Appendix 02: Study Information Sheet

Project name: Onion-Health
Name of researcher Yuanlu Shi

Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information (Yuanlu Shi, prconion@leeds.ac.uk). Thank you for taking time to read through the information and deciding whether you wish to take part.

Introduction
The main goal of the study is to examine the effect on men of quercetin, a compound which belongs to a family of plant compounds and present in a wide variety of fruits and vegetables, including apples, berries, brassica vegetables, capers, grapes, onions, shallots, tea, and tomatoes, as well as many seeds, nuts, flowers, barks, and leaves.

Am I qualified, and why?
About 50 candidates who fulfil the following criteria (including but not limited to) would have a chance to participate in this study
- Male
- Non-smoker
- Not a heavy drinker
- Age between 19-65 years old
- BMI: Normal or Overweight (18.5 - 29.9 kg/m²)
- Willing to maintain your regular lifestyles and usual extent of physical activities throughout the study (over 3 months)

Can I withdraw?
Your participation in the research is entirely voluntary. If you do decide to take part you will be given this information sheet to keep (and be asked to sign a consent form). You can still withdraw at any time within 6 months from the date you sign on the consent form, without affecting any benefits that you are entitled to, and are not obliged to give a reason.

What will happen to me and what will I be expected to do?
You are required to give written informed consent prior to beginning the study and fill in a health assessment. A subject code will be assigned to protect your confidentiality so you will have complete privacy during the whole study and future data analysis.

Stage 1
The project contains two stages. The first stage focuses on the collection of your information from blood sample, anthropometric measurements and questionnaire. You will be informed of whether you are suitable for the next stage (it may take couple of days to process this information).
Stage 2
There are two separate 4-week phases of study in the second stage. You are expected to have one dose of supplement daily for the two phases. The 4-week washout period between the two phases will not require any supplement intake. You will be seen in the School of Food Science and Nutrition for seven times at day 1, 15, 29, 57, 71 and 85 (once every other week). Urine sample collection will be during the day before each visit. After overnight fasting, you bring the urine to the school and a single blood sample (2 ml) will be taken. Some measurements like weight, height and blood pressure, etc., will also be done before breakfast.
What are the possible disadvantages and risks of taking part?
Due to the routine visit and the self-management of urine sampling, you may need time to consider the convenience and willingness to follow the plan. So please make sure that you are willing to and are able to follow the diet strictly, i.e. you do not have history of allergy to onion food and you are not opposed to eating onion or relevant supplement. There are no additional risks involved as the procedures involved are according to standard guidelines.

What are the possible benefits of taking part?
Whilst there are no immediate benefits for those people participating in the project, the supplement may be potentially beneficial to your body function.

Will my taking part in this project be kept confidential?
Yes. The result of the data obtained will be reported in a collective manner with no reference to a specific individual. Hence, the data from each individual will remain confidential. As a subject you have the right to know the results only of the total analysis.

What will happen to the results of the research project?
Once all participants have completed the study, the information obtained will need to be collected and analysed before any results are published. This is likely to take at least one year to be finalised. If you would also like to know the results of the study, the research team will be able to give this information to you when it becomes available. You will not be identified in any report or publication. Data of the volunteers who withdraw within 6 months from the date he signs on the consent form will be removed from the analysis.

Who is organising and funding the research?
The research is organised by the Food Biochemistry Group, School of Food Science and Nutrition, University of Leeds, and it is a part of a study for a PhD degree. This study is not been funded by any organisation or company.

Payment and Compensation
All participants of the first stage will receive some complimentary chocolates for their time. Participants who complete the second stage will receive £40 by bank transfer as a thank-you for participating. You do not have to pay for anything in participating in this study and there is no reimbursement available from the research group as well. In the unlikely event that this study results in the development of any marketable product(s), you will have no ownership interest in the product and no right to share in any profits from its commercialization whatsoever.

Who do I contact for further information?
Yuanlu Shi
Lead researcher
School of Food Science & Nutrition
University of Leeds
Email address: prconion@leeds.ac.uk

Thank you for your consideration to join this study.
You will be given a copy of this document and the signed consent form for your personal records.
You have been asked to collect a 24-hour urine sample. This procedure measures certain products in your urine. For accurate results, it is important to collect all your urine for exactly 24 hours.

**Preparation**

1. At the beginning of each phase, you will be given another one set of backup package because you may need more than one storage container to contain all of your urine for the 24-hour period, you may want to keep one set at the place you work just to be safe or you may make mistake when you were not used to it and were asked to start over with a sterile storage containers from the backup package on the next day, etc..

2. At each visit, you will be given one 3-litre, sterile (completely clean) urine storage container

3. Make sure each storage container has a code tag with your subject code written on it. Do NOT attempt to empty the container or to rinse the container because about 3 grams of Ascorbic Acid (known as Vitamin C) was added inside. Do NOT touch the inner side of the container for the same reason.

**Procedure**

1. You should dispose of the first urine in the morning of the collection day and this is the start time of the collection. Write the date and time on the urine collection form (*Appendix 9, part i*).

2. For the next 24 hours, collect each voided urine, including the first urine on the following day. To collect, urinate directly into your storage container.

3. If you need to use more than one container during the 24-hour period, use one container at a time. When it is full, collect your urine in the next container.

4. Exactly 24 hours after you started the test, urinate one last time in your storage container. This is the end of your collection. Write the date and time the test ended on your storage container and urine collection form (*Appendix 9, part i*).

5. Please bring the urine to the researcher as soon as possible. To prevent leaks, make sure the lid is on tightly, and that the container is transported upright inside the plastic bag. Avoid exposure to external heat sources; direct, prolonged sunlight; dust; corrosive chemicals; and moisture.

If you have questions about the procedure, please contact the researcher, Yuanlu Shi by e-mail prconion@leeds.ac.uk, you can find her in the cluster room I.07 at School of Food Science and Nutrition, University of Leeds (LS2 9JT).

**Reference:**

Appendix 07: Calendar: TASK LOG and REMINDER with instructions

This form is designed for your convenience as a reminder.

Project name: Onion-Health
Name of researcher: Yuanlu Shi

Diagram of research program

- Please maintain your regular lifestyles (including dietary habits) and usual extent of physical activities throughout the study.
- During the whole period of study, please avoid having other onion products in considerable amounts.

If you have questions about the procedure, please feel free to contact the researcher, Yuanlu Shi by e-mail preconion@leeds.ac.uk or you can find her in the cluster room I.07 at School of Food Science and Nutrition, University of Leeds (LS2 9JT).
This is an instruction table of the tasks you should do in the second stage.

<table>
<thead>
<tr>
<th>Tasks</th>
<th>Descriptions of task</th>
<th>Repeat</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>1. Collect urine and store the container properly. <em>(Appendix 8,9 Part I)</em></td>
<td>2 weekly</td>
</tr>
<tr>
<td></td>
<td>2. Do NOT eat or drink anything except plain water form 10 pm.</td>
<td>7 times</td>
</tr>
<tr>
<td>B</td>
<td>1. Turn in the urine container and urine collection from to the school.</td>
<td>2 weekly</td>
</tr>
<tr>
<td></td>
<td>2. A single blood sample will be taken.</td>
<td>7 times</td>
</tr>
<tr>
<td></td>
<td>3. Have a breakfast in the School of Food Science and Nutrition.</td>
<td>@school</td>
</tr>
<tr>
<td></td>
<td>4. Bring the clean urine collection containers and supplement with you.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Have the supplement with breakfast.</td>
<td>Daily</td>
</tr>
<tr>
<td></td>
<td></td>
<td>28 times</td>
</tr>
<tr>
<td></td>
<td></td>
<td>× 2</td>
</tr>
</tbody>
</table>

- **DO NOT exceed stated dose** (i.e. **DO NOT** attempt to remedy).
- **Please notify the researcher** if you failed to collect the urine sample at agreed date or failed to fast before blood sampling day. In this case, usually you will be asked to use the backup package (including another set of urine collection equipment and another set of supplements).

Yuanlu Shi by e-mail prconion@leeds.ac.uk or you can find her in the cluster room I.07 at School of Food Science and Nutrition, University of Leeds (LS2 9JT).