

**PERSON WITH PARKINSONS CONSENT FOR PARTICIPATION IN RESEARCH
STUDY**
(Version 2.0 25/01/2021)

Study Number (if applicable):

Study Title Assessing the Impact of Exercise Classes on Non-Motor Symptoms in People with Parkinson's during the COVID-19 Pandemic.

Name of Chief Investigator: Prof. Aideen Sullivan

Thank you for considering participating in this research project. The purpose of this document is to explain to you what the study is about and what your participation would involve, so as to enable you to make an informed choice.

What is the purpose of this study?

The purpose of this study is to examine the impact of taking part in exercise classes on symptoms of Parkinson's, such as sleep, mood and daily activity. We are also interested in recruiting family members or caregivers to the study, to assess their quality of life during the COVID-19 lockdown periods. Should you choose to participate, you will be asked to complete an online survey, which will include questions on your medications, age, sex, how you sleep, how you are feeling and what are your day to day activities. The survey will take about 20 minutes to complete.

Why have I been chosen?

You have been asked to take part in this research project as you have a diagnosis of Parkinson's disease and are taking part in exercise classes tailored for people with Parkinson's.

How many people will take part in this study?

We hope to recruit 200 people to take part in this study

Do I have to take part?

Your participation in this study is completely voluntary.

- If you decide to take part, you will be asked to complete a consent form (at the end of this information leaflet online).
- If you decide to take part, you are free to withdraw at any time without giving a reason and without any disadvantage to your future medical treatment.
- If you decide not to take part, this will not put you at any disadvantage regarding your current treatment or exercise programme.

What will happen if I agree to take part?

- If you agree to take part, you will be asked to take an online survey that you can access through a link to a secure website.
- The survey will not take more than 20 minutes. You can take breaks while completing the survey, if you need to. The questions are split up into 7 sections. You can take a break after each section and come back to complete it. We just ask that you complete it within a day.
- Questions will be asked regarding your health, medications, COVID-19 pandemic, exercise, your quality of sleep, your mood and your daily activities. You don't need to answer questions that you are uncomfortable with.

What are the possible benefits of taking part?

You may not receive any benefit from taking part in this study. The information we gather from you and the other participants will help us to understand more about the role of remote and in-person exercise classes for people with Parkinson's during the current COVID-19 lockdowns.

What are the possible risks of taking part?

We do not believe that there are any risks of taking part in this study. Participation is voluntary, and it will not affect any future treatment that you might receive for your condition. You may withdraw from the study at any time.

If any concerns are raised for you as a result of taking the survey, please contact your own GP or Neurologist. The contact details for the Samaritans are a free 24-hour telephone number: 116 123, email jo@samaritans.ie or through the Samaritans Self-Help App.

The risks involved in the exercise programme will be discussed with you by your exercise coordinator. Please also familiarise yourself with the safety information provided by your exercise coordinator.

UCC Clinical Studies Data Protection Notice

At University College Cork, we treat your privacy seriously. Any personal data which you provide to the University will be treated with the highest standards of security and confidentiality, in accordance with Irish and European Data Protection legislation. This notice 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.

What about confidentiality?

All information about you will be kept strictly confidential, and any personal data provided to us during the study will be processed fairly and lawfully. Signing the Informed Consent Form means that your personal data will be used for the purposes outlined in the Patient information leaflet (PIL). You are entitled to withdraw your consent at any time. All data that are collected during the study are subject to the same regulations as the data collected for your health care. We will keep your personal details on secure computers. We need your personal email address to be able to communicate with you, this email will not be shared with anyone outside the study team. Your name and contact details will not be disclosed to anyone else except for the study staff. The survey results will be **coded**, this means that your personal details such as email address will be removed. There will be no link between your survey answers and your personal details. Every person that has access to your uncoded data in the research team is subject to professional secrecy and confidentiality.

The content of the exercise classes will be completely confidential, and your name (or other identifying information) will not be recorded for this study.

The results of this study may be published in a medical journal, but it will not be possible to identify you from the publication. We will store the results of the surveys securely for 15 years. Thereafter, they may be stored for a longer time if required by law, or they will be destroyed in line with confidential waste destruction guidelines. Results of the study will be provided to the Clinical Research and Ethics Committee of the Cork Teaching Hospitals (CREC) in compliance with national and international regulations on clinical studies.

Who will access my personal data?

Your uncoded data will only be accessible to study researchers, quality representatives from the study Sponsor (Monitors and Auditors), and the Clinical Research Ethics Committee of the Cork Teaching Hospitals (CREC) 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 study researchers will use your personal data within the scope defined above. If the study researchers wish to use your data for a purpose other the purpose specified, the researcher must contact you again to give you more information and ask your permission to use your data for the new purpose.

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) (g) of the GDPR). If you require further information on the legal basis for processing your personal data, please contact UCC's Data Protection Officer – details below.

Right of Access and Rectification

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

- to find out if we use your personal data, access your personal data and receive copies of your personal data;
- 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 UCC;
- to exercise your right to data portability where applicable (i.e. obtain a copy of your personal data in a commonly used electronic form);
- to withdraw your consent to the processing of your data at any time without giving a reason by notifying your decision to the study researcher. If you withdraw your consent for data processing, your participation in the study stops and no further data will be collected from you. Your study Researcher will present you the options you have concerning your personal data.
- If, for any reason, you stop completing the online surveys, your study Researcher may decide to withdraw you from the study. If this happens, we

will continue to hold your data for research purposes unless you inform us that you do not want us to hold your data any longer.

- Along with study withdrawal, you have the right to request the deletion of data about you if your data are no longer necessary for the purposes of processing or there is no other legal ground for their further processing.

If you wish to exercise any of these rights, please address your request to the study researcher or the Data Protection Officer, University College Cork (details below).

What if I have a question or Complaint?

University College Cork (UCC) is the Data Controller for this research project. If you have any complaints in connection with our processing of your personal data, you can contact UCC's Data Protection Officer (DPO): DPO, Information Compliance Section, Office of Corporate & Legal Affairs, University College Cork, Western Road, Cork E: foi@ucc.ie Tel: +353 21 4903949

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.

If you have a question about the survey please contact the members of the study team who will be happy to answer any questions. The email for the study is PDSTUDY@ucc.ie

If your question is about the exercise programme please contact your exercise co-ordinator.

AGREEMENT TO CONSENT

Study Number : _____

The research project has been fully explained to me. All experimental procedures have been identified and no guarantee has been given about the possible results. I have had the opportunity to ask questions concerning all aspects of the project. I am aware that participation is voluntary and that I may withdraw my consent at any time. I am aware that my decision not to participate or to withdraw will not restrict my access to health care services normally available to me. Confidentiality of records concerning my involvement in this project will be maintained in an appropriate manner. When required by law, the records of this research may be reviewed by government agencies and sponsors of the research.

I understand that the sponsors and investigators have such insurance as is required by law in the event of injury resulting from this research.

I, the undersigned, hereby consent to participate as a subject in the above-described project conducted online and at the in-person exercise class locations. I have received a copy of this consent form for my records. I understand that if I have any questions concerning this research, I can contact the Chief Investigator listed above. I understand that the study has been approved by the Cork Research Ethics Committee of the Cork Teaching Hospitals (CREC) and if I have further queries concerning my rights in connection with the research, I can contact CREC at Lancaster Hall, 6 Little Hanover Street, Cork, 021 4901901 or email crec@ucc.ie.

I have read and understand the study: yes ☐ no ☐

I agree to participate in this research: yes ☐ no ☐

I grant permission for the data collected to be used in this research only:

yes ☐ no ☐

I understand that my anonymised data will be stored at UCC for 15 years:

yes ☐ no ☐

Can you please confirm you are over 18 years of age?

yes ☐ no ☐

I agree to be contacted by email

yes ☐ no ☐

