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Frailty and sarcopenia experience in persons with Parkinson's disease

Submission date
23/05/2025

Recruitment status
No longer recruiting

Registration date
23/05/2025

Overall study status
Ongoing

Last Edited
23/05/2025

Condition category
Nervous System Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Parkinson’s disease (PD) is a neurological 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 no cure for PD. Tablets are used to treat the symptoms. Specialists also suggest that exercise can help PwP. PD is associated with ageing and as a result there are more people than ever living with PD in Ireland.
Frailty and sarcopenia are two different conditions, also more common in older people. Frailty is when a person becomes more vulnerable to stressors and illness, and they are not as healthy as when they were younger. Sarcopenia is when someone has less muscle mass than before, and their muscles do not work as well. There is no specific medication for frailty or sarcopenia, but exercise and good diet can help. Identifying people who have either frailty or sarcopenia is difficult in a busy clinic.
All three conditions are more common in older people and can progress over time. Each condition can make it harder for people to manage their everyday life. This can have a negative effect on a person’s wellbeing.
Very little research has been done on frailty and sarcopenia in PD. We do know that PwP are more likely to have frailty or sarcopenia than people without PD. PwP have been omitted research studies on sarcopenia and frailty in the past. This is because people often don’t consider sarcopenia and frailty as a reason for worsening PD symptoms. Both sarcopenia and frailty can affect a PwP’s wellbeing and ability to be able to manage their daily life.
To see if this is true, in this study the researchers will invite PwP for tests to identify if they have sarcopenia and/ or frailty. They will also interview PwP to understand their views on their wellbeing, day-to-day life, memory, and ask about their diagnosis of PD. All these tests have been used in research before.
PwP who are either frail or sarcopenic will be asked to come back to talk about their feelings and experience of living with PD, what sarcopenia and frailty mean, have they engaged in exercise, and what is important to them for their future.
A study like this has not been done before in Ireland, and it will be the first to establish frail or sarcopenic PwP views on various aspects of their life. It is hoped that the results of this study may guide future research.
Study aims:
1. Identify the evidence for interventions addressing sarcopenia and frailty in PwP.

2. Establish the prevalence of sarcopenia and frailty in PwP in an Irish setting.
3. Explore PwP perspectives and experiences of living with sarcopenia and frailty.

Who can participate?
People diagnosed with idiopathic Parkinson's disease, over the age of 18 years old, attending movement disorder clinics in University Hospital Waterford can participate.

What does the study involve?
The study involves initially attending for an in-person assessment to determine frailty and sarcopenia status in PwP. At this assessment, other variables such as height, weight, age, PD characteristics, cognition, and physical activity levels will be recorded.
Persons with PD who are identified as either frail or sarcopenic will be invited to attend for a semi-structured interview to explore lived experiences of key topics such as diagnoses, exercise, nutrition, and PD.
There will be no changes to medications or blood samples taken.

What are the possible benefits and risks of participating?
There are no guarantees that this study will be of benefit to participants. The limited evidence would show that sarcopenia and frailty are more common in PwP. All three can have an impact on life for PwP. 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 benefits to other PwP in future.
Potential risks include fatigue, emotional distress, and confidentiality breaches. Measures will be in place to minimize these potential risks.

Where is the study run from?
The assessments for this study will take place in the Waterford Integrated Care of the Older Person Hub in University Hospital Waterford. The study is being sponsored by the Royal College of Surgeons, Ireland.

When is the study starting and how long is it expected to run for?
October 2024 to July 2026

Who is funding the study?
The study will be funded by the Royal College of Surgeons in Ireland (RCSI) under the Strategic Academic Recruitment (StAR) program

Who is the main contact?
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Contact information

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Public, Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Establishing the prevalence of frailty and sarcopenia in persons with Parkinson's disease and exploring the impact of these conditions on Parkinson's disease

Acronym
FRASE-PD

Study objectives
The prevalence of frailty and sarcopenia is higher in persons with Parkinson's disease (PwP) in Ireland compared to the general population (11% prevalence of frailty in those >55 years, and 8.1% prevalence of confirmed sarcopenia among older adults, as per the literature).

Study aims:
1. Identify the evidence for interventions addressing sarcopenia and frailty in PwP.
2. Establish the prevalence of sarcopenia and frailty in PwP in an Irish setting.
3. Explore PwP perspectives and experiences of living with sarcopenia and frailty.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 07/05/2025, HSE South East Research Ethics Committee (Research Ethics Office, University Hospital Waterford, Dunmore Road, Waterford, X91 ER8E, Waterford, X91 ER8E, Ireland; +353 (051) 842 026; SERegionalResearchEthics@hse.ie), ref: Application Reference No. 25.22

Study design
Single-site mixed methods cross-sectional study

Primary study design
Observational

Study type(s)
Quality of life, Screening

Health condition(s) or problem(s) studied
Parkinson's disease

Interventions
This will be a cross-sectional study, aiming to identify the prevalence of sarcopenia and frailty in PwP at a single hospital site in Ireland. Three work packages are proposed to achieve this.

Work Package 1: Scoping Review
An extensive narrative review will be undertaken to establish whether the clinical characteristics of PD confound conventional frailty and sarcopenia studies. Then a comprehensive scoping review will be conducted to establish whether conventional frailty interventions deliver benefit to frail or sarcopenic PwP.

Estimated timeframe: 6 months

Work Package 2: Quantitative Study
Data will be collected in one visit, assessing baseline demographics, PD-specific characteristics, and other clinical assessments as detailed below. Frailty and sarcopenia criteria, as detailed below, will also be applied at this point to establish a potential diagnosis of either or both in PwP. Participants will then be allocated to subgroups, including non-frail (PwP-nF), non-sarcopenic (PwP-nS), frail (PwP-F), sarcopenic (PwP-S), and frail/sarcopenic (PwP-FS) for the purposes of data analysis.

Estimated timeframe: 1 year (will run concurrently with WP3)

Work Package 3: Qualitative Study
PwP identified as either frail or sarcopenic will then be invited to participate in a semi-structured interview exploring their perceptions, lived experiences, and priorities of living with concurrent frailty/ sarcopenia and PD. PwP will be split into two groups (PwP-F and PwP-S) for data analysis and to link to the quantitative study. The researchers will endeavour to have a diverse population with no restrictions on gender or age. Thematic analysis will be used for qualitative data. Interviews will preferably be in person to ensure confidentiality and avoid technological issues, but a remote option may be considered on a case-by-case basis (Microsoft Teams)

Estimated timeframe: 1 year (will run concurrently with WP2)

This observational study will establish the prevalence of frailty and sarcopenia in an Irish cohort of persons with Parkinson's disease. Eligible participants will be invited for a brief assessment where the following outcome measures will be assessed:
1. Demographics: age, gender, rural/ urban, education
2. Anthropometric data: weight, height, body mass index, body composition (bioimpedance analysis)
3. Carotenoid status: baseline skin carotenoid status using a handheld machine (non-invasive)
4. Cognitive status: Montreal Cognitive Assessment (MOCA)
5. Frailty status: Frailty index (Adapted from Tan et al. [2018]), Fried's Frailty Index, Clinical Frailty Scale
6. Sarcopenia status: SARC-Calf, EWGSOP2 Criteria
7. Parkinson's disease specific characteristics: levodopa equivalent daily dose (LEDD), age of onset of PD, disease duration, MDS-UPDRS (need ethical approval before scale can be provided), PDQ-39, Schwab & England ADL Scale, PDQ-Exercise, Hoehn and Yahr Scale,
8. Other: IPAQ-SF

Participants will be advised to continue their current medication regimen as prescribed by their Movement Disorder specialist or GP. Assessments will be scheduled 1-2 hours post ingestion of morning dopaminergic medication (i.e. when participants are in "ON" state"). Participants will not be advised to change their dietary or physical activity habits during the study. Some data may have been routinely collected as part of movement disorder clinic.

Intervention Type
Mixed

Primary outcome(s)
The prevalence of both sarcopenia (as assessed by the European Working Group on Sarcopenia in the Older Person 2 and SARC-Calf tools) and frailty (as assessed by the frailty phenotype and the cumulative deficits model) in an Irish cohort of Persons with Parkinson's Disease (PwP), measured in one visit.

Key secondary outcome(s))
1. The perspectives and lived experience of PwP living with sarcopenia and frailty explored through semi-structured interviews using reflexive thematic analysis
2. Demographics as assessed by key questions such as age, gender, address, and education level
3. Anthropometric data as assessed by weight, height, body mass index, and body composition (bioimpedance analysis)
4. Carotenoid status as assessed by skin score from handheld machine

5. Cognitive status as assessed by the Montreal Cognitive Assessment
6. Parkinson's specific characteristics related to frailty or sarcopenia as determined by levodopa equivalent daily dose, disease duration, Movement Disorder Society Sponsored Unified Parkinson's Disease Rating Scale
7. Quality of life as assessed by Parkinson's Disease Questionnaire 39 and semi-structured interview
8. Physical Activity Level as assessed by the International Physical Activity Questionnaire Short Form

The quantitative outcome measures will be measured in one visit. Participants who are identified as frail or sarcopenic will then be invited back for a second visit to complete the qualitative aspect of the study (i.e., semi-structured interviews).

Completion date
01/07/2026

Eligibility

Key inclusion criteria
1. Adults aged more than 18 years old
2. Diagnosed with idiopathic Parkinson’s disease

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
110 years

Sex
All

Key exclusion criteria
1. Pregnant or breastfeeding participants
2. Significantly impaired functional ability, likely to affect their ability to attend for assessment
3. Significant cognitive impairment, likely to affect their ability to provide informed consent
4. Parkinsonism, not classified as idiopathic PD
5. Life expectancy of less than six months or receiving palliative care input
6. Participants with implanted medical devices such as pacemakers, deep brain stimulators and defibrillators will be excluded from the sarcopenia sub-arm due to potential interaction with bioelectrical impedance analysis (BIA)

Date of first enrolment
01/06/2025

Date of final enrolment
01/02/2026

Locations

Countries of recruitment
Ireland

Study participating centre
University Hospital Waterford
Dunmore Road
Waterford
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X91 ER8E

Sponsor information

Organisation
Royal College of Surgeons in Ireland

ROR
https://ror.org/01hxy9878

Funder(s)

Funder type
University/education

Funder Name
Royal College of Surgeons in Ireland

Alternative Name(s)
Coláiste Ríoga na Máinleá in Éirinn, RCSI

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
Ireland

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication

IPD sharing plan summary
Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			23/05/2025	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes