REC Reference Number: 10/H0716/85

PREDICT-PD

Participant Information Page (Version 20)
Date: 09 September 2026

Please read this in full before agreeing to participate. If you have further questions, please contact us by email or telephone.

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About Parkinson's

What is Parkinson's?

Parkinson's is a progressive neurological condition.

One person in every 500 has Parkinson's. That's about 120,000 people in the UK. Most people who get Parkinson's are aged 50 or over but younger people can get it too. One in 20 is under the age of 40 when first diagnosed.

People with Parkinson's don't have enough of a chemical called dopamine because some relevant nerve cells in their brain have died.

Without dopamine people can find that their movements become slower, so it takes longer to do things.

The loss of nerve cells in the brain causes the symptoms of Parkinson's to appear, which include tremor, rigidity and slowness of movement.

There's currently no cure for Parkinson's and we don't yet know why people get the condition.

How is Parkinson’s diagnosed?

At present, the diagnosis of Parkinson’s is made clinically. This means that the doctor examines the person and takes a detailed history of their symptoms.

Sometimes brain scans are used for uncertain cases but there is currently no conclusive test for Parkinson’s.

The early signs of Parkinson’s may include problems with movement like tremor, stiffness, slowness of movement, difficulties with handwriting and loss of facial expression. Other symptoms, not related to movement, can also be present like loss of sense of smell, dizziness on standing, depression, constipation and sleep problems.

Why do we want to diagnose Parkinson’s earlier?

One reason why we don’t yet have a cure for Parkinson’s is because the movement symptoms of the condition only appear once 70-80% of the nerve cells have already been lost.

The nerve cells start dying many years before symptoms appear but we don’t know enough yet about these early stages.

If we could identify people early – before the movement symptoms appear – we would be in the best possible position to slow, stop or even reverse Parkinson's.

How could we identify people at risk of Parkinson's before the symptoms appear?

Research suggests that problems including dizziness on standing, anxiety, depression, drops in blood pressure, constipation and loss of sense of smell may occur up to 20 years before the movement problems of Parkinson's appear.
Many older people probably experience some of these problems at some stage. But finding people who experience several of these issues together may help us identify people at high risk of Parkinson's.

About PREDICT-PD

What is the PREDICT-PD project?

PREDICT-PD is an innovative project that aims to identify people at high risk of Parkinson's before the symptoms appear.
We are using a set of simple online tests that screen for factors linked to increased risk of Parkinson's.

We want to know whether a person's combined score in these tests can tell us about their risk of developing Parkinson's.

Will your project identify people who will get Parkinson's?

No. Although we have some idea of what the very early stages of Parkinson's might look like, we don't know yet if our tests can accurately predict people at high risk of Parkinson's.

This study will help us refine the tests so that we can determine risk of Parkinson’s with the best possible degree of accuracy.

If we can predict Parkinson’s, we hope to one day have treatments for those at high risk that could slow or prevent the condition progressing.

What’s special about the PREDICT-PD project?

PREDICT-PD is innovative because it is conducted almost entirely online.

This means participants don’t even need to leave their homes to take part, and we can process lots of information quickly, cheaply and efficiently.

We hope that using the Internet will mean more people take part and potentially benefit from its results.

PREDICT-PD is also unique because it focuses on the earliest known symptoms of Parkinson’s.

Taking part in PREDICT-PD

Who can take part in the study?

We are looking for healthy people aged between 50 and 80 years, who have access to the Internet, and do not have a current diagnosis of Parkinson’s. People with a family history of Parkinson’s are also encouraged to participate.

Who cannot take part in the study?

1. People who have been diagnosed with Parkinson's or other movement disorders, dementia, stroke or motor neurone disease.

2. Certain drugs can contribute to or cause Parkinson's-like symptoms. We may exclude some participants from the analysis if we think their previous or current medication may affect the results of the study.

Are there any exceptions to these criteria?

Yes. The research team will approach some specific groups so that they can act as comparisons for the online, 'self-referring' PREDICT-PD participants. Some groups of individuals are at increased risk of Parkinson's because they have another pre-existing medical condition. Examples of patient groups at elevated future risk of Parkinson's include: an uncommon form of sleep disorder known as RBD (REM-Sleep Behaviour Disorder); individuals with Pure Autonomic Failure (PAF) which causes blood pressure to drop when standing leading to dizziness or fainting; late-onset mood disorders such as anxiety or depression; and individuals with adult-onset smell loss and no clearly identifiable cause.
Up to 200 individuals will be recruited for each of these special groups. Participants with unexplained smell loss will be identified through dedicated smell and taste clinics, through specialist clinics for autonomic problems and from primary care records for PAF, through the mental health services for late onset mood disorders, and through epilepsy and sleep medicine clinics for RBD patients. Finally, an additional positive control group of patients with established Parkinson's will be recruited from clinics at UCL Partners' hospitals. As an exception to the inclusion criteria, participants under the age of 50 may be included in research studies where required as controls for research development, assay development or pilot studies investigating validity of methods and devices.

All positive control groups will undergo the same investigations as regular 'self-referring' PREDICT-PD participants including: the online screening questionnaire, keyboard tapping test, smell testing, neurological examination, and perhaps blood/urine/saliva collection or additional surveys.

Do I have to take part in the study?

No. There is no obligation to take part in the study, and the decision to participate rests entirely with you.

You also have the right to withdraw from the study at any point, and are not obliged to provide a reason.
If you do choose to participate, please read the information on these pages carefully. You will then be asked to read and complete a consent page before registering on the website.

I'd like to take part. What do I have to do?

First, you will need to register with the PREDICT-PD website. If you have participated in previous years, you will already be registered.

Next, you'll be asked to complete an online questionnaire that collects information on various medical and lifestyle factors that may influence risk of Parkinson's. This questionnaire takes about 30 minutes to complete.

After the questionnaire, you will be asked to take the keyboard tap test – a simple test on the PREDICT-PD website. This is not a typing test. The test helps us measure the accuracy and speed of movement in your arms. After the tapping test there are some brief mental and memory tests.

Participants will be sent a smell test through the post in the future. The smell test contains 6 'scratch and sniff' odours and full instructions on how to complete it. You fill in your answers to the smell test on the PREDICT-PD website (you will need to log in again). Participants that get lower scores on the initial smell test may be sent a more detailed follow-up smell test containing 40 items. There may be some additional questionnaires offered to willing participants who participate in the 40-item smell test, to find out more

about participants' views towards risk disclosure to further our understanding of this.

We may request a sample of saliva for genetic testing, a sample of blood using a self-collection kit and/or special cards, and a nasal sample collected via nasal swabs or nasal washes. Instructions will be enclosed on how to collect saliva, blood, and nasal samples and how to return the samples along with the completed smell tests. Some participants will be invited to complete blood pressure measurements at home. If necessary, a blood pressure measurement device will be sent in the post with written instructions on how to check your blood pressure. This will need to be returned either in person or through pre-paid postage once the study is complete.

Participants may also register within the website to participate in a forum to gather community feedback on relevant topics which may inform further research.
Some participants may be contacted by telephone to verify their diagnoses and answers to the online questionnaire.

Will I find out my predicted risk of Parkinson's?

No. People involved in this study will not discover their individual risk score.

This is the first study of its kind. So whilst our tests may suggest some people could be at increased risk, at this stage we can't be certain the scores have any meaning.

However, if you score poorly on the smell test we might ask if you would like to be referred for further investigation. This is because lots of people have a treatable cause of adult-onset smell loss after further testing. It is important to remember that whilst late-onset smell loss is a risk factor for Parkinson's, most people that lose their sense of smell will not get Parkinson's and may have a cause that is easily treated. If the results of the study suggest that you

have pure autonomic failure and you / your doctor was not aware of this, we will advise your GP to refer you to the local specialist clinic.

We're really keen to keep participants involved. We'd like to update you either in person or through the PREDICT-PD website to tell you about how your involvement is helping us learn more about Parkinson's.

Will I be contacted by the research team when the tests are completed?

Yes. We will contact participants via email soon after they have completed the first round of tests and ask them to submit their NHS number via the study website. The reason for this is that we can then verify some of the information collected via the study against NHS medical records and find out about any medical events that happen to participants during or after the study. We will also use the NHS Digital Patient Demographic Service (PDS) to look up the NHS numbers, dates of birth and addresses of participants who have consented for us to do so. The PDS helps healthcare professionals to identify patients and match them to their health records. It also allows them to contact and communicate with patients.

We will also contact up to 600 people who have taken part in the research by email or telephone, to see if they would be willing to participate in a clinical visit (see below). If you are contacted, this does not necessarily mean that you are at higher risk. We will contact people with the most varied scores and some people at increased risk of Parkinson's having specific pre-existing medical condition. Participants with suspected or confirmed pure autonomic failure will complete further specific questionnaires to assess problems related to low blood pressure and invited to take part in a clinical visit (see below).

Part of the online questionnaire that you will complete online, contains some questions relating to a sleep condition called REM sleep behaviour disorder (RBD). The diagnosis of RBD requires performing an overnight inpatient sleep study at an experienced sleep centre. If your answers to the questionnaire

suggest that there is a possibility you may suffer from RBD, you will be offered a telephone interview with a member of the research team. If the outcome from that interview is that RBD is suspected, we will contact your GP and advise to refer you to the Sleep Disorders Centre at Guy's and St Thomas' NHS Foundation Trust. If the interview highlights other possible sleep disorders, we will advise your GP to your local sleep clinic or to the Sleep Disorders Centre at Guy's and St Thomas' NHS Foundation Trust. Many sleep disorders are treatable and affect quality of life, so we believe it is important that they are identified.

We may also want to contact you to invite you to participate in additional research projects that are related or linked to PREDICT-PD.

How long will I be involved in the study?

During an earlier phase of the study, approximately 1,400 participants were recruited. We now want to recruit a total of 17,000 participants and follow the total group until the end of August 2027 as a minimum. Participants will be invited to complete the online tests on an annual basis.

Clinical visits

Those participants that are invited to undergo clinical examinations will be contacted after data have been initially analysed. One of the doctors on the study team will offer to travel to examine you in your own home or offer to cover travel expenses for you to attend a Barts Health NHS Trust or UCLH NHS Trust hospital, or a QMUL or UCL research site. They may request that the examination be recorded on video, so that a senior movement disorders specialist can verify the examination findings. They will measure your blood pressure. We will ask you to participate in some short memory tests and a sample of handwriting will also be collected.
Some other visits will take place in the hospital facilities in order to assess as many participants as possible in one day. From 2020, we will also offer clinical

visits that take place remotely via video, but which gather the same information from participants as in person visits.

Collection, Storage and Analysis of Biological Samples

Participants that are involved in clinical visits may also be invited to donate biological samples to the study in the form of saliva, blood, urine, nasal swabs/washes, spinal fluid and skin biopsy. Increasingly we are recognising that there are chemicals and compounds contained in blood, skin and urine that may further define an individual's risk of future Parkinson's. The long-term aim of PREDICT-PD is to be non-invasive, but collection of these samples in a proportion of participants may allow us to decide on the future potential for use.

Taking a blood sample may cause mild pain and carries a small risk of bleeding, bruising, or infection (in less than 1% of people). Qualified health professionals will collect blood samples and the participant will collect their own urine. Approximately 30ml of blood and 30ml of urine will be collected (30ml is equivalent to 2 tablespoons). Qualified health professionals will collect the skin biopsy. This will involve local anaesthetic of Lidocaine with epinephrine solution. A sterile 3mm skin punch will be used to collect the specimen. Skin biopsy samples will be used to detect key diagnostic biomarkers involved in the development of Parkinson's. Saliva will be used for genetic studies of Parkinson's risk. Nasal swabs/washes will be used to detect key proteins involved in the development of Parkinson's.

Some participants have been invited to take part in additional research studies that are related to PREDICT-PD. From the participants invited to take part in the Parkinson's Progression Markers Initiative (PPMI), we wish to store spinal fluid (known as CSF), which is collected as part of PPMI. In PPMI 15-20ml of CSF is collected at the first visit. During this visit, a further 15ml will be collected and stored alongside PREDICT-PD samples. This ensures that participants will only have one procedure, but the samples will be retained by

two studies (PPMI and PREDICT-PD). CSF samples will be stored at -80°c and analysed at Queen Mary University of London laboratories and/or partnering laboratories.

All samples will be labelled with a unique number to keep participants anonymous. Samples will be transported to the laboratories at Queen Mary University of London and/or University College London for storage and analysis. Additional tests may be requested from external companies and collaborative research centres if required, including sites in the UK, Europe and outside Europe worldwide. Any samples left over at the end of this project may be used in future ethically approved research or transferred to an approved biobank.

Some testing may be deferred for months or even years until a later stage of the study, and until that time the samples must be securely stored. By participating in this stage of the study you give permission for storage of these samples for an indefinite period until we conduct all of these analyses. Again, you have the right to withdraw your consent at any time.

Due to the experimental nature of the planned analyses, in the unlikely event that we find a specific gene that increases Parkinson’s risk we will not inform you or your GP of this, or the results of any of the tests performed on blood/urine/saliva/nasal swab/wash/spinal fluid samples.

You will continue to have access to the general results of the study, including analyses of samples and data, when the analyses are reported in the medical literature. We will keep you informed of publications arising from the research.

Collection, Storage and Analysis of Movement data

Some participants may also be sent devices to wear on their wrists or the small of their backs to record their movement throughout the day and night. Some of the key changes in Parkinson’s are related to people’s movement. There might therefore be some subtle changes in how people move while

going about their normal everyday activities which could be related to future Parkinson's risk.

Participants who will have their movement recorded will be sent two watch-like sensors which they should wear continuously for 3-7 days and nights, only taking them off before they wash or swim. After this you will send the devices back to the PREDICT-PD team in an envelope with pre-paid postage which we will provide you with.

All the movement data will be labelled with a unique number so as to not identify the participant. This anonymised data may be sent to the companies which make the devices (Global Kinetics Corporation and Axivity) so that they can generate a summary of the movement recorded. Members of the PREDICT-PD research team might also work with the raw data collected from the devices in order to try and identify new, non-standard, subtle changes in how people move which might be related to future risk of Parkinson's.

Collection, Storage and Analysis of Sleep data

Data from the inpatient video-polysomnography performed during routine clinical assessment at Guy's and St Thomas' NHS Foundation Trust (GSTT) will be accessed, reviewed, anonymised and collected by Dr Perez-Carbonell for research purposes; however, the audio-video footage from inpatient video-polysomnography will only be accessed, reviewed and analysed, not transferred or stored for research purposes by the PREDICT-PD researcher.

Some participants with a planned inpatient video-polysomnography at the Sleep Disorders Centre at GSTT will be invited to also have a video-polysomnography performed at their home by an external provider called Independent Physiological Diagnostics (IPD). For participants having consented to have a home video-polysomnography performed, their personal and contact details would be shared with IPD to have this test done. The personal data transferred and processed includes first name, middle name, last name, date of birth, gender, , patient's addresses, email addresses,

telephone numbers; as well as medical history, images of patient - video recording, and sleep physiological data. The home video-polysomnography includes audio-video recording during sleep (video camera placed to face the bed where the participant is sleeping), and measurement of further physiological sleep data (brain activity, breathing characteristics, muscle activity on chin and limbs, and basic cardiological parameters). IPD will collect, organise, store (host), retrieve and process the personal, clinical and sleep data -including the audio-video recording- of participants undergoing home video-polysomnography, following the terms outlined in the data processing addendum within the agreement between QMUL and IPD. Once the data has been analysed and reviewed, IPD will provide the PREDICT-PD researcher with a summary of the home video-polysomnography. Facial or other images from the home video-PSG recording will not be blurred as this can affect the accurate analysis of possible dream enactment behaviours

For the purpose of this research, a Sleep Consultant at GSTT and PREDICT-PD researcher will also access, review, anonymise and collect data from home video-polysomnography performed by IPD; however, the audio-video footage from home video-polysomnography will only be accessed, reviewed and analysed, not transferred or stored for research purposes by the PREDICT-PD researcher. Images from the home video-polysomnography recordings won’t be de-identified; Dr Laura Pérez-Carbonell is the clinician identifying participants from her clinic, and the PREDICT-PD researcher reviewing the participants’ home video-polysomnography recordings within the IPD platform after these are analysed by the IPD team.

Significant clinical incidental findings from home video-polysomnography will be communicated to participants and treating clinicians. Participants will also be under the care of the Sleep Disorders Centre at GSTT, where further assessment or management advice as clinical indicated would be provided.

The video recording from the home video-polysomnography will be reviewed at specific time points where there is evidence of an arousal from sleep or

increased movement activity, and at other times where this is clinically appropriate to support the analysis of the sleep study.

As part of your participation in this sub-study, you are asked to sleep by yourself (not share the bed or the bedroom) on the night of the home video-polysomnography. During the home video-polysomnography booking process, you will receive a call from the IPD's administration team. During the call, the IPD team will let you know that a camera will be set up in your bedroom facing the bed to record video and audio; if you or a household member had any concerns about privacy, you can contact the IPD team to discuss this. During the home video-polysomnography set-up, the IPD Clinical Physiologist will again discuss with you camera positioning and what angle the camera is capturing.

We recognise that, because the recording takes place in your home, there is a possibility that footage of a private or intimate nature may occasionally be captured. If this occurs, only one appropriately qualified IPD Clinical Physiologist, who is responsible for reporting the home video-polysomnography study, will review the relevant footage where necessary. The IPD Clinical Physiologist will record the time at which the private or intimate footage occurred so that members of the research team reviewing the video recordings will be able to avoid viewing that section of the recording. The researcher reviewing the recordings for the purposes of the study will therefore not review video footage identified as being of a private or intimate nature. All video recordings will be handled confidentially and securely and will only be accessed by authorised members of the clinical and research teams in accordance with the procedures described in this information sheet.

The duration of data processing and retention as part of this project within PREDICT-PD will be the duration of the agreement between IPD and QMUL (initial term is 12 months with the possibility of being renewed) and for a period of 30 days after termination of the agreement, unless otherwise required by law. For the purpose of this sub-study, data held by QMUL will be pseudoanonymised (codes will be given to each participant and the key for

those codes will be kept in a separate computer) and stored for an undetermined period, as pre-specified in the PREDICT-PD protocol.

You can stop being part of this sub-study at any time, without giving a reason, but we will keep information about you that we already have. Physiological data already collected/processed prior to withdrawal will be retained and analysed in anonymised form after withdrawal. Audio/video recordings already collected/processed prior to withdrawal will be analysed and reviewed but not transferred or stored.

Home video-polysomnography recording and safeguarding

Although the purpose of reviewing the home video-polysomnography recordings is to assess sleep and sleep-related behaviours, it is possible that information unrelated to the research may occasionally be observed. If information obtained during the study gives rise to a concern about your safety or wellbeing, or the safety or wellbeing of another person, the IPD and research team may need to take appropriate action.

Any such concern will be assessed in accordance with the IPD Safeguarding Policy for Adults. Where appropriate and safe to do so, we would normally discuss the concern with you before sharing relevant information. However, there may be circumstances in which information needs to be shared without first informing you, for example where this is necessary to protect you or another person from a risk of serious harm or where there is another legal or professional obligation to act.

Only information relevant to the safeguarding concern would be shared, and only with appropriate safeguarding services, healthcare professionals, or relevant authorities, in accordance with applicable law, professional responsibilities and safeguarding procedures.

The home video-polysomnography recording is not monitored in real time and should not be regarded as a means of providing emergency support,

supervision or protection. If you require urgent medical assistance or are concerned about your immediate safety or the safety of another person, you should contact the appropriate emergency or healthcare services in the usual way.

Will my involvement be confidential and will my data be shared?

Yes. All information you provide will be kept strictly confidential and will not be personally identifiable.

Our website is compliant with the highest international standards of data protection and data handling.

We do however want to contribute to international efforts to understand more about Parkinson's and the sharing of anonymous data and results from the study are part of that. This is very important to help us answer major questions about Parkinson's that require information on large numbers of people, but also to avoid repetition and wasting of research funds. We will only share data with specific parties after they submit a written request, and our committee has deemed them to be appropriate. Individual data will be completely anonymous, meaning that there will be no way of identifying the individual from it and no one from outside the PREDICT-PD study team will be able to contact you.

You can find out more about how we use your information by reading the Data Information Pack at the end of this document.

What are the benefits in taking part?

You will receive no payment for your assistance with this study.

Of the 14,000+ participants we aim to recruit to the PREDICT-PD study; only around 200 are likely to develop Parkinson's at some stage in the future. If

anyone in the study does develop Parkinson's, they could potentially have earlier access to diagnosis and treatment.

By taking part in this study, you will be helping us find ways of diagnosing Parkinson's at the earliest possible stage. This could potentially pave the way to better treatments and a cure – benefiting people with Parkinson's all over the world.

What are the risks of taking part?

There are no anticipated risks in being part of this study. The information we collect will not be personally identifiable and will be entirely confidential.

Who has reviewed the ethical aspects of the study?

This study has been reviewed and approved by the 'London - Queen Square REC' in January 2011, April 2011, August 2012, September 2013, January 2014, July 2014, November 2015, September 2016, January 2018, July 2018, December 2019, January 2020, January 2021, March 2021, April 2022, September 2023, November 2024, and January 2026.

What if I have further questions?

You are welcome to discuss the study with Faith Zainab Tuma (study coordinator), or Prof Alastair Noyce or Professor Anette Schrag.

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For more information on Parkinson's and how to get involved in other studies, please visit Parkinson's UK's website. **parkinsons.org.uk**

How will we use information about you?
We will need to use information from you and/or your medical records for this research project.

This information will include your:

- Name *
- Initials *
- NHS number *
- Contact details *
- Date of birth *
- Medication
- Medical conditions
- Questionnaire data
- Keyboard and website test results
- Smell test results
- Wearable test results
- Sleep test results (audio-video recordings from these will be accessed, reviewed and analysed within the IPD platform, but not transferred or stored)
- DNA and genetic data results

People will use this information to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

We will keep all information about you safe and secure.

Some of your information (but none indicated with an asterisk above *) may be sent to collaborators in other countries. They must follow our rules about keeping your information safe.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

What are your choices about how your information is used?

- You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.
- If you choose to stop taking part in the study, we would like to continue collecting information about your health from central NHS records, your hospital or your GP. If you do not want this to happen, tell us and we will stop.
- We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.
- If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study.

Where can you find out more about how your information is used?

You can find out more about how we use your information

- At https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/data-protection-and-information-governance/gdpr-guidance/templates/template-wording-for-generic-information-document/
- Our leaflet available on predictpd.com
- By asking one of the research team

- By sending an email to predictpd@qmul.ac.uk or data-protection@qmul.ac.uk
- By ringing us on 020 7882 8953.

Data Flow Overview

