you are free to go home. We will ask you to continue with the diet which does not contain some plant-based foods until the following morning and also to store all your urine samples in a container provided. The following morning we will collect another 12 mL blood and urine sample and that will complete the first intervention session. There will be a second identical intervention session, but this will take place at least one week after the first.

Study Diagram

<table>
<thead>
<tr>
<th>Consent</th>
<th>Screening Visit</th>
<th>if subject suitable</th>
<th>Recruitment</th>
<th>Randomisation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Visit 1</td>
<td>Prescribed Diet (-72 h)</td>
<td>Fast (-10 h)</td>
<td>Blood &amp; Urine Sample (0 h)</td>
<td>Intervention</td>
</tr>
<tr>
<td>Visit 2</td>
<td>Prescribed Diet (-72 h)</td>
<td>Fast (-10 h)</td>
<td>Blood &amp; Urine Sample (0 h)</td>
<td>Intervention</td>
</tr>
</tbody>
</table>

Expenses and payments

We will refund your travel expenses up to £50 from home/ work to the Rowett Institute on completion of the study.

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

You will be greatly contributing to the scientific knowledge of which components in our diet benefit our health. If you wish, we will be happy to keep you informed regarding the outcomes of the study and also to provide you with a copy of any publications that may result from your participation in our study.

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

We will ask you to modify your diet prior to and during the intervention study. We will ask you to abstain from eating plant-based foods such as fruits, vegetables, cereals, spices. These are components of a healthy diet and you may feel some gastrointestinal discomfort due to the lack of fibre. We will also ask you to limit consumption of tea coffee and alcoholic beverages.

What will happen to the samples I provide?

All the samples will be coded to maintain confidentiality. We will store these samples for the duration of the study and keep some in reserve up until 10 years for future relevant analysis.
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 the Human Nutrition Unit Manager; Ms Sylvia Stephen (01224438607, sylvia.stephen@abdn.ac.uk), you may contact the Head of Human Studies Management Committee; Prof Baukje deRoos (01224438700, B.deroos@abdn.ac.uk). The Institute carries indemnity insurance for any harm or adverse event and Prof deRoos can be contacted for further information.

Who has reviewed this study?
This study has been reviewed and approved by The Rowett Institute Ethical Panel.

Who is organising and funding the research?
This study is funded by the Scottish Governments Rural and Environmental Science and Analytical Services Division as part of its Strategic Research Program.

What will happen to the results of the research study?
The results will be used to support scientific data on the potential health benefits of consuming. They will form part of a PhD thesis and possibly in scientific reports, presentations and publications. You will not be identified in any report/publication.

Will my taking part be kept confidential?
Your anonymity will be guaranteed in any internal report or conference presentation relating to this study. A confidential participant log will record details of names and addresses of participants to enable dropping-off of foods, etc. In all documentation (except the consent form) the participant will be identified by a code allocated to them in the participant log. All of the data will be held in locked cabinets, in locked offices and/or on password protected computers. All data will be stored for a maximum of 10 years, after which they will be destroyed.

CONTACTS FOR STUDY
Name: Dr Wendy Russell
Rowett Institute
University of Aberdeen
Foresterhill
AB25 2ZD
Tel: 01224 438777
Email: W.Russell@abdn.ac.uk

Name: Olivia Watt (PhD student)
Rowett Institute
University of Aberdeen
Foresterhill
AB25 2ZD
Tel: 01224 438700
Email: O.Watt@abdn.ac.uk