PARTICIPANT INFORMATION SHEET

Title: Effect of a novel protein ingredient combined with oral nutritional supplement on appetite in older adults

Researchers: Dr Katy Horner, Ms. Lisa Vigo (Research Assistant), Mr. Luccas de Faria (Research Assistant), Ms. Sion Ormond (Research Assistant)

School: School of Public Health, Physiotherapy and Sport Science, University College Dublin

Thank you for taking the time to read this information sheet. Participation in this study is completely voluntary. The following information provides more details on the study. If you have any questions, please ask.

What is this research about?

This study will investigate the effect of a novel protein ingredient added to an oral nutritional supplement on appetite and energy intake in adults >60 years.

Why are we doing this research?

Reduced appetite can occur with ageing and is linked to a higher risk of undernutrition, poorer physical function and becoming frail. Strategies to increase appetite are needed to improve healthy ageing. This study follows on from previous work which has found a novel ingredient in whey protein (derived from whole milk) that may help to increase appetite and energy intake. This study will compare the effects of the ingredient added to an oral nutritional supplement (ONS) versus the ONS alone versus the novel ingredient dissolved in water on appetite in older adults. By studying this nutrition supplement in older adults, this will help to provide greater information on possible nutrition strategies to improve healthy ageing.

Why have you been invited to take part?

You have been invited to participate because you:

- Are aged 60 years or older
- Are community-dwelling (without assistance)
- Have a BMI of 20-25kg/m^2
- Have no medical conditions that impact appetite/taste and not be taking any medication known to impact appetite or taste
- Are not a heavy smoker (<10 per day)
- Have not had a loss of taste due to previously contracting COVID-19

Other inclusion criteria also apply. If you are interested in participating in this trial, your full eligibility will be assessed during a screening visit.

How will my data be used?

This data may be published in the form of one or more scientific papers. You will be assigned a study code number, and this code will be used to input the data generated from the study. Your data will be secured in a password-protected database, where it will be stored safely for up to ten years. None of your details will be shared with any third parties.

What will happen if you decide to take part in this research study?

Screening (Approx. 20 minutes via telephone/email)

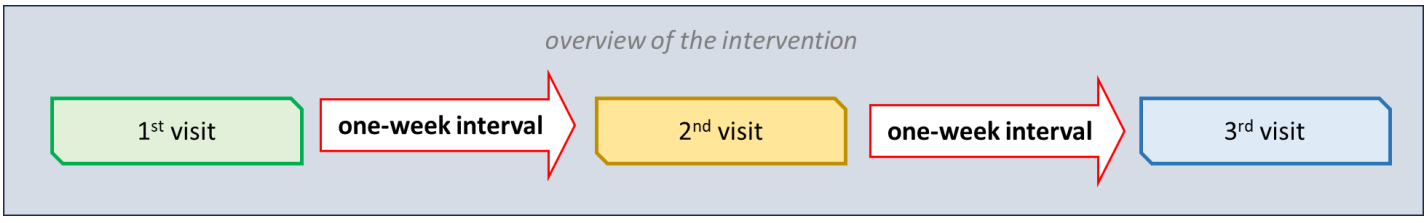
You will first be asked to complete a screening questionnaire to ensure you are eligible to participate in the study. This will be done by telephone or by email.

In-person Screening Visit and Baseline measurements (Approx. 1 hour at UCD)

If you are eligible based on the phone/email screening, you will be asked to attend a short in-person screening visit at UCD in the morning. At this visit, we will confirm your height and weight measurement, and answer any further questions you may have about the study. If you are eligible, you will be asked to sign a consent form, and to complete a questionnaire about your eating behaviour. We will then measure your body composition and your resting metabolism. These measurements will take about 30 minutes to complete. You will be asked to sit inside a BodPod for 3-4 minutes, which is a simple non-invasive test which calculates your body composition using air displacement plethysmography. For this measurement, it is important you are wearing close-fitting clothing. You will then be asked to lie down on a bed for about 20 minutes, and we will measure your resting metabolism. This is the amount of energy your body is using to maintain function at rest. We will place a ventilated hood over your head and measure the amount of oxygen your body uses and carbon dioxide produced. From this we can calculate your energy needs at rest. In total, this visit will last approximately one hour.

Three Test Visits to UCD

You will then be asked to attend three main testing sessions at the *Institute for Sport and Health* at UCD. These will be scheduled approximately one week apart (see diagram below).



You will be asked to come to the Institute in the morning after an overnight fast on all three occasions. All test visits will follow an identical procedure, except that you will be given a different nutritional supplement to consume. On one visit, you will be asked to consume the novel protein ingredient added to an ONS. On another visit you will be asked to consume the ONS on its own, and on a third occasion, you will be given the same novel whey protein ingredient dissolved in still water. The order of nutrition supplement will be randomised.

The following information provides a detailed description of what will happen at each visit:

- A fasting blood sample will be collected and you will be asked to complete a questionnaire regarding your appetite. This questionnaire takes approximately one minute to complete.

- You will then be provided with one of the nutritional supplements (novel whey protein ingredient in ONS, ONS on its own or novel whey protein ingredient in water).

- Thirty, sixty and ninety minutes later, blood samples and appetite questionnaires will be collected.

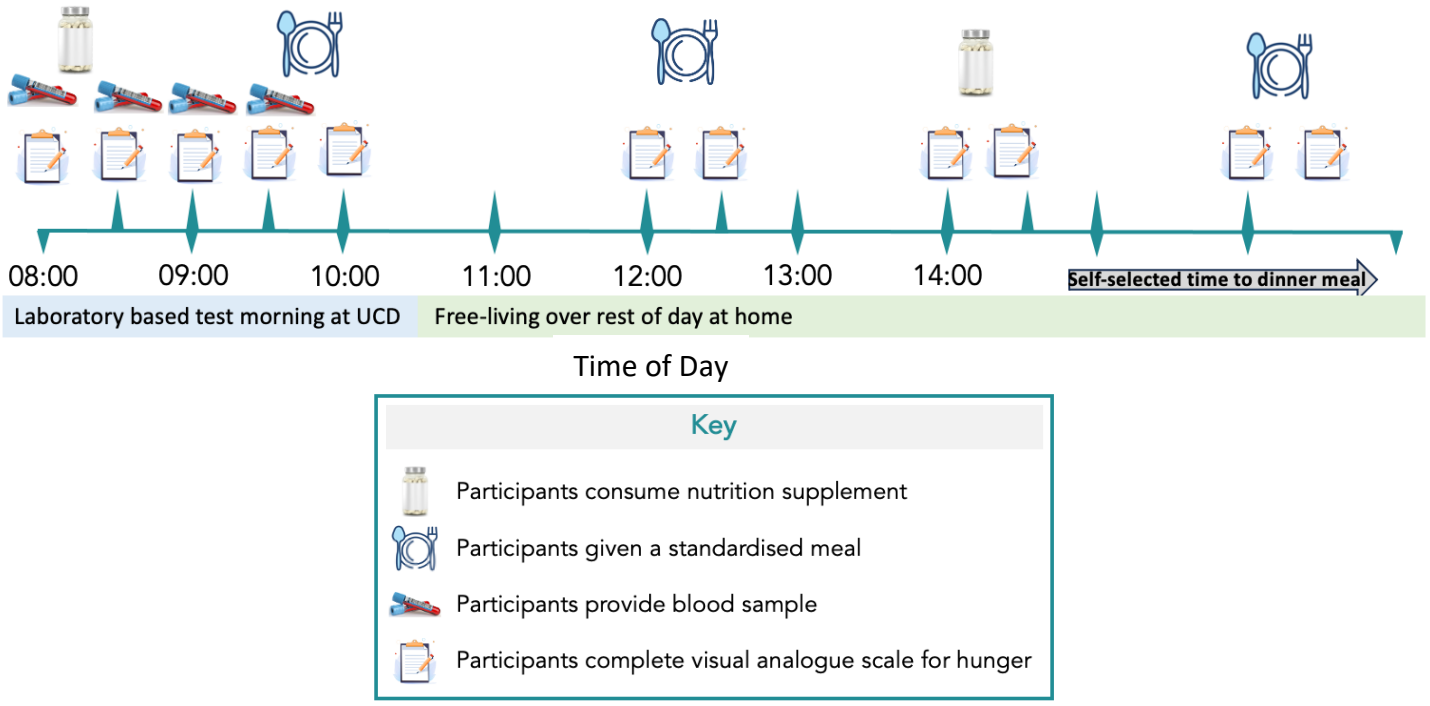
- You will then be given a breakfast meal. Your breakfast will be an *ad libitum* meal, that means you can eat as much as you wish until you are comfortably full. After the meal, we will ask you to fill out another appetite questionnaire and a computerised food preference questionnaire assessing how much you like different foods. This completes the test morning at UCD, lasting approximately 2.5 hours.

- You will be given the following to bring home (a) lunch and dinner meals, (b) questionnaires that you are asked to complete before and after your meals, and (c) one of the test supplements. Over the course of the following six hours you are asked to undertake sedentary activities such as reading, watching TV or using a laptop during this time. We will ask you to eat the lunch meal provided to you two hours after your breakfast. An hour and a half later, you will be asked to drink the nutritional supplement provided to you.

- You are then asked to consume your dinner meal whenever you feel like doing so. You will be asked to record the time that you consume your meal at, and any other foods you consume that evening.

- You are asked to keep the completed questionnaires for the researcher to collect at the next visit.

An overview of what each test visit will involve is shown below. Approximate time of day is also shown.



How will your privacy be protected?

If you participate in the study, your identity will remain confidential and you will be assigned a unique study ID number. Your name will not be used or disclosed to anyone. All information which is collected about you during the course of the research will be kept strictly confidential. The data will be stored on a password protected computer. Any information about you such as your name and address will be removed once the data has been entered so that you cannot be recognised from it. This research will be carried out in compliance with the relevant GDPR regulations.

What are the benefits of taking part in this research study?

There are no direct benefits to you for participation in this study. However, your collaboration will help us to develop better nutrition strategies to enhance appetite in older adults and help combat undernutrition with ageing. You will be provided with all meals on the testing visits.

Will I be paid for taking part in this study?

You will not be paid in cash. However, it is recognised that participation involves time commitment on each of the study test visits (approx. 2.5 hours). To compensate you for your time, you will be provided with a 50-€ One4all voucher, at the end of each testing visit (150 euro in total for all three test visits).

Will my expenses be covered for taking part in this study?

Yes. You will be re-imbursed for any travel cost such as UCD parking.

What are the risks of taking part in this research study?

There exists only minimal risk in the present study. When a blood sample is drawn, there may be a small amount of discomfort when the needle punctures the skin and potential for a small amount of bruising to occur. To ensure this risk is kept to a minimum, all samples will be collected by a trained and experienced phlebotomist. As this study involves coming into UCD, and a small amount of contact with a researcher during height and weight measurements, there is also risk of contracting COVID-19. However, several steps will be taken to ensure this risk is minimized. All food items will be prepared according to the guidelines of the Food Safety Authority of Ireland, in light of coronavirus public health measures and all surfaces and contact points will be meticulously cleaned and disinfected before and after each testing session.

Can you change your mind at any stage and withdraw from the study?

Absolutely. Your participation is entirely voluntary, and you can choose to withdraw from the study at any point without any consequence. To withdraw you can simply contact use using the details below and request that your data be removed and destroyed. However, at the end of the study when all data collection is complete, withdrawal will no longer be possible.

How will you find out what happens with this project?

If you wish to find out the results of the project, please let us know and we will inform you of the results when the project is finished. We will not be able to provide individual data as all of our analysis will be done using coded samples and data only.

Who is organising and funding this research?

This study is funded by Food for Health Ireland (FHI). The FHI-3 project is funded by Enterprise Ireland and industry [TC201800025]. You can read more about FHI at the following website: https://www.fhi.ie/

In addition, you will find information about the present study on our study's webpage:

https://www.ucd.ie/foodandhealth/more/humanhealthstudies/pronutritionstudy/

Contact details for further information

If you would like any more information on this study, please feel free to contact the research team at pro.nutrition@ucd.ie OR (089) 225 8877