

You are being invited to take part in a research study. Before you decide it is important you understand why the research is being done, and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Please ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part. Thank you for reading this.

### **What is the purpose of this study?**

This study will investigate possible indicators (biomarkers) of whole-grain intake. The aim of the study is to try and find out whether certain substances present in whole grains are absorbed in the gut and appear in blood and urine, and how the mixture of metabolites in blood changes after eating different wholegrain foods.

### **Why have I been chosen?**

We are looking for men and women who are non-smokers and over the age of 18 years to take part in this study. We will be recruiting 64 volunteers in total from the Newcastle upon Tyne area.

### **Do I have to take part?**

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 on your 'Induction Visit'; you will be given a copy of this to keep. However, you will be free to withdraw from the study without giving a reason anytime up to the end of your final visit. Shortly after this, all data will be fully anonymised, and therefore, from this point forward it will not be possible to withdraw any data from the study.

### **What will happen to me if I take part?**

If you decide to take part and you are a suitable volunteer for the study, we will ask you to exclude any wholegrain foods from your diet for a period of 4 weeks (we will give you a list of foods to avoid). After this 'washout period', you will be randomly allocated to one of two different groups. For each of the two groups we will provide you with a number of different foods including bread, breakfast cereals, and pasta and ask you to substitute these for similar foods you normally eat in your diet. In one group these foods will be made from wholegrain wheat, in the other group the foods will be made from wholegrain rye. For the first 4 weeks following the washout period, we will ask you to consume 3 servings/day of these foods (for example, 1 serving = 1 slice wholemeal bread or  $\frac{1}{2}$  a bowl of cereal) and for the subsequent 4 weeks we will ask you consume 6 servings/day. We will provide you with the study foods regularly (every 2 weeks) and will also advise you on the amounts of these foods we would like you to eat. In total, the study will last for about 3 months.

### **What else do I have to do?**

If you agree to take part we will ask you to visit **the Clinical Research Facility, RVI** on six occasions, twice after the four-week washout period, then twice each after a further 4 and 8 weeks (12 weeks in total) respectively. Each pair of visits after every 4 week periods will usually take place within 2 days of each other. On the evening before each visit we will ask you to eat a standard meal (and water) which we will provide and then you will need to fast from 9 pm; this means that you should not eat or drink anything except water until you complete your visit the following morning.

At the first visit of each occasion, we will take a blood sample (30ml/6 teaspoons of blood) from your arm and will also measure your height, weight, waist circumference, body fat and blood pressure using non-invasive procedures and will ask you to complete a physical activity questionnaire. We will also ask you to collect your urine for 24 hours the day before and bring it to this visit (appropriate containers and full instructions on how to do this will be provided). This visit will last approximately 45 minutes.

At the second visit, on each occasion, we will take a small blood sample (20ml/4 teaspoons of blood) and a small urine sample (20ml). This visit will last approximately 30 minutes.

We will ask you to collect foods from **the Clinical Research Facility, RVI** after the wash-out period and then after every 2 weeks.

Finally, we will ask you to complete a questionnaire on 4 occasions to record how often you have eaten certain foods at specific periods during the study (known as a 'Food Frequency Questionnaire'). We would also like you to tell us about your general wellbeing after meal times during these 4 occasions by completing an additional 'After Meal Wellbeing Questionnaire'. Whether you decide fill this questionnaire is entirely up to you and your decision will not affect the rest of your participation in this study.

### **What will happen to the samples I provide?**

Blood and urine samples provided will be tested for substances present in wholegrain foods. Lipid profile (e.g., cholesterol) and glucose will also be measured in blood. A small amount of the blood taken at study visits will be stored (for up to 10

years) for future tests to confirm results. DNA samples from blood will also be stored to carry out genetic tests if necessary as part of this study. These genetic tests will be used to help understand how different people respond differently to eating wholegrain foods. All stored plasma and DNA samples will be coded so that no one can be identified from these samples.

**What are the possible disadvantages and risks of taking part?**

Taking blood samples may cause minor discomfort and there is a small chance of minor bruising afterwards. If a new diagnosis of high blood pressure is made, this could affect your future insurance status (e.g. for life insurance or private medical insurance).

**What are the possible benefits of taking part?**

If we discover any abnormalities of significance in your lipid profile, blood glucose or blood pressure, we will inform you and your GP. Although you will derive no further individual benefit, the knowledge gained from this study will help our research into identifying biological indicators of whole-grain intake in the diet that will prove valuable for future research.

**What will happen if anything goes wrong?**

Any complaints you have about this study should be made to Dr. Chris Seal, Newcastle University ([chris.seal@ncl.ac.uk](mailto:chris.seal@ncl.ac.uk) or 0191-2227650) and will be fully investigated.

**Will my taking part in this study be kept confidential?**

Any information which is collected about you during the course of the research will be kept strictly confidential. Your GP will be notified that you are participating in this study. He/she will be notified if any abnormal results of significance to your health are found.

**What will happen to the study results?**

We will publish the results of the study in a scientific journal and on the project website. You will not be personally identified in any publications. We will be happy to discuss the overall results with you when the study is completed, and will let you know where you can obtain a copy of the published results if you wish.

**Who is organising and funding the study?**

This study is being organised by Newcastle University. The Food Standards Agency is funding the research. In recognition of your time commitment, you will be paid an honorarium of £90 at the completion of the study. Any travel expenses will also be re-imbursed.

**Who has reviewed the study?**

This study has been reviewed by the Food Standards Agency, Newcastle NHS Trust and a Research Ethics Committee.

**Contact for further information**

If you would like any further information about this study, please do not hesitate to contact **Dr. Sumanto Haldar on 0191 222 6619**

**And finally...**

Thank you for having taken the time to read this information sheet and for your interest in the study.



**GrainMark Study**



**GrainMark**

**Information Sheet for Participants**

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