

Information Sheet – Glycaemic Response and Insulin Response testing of foods

Invitation

You are being invited to take part in a research study. Before you decide, 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.

What is the purpose of the study?

The glycaemic response (GR) is the degree to which a food raises the blood glucose levels compared with a standard food. The insulinaemic response (IR) is the degree to which a food raises the blood insulin level compared with a standard food. Foods with a lower GR and IR may help people control their hunger, their appetite, their blood sugar levels and possibly their weight. Various factors, e.g. food composition and preparation, can affect the GR and IR of foods. The Functional Food Centre is internationally recognised as being a leading centre for research into glycaemic response and we continue to be one of the largest centres in Europe working in this area. Through our research we have a large and growing database that enables us to analyse how people's blood glucose and insulin responds to different ingredients in foods and drinks and to identify those ingredients that help to better control blood glucose levels.

We share our expertise with the food and nutrition industry worldwide by providing research and consultancy services to them. In a quest to provide healthy foods and drinks, food and ingredient manufacturers and suppliers are working to develop new products that have a low insulin index (II). We test products on behalf of these companies and measure the glucose and insulin value. These companies fund the tests on their own products. This work also enables us to grow our research database and therefore helps develop our understanding further.

The purpose of this study is to determine the GR and IR values of a range of foods.

Why have I been invited to participate?

You have expressed an interest in taking part in this study and this information has been provided to help you understand what is involved if you do decide to participate.

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 given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason. At least 24 other people will take part in this study.

For students of Oxford Brookes University, choosing to either take part or not take part in the study will have no impact on your marks, assessments or future studies.

What will happen to me if I take part?

In outline the study will involve eating or drinking a test product and having your blood glucose measured over 2 to 3 hours by a trained researcher taking finger prick samples. The rest of this section describes the procedures involved in more detail.

You are eligible to take part in the study if you:

- are aged 18-60 years
- have a BMI $\leq 30\text{kg/m}^2$ (BMI means Body Mass Index - we will measure this for you)
- have no known diabetes or impaired glucose tolerance
- have no known food allergy or intolerance
- have no medical condition(s) or medication(s) known to affect glucose regulation or appetite and/or which influence digestion and absorption of nutrients
- have had no major medical or surgical events requiring hospitalisation within the preceding 3 months
- do not use steroids, protease inhibitors or antipsychotics.

If you are eligible and you do decide to take part, then this is what the study will involve:

- Each test session will last for approximately 2 to 3 hours. You can decide how many test sessions you do in a week – it could be 1, 2 or 3, but you need to leave at least 1 day between tests
- On your first visit you will be asked to sign a consent form and fill in a health questionnaire. We will also measure your:
 - Height and weight (in order to estimate your body mass index (BMI)) – a measure of weight status)
 - Blood pressure
 - Waist circumference.
- Each test session will involve the following:
 - Two fasting blood glucose measurements (at -5 minutes and 0 minutes) – this involves two small finger-pricks using disposable individual lancets
 - Consumption of the standard or test food/drink
 - Further finger-prick blood samples at 15, 30, 45, 60, 90 and 120 (and 150 & 180 minutes for 3 hour tests) minutes after the start of the meal
 - Each test session requires a **maximum** of 10 finger pricks
 - At the same time intervals, you will be asked how hungry you feel.
- The testing will take place in the GI lab (room S403) for the fasting measurement and to eat the food. Subsequent measurements will also take place in the lab. You can choose to stay in the lab or come back at the specified time (by special agreement, these measurements can be taken at your office if you are unable to return at the specified times).
- Once you have finished a test you will be offered a snack

How to prepare for the study

- You need to fast overnight (approximately 10-12 hours) – this means **no food or drink**, although you are allowed to drink water in moderation
- For example, if you start your test session at 8.30 am, you need to stop eating/drinking (apart from water) at 8.30 pm the previous evening
- On the day before a test
 - limit your caffeine intake (maximum of 2-3 cups of coffee/tea)
 - limit your alcohol intake (maximum of 1 glass of wine/1 pint of beer) - **not to be consumed in the evening**
 - restrict participating in intense physical activity (e.g. long periods at the gym, excessive swimming, running, aerobics)
- On the day of your session, please wear loose, comfortable clothing where outer garments and footwear can easily be removed
- Limit smoking the day before and do not smoke on the morning of the test.

Health and safety

Your comfort and health and safety are of primary concern to us:

- Each measurement requires only a few drops of blood, therefore the finger-prick will be small, with minimal discomfort. A light bruising may also occur in some people, but this should disappear itself within a couple of days and will not affect your ability to work.
- Trained personnel will take finger-prick blood samples using standard procedures
- Finger-pricks are made using disposable individual lancets to avoid the possibility of contamination.

What are the possible benefits of taking part?

- The study will provide valuable information on the value of insulin index (II) for various foodstuffs that will form part of the study
- This information will be used to supply details on the II of foodstuffs in order to select and identify low II foods for recommending to the public for improved health and well-being

This study has received clearance from the University Ethics Committee at Oxford Brookes University. If you have any concerns about the conduct of this project, you can contact the Chair of the University Ethics Committee (ethics@brookes.ac.uk).

- You will receive information about your own body profile, including anthropometric and body composition measurements
- You will receive £10 of Amazon or book vouchers per test session.

Will what I say in this study be kept confidential?

All information collected about you will be kept strictly confidential (subject to legal limitations).

- All samples and records will be coded and will only be available to the researchers involved in the study; your name will never appear in any published work
- All data will be securely stored at the University for a minimum of 10 years in accordance with the University's policy on academic integrity
- You are free to withdraw from the study at any time, without giving a reason, and to withdraw any unprocessed data previously supplied

What should I do if I want to take part?

If you want to take part in this study, please contact:

| | | |
|---|----|---|
| Patricia Shaw | or | George Saltaouras |
| Functional Food Centre | | Functional Food Centre |
| Oxford Brookes University | | Oxford Brookes University |
| Gypsy Lane Campus | | Gypsy Lane Campus |
| Oxford | | Oxford |
| OX3 0BP | | OX3 0BP |
| Email: p.shaw@brookes.ac.uk | | Email: gsaltaouras@brookes.ac.uk |
| Tel: 01865 483283 | | Tel: 01865 483283 |

What will happen to the results of the research study?

At the end of the research, the results will be included in a detailed report submitted to the funding body. No information about individual participants will be included in this report and it will not be possible to identify you. In addition, it is anticipated that some results may be published in peer-reviewed journals and presented at meetings and conferences. Participants will not be identified in any publications. Additionally, the data will be incorporated into our larger research database analysing glycaemic response.

In order to measure the GR and IR of a product, data is required from a minimum of 24 people. You will therefore not receive your own GR/IR results once you have completed the study. However, if you wish to be debriefed, you will be able to contact the research team.

Who is organising and funding the research?

This research is being conducted by the Functional Food Centre, Department of Health and Social Care, Faculty of Health and Life Sciences.

Who has reviewed the study?

This research has been approved by the University Research Ethics Committee, Oxford Brookes University.

Contact for Further Information

If you have any questions regarding this study, you can contact either:

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|---|---|---|
| Dr. Helen Lightowler | Dr. Sangeetha Thondre | Dr Miriam Clegg |
| Functional Food Centre | Functional Food Centre | Functional Food Centre |
| Oxford Brookes University | Oxford Brookes University | Oxford Brookes University |
| Gypsy Lane Campus | Gypsy Lane Campus | Gypsy Lane Campus |
| Oxford | Oxford | Oxford |
| OX3 0BP | OX3 0BP | OX3 0BP |
| Email: hlightowler@brookes.ac.uk | Email: Pthondre@brookes.ac.uk | Email: mclegg@brookes.ac.uk |

Thank you

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

Date: 6th March 2014

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