

An observational study on the effect of social isolation on Parkinson's Disease patients during UK lockdown measures in response to the COVID-19 outbreak

Patient Information Sheet – PD Patients

Severe Acute Respiratory Syndrome Coronavirus-2 (SARS-CoV-2) is a new type of Coronavirus. COVID-19, the disease caused by SARS-CoV-2 infection, was first identified in Wuhan in mainland China in December 2019. COVID-19 usually presents with mild respiratory symptoms, fever and cough, but some older patients, and those with pre-existing conditions, may develop more severe disease. Some patients also experience neurological symptoms. In the United Kingdom (UK), a 12 week self-isolation has been recommended for vulnerable populations to protect these high risk groups.

Social isolation can be considered a risk factor for ill-health. This study will look at the effect of social isolation on vulnerable populations such as people with Parkinson's disease (PD), during the COVID-19 pandemic.

PD is a progressive neurodegenerative disease which is more common in older people. It can cause both motor and non-motor symptoms, which make it harder to socialise and perform daily activities, causing difficulties at work, and problems with relationships. PD patients often have mental health problems.

Older advanced PD patients may be even more vulnerable to COVID-19 if they suffer from shortness of breath and a weak cough reflex. In addition, the pandemic might have possible indirect effects on PD, such as the impact of self-isolation, loneliness, stress and anxiety as well as the effect of not moving during the long lockdown period.

Please take time to read the following information carefully to decide if you want to take part. It's important that you understand why we want to do this study and what it will involve. Please discuss with others if you wish and ask us if there's anything that's not clear or if you'd like more information.

Why are we doing the study?

We'd like to improve our knowledge on whether loneliness affects PD symptoms including non-motor symptoms, sleepiness, anxiety, depression, energy levels and disease severity. We'll use the results to directly assess and investigate the effects of social isolation during the COVID-19 pandemic; and whether that isolation causes loneliness, affects PD symptoms and quality of life in patients with PD.

Why have I been asked to take part?

We're inviting people with Parkinson's who attend our outpatient clinics or have volunteered to be contacted.

Do I have to take part?

No. It's up to you whether to take part. If you do decide to take part, you'll be given this information sheet to keep and be asked to sign a consent form. You can stop taking part at any time without giving a reason; and if that's the case, we'll keep the information about you that you've given us only if you agree.

If you decide not to take part, or change your mind after you've started, that won't affect the routine clinical care or treatment you receive.

What will happen to me if I take part?

We'll post/email the information sheet and answer any questions you may have. If you wish to take part, you'll sign a consent form and post/email it back to us. You will have the choice to complete the questionnaires over the phone with the study team or receive them via post or email to complete at home and return to the study team (in a prepaid stamped return envelope or electronically via email). The phone survey takes about 20-30 minutes to complete. Additionally, you can choose to complete the questionnaires via an online platform. The online form can be found on SmartSurvey, a user-friendly UK-based provider of digital survey solutions fully compliant with EU Privacy Laws and registered under the Data Protection Act. They have robust measures in place to secure their users' data. The survey can be accessed on

<https://www.smartsurvey.co.uk/s/preview/270RB3/E37CF3341EB9D2D15D54A1FA4EFD5C>
[preview link].

Many of the questions are routinely used in the clinic and it's likely you may have answered some of them in the past. We'll ask if you're happy for us to use information about your Parkinson's from any previous studies.

What are the possible disadvantages and risks of taking part?

None.

What are the possible benefits of taking part?

You won't get any direct benefit from taking part, however the research team hope to understand if the self-isolation during the COVID-19 pandemic has affected your PD and quality of life.

What if something goes wrong?

It is extremely unlikely that you will come to any harm by taking part in this study. The study doesn't include any drug interventions or injections. However, your GP will be notified should signs of distress be detected.

If you have a complaint, or any concerns about the way you have been approached or treated during the course of this study, you can ask to speak to the hospital's complaints manager. If you have a concern about any aspect of this study, ask the researcher who will do their best to answer your questions. If you remain unhappy and wish to complain formally you can contact your local PALS group:

King's College Hospital Patient Advice and Liaison Service (PALS)

Online: <https://www.kch.nhs.uk/contact/pals>

Email: kch-tr.PALS@nhs.net

Phone number: 020 3299 3601, 9am to 4.30pm, Monday to Friday (excluding bank holidays)

Post: Patient Advice and Liaison Service, King's College Hospital NHS Foundation Trust, Denmark Hill, London SE5 9RS

Will my taking part in this study be kept confidential?

All information collected in the study will remain strictly confidential just like your medical records. The information will be put into a computer and analysed, but you'll not be identified when the results are reported.

What will happen to the results of the research study?

If you agree, the data obtained from the study will be compared to data from other studies you take part in. The results will be published in medical journals, but you'll not be identified. The results will also be disseminated to patient groups such as the Parkinson's UK and discussed in national and international meetings on Parkinson's.

What happens if I lose capacity to take part during the trial?

If you lose capacity to take part during the trial, you will be withdrawn from the study and we will not contact you again. If you agree, we will keep the information you have already provided to be used in the study analyses.

Who is organising and funding the research?

The study is being organised and funded by EUROPAR, a group of academics dedicated to research in non-motor aspects of Parkinson's and part of the International Movement Disorders Society Parkinson's Disease Non-Motor Study Group.

Who has approved the study?

The South Central – Oxford B Research Ethics Committee (REC) has approved this study. The committee consists of medical and lay members of the public and are independent of the sponsor (King's College Hospital (KCH) and the research team; and they protect your safety, rights, well-being and dignity).

General Data Protection Regulation

The sponsor is KCH, based in the UK. We'll use your information in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. KCH will keep identifiable information about you for 5 years after the study has finished.

Collected data will be stored in a local research database on a secure NHS drive managed by the Chief Investigator. Only the research team will have access to these data.

Your rights to access, change or move information are limited, as we manage your information in specific ways for the research to be reliable and accurate. To safeguard your rights, we'll use the minimum personally identifiable information possible.

You can find out more about how we use your information at www.hra.nhs.uk/information-about-patients/ or by contacting the study team, whose contact details are at the bottom of this information sheet.

Health and care research should serve the public interest, which means that we have to demonstrate that our research serves the interests of society as a whole by following the UK Policy Framework for Health and Social Care Research.

For help and support, please visit www.kch.nhs.uk/patientsvisitors/help-and-support/chaplaincy or www.parkinsons.org.uk/information-and-support/support-you.

If you wish to raise a complaint on how we have handled your personal data, please contact our Data Protection Officer at kch-tr.dpo@nhs.net. If you are not satisfied with our response or believe we are processing your personal data in a way that is not lawful you can complain to the Information Commissioner's Office (ICO).

KCH will collect information from you for this research study in accordance with our instructions. KCH will use your name, NHS number and contact details to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Individuals from KCH and regulatory organisations may look at your research records to check the accuracy of the research study.

The only people in KCH who will have access to information that identifies you will be people who need to contact you about the study or audit the data collection process. People who analyse the information will not be able to identify you nor find out your name, NHS number or contact details.

Contact

Please contact the following researchers if you'd like more information:

Professor K Ray Chaudhuri
Chief Investigator
Neurology Department
King's College Hospital
Email: ray.chaudhuri@nhs.net

Pavlos Zinzalias
Research Coordinator
Neurology Department
King's College Hospital
Tel: 0203 299 7189 / 077 4595 3823
Email: p.zinzalias@nhs.net

If you decide to take part in this study, you can keep this information sheet and send/email back a signed consent form.

Thank you for reading this information sheet and for considering to take part!