School of Biomedical, Nutritional and Sport Sciences
Newcastle University
Faculty of Medical Sciences
Framlington Place
Newcastle upon Tyne
NE2 4HH United Kingdom

PARTICIPANT INFORMATION SHEET (Version 1.0 06/01/2023)

Appetite responses to a leucine-enriched glycomacropeptide (GMP) based protein products in older adults

Thank you for expressing an interest in taking part in this study. Before reading on, please be aware that you are under no obligation to partake. Participation is entirely voluntary. If after reading this document you do not wish to take part, we thank you for your consideration.

This study has undergone all necessary risk assessments and follows the ethical guidelines of Newcastle University. Ethical approval has been granted by the Faculty of Medical Sciences Research Ethics Committee.

The study…

We are recruiting older adults to take part in our study exploring appetite responses to different types of protein. If you are over 65 years old, are at or below your ideal weight, do not exercise often and regularly, do not smoke, and are free from metabolic disease such as cardiovascular disease, high blood pressure or diabetes, then we welcome you to take part.

The following will provide more information about our study. If you have any further questions, please do contact a member of the research team, using the contact details at the end of this document.

Why are you conducting this study?

As we age, it is important to maintain muscle mass and strength, so as to maintain physical function and help avoid frailty. To support the maintenance of muscle and strength, it is recommended that we consume an adequate amount of protein, which is not always easily achieved. This is made even more difficult if appetite is low, with many people experiencing a decrease in appetite with age. To complicate matters further, protein is particularly filling, so trying to increase protein intake can then have the knock-on effect of leaving you feeling full more quickly and for a longer time after a meal.

We are interested in trying to determine appetite responses to different proteins, in an effort to identify which proteins might provide the essential nutrients for promoting muscle maintenance while not leaving us as full up. The extent to our feelings of fullness and hunger after consuming food and drink is partly governed by changes in appetite-related hormones, and we think different proteins will effect these hormones differently. In this study, we will explore appetite and appetite-related hormone responses to two milk-derived proteins: whey protein and glycomacropeptide.

tel: +44 (0) 191 208 8200
bns.ugadmin@ncl.ac.uk
www.ncl.ac.uk/bns

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What would my participation entail?

If you decide to take part, we will ask you to visit the Human Nutrition Laboratory on four occasions.

Visit 1: On your first visit, we will ensure that you are fully aware of what participation in the study will entail and answer any questions you may have about the study. We will then obtain your written consent to confirm you want to partake. Next, we will measure your body composition, height and weight using scales which send a very low current electrical impulse through your body to estimate the amount of fat and muscle tissue. This procedure is completely painless: you will not feel the impulse at all. We will then ask you to complete two questionnaires relating to your eating, and use an online program called Intake24 to recall the previous day's food intake. We will enquire about your health and ask some questions in relation to your medical history, to ensure you are healthy and that your participation in the study will be completely safe.

We will then ask you to consume a small sample of the protein drinks and the lunch meal you will be provided with in the experimental trials. This is to check palatability and ensure you are happy to consume these in your future visits. We will ask you rate taste, texture and palatability on pen and paper scales.

We will finish the visit by explaining exactly what will happen on your subsequent visits, which will be the main experimental trials. We will provide you with a food diary and an evening meal. Using the food diary, we will ask you to record all food you eat on the day before your trial visit. We will also ask you to consume an evening meal which we will provide for you (macaroni and cheese/beef hash, a yoghurt for dessert and a drink of orange juice) on the evening before your trial visits. This first visit will last approximately 45 minutes.

Visits 2, 3 and 4: The second, third and fourth visit will be your experimental trials. We will ask you to arrive at the Human Nutrition Laboratory in the morning, after an overnight fast, without consuming breakfast (although, we will ask you to drink some water upon waking). We will also ask you to please abstain from doing exercise and consuming caffeine on the day before your experimental trials. When you arrive, we will ask you to rate your appetite using a pen and paper scale before inserting a cannula into a vein in your arm, which will allow us to take blood samples throughout the trial without having to repeatedly puncture a vein. We will take a small blood sample at this point, before providing you with a breakfast drink. This will either be one of two protein drinks or water. Once you have finished breakfast, you will rest for a period of 4-hours. During this time, we will ask you to be seated, but you will be free to read, watch television, play electronic games, etc. We will take blood samples and ask you to rate your appetite at the 0.5, 1, 1.5, 2, 3 and 4-hour time points. At the 4-hour point, we will remove the cannula and then provide you with a pasta and sauce lunch meal. After lunch, the trial will finish. The visit will last approximately 5-5.5 hours. We will ask you to record any food you eat for the remainder of the day, using a food diary with which we will provide you.

What data would you collect and what would you do with it?

We will measure your height and weight, and ask you about your metabolic health and any medication that you are currently taking. We will retain your contact detail (usually limited to your email address) for correspondence during the study.

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From the blood samples, we will measure the concentration of the hunger hormone ghrelin, and two hormones known to signal fullness, known as cholecystokinin and peptide YY. These data will provide some information about the biological regulation of appetite but will not provide any other insight into your health. We will also measure the amount of food you eat at the lunch meal.

This study complies with the General Data Protection Regulation (GDPR). All information collected about you will be kept strictly confidential and stored safely and securely on the researcher's password-protected university account. When storing your data, you will not be identified within the document; you will be allocated a unique study ID, enabling your data to stay confidential. The Principal Investigator (Dr Adrian Holliday) will maintain and manage all data, sharing it when necessary with chosen co-investigators, internal to Newcastle University. Data will be stored for a period of ten years, before being disposed of securely. All hard copies of data will be stored in a locked filing cabinet in a locked room.

When we collect blood samples, we will separate the plasma from your blood cells. The blood cells, which contains your DNA, will be disposed of immediately. Only plasma, which does not contain your DNA, will be stored. Plasma will be stored in a freezer and analysed at the end of the study.

Any sharing or dissemination of your research data will be done anonymously, with your permission. There will be no way of identifying you from the data disseminated. Your personal information, such as names and contact details, will not be shared or disseminated. Personal data will not be used for purposes than those explained in this document. Research data may be used in collaborative or follow-up studies. In such an instance, your data will be stored and handled in exactly the same manner as explained here.

What are the benefits to me of taking part in this study?

As a sign of our gratitude for takin part in the study, you will receive a £40 Amazon voucher. The experimental data we obtain in the study could be the first step in informing new food products and supplements to help undernourished older adults increase protein intake – helping maintain muscle mass and decreasing frailty – without excessive and inhibitive feelings of fullness. By taking part in this research, you will be helping us to achieve our goal of improving diet, health, and wellbeing as we age.

Are there any risks associated with taking part?

There is a risk of harm associated with venous blood sampling. Infection of the puncture site can occur (although this is very rare), and the procedure of inserting the cannula can cause some discomfort. The insertion of the cannula can cause a sharp scratch of pain, and the cannula itself can cause an uncomfortable feeling when first inserted. Both these sensations are typically short-lived. After the cannula is removed, some bruising can appear over the next 12-72 hours. All cannulations and blood sampling will be conducted by a qualified and experienced phlebotomist (12 years' experience of venepuncture and cannulation). We will use antiseptic procedures throughout the cannulation and the blood collection procedures to reduce the risk of infection. To limit the risk of contamination, personal protective equipment (PPE) of gloves, lab coat

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and goggles will be worn by the researcher at all times when cannulating and obtaining blood samples. To minimise the risk of bruising, pressure will be applied to the cannulation site when the cannula is removed.

Should you suffer any adverse reaction to blood sampling, or in the case of any emergency, a person trained in administering emergency first aid will be present at all times. The laboratory is fitted with a defibrillator and at least one of the research team or laboratory support staff will be defibrillator trained. The laboratory is also fitted with a telephone for contacting emergency services. There will always be at least two researchers/support staff on present during trials to ensure we can act rapidly in the event of an emergency.

Each blood sample will take a very small amount of blood of around 8mL. This is less than one-and-a-half teaspoons of blood. In total, we will take approximately 56mL of blood each trial. This is much less than, for example, the 470mL that would be taken if you donated blood.

What if I want to withdraw from the study?

You have the right, and are free, to withdraw from the study at any point. You can do so with no explanation or reason. You can decide to withdraw your data at any point, even after you have finished the study. To withdraw, simply contact a member of the research team, or the independent member of staff (see contact details, below). This is a member of staff within the School of Biomedical, Nutritional and Sport Sciences who is not involved in this research study.

What happens if something goes wrong?

If at any point you are uncomfortable about your participation in the study, or are unhappy with the conduct of a member of the research team, you are encouraged to contact the independent member of staff (see contact details, below).

What do I do now?

If you wish to take part in the study, or if you have any further questions, please contact the Principal Investigator, Dr Adrian Holliday (adrian.holliday@newcastle.ac.uk; 0191 2080564)

If you do not wish to take part, we thank you for your expression of interest and for taking the time to read this document.

Contact details

Principle Investigator: Adrian Holliday
Email: adrian.holliday@newcastle.ac.uk
Telephone: 0191 2080564

Independent University Contact: Dr Adam Coussens
Email: adam.coussens@newcastle.ac.uk
Telephone: 0191 2080562