Ospidéal Ollscoile Phort Láirge
University Hospital Waterford

Patient Information Leaflet

Study title: The effect of a standardised exercise and nutritional intervention on clinical and biochemical markers of frailty in frail older adults

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Researcher's title: MD Student

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Supervisor's title: Consultant Geriatrician, UHW

Supervisor's name: Prof. Ríona Mulcahy

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You are being invited to take part in a research study to be carried out at University Hospital Waterford by Dr. Pádraig Bambrick, under the supervision of Dr. John Cooke and Prof. Ríona Mulcahy. The study will be based in the Department of Geriatric Medicine in University Hospital Waterford (UHW), in collaboration with the Department of Sport & Exercise Science in Waterford Institute of Technology (WIT)

Before you decide whether or not 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. If you decide not to take part it won't affect your future medical care.

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. If you do opt out, rest assured it won't affect the quality of treatment you get in the future.

Why is this study being done?

"Frailty" is a medical term for a condition that affects a large number of people as they get older. In many ways, it refers to what people mean when they say someone is "getting old". One of the main ways to identify frailty is to look for evidence of weight loss, weakness, slowness, reduced activity or a feeling of exhaustion. Another is to count up the number of illnesses or impairments someone has accumulated over their life.

Frailty is common and becoming even more so. Overall, about 1 in 10 people are frail. This increases as we age, rising to almost 1 in 4 over the age of 90

Frailty means that an individual is less well able to tolerate anything that may affect their wellbeing (for example, infection, side-effects of medications, hospital admission or medical procedures). We know that unfortunately, the more frail a person is, the more likely they are to develop a range of illnesses, be admitted to hospital or require nursing home care.

Thankfully, more and more research shows that exercise and nutritional supplements can slow the onset of frailty. This is great for those older adults that are still fit or are showing only the very early signs of frailty ("pre-frail") but what about older adults that are already frail?

This research study is taking place to find out if the benefits of exercise and nutrition also apply to frail individuals and can actually reverse frailty.

Who is organising and funding this study?

This research study will be primarily organised by Dr. Pádraig Bambrick over two years from Jul 2018 to July 2020, to achieve the academic qualification of MD as part of his specialist training in Geriatric Medicine. The study will be supervised by Dr. John Cooke, Prof. Ríona Mulcahy and Dr. Michael Harrison, as listed above.

The project will be funded mainly by the Royal College of Surgeons in Ireland (RCSI) under the Strategic Academic Recruitment (StAR) program. There may also be smaller contributions for various sources, including the pharmaceutical industry, to assist with additional costs.

No payments will be received by any of the research team to undertake the study.

Why am I being asked to take part?

You have been asked to participate because according to assessments carried out in the clinic, you have been given the medical diagnosis of "frailty". As discussed above, the aim of the intervention is to see if exercise and nutritional supplements can reverse this process.

You have no obligation to participate and not doing so will have no impact on the medical care you receive, either now or in the future. If you still have questions after reading through this document, a member of the research team would be happy to explain things. If you would like, you can specify a relative/friend/carer that might be able to assist you in understanding and help you to make an informed decision.

How will the study be carried out?

The study will involve three exercises classes per week, lasting approximately one hour each, for eight weeks. You will be encouraged to attend all three but if you are unable to attend for any reason (but still well enough to exercise) then you can substitute it with a home exercise session that will be provided at the start of the program. However, we expect the best results for those that attend most frequently.

The classes will take place at the WIT Arena and will be run by the staff there. There will be six to eight participants per class. We aim to recruit about ninety individuals to the study in total.

To maximise the benefits of the exercise classes, we will also provide a nutritional supplement of 250ml of protein-supplemented milk twice daily to increase your protein intake over the course of the eight weeks. As per the manufacturer's advice, anyone with a known allergy or intolerance to milk or soya should avoid this product and so will not be eligible for inclusion.

To demonstrate an effect, we need two separate groups to compare to each other. For this reason, each individual will be randomly assigned to starting the intervention immediately or to wait until the second round.

What will happen to me if I agree to take part?

If you decide to participate, a suitable time will be arranged for you to return to the Age-Related Care Unit (ARCU) of UHW to meet with the lead researcher, Dr. Bambrick. Here, you will undergo a range of assessments (which may take a number of hours). These include

1. Measuring your height, weight and waist circumference
2. Measuring your frailty status in two ways
    a. recording your walking speed, grip strength and asking questions about weight loss, fatigue and activity levels
    b. checking how many medical conditions you have from a list of 36 possibilities
3. Testing your memory, concentration and language (using a common scoring system called the Montreal Cognitive Assessment)
4. Screening for mood symptoms and using a questionnaire to enquire about your quality-of-life
5. Taking a blood sample
6. Assessing the stiffness of your arteries (which can increase with age) using a non-invasive scan (ultrasound) of your neck and groin
7. Possibly undergoing a DEXA scan to examine your body mass composition

You will also be provided with information regarding your nutritional supplement. You may also be asked to attend the main WIT campus on the Cork Road to have a DEXA scan performed on a separate day.

Following random assignment to one of the two groups, you may be allocated to the immediate intervention group or the wait-list group. Those in the immediate intervention group will be asked to attend the WIT Arena three times a week over the following eight weeks and to take their nutritional supplement over the same period while those in the wait-list group will continue as normal.

At eight weeks, all participants will undergo repeat testing. After this, the immediate intervention group will stop attending the classes and will no longer be obliged to take the nutritional supplements. Those in the wait-list group will now commence the intervention.

After eight more weeks (sixteen weeks in total), all participants will undergo assessment for the final time and the study will be over.

Overall, the testing involved will be non-invasive and will not involve significant amounts of additional radiation. There will be a need for additional blood tests at each of the assessments. Your medical notes will only be accessed by Dr. Bambrick.

The main risk involved is the potential for injury or adverse medical event as a result of the exercise intervention. It is very difficult to estimate the risk accurately but the available evidence would suggest it is low. To minimise this risk, the intervention will begin at a low level of intensity and will only escalate within what the participant feels is comfortable, using the rating of perceived exertion (RPE) scale. For emergency situations, an automated cardiac defibrillator will always be available within the WIT Arena, with staff members trained in its use.

Video/and or Audio recordings?

Participants will have the option to have their photo taken or short video testimonial recorded at the start and finish of the study as qualitative (descriptive) way to communicate the effect of the intervention on their wellbeing. They would retain complete control over the use of any of these photos/recordings in publications arising from the study.

What other treatments are available to me?

The alternative to participating in this study is to follow the advice of the doctor in clinic about how best to manage the effects of frailty. This would be best accomplished by liaising with your GP and agreeing on a plan to maximise your physical and mental health.

What are the benefits?

There are no guarantees that this intervention will be of benefit to you. The available evidence would suggest that exercise and nutritional supplementation can improve physical function and psychological wellbeing in older adults. However, this has not been conclusively shown in frail older adults and that is the question that this study aims to answer.

What are the risks?

Engaging in exercise brings an associated risk of minor complications such as muscle aches or strain. If people have a history of (or several risk factors for) heart disease or lung disease, there may also be a risk of more serious adverse effects. It is difficult to put an exact figure on this risk as it differs from person to person. To limit this risk, we will ask a set of screening questions and give advice about how to know when you might be exercising too vigorously. For emergency situations, an automated cardiac defibrillator will always be available within the WIT Arena, with staff members trained in its use.

The other potential drawback of participating in this study is that it will require a significant time commitment (at least 24 hours of classes over eight weeks, with additional travel time). If you do not feel you are in a position to give that level of commitment then this study may not be appropriate for you.

What if something goes wrong when I'm taking part in this study?

There will not be medical supervision available during the majority of the classes so if you suffer an adverse effect during a session or at another time over the course of the study, you will need to seek medical attention from your General Practitioner or local Emergency Department, as appropriate.

If you have any concerns or complaints regarding the intervention or your involvement then we would be more than happy to discuss these. Contact details will be provided for a member of the research team (during normal working hours).

Will it cost me anything to take part?

There will be no payments for participating in this study. Travel expenses will not be reimbursed.

Is the study confidential?

Records

The information recorded about you as part of this study will remain confidential between you and the researcher. No paper records will contain personal identifiers. Instead, they will be marked with a code which requires a key, held only by the researcher. These paper records will be securely stored in a locked filing cabinet and then transferred to an electronic record where

they will be irreversibly anonymised. From this point, it will be impossible to identify you from your data.

Anonymised data may be shared with researchers within the RCSI research network for assistance with statistical analysis. Once the study has been completed, a master copy of the trial data will be kept for a period of five years in case the data needs to be re-examined for verification of the findings, as recommended by international guidelines on conducting trials.

Your GP will not be contacted for the purposes of this study. As discussed above, your medical records will be accessed by the researcher only as part of your assessment.

Samples
All blood samples will be transported to the WIT Health Sciences building on the day of collection for storage in the Ultra-Low Temperature (ULT) freezers there. They will be fully anonymised. Only the research team working on this study will have access to your samples, for use for the purposes explained above. No genetic testing will be performed.

Results
The results of the assessments will be freely available to you on request. The results will not be routinely shared with your GP/consultant but you are free to do with them as you wish. The aim is to accumulate sufficient data to allow publication of results in medical journals and presentation at conferences. All data will be irreversibly anonymised at this point.

Records
Any photographs, voice or video recordings will only be used for research publications or promotional material arising from the study and only with the permission of the individual. Only the research team (researcher and supervisors) will have access to them. Any material not used will be destroyed at the conclusion of the study.

Future Research Studies
No information or samples will be retained for use in a future research study.

Data Protection

1. We will be using your personal data to investigate the effect of exercise and nutritional supplementation on frailty in older adults.

2. The legal basis under which your data will be processed is

    a. Article 6(1)(f) - processing is necessary for the purposes of the **legitimate interests** pursued by the controller or by a third party, except where such interests are overridden by the interests or fundamental rights and freedoms of the data subject which require protection of personal data, in particular where the data subject is a child

    and

    b. Article 9(2)(j) - processing is necessary for archiving purposes in the public interest, **scientific** or historical research purposes or statistical purposes in accordance with Article 89(1) based on Union or Member State law which shall be proportionate to the aim pursued, respect the essence of the right to data protection and provide for suitable and specific measures to safeguard the fundamental rights and the interests of the data subject.

3. Only the main researcher in this study (Dr. Pádraig Bambrick) and the academic supervisors (Dr. John Cooke, Prof. Ríona Mulcahy and Dr. Michael Harrison) will have access to the data.

4. An electronic master file of all trial data will be stored in an anonymised form for five years after the conclusion of the trial.

5. All data subjects have the right to withdraw consent at any point.

6. All data subjects have the right to lodge a complaint with the Data Protection Commissioner.

7. All data subjects have the right to request access to their data and a copy of it, unless their request would make it impossible or make it very difficult to conduct the research.

8. All data subjects have the right to restrict or object to processing, unless their request would make it impossible or make it very difficult to conduct the research.

9. All data subjects have the right to have any inaccurate information about them corrected or deleted, unless their request would make it impossible or make it very difficult to conduct the research.

10. All data subjects have the right to have their personal data deleted, unless their request would make it impossible or make it very difficult to conduct the research.

11. All data subjects have the right to data portability, meaning they have a right to move their data from one controller to another in a readable format.

12. No automated decision making/profiling will be undertaken from the processing of your data.

13. If it were, all data subjects would have the right to object to automated processing including profiling if they wish.

14. All data subjects must be informed if their personal data is to be further processed for purposes beyond those outlined in this document and be provided with with information on those other purposes.

15. All data subjects must be informed if you their data is to be transferred to a country outside of the EU or an international organisation and be advised of the safeguards put in place to protect their data.

Where can I get further information?

If you have any further questions about the study or if you want to opt out of the study, you can rest assured it won't affect the quality of treatment you get in the future.
If you need any further information now or at any time in the future, please contact:

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