U-PROTEIN

An Roinn Talmhaíochta, Bia agus Mara
Department of Agriculture, Food and the Marine

Department of Agriculture, Environment and Rural Affairs
www.daera-ni.gov.uk

QUEEN'S UNIVERSITY BELFAST

Participant Information Sheet

Title of the project: Digestibility of broad bean (faba bean) protein compared to whey protein

We are inviting you to take part in the above research study by Queen's University Belfast. This study is part of a bigger project entitled "Unlocking Protein Resource Opportunities To Evolve Ireland's Nutrition – U-PROTEIN" which has been funded by Department of Agriculture, Environment and Rural Affairs (DAERA) in conjunction with Department of Agriculture, Food and Marine (DAFM) through the DAFM 2019 Competitive Research Fund (CRF 19/R/702). The study will take place Northern Ireland Clinical Research Facility, U Floor, Belfast City Hospital tower block.

Before you commit to this study, it is vital that you understand why we are doing this research and what the research entails. Please take some time to read over the following information and, if you have any questions, please contact us using the details given at the end of this leaflet.

Thank you for reading this.

1. Invitation paragraph

As a population, we get most of our protein from animal sources with some protein coming from plant sources including peas, beans and cereals. Plant-rich diets are recommended for both health and environmental sustainability and in recent years there has been increased interest in how we can maximise land use efficiency in the UK and Ireland by growing a wider range of plant crops. One plant protein source of interest is faba beans, more commonly known as broad beans. Faba beans are high in protein but it is not known if this protein is readily digested in comparison to high quality animal proteins, such as whey protein that comes from Cow's milk. How a protein is digested influences things like the secretion of gut hormones that influence appetite, and the levels of glucose in the blood. Faba bean protein is a potentially valuable protein source for humans and it is possible to buy faba bean protein powders from a range of major retailers.

2. What is the purpose of the study?

This study will examine how well faba bean protein is digested and how this affects metabolism compared to whey protein when they are consumed as a drink alone or in combination with glucose (a simple sugar that is the bodies main source of energy).

3. Why have I been chosen?

We are inviting generally healthy people aged 18 to 40 years, with a Body Mass Index over 18.5 kg/m^2 (and/or weight ≥50kg) to take part in this study.

You would not be able to take part in this study if:

- currently, or in the past, you have taken medication known to affect glucose regulation, appetite, digestion or absorption of nutrients
- have had a major medical or surgical event requiring hospitalisation within the past three months
- have any known food allergy or intolerance including lactose intolerance or milk allergy
- are pregnant or lactating
- have donated blood to the NI Blood Transfusion Service in the last 12 weeks for men or 16 weeks for women

4. 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 given this information sheet to keep and you will be asked to sign a consent form. If you choose to take part, you can change your mind at any time and withdraw from the study without giving a reason.

If you withdraw from the study any data or samples you have provided up to that point will be used unless you request otherwise.

If you wish to withdraw your data after the study has been completed, you can do this by contacting the study team (details given on page 7). This will only be possible before the data has been analysed.

If you wish to withdraw your samples after the study has been completed, you can do this by contacting the study team (details given on page 7). Any remaining sample will be destroyed on request.

5. What will happen to me if I take part?

After you read this leaflet we will contact you to discuss the study in more detail and answer any further questions you may have.

If you decide to take part, you will be asked to sign the consent form for the study and complete some study measurements (described below).

If you agree to take part in this study, you will attend the NI Clinical Research Facility, U Floor, Belfast City Hospital tower block on four occasions, at least one week apart. At each visit you will be asked to consume one of the following drinks:

- Whey protein OR
- Faba bean protein OR
- Whey protein in combination with glucose (50g, for example this is equivalent to consuming a small pack of glucose tablets) OR
- Faba bean protein in combination with glucose (50g)

The protein content of the drink will be based on your body weight but will be roughly between 20-40g protein (for example, this is the amount of protein contained in a chicken breast).

All drinks will be prepared using bottled water (about 450 mls) together with the protein powder, glucose powder if required and flavoured with a sugar free flavouring (such as a sugar free fruit cordial).

A computer will randomly decide what order you take the drinks in.

At each visit (total 4 visits), you will come to the Northern Ireland Clinical Research Facility (NICRF) in morning time in a fasted state (no food from 9pm the night before). Each visit will last about 2.5 hours.

You will be asked to complete a questionnaire and have some measurements taken as explained below. A nurse from the Clinical Research Facility will insert a cannula (small needle) in your arm and will take a blood sample. You will then be given the drink to consume within 15 minutes. Blood samples will be collected again via the cannula after 30 minutes, 60 minutes, 90 minutes, and 120 minutes. In total at each visit, 60mls of blood (about 4 tablespoons) will be collected. After consuming the drink and completing the questionnaire and measurements you will be free to relax for the duration of the visit. At the end of the visit, the nurse will remove the cannula from your arm and you will then be given a snack and a drink to take away with you.

A token of appreciation in recognition of the time it takes to participate in this research will be given – a £100 voucher will be given after the first two visits, and a further £100 voucher will be given after the last two visits; £200 in total if all four visits are completed.

Questionnaires

At the first visit you will be asked to complete a short lifestyle questionnaire which includes questions about sex, age, usual food and drink consumption, alcohol intake, usual physical activity level and smoking status. This will take 5-10 minutes to complete.

At each visit you will also be asked to rate your hunger each time we collect a blood sample (Time 0, then at 30, 60, 90 and 120 minutes). This will take less than a minute.

At each visit you will be asked to indicate what you thought of the taste and texture of the drink you had. This will take less than a minute.

Body measurements

At the first visit, your height, weight and waist circumference will be measured.

Blood Samples

As indicated above, blood samples will be collected at the beginning of each visit (time 0) and again after 30 minutes, 60 minutes, 90 minutes, and 120 minutes. In total at each visit, 60mls of blood (about 4 tablespoons) will be collected. We will measure nutritional and metabolic markers in these blood samples including gut hormones, insulin, glucose and levels of amino acids (small parts of proteins).

With your permission, we would like to store some of the samples you have given us at the end of the study for future use. These samples will be stored in Queen's University Belfast. Storage of these samples will enable us to undertake more research if new knowledge and technology becomes available. We do not know for sure what these future studies will be but they may involve sharing samples with collaborators abroad or research in collaboration with partners such as commercial companies. You can indicate on the consent form if you agree to let us retain samples for future use in other ethically approved studies.

6. What are the possible risk or disadvantages of taking part?

As a result of you participating in this study, you will be helping us to understand how faba bean protein is digested and how it effects metabolism compared to whey protein.

The are no disadvantages to taking part apart from the time and commitment that is asked of research participants as described above. Participants will be expected to attend the NICRF for study appointments.

The content of the drinks, either faba bean or whey protein, with or without glucose, are available to purchase, widely consumed and are well tolerated so the risk of any adverse effect is very low.

There are potential hazards associated with taking blood samples such as minor discomfort, fainting and bruising associated with the insertion of the cannula and providing blood. However, these risks are minimal and blood samples will be collected by a fully trained member of staff to ensure the safe collection of the blood samples and you will be supervised at all times during the visit to ensure you are comfortable.

7. What are the potential benefits of taking part?

As a result of you participating in this study, you will be helping us to understand how faba bean protein is digested and how it effects metabolism compared to whey protein. This will help a range of stakeholders including farmers, food producers and nutrition and health experts understand more about how faba beans can support human health.

8. What if something goes wrong?

If you have any concerns about any aspects of the study, you can contact the Chief Investigator, Professor Michelle McKinley (m.mckinley@qub.ac.uk). Should you remain unhappy and wish to make a formal complaint, you can contact the Research Governance Team at Queen's University Belfast (Telephone: 028 9097 2529; Email: researchgovernance@qub.ac.uk).

9. Will my taking part in the study be kept confidential?

Yes, all your data will be treated with the strictest confidence and your details will not be shared with anybody outside of the research team.

Any information collected from you will be stored securely on password protected files on password protected computers that only the research team can access. Hard copies of documents will be kept in locked filing cabinets in locked offices that are only accessible to the research team and are located in a building that is locked outside normal working hours.

Study data will be kept separate from personal information (such as name and contact information). Only members of the research team will have access to view identifiable data. However, in some instances, inspectors from regulatory authorities may need to access data for checking the quality of the research. All members of the research team

and regulatory bodies are trained in data protection and will comply with the requirements of data protection legislation.

Once the study is complete and it is no longer necessary to keep identifiable information or contact details, we will destroy our records of this personal information.

This research will be conducted in compliance with data protection legislation. For more information about how we look after your information, how to access your rights and who to contact if you have any queries or concerns about data protection please visit the Queen's University Belfast website –
www.qub.ac.uk/privacynotice/Research/ListofResearchPrivacyNotices/PrivacyNoticeforResearchParticipants

10. What will happen to the results of the research study?

Once we have finished the study, we will write our reports in a way that no-one can work out that you took part in the study and we will share the study findings with a range of audiences including the public and the scientific community. In order to promote transparency and public accessibility to research, anonymous data from this study will be made available through a publicly available online data repository.

If you are interested in the outcome of this project, we will securely keep your contact details and, when the study is over, we will send you a summary of the results. We will ask you whether this is something you would be interested in when you complete the consent form.

11.Who is organising and funding the research?

This study is being organised by staff from the School of Medicine, Dentistry and Biomedical Science and the School of Biological Sciences at Queen's University Belfast. This study is part of a bigger project entitled "Unlocking Protein Resource Opportunities To Evolve Ireland's Nutrition – U-PROTEIN" and is funded by Department of Agriculture, Environment and Rural Affairs (DAERA) in conjunction with Department of Agriculture, Food and Marine (DAFM) through the DAFM 2019 Competitive Research Fund (CRF 19/R/702).

12. Who has reviewed the study?

This study has been reviewed and ethical approval has been granted by QUB Faculty of Medicine, Health and Life Sciences Research Ethics Committee.

Contact for Further Information

The research study team can be contacted at any time with any concerns you may have before, during and after the study.

Name of Researcher: Dr Clare Kelly, Research Fellow, Centre for Public Health, School of Medicine, Dentistry and Biomedical Sciences, Institute of Clinical Sciences Block B, Grosvenor Road, Belfast, BT12 6BJ
E-mail: clare.kelly@qub.ac.uk
Tel: 07810 810491 (study mobile)

Name of Researcher: Dr Eleni Spyreli, Research Fellow, Centre for Public Health, School of Medicine, Dentistry and Biomedical Sciences, Institute of Clinical Sciences Block B, Grosvenor Road, Belfast, BT12 6BJ
E-mail: eleni.spyreli@qub.ac.uk
Tel: 07810 810491 (study mobile)

Name of Primary Investigator: Professor Michelle McKinley, Professor, Centre for Public Health, School of Medicine, Dentistry and Biomedical Sciences, Institute of Clinical Sciences Block A, Grosvenor Road, Belfast, BT12 6BJ

E-mail: m.mckinley@qub.ac.uk
Tel: 02890 97 8936

Thank you for your interest in this study and for taking the time to read through this information sheet. Please do not hesitate to contact us if there is anything that you are unsure about or if you would like more information on this study.