Ospidéal Ollscoile Phort Láirge
University Hospital Waterford

Patient Information Leaflet

Study title: "FRAilty and Sarcopenia Experience in persons with Parkinson's Disease- FRASE-PD"

Researcher's name:	**Dr. Chris Reidy**
Researcher's title:	**MD Candidate**
Principal Investigator's name:	**Prof. Riona Mulcahy**
Principal Investigator's title:	**Consultant Geriatrician**
Telephone number of principal investigator:	**051-842545 (WICOP Hub)**
Joint Data Controller's Identity:	**University Hospital Waterford**
Data Protection Officer's Identity:	**HSE DPO, Mary Deasy**
Data Protection Officer's Contact Details:	**HSE National Data Protection Office, Dr Steevens Hospital, Steevens Lane, Dublin 8, D08 W2A8 EEmail: dpo@hse.ie**
Data Controller's/joint Controller's Identity:	**Royal College of Surgeons in Ireland**
Data Protection Officer's Identity:	**RCSI DPO, Dónall King**
Data Protection Officer's Contact Details:	**Data Protection Officer Royal College of Surgeons in Ireland 123 St Stephen's Green Dublin 2, D02 YN77 Email: dataprotection@rcsi.ie**

You are invited to take part in a research study led by Dr. Chris Reidy (MD Candidate) under the supervision of Prof. Riona Mulcahy, Consultant Geriatrician at University Hospital Waterford (UHW).

You should read the information provided below carefully before deciding to take part. 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'.

Your usual medical care will continue and your decision to take part in this study will have no impact on your care. You do not 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. 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?

Parkinson's Disease (PD) is a condition that affects movement. It is more common as we age. People with Parkinson's disease (PwP) have slow movements, stiff muscles, and limb shaking. There is currently no known cure for PD. Tablets are used to treat the symptoms described above. Specialists also think that exercise can help PwP. There are more people than ever living with PD in Ireland and this number will get bigger in the future.

All these symptoms contribute to you feeling poorly. They affect your wellbeing and quality of life. PD can also affect how you do daily tasks (functional ability). This includes dressing yourself, completing chores, and hobbies. Research tells us that PwP have poorer wellbeing for many reasons. PwP can also be less active than people without PD.

Two other conditions, Frailty and Sarcopenia, can also affect your wellbeing and functional ability for different reasons.

Frailty is a medical term for a condition that is more common as we age. People use the word "frail" when they are talking about someone "getting old". However, it can affect people of all ages. People who are frail have weight loss, lower activity levels, weakness, slowness, and can feel very tired. Another way to see if someone is frail is to count the numbers of illnesses that person has from a list.

Sarcopenia is where you have less muscle and are not as strong as before. It can be common in older people. It can make things such as walking, standing up or carrying items much harder. Sarcopenia can be made worse by not getting enough exercise, not eating well, and the presence of chronic medical conditions.

While there is no medication for frailty or sarcopenia, exercise and diet can help. It is possible that you may have either frailty and sarcopenia and not be aware of it. Studies have shown that both conditions are more common in PwP.

Frailty, Sarcopenia, and Parkinson's disease can all affect your wellbeing and functional ability. There has been little research into how all three conditions can interact and affect a person together. Our research aims to identify the rates of frailty and sarcopenia in PwP in an Irish population. We will also see how they affect the wellbeing and functional ability of PwP.

If you meet the criteria for sarcopenia or frailty, you may be invited for an interview to explore your feelings on PD, sarcopenia, and frailty, and important areas such as exercise and wellbeing.

Who is organising and funding this study?

This research study is led Dr. Chris Reidy. It will take place over two years from July 2024 to July 2026 to achieve the academic qualification of MD. This is part of his specialist training in Geriatric Medicine. This study will be supervised by Prof. Riona Mulcahy (Consultant Geriatrician, UHW), Dr. Padraig Bambrick (Consultant Geriatrician, UHW), Prof. John Cooke (Consultant Geriatrician, UHW) and Prof. John Nolan (Chair for Human Nutrition Research, SETU).

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 take part because you have Parkinson's Disease (PD), and you attend a Parkinson's Disease clinic in UHW. We aim to see if you meet criteria for frailty or sarcopenia, and if you do, how it impacts your wellbeing and day-to-day life

You do not have to take part in this study. If you decide that the study is not for you, it will not affect the medical care you receive in UHW. If you still have questions after reading through this document, a member of the research team would be happy to try to explain things more

clearly. If you would like, you can name a relative/friend/carer that might be able to help you understand it more clearly, before deciding.

How will the study be carried out?

We are aiming to recruit around 170 PwP in total. This research study will involve a 60-minute assessment in the Waterford Integrated Care of the Older Person (WICOP) hub in Waterford Residential Care Centre. Here we will record data such as your height, weight, and age. We will assess aspects of your PD diagnosis. Finally, we will ask you to complete a few tasks which will help decide whether you may have sarcopenia or frailty. These will be explained in detail below.

If you meet criteria for frailty or sarcopenia, you will be invited back later to discuss your feelings towards the diagnosis, exercise, nutrition, and PD in general. The interview will last around 60-minutes also.

You will not be asked to give blood or perform any exercise.

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. Chris Reidy at the WICOP hub at the Waterford Residential Care Centre. Here, you will undergo several tests (which may take a couple of hours). These include:

- Measuring your height, weight, and BMI (Body Mass Index)
- Asking questions about you
    - Age, gender, marital status, whether you live in the city or country
- Testing your memory, concentration, and language
    - Using a scoring system called the Montreal Cognitive Assessment or MOCA
- We will ask several questions specific to your diagnosis of PD
    - Assessing how often you experience difficulties across different areas of your daily life (PDQ-8, MDS-UPDRS I and II)
    - Medications, how long you have had PD, presence of freezing episodes, falls history
- Testing for the presence of sarcopenia in two ways
    - EWGSOP2 criteria (testing your grip strength, testing how much muscle you have by standing on a scale called a bioelectric impedance analyser, and seeing how fast you can walk- if you are able)
    - SARC-Calf (4 questions relating to sarcopenia, and a measurement of how big your calf muscle is)
- Testing for the presence of frailty in three ways
    - Fried Frailty index (how fast you can walk, your grip strength, and asking questions about weight loss, fatigue, and activity levels)

- Electronic Frailty Index (how many medical conditions you have from a list of 36 problems)
- Clinical frailty scale

It is possible that you may have completed some of these recently in clinic (i.e., within the last 3 months), in which case you will not have to repeat them.

Following the completion of the initial assessment, you may be invited to return for a follow up interview if you are found to have sarcopenia or frailty. Here you will be asked several questions about your diagnosis of PD, how you feel about sarcopenia and frailty, your thoughts on exercise and nutrition, and anything else which may be important to you. This may be a stressful event discussing these topics, and you do NOT have to do so. If you do decide to do the interview, you can choose to stop it at any point if it becomes too stressful.

If you are found to be frail or sarcopenic, a letter will be sent to your Movement disorder specialist or GP for further management.

Your participation in the study will then be complete.

You will not be asked to stop any of your medications, and we will aim to conduct the initial assessment within 1-2 hours of your last dose of Parkinson's medications (to ensure your PD symptoms are best treated). You will not have to provide any blood samples.

Overall, the testing involved will not be invasive. Your medical notes will only be accessed by Dr. Chris Reidy, with your permission. Only the necessary information will be recorded, and the results will be stored safely. You will not be identifiable from your data.

Video/and or Audio recordings?

With your permission we will securely record the conversation had during the interview process on Microsoft Teams. This is to allow the conversation to be transferred into writing, so the data can be analysed, and key points found. You have the right, should you wish, to review and edit any transcripts to which you have contributed. The recorded data will be transcribed by the research candidate.

What other treatments are available to me?

You do not have to take part in this study. If you decide that the study is not for you, it will not in any way affect the medical care you receive in UHW.

What are the benefits?

There are no guarantees that this study will be of benefit to you. The limited evidence would show that sarcopenia and frailty are more common in PwP. All three can have an impact on your life. The results of this study may guide future studies in the field, potentially regarding developing an intervention to address frailty and sarcopenia in PwP. This intervention could provide benefit to other PwP in future.

What are the risks?

Given that we will be collecting personal information about you and your health status, there is also the risk of a confidentiality breach. This will be minimised by coding and protecting data with passwords and storing it securely in password-protected laptops and locked filing cabinets.

Given the assessment and potential for interview, you may experience fatigue during the study. The assessments will be as streamlined as possible to address this, and you are free to withdraw at any stage.

You may feel anxiety and stress discussing your Parkinson's disease diagnosis, potential sarcopenia or frailty, and experience with exercise. The interview process will be explained in detail, and there will be a time between your initial assessment and interview to think about everything. You are not obliged to attend for interview. If you do experience any discomfort, you can stop the interview at any point.

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

The initial assessment and interview will be conducted by a healthcare professional. However, if you suffer an issue 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 experience any emotional distress during the interview, you will be asked to attend your primary care doctor for follow up.

If you have any concerns or complaints regarding the study 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
Your medical records will be accessed by the researcher only as part of your assessment.

The information recorded about you as part of this study will remain confidential between you and 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 (Prof. Riona Mulcahy) and MD student (Dr. Chris Reidy) will have access.

It may be necessary to share your data with researchers within the RCSI research network for assistance with statistics. If this was required your data would be coded 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.

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. No identifiable personal data will be included in publications or conference proceedings.

Records
Any voice recordings will only be used for research publications or promotional material arising from the study and only with the permission of the individual. The interview process will be recorded through Microsoft Teams, and the recordings will be transcribed by the primary researcher. Your recording will be given a study ID and any identifiable information will be removed. The audio recordings will then be deleted.
Any material not used will be destroyed at the conclusion of the study. You have the right, should you wish, to review and edit any transcripts to which you have contributed.

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

HSE Research Data Protection Information

In the HSE we treat your privacy seriously. Any personal data used by the HSE will be treated with the highest standards of security and confidentiality, in accordance with Irish and European Data Protection legislation. This information sets out details of the information that we collect, how we process it and who we share it with. It also explains your rights under data protection law in relation to our processing of your data.

Who we are

Throughout this Notice, "we", "us" and "our" refers to **University Hospital Waterford** as a HSE Hospital and as study data controller.

How we will use your personal data

No personal data will be collected in this study. Any information provided in the questionnaire is completely anonymous and confidential.

Who will access my personal data?

Data collected will only be accessible to the study researcher and the UHW REC so that they can check if the study is being conducted to the best standards.

Results of the study will be provided to the ethics committee approving the study in compliance with national and international regulations on clinical studies.

The purpose and legal basis for collecting your data

By completing and returning the questionnaire consent has been implied by the participant.

The General Data Protection Regulation (GDPR) allows us to process your data because the research is of substantial public interest (Articles 6(1) (e) and 9(2) (j) of the GDPR). We have also sought your consent to process your data in accordance with the Health Research Regulations. If you require further information on the legal basis for processing your personal data, please contact HSE's the relevant Data Protection Officer – details below.

How long we will keep your data

The data collected in the study will be kept for a period of up to 10 years after the end of the study. Thereafter, they may be stored for a further period of time for legal reasons (e.g. revised retention obligations), or more if required by law.

Your rights

You have various rights under data protection law, subject to certain exemptions, in connection with our processing of your personal data, including the right:

- No personal data will be collected as part of this study
- the information provided will be anonymous and therefore the researcher will be unable to provide a copy or remove the data provided from the study once the questionnaire is submitted.

  or to have inaccurate/incomplete information corrected and updated;

- in certain circumstances, to have your details deleted from systems that we use to process your personal data or have the use of your personal data restricted in certain ways;
- to object to certain processing of your data by the HSE;

If you wish to exercise any of these rights, please address your request to the Principal Investigator or the Data Protection Officer.

Questions or Complaints

If you have any questions in relation to this study, please contact the Research team (Dr. Chris Reidy) on **051-842545** or chris.reidy@hse.ie

If you have any complaints in connection with the processing of your personal data by the HSE, you can contact HSE Data Protection Officer (DDPO):

Deputy Data Protection Officer South; Consumer Affairs, HSE South-West, 1 A & 1B, Ground Floor, Erinville, Western Road, Cork. Eircode: T12 EDK0

Phone: Cork Office: 021 492 1553; Email: ddpo.south@hse.ie You also have the right to lodge a complaint with the Data Protection Commission if you are unhappy with our processing of your personal data. Details of how to lodge a complaint can be found on the Data Protection Commission's website (www.dataprotection.ie), or by telephoning 1890 252 231.