Patient Information Leaflet (Peritoneal Dialysis)

Study title: The effect of exercise and nutritional supplementation on frailty and dialysis-related measures in End Stage Kidney Disease patients

Principal investigator's name:	**Dr Catherine Brown**
Principal investigator's title:	**Consultant Nephrologist**
Telephone number of principal investigator:	**051-842753(Dialysis Unit)**

Data Controller : HSE

Joint Controller's Identity: Dr Catherine Brown

Joint Controller's Contact Details: 051-842753(Dialysis Unit)

Joint Controller's Identity: Dr Robert Casey

Joint Controller's Contact Details: 051-842753(Dialysis Unit)

Joint Controller's Identity: Dr Padraig Bambrick

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Joint Controller's Identity: Dr Sean Leavey

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Data Protection Officer's Identity: HSE DPO, Mary Deasy

Data Protection Officer's Contact Details: 021-4928538, email: dpo@hse.ie

You are being invited to take part in a research study to be carried out at University Hospital Waterford by Dr Robert Casey under the supervision of Dr Catherine Brown, Consultant Nephrologist in University Hospital Waterford.

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", however it is a condition that can affect people of all ages. 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. It is also very common for patients on dialysis with approximately 3 in 10 people on dialysis being frail.

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. Some research has also demonstrated the benefits of 'reversing frailty' in the general population with exercise and nutrition. However very few studies have included patients who are on dialysis.

This research study is taking place to find out if the benefits of exercise and nutrition also apply to frail individuals with kidney disease who are receiving dialysis and whether this intervention can actually reverse frailty in this population.

Who is organising and funding this study?

This research study will be primarily organised by Dr. Robert Casey over two years from July 2023 to July 2025, to achieve the academic qualification of MD as part of his specialist training in Nephrology. The study will be supervised by Dr. Catherine Brown(Consultant Nephrologist), Dr Sean Leavey(Consultant Nephrologist) and Dr. Padraig Bambrick(Consultant for Medicine for the Elderly), as listed above.

The project will be funded by the Royal College of Surgeons in Ireland (RCSI) under the Strategic Academic Recruitment (StAR) program.

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 Dialysis Unit, you have been identified as being “frail” or “pre-frail”. 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 sessions per week, lasting approximately one hour each, for twelve weeks. These exercise sessions will occur at home. Prior to partaking in the home exercise programme you will partake in a number of training sessions in the dialysis unit to ensure you are happy you can complete each exercise competently and safely. The intensity and rate of escalation will be individualised to each participant. You will be encouraged to perform all three sessions during the week but if you are unable to perform the exercise session for any reason let us know and when you will be able to restart the exercise sessions. We expect the best results for those that participate in the sessions most frequently.

We aim to recruit 32 individuals to the study in total.

To maximise the benefits of the exercise classes, we will also assess your protein intake. You may be provided with a nutritional supplement of protein daily to increase your protein intake over the course of the 12 weeks if necessary. The protein source will be individualised for each patient with assistance from the renal dietician in University Hospital Waterford.

To demonstrate an effect, we need two separate groups to compare to each other. For this reason, each individual will be randomly assigned to either starting the intervention and completing it over a 12 week period or continuing to receive your current standard of care and will not partake in the exercise and nutritional intervention.

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 meet with the researcher, Dr. Robert Casey at the Dialysis Unit, University Hospital Waterford. You will undergo a range of assessments (which may take a couple 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(Blood samples taken will be part of your routine monthly bloods and we will access the results of these tests)

You will also be provided with information regarding your nutritional supplement.

Following random assignment to one of the two groups, you may be allocated to the intervention group or the "control group"(control group means that you will not participate in the intervention but will continue with your current standard of care). Those in the intervention group will be asked to perform exercise sessions three times a week over the following 12 weeks and to take their additional nutritional supplement over the same period while those in the "control group" will continue as normal. The three exercise sessions will be performed at home and last approximately an hour each. Prior to starting this exercise programme you will receive training in the dialysis unit to ensure you are happy you can complete each exercise safely.

At 12 weeks, all participants will undergo repeat testing. After this, the intervention group will stop performing the exercise sessions and will no longer be obliged to take the nutritional supplements.

After 6 more weeks (18 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. There will <u>not</u> be a need for additional blood tests on top of the blood samples taken at your routine monthly bloods. Your medical notes will only be accessed by Dr. Robert Casey.

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.

Video/and or Audio recordings?

There will be no video or audio recordings recorded during this study.

What other treatments are available to me?

The alternative to participating in this study is to follow the advice of your doctor about how best to manage the effects of frailty. This would be best accomplished by liaising with your GP and primary nephrologist 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 frail adults in the general population. However, this has not been conclusively shown in frail adults with kidney disease on dialysis 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.

The other potential drawback of participating in this study is that it will require a commitment to participate with the exercise sessions which will last for approximately an hour. 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?

You will complete most of your exercise programme at home and therefore will be unsupervised for many of your exercise sessions. Therefore, if you suffer an adverse effect during a session, 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?

You will not incur any additional costs by participating in this study. There will be no payments for participating in this study.

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 encrypted at point of storage on local secure storage and only the Principal Investigator (Dr Catherine brown) and MD student (Dr Robert Casey) will have a decryption key.

It may be necessary to share your data with researchers within the RCSI research network for assistance with statistical analysis. If this was required your data would be anonymised prior to transfer to other researchers and from this point, it would be impossible to identify you from your data.

Once the study has been completed, all hard copy data will be destroyed. A master electronic 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 processed by the laboratory staff in University Hospital Waterford and disposed of as is standard procedure in University Hospital Waterford. We will collect the results of your blood samples and store this data as detailed 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/Primary 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.

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 adults on dialysis.

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. Robert Casey) and the academic supervisors (Dr. Catherine Brown, Dr Padraig Bambrick and Dr. Sean Leavey) will have access to the data.

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

5. There is a risk of data breach which if occurred could share your personal data with unwanted parties. However, the measures listed above will minimise this risk.

6. All data subjects have the right to withdraw consent at any point. To withdraw consent from this study please contact researcher-Dr Robert Casey using the contact details listed above.

7. All data subjects have the right to lodge a complaint with the Data Protection Commissioner. If you are not satisfied with our response or believe we are processing your personal data in a way that is not lawfull, you have the Right to complain to the supervisory authority @ 21 Fitzwilliam Square South, Dublin 2, Ireland https://www.dataprotection.ie

8. 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.

9. 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.

10. 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.

11. 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.

12. 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.

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

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

15. 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 information on those other purposes.

16. All data subjects must be informed if 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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