

## Participant Information Sheet

### Introductory Statement

**Research Study Title:** “MoveWell Parkinson’s Programme’: A 6-week evidence-based hybrid (online and in-person) multimodal exercise programme for people living with Parkinson’s Disease in Ireland.

### Researchers:

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### What is this research about?

The purpose of this research study is to examine the feasibility, acceptability and benefits of a 6-week evidence-based hybrid (in-person and online) multimodal exercise programme for people living with Parkinson’s Disease.

### Why is this research being conducted?

Parkinson’s disease (PD) is a progressive neurological disorder characterised by motor symptoms such as tremors, rigidity, and bradykinesia (slowed movements), as well as non-motor symptoms including cognitive decline and mood disorders. Multimodal exercise interventions incorporating strength, balance, flexibility, mobility, and aerobic exercise have been shown to yield significant improvements in motor and non-motor symptoms of PD. To our knowledge, there are currently no structured 6-week hybrid multimodal exercise programmes for people living with PD in Ireland, which are underpinned by clinical exercise physiology and incorporates exercise education. By facilitating multimodal exercise with different levels of difficulty for each exercise and providing an educational component, this 6-week intervention seeks to address some of the multifaceted challenges faced by people living with PD, ultimately striving to improve their functional abilities and quality of life.

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

Male and female participants aged 18+ years who are living with Parkinson’s Disease and residing in county Laois and county Offaly will be invited to participate in this research study. This includes people diagnosed with early-onset Parkinson’s Disease (diagnosis of Parkinson’s disease before the age of 50 years) or those in stage 1.0 – 3.0 Parkinson’s Disease, defined using the Hoehn and Yahr Scale (Hoehn and Yahr, 1967). Participants with additional injuries and clinical conditions (including cardiovascular disease, type 2 diabetes, arthritis, osteopenia, osteoporosis, back pain, and joint pain) will not be excluded from this study as they will benefit greatly from multimodal exercise training. Please note, if you have unstable angina and/or heart failure, you will be unable to participate in this research study.

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

**Screening:** If you are interested in taking part in this research study, you will be asked to complete the physical activity readiness questionnaire (PAR-Q & You). This questionnaire screens for injuries and illnesses that will determine your suitability for the study. If you answer ‘yes’ to any of the PAR-Q questions, you will be required to obtain medical clearance from your local General Practitioner (GP) to take part in this study.

**Pre- and Post-Intervention Testing:** Pre- and post-intervention testing will occur the week before and the week after the 6-week intervention (week 0 and week 7) respectively, in a community hall in Portlaoise, county Laois. Following detailed explanations, you will be asked to perform a MiniBEST (balance), 10-meter walk test (walking speed), 5 sit-to-stand (lower-body muscle strength), timed up and go test (mobility), 6-minute walk test (aerobic capacity), and 30-second bicep curl test (upper-body muscular strength and endurance). The testing session will be structured accordingly, to ensure you

have rest periods between the tests. You will also be asked to complete an online questionnaire on Qualtrics before and after the 6-week intervention (week 0 and week 7, respectively) which will examine your physical activity participation, multimodal exercise participation, freezing of gait, fatigue, confidence to complete activities of daily living, quality of life, and wellbeing.

**6-Week Intervention:** Following the completion of pre-intervention testing, you will start your 6-week intervention of multimodal exercise training. You will be asked to attend 2 \* 60-minute in-person community-based multimodal exercise classes per week and 1 \* 40-minute live online multimodal exercise class per week. The live online exercise classes will be delivered using Zoom by trained exercise professionals and will be additionally monitored by a clinical exercise physiologist. You will be asked to turn on your camera during the live online exercise classes so we can monitor your technique. You will also be asked to attend 1 \* 10-minute in-person exercise education workshop every week, after one of your in-person exercise classes. These will also be recorded and made available in an on-demand library. There will be substitute multimodal exercise classes available in your on-demand library if you cannot complete any of the live exercise classes in a particular week.

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

All data will be stored and handled in compliance with GDPR guidelines. You will be provided with a unique ID research code at the start of the research study so all data collected (hardcopy or electronic) will be recorded, stored, and published anonymously so you cannot be identified. The electronic document (master linking file) containing your name, corresponding research ID number, email address and phone number will be stored on a restricted-access password-protected secure DCU Google Drive folder that can only be accessed by the study investigators via multi-factor authentication. This data file will be deleted after the completion of this research study. All hardcopy data we gather will be stored in a locked filing cabinet in a locked office that can only be accessed by the study investigators. All hard copies will be destroyed *via* shredding after the study is completed. All pseudoanonymised data will be stored on a restricted-access secure password protected DCU Google Drive folder that can only be accessed by the study investigators for the purpose of analysing the findings accessible via multi-factor authentication. Once the master linking file has been deleted following completion of the study, the data will become anonymous. This anonymised electronic data will be kept indefinitely for publication purposes and may be provided to external researchers for secondary data analysis if requested (e.g. to complete a meta-analysis). The findings of this study will be reported in a research article in a peer-reviewed journal, presented at national/international conference(s), shared on social media and through other media outlets, and amongst Local Sports Partnerships but only group anonymised data will be reported. DCU will act as the Data Controller for this research project. This study will be conducted in compliance with the General Data Protection Regulation (GDPR), and if you have any concerns regarding how your data in this study has been handled, you can contact: DCU Data Protection Officer, Mr. Martin Ward – ([data.protection@dcu.ie](mailto:data.protection@dcu.ie) Tel: 01-7005118/01- 7008257) who will handle any data protection concerns arising from this research. An individual also has the right to report a complaint concerning the use of personal data to the Irish Data Protection Commission: <https://www.dataprotection.ie/>

### **How will your privacy be protected (including any legal limits to confidentiality)?**

Confidentiality and privacy are of utmost importance. While we collect personal information (e.g., name, email address, phone number, etc.), these will not be published in an identifiable manner. You will be provided with an individualised research study code so all data collected will be anonymised. The electronic document containing your name, corresponding research ID number, email address and phone number will be deleted after the completion of this research study and will not be published in any form. Confidentiality of information provided can only be protected within the limitations of the law. It is possible for data to be subject to subpoena, freedom of information claim or mandated reporting by some professions.

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

Following the completion of the 6-week intervention, you will be provided with a full report of your results from the pre- and post-intervention tests, which will include feedback on the changes, if any, that occurred. You may experience improvements in balance, lower- and upper-body muscle strength and endurance, mobility, aerobic capacity, physical activity participation, multimodal exercise participation, freezing of gait, fatigue, confidence to complete activities of daily living, quality of life, and wellbeing. All the tests and exercise classes will be provided free of charge and will be delivered by trained professionals.

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

There are minimal risks to participants who are involved in the research project. Exercise does carry a risk of injury, such as a pulled muscle, muscle soreness or in extreme cases abnormal heart rhythm, heart attack or death. To minimise these risks, you will be asked to complete a PAR-Q to determine your suitability for the study. You may need to obtain medical clearance from your GP if you answer 'yes' to any of the questions on the PAR-Q form. All in-person pre- and post-testing sessions and exercise classes and online exercise sessions will include an appropriate warm-up and cool down (15 minutes) and stretching to reduce the risk of injury. This also significantly reduces the risk of adverse events for people who have cardiovascular conditions. You will also receive education on exercise intensity and be advised to exercise at an intensity that is appropriate for you. You will be provided with colour coded rate of perceived exertion (RPE) cards (green = low intensity, orange = moderate intensity, red = high intensity) and instructed on how to use these during the online exercise sessions when exercise instructors ask for an exercise intensity check. You will be monitored throughout pre- and post-testing and during in-person and online exercise classes by a team of trained professionals, including a clinical exercise physiologist and phase IV cardiac rehabilitation specialist. You will also be asked to have your phone with you during testing and the in-person classes, and when you're exercising at home in case, we need to contact you privately. If you have any complex cardiovascular conditions, you will be provided with a heart rate monitor and taught how to record your heart rate and be given advice on the heart rate ranges you need to stay within during the online exercise classes.

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

Your participation in this research study is voluntary. You may withdraw from the research study until the point at which this research is published or following completion of the project as your name and linked unique ID code will be permanently deleted at that point. You can withdraw by contacting any of the study investigators by email or phone. Changing your mind or not taking part in this research will not affect your relationship with DCU, EduFIT or Laois Sports Partnership.

**How will you find out what happens with this project?**

If you would like information on the results of this research study, this information will be provided once you email any of the researchers using their contact information below.

**Is this study free to participate in? Who is funding this project?**

Yes, this study is free to participate in as it has received funding from Sport Ireland in partnership with Laois Sports Partnership (LSP). Only the group anonymised data (no individual data) will be reported and shared with the funders. EduFIT is a health education and functional fitness company based in Laois. They consist of a team of clinical exercise physiologist, exercise physiologist, nutritionist, health researchers and fitness instructors. Their specialist areas of expertise include functional healthy ageing, physical inactivity, space physiology, the prevention, treatment and management of non-communicable chronic disease, and women's health and menopause. They offer exercise classes, workshops and courses in these areas.

**Contact details for further information:**

If you have any questions at any time, please contact:

Dr Siobhán O'Connor, FT215, School of Health and Human Performance, Polaris, Dublin City University, [siobhan.oconnor@dcu.ie](mailto:siobhan.oconnor@dcu.ie), [017008579](tel:017008579).

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If you have concerns about this study and wish to contact an independent person, please contact:

The Secretary, Dublin City University Research Ethics Committee, c/o Research and Innovation Support, Dublin City University, Dublin 9. Tel 01-700 8000, e-mail [rec@dcu.ie](mailto:rec@dcu.ie)