

## Participant Information Leaflet

**Title of Project:** Protein supplement and exercise training for the treatment of malnutrition and sarcopenia risk in older adults who receive supportive home care:  
POWER Study

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Supervisor's name:	Associate Professor Caitriona Cunningham
Supervisor's title:	Associate Professor, School of Public Health, Physiotherapy and Sports Science
Supervisor's name:	Dr Katy Horner
Supervisor's title:	Lecturer/Assistant Professor, School of Public Health, Physiotherapy and Sports Science
Researcher's School	UCD School of Public Health, Physiotherapy and Sports Science
Researcher's Address	UCD Institute of Sport and Health University College Dublin, Newstead Block C, Belfield, Dublin 4.

You are being invited to take part in a research study. Before you decide whether you wish to take part, you should read the information provided below carefully and, if you wish, discuss it with your family, friends, or GP (doctor).

Take time to ask questions – don't feel rushed and don't feel under pressure to make a quick decision. You should clearly understand the risks and benefits of taking part in this study so that you can make a decision that is right for you. This process is known as 'Informed Consent'.

You don't have to take part in this study. You can change your mind about taking part in the study any time you like. Even if the study has started, you can still opt out. You don't have to give us a reason.

Funding for this project has been provided by Nutricia Ireland Ltd. The funders will have no role in the study design or collection, analysis and interpretation of the study data.

Thank you for taking the time to consider this invitation.

### **What is this research about?**

This research is about adults (over the age of 70) who are at risk of both malnutrition and sarcopenia, who are living at home and are receiving some form of home care. The aim of this research study is to see if a protein supplement plus an exercise programme will be helpful to improve the malnutrition risk compared to an exercise programme alone.

### **Why am I doing this research?**

This is an important research topic, and I am delighted to be a part of it. I want to help adults who live at home to get enough protein in their diet and to become more active, whatever their age.

Malnutrition occurs when a person is not able to eat enough food. Many older people lose their appetite and interest in food. This can cause problems, but it is possible to reverse these problems through improvements in diet. Sarcopenia occurs when a person loses their muscle and cannot carry out the same activities, they once found easy to do, for example climb stairs.

This study will see if adults (70+ years) who are at risk of both malnutrition and sarcopenia and who have home care improve their nutrition and muscle function after taking a protein drink and completing an exercise programme for 12 weeks compared to completing an exercise programme alone.

This study will take place over 24 weeks. There are twelve weeks of taking the protein drink and the exercise programme and twelve weeks of monitoring. There will be two groups, one group will take the protein supplement and do the exercise programme and one group will only do the exercise programme.

Protein builds and repairs muscle which can become damaged due to wear and tear. As a person gets older, they need to eat more protein. To make up protein, building blocks called amino acids are needed. Nine of these building blocks are referred to as essential amino acids. This means that our body cannot make them and we must get them from our food. One of these amino acids is called leucine and it is found mainly in animal foods such as milk, cheese and meat. Some research shows that taking a regular amount of leucine each day can benefit a person's overall and muscle health.

The protein drink is provided in 200 mL bottles with 300kcal per serving. The protein (21 g), leucine (3 g) and vitamin D (10 µg) are added to the drink to benefit your nutritional health as well as your muscle health.

### **Why have you been invited to take part?**

You have been invited to take part in this study because you responded to the advertisement, and you satisfy the eligibility criteria as outlined below. We hope to recruit 40 women and men.

Eligibility Criteria
<ul style="list-style-type: none"><li>• Living at home</li><li>• 70+ years of age</li><li>• Getting home care from family or a professional carer</li></ul>

## **How will your data be used?**

Data collected from you as a participant will be treated with the utmost confidentiality and will be anonymised by our computer systems. Only the research team; Ms. Catherine Fallon, Professor Clare Corish, Associate Professor Caitriona Cunningham, and Dr Katy Horner, will be able to access your data and we, the researchers are not allowed to share your information. This will be carefully written down in our data management plan.

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

After you have read the Participant Information Leaflet, we will arrange a suitable date and time for the PhD student to call you to answer any questions you may have. If you are happy to continue, we will ask you to complete the Screening Questionnaire by phone. Within the Screening Questionnaire, we will ask you about your nutrition (Mini-Nutritional Assessment-Short Form) and muscle health (SARC-F). We will also ask you about your medical status (PAR Q+) to ensure that you can safely partake in the exercise classes.

The PAR Q+ questions will ask if you have any health issues or symptoms that may affect your physical or mental health (for example blood pressure, osteoporosis, Alzheimer's disease, dementia, depression). This questionnaire is also used to identify any potential issues so we can advise you to seek guidance from your GP.

This study will be conducted from University College of Dublin; however, we will be travelling to you as the participant. You will not have to come to the University. We will organise appointments on three occasions to take some muscle measurements (none of these are invasive) and we will ask you to fill out questionnaires either online or in paper format.

If you decide to take part in the study, a suitable appointment date and time will be arranged with you. The trained researcher, Ms Catherine Fallon will come and carry out the first appointment. We will arrange a follow up appointment 12-13 weeks and 24-25 weeks later to redo the appointment (which may take several hours). After you have signed the informed consent sheet, you will be randomly assigned to one of the groups below:

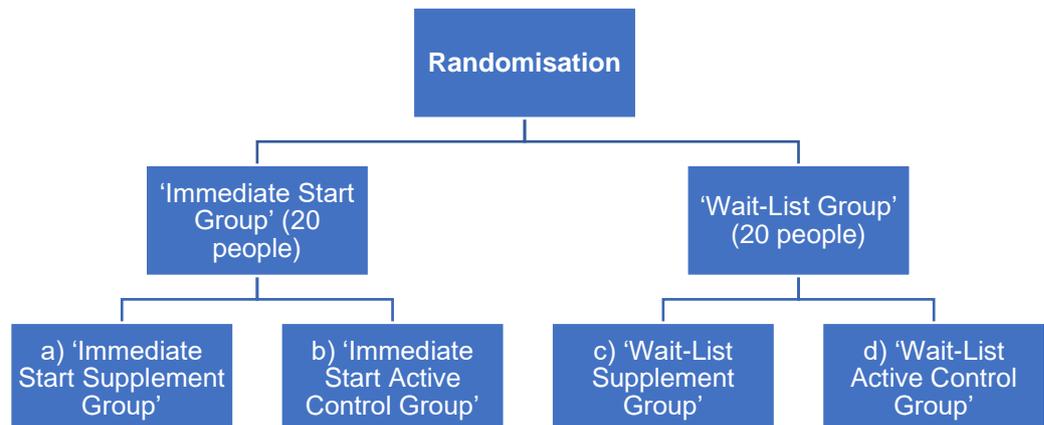
The **'Immediate Group'**

OR

The **'Wait-List Group'**

You will then be further split into four groups:

- a) 'Immediate Protein Drink + Exercise Group'
- b) 'Immediate Exercise Group'
- c) 'Wait-List Protein Drink + Exercise Group'
- d) 'Wait-List Exercise Group'



**Figure 1 Outline of the four groups.**

### 'Immediate Group'

The 'Immediate Group' will start the programme and the 'Wait-List Group' will continue their normal diet and activities for 12 weeks. After 12 weeks of taking the protein drink and participating in the exercise class, the 'Immediate Group' will have another appointment with the researcher. After the 2<sup>nd</sup> appointment, the 'Immediate Group' no longer needs to have the protein drink or exercise class. They will have a 3<sup>rd</sup> (final) appointment on week 24-25.

### 'Wait-List Group'

After 12 weeks, the 'Wait-List Group' will have a shorter 2<sup>nd</sup> appointment and will then start the 12-week intervention. After the 12-week intervention (week 24), their final appointments will be scheduled.

The appointment will include assessment of:

1. Height, weight, and muscle mass (approx. 5 mins)
2. Mid upper arm and calf circumferences (approx. 5 minutes)
3. Nutritional status using the Mini Nutritional Assessment Questionnaire-Full Form (10-15 mins)
4. Cognition using the Mini Mental State Examination (10-15mins)
5. Activities of daily living (5 mins)
6. Quality of physical & emotional health (2-5 mins)
7. Geriatric Depression Score-15 (approx. 5 mins)
8. 24-hour dietary recall to assess your dietary patterns and allows the researcher to suggest the best time for you to consume the protein drinks (approx. 20 mins)

Questionnaires will take between 40-50 minutes depending on the answers given.

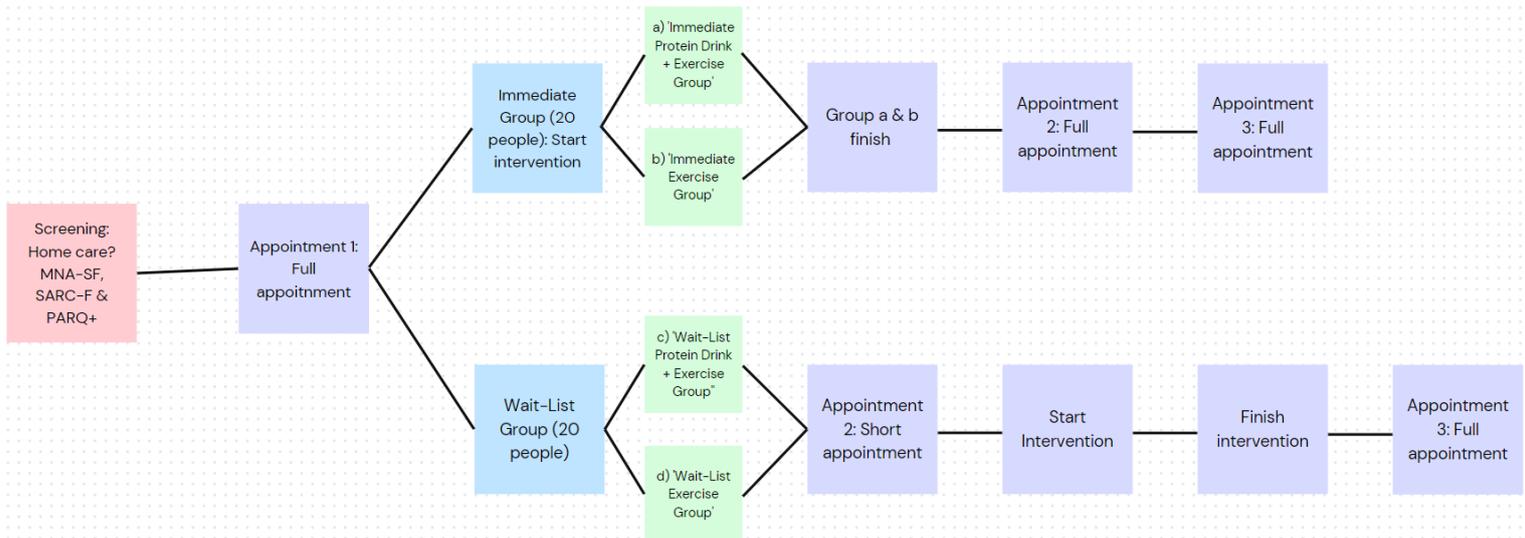
9. Testing your muscle strength and function with four tests: 4-metre Gait Speed, five times sit-to-stand test, handgrip strength and a stand up to walk to sit test (Timed get up & go).

The muscle strength and function tests will take between 10 to 15 minutes to carry out.

- If you are in the 'Protein Drink + Exercise Group' (a or c), you will be provided with information regarding your protein drink.
- Intervention will begin (week 1):
- The 'Immediate Group' will begin the exercise programme for 12 weeks, two times a week using Zoom. The 'Wait-List Group' will continue as normal for those 12 weeks.
- At week 12-13, all participants will undergo home testing again. The 'Immediate Group' will get the full assessment and will stop attending classes and will no

longer take the protein drink. The 'Wait-List Group' will have the nutritional assessment re-done. They will then begin the intervention.

- After 12 more weeks (24 in total), all participants will undergo assessment for the final time and the study will be over.
- The protein drink will be taken twice a day for the 12 weeks of the intervention. It is important that you feel comfortable adding a protein drink to your diet everyday as compliance is essential. The protein drink is not a meal replacer, it can be taken with meals, but we would prefer if you drink it on its own as the protein drink could make you feel full. This will be further discussed with you at the 1<sup>st</sup> appointment.
- The exercise programme will be delivered online through Zoom so you will not have to come to the University to do the exercise. We will set you up with a Zoom account online so that you can attend the classes. A timetable for the exercise sessions will be sent to you when everyone is registered on the study.



### How will your privacy be protected?

If you participate in the study, your identity will remain confidential and will only be accessible to the PhD student and the student's primary supervisor (study Principal Investigator/PI), and you will be assigned a unique study ID number. The study ID number connecting your identity to the data records will be stored in a password protected file on a secure drive on an encrypted laptop.

Your personal data (name, address, phone number, email address, date of birth) will not be published or disclosed to anyone. All other data collected during the study will be anonymised, analysed and stored for up to 10 years. All your personal data will be removed from the records once the intervention is complete so that you cannot be recognised. This research will be carried out in compliance with General Data Protection Regulations.

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

Taking part in this study, will help us to understand if a protein drink plus an exercise programme can help your nutritional status. This will help future research for older people.

You may also benefit from taking part in the study. Whether taking the drink or not, you should benefit from our exercise programme that can help improve your muscle strength and function and overall health status.

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

The research study will require three appointments over 24-weeks, which require face-to-face meeting and interaction. There will be a very small risk of exposure to COVID-19. This risk of COVID-19 will be minimised; the research nutritionist will use personal protective equipment and good hygiene standards in compliance with Health Service Executive (HSE) guidelines throughout the appointments.

Resistance exercise can cause muscle aches or strains, but our programme is designed to minimise the aches by warming up and cooling down after the exercise. There is a risk of falling during the appointment and exercise class. To prevent this, we ask you to wear correct shoes and have something to catch onto during the classes. And always keeps your mobile phone close by. We will take your emergency contact details at the first appointment for your safety.

There is a very slight chance the protein drink won't agree with you. If you experience any discomfort when consuming the protein drink, please let us know straight away.

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

You can decide to withdraw from the study at any point prior to the transcripts being anonymised without any consequence. You can contact the researchers to request this. This study requires a significant time commitment (12 weeks) and at weeks 24 to 26, there will be a day that requires time commitment for the final appointment. If you do not feel you are in the position to give that much commitment, then this study may not be for you.

### **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.

### **Contact details for further information**

If you have any further questions about the research or would like information on the findings, you can contact Ms Catherine Fallon.

Thank you for taking the time to read and consider our study.

# Intervention Timeline

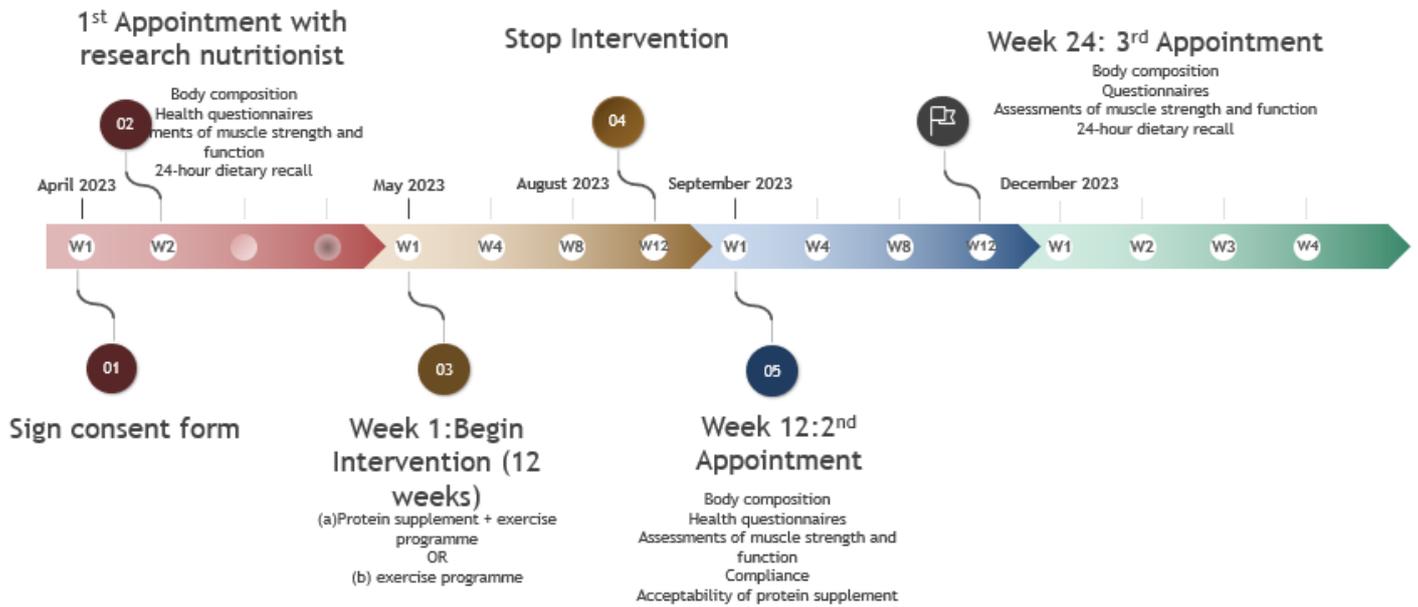


Figure 3 Timeline of Immediate Group intervention

# Staggered Intervention Timeline

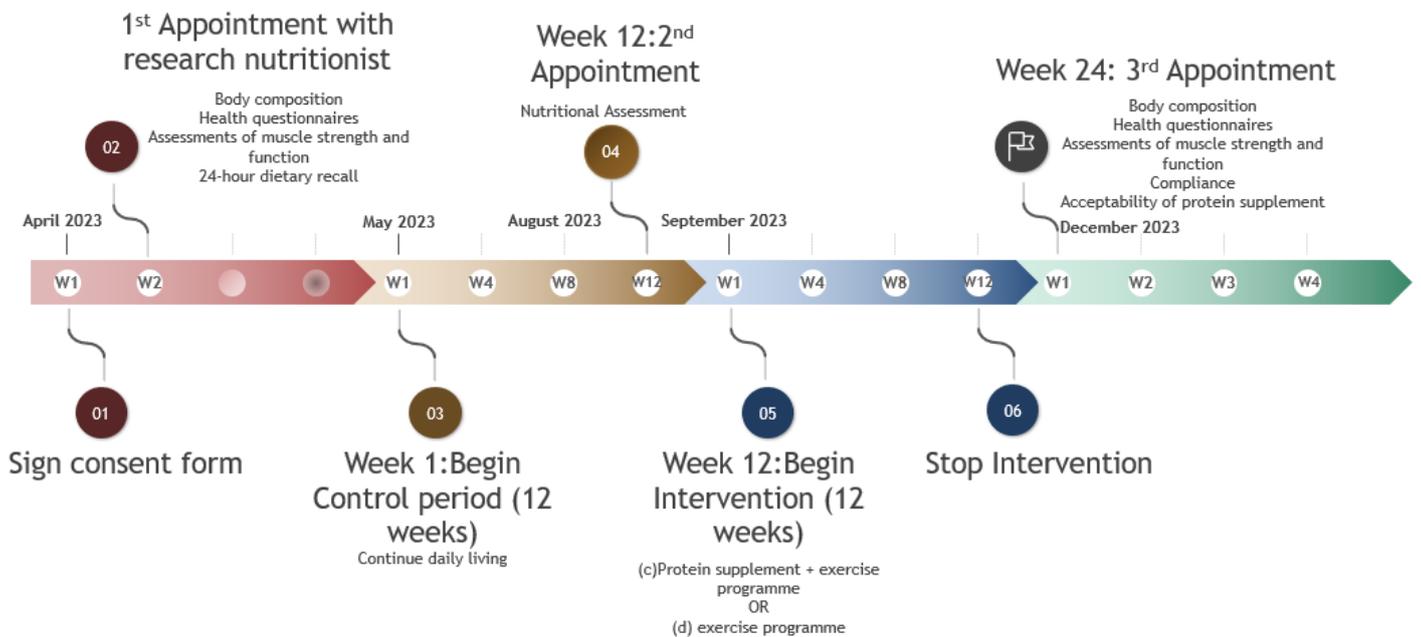


Figure 4 Timeline of Wait-List Group intervention