King's College Hospital NHS
NHS Foundation Trust

KING'S College LONDON

Participant information sheet

Intelligent Parkinson early detection guiding novel supportive interventions (i-PROGNOSIS)

Special data collection study (S Data collection study)

Dear participant,

Parkinson's disease (PD) is a slow progressive condition, generally starting in middle to older age. PD presents with motor symptoms (such as shaking in particular of the hands and arms, stiffness of the muscles, and slowness of movements) and non-motor symptoms (such as sleep problems, pain, cognitive problems, changes in mood, constipation, and olfactory disturbances). PD can be treated symptomatically by multidisciplinary care including medication and supportive therapies but cannot be cured.

Furthermore, in spite of the knowledge that some symptoms such as rapid eye movement (REM) sleep behaviour disorders (RBD), hyposmia (a reduced ability to smell and to detect odours) and major depression can predate the diagnosis of Parkinson's for years, no specific system has been developed for earlier treatment of PD when the early symptoms and signs (prodromal) develop.

The i-PROGNOSIS project is funded by European Horizon 2020 research grant and sponsored by King's College London and King's College Hospital NHS Foundation Trust. It aims to collect data from a wide participant group including healthy volunteers and patients with PD in order to develop tests for early detection of PD. This research focuses on identification of specific symptoms (movement and non-motor) which can aid a future diagnosis of PD. This will also help to identify potential patients with prodromal PD symptoms as soon as neuroprotective treatment is available. Furthermore, the project will develop strategies to improve and maintain health related quality of life of patients with PD.

The i-Prognosis Project covers different stages, in which you as a study participant can take part at any time you prefer. The first stage of the i-Prognosis Project, the so called GData Phase, collects general data from the use and interaction of study participants with their smartphones by the i-Prognosis App. This phase will run in parallel with SData phase till the end of the project. The i-

PROGNOSIS app runs on the smartphone silently in the background and will capture the use and interaction of study participants with their smartphone during daily activities. This i-Prognosis GData Study was evaluated positively by the East Dulwich Research Ethics Committee (ethical ID: 17/L0/0909). The next stage of the i-PROGNOSIS Project, the so called SData Study aims to perform a medical evaluation protocol as well as to broaden the i-Prognosis App with a Smartwatch.

What is the purpose of the project?

The aim of the i-PROGNOSIS project is to investigate whether the i-PROGNOSIS app can help to identify patterns that are associated with already known movement and non-motor symptoms of PD. Furthermore, the data gathered from this project will help to develop an optimized app and corresponding computer programs which can recognise changes in behaviour related to movement and non-motor symptoms, which might be indicative of early PD. This happens primarily in the GData study.

The Special data collection study (SData phase) is a continuation of GData study of i-PROGNOSIS project. The purpose and goal of the the SData phase is to get concomitant (simultaneous) assessment of motor and non-motor symptoms suggestive of PD by movement disorders specialists in addition to the objective data being captured by the smart watch and the i-PROGNOSIS app. SData phase study also aims to optimize the i-Prognosis App as well as the corresponding computer algorithms.

Who can participate?

In the SData Study three different groups of possible participants are defined in the following:

- Group 1: Study participants of the GData Study, who have contacted King`s College Hospital actively by themselves to obtain a medical evaluation only, after they were notified that they are eligible via the iPrognosis (GData study) app.
- Group 2: Study participants of the GData Study, who have contacted King`s College Hospital actively by themselves to obtain a medical evaluation, after they were notified that they are eligible via the iPrognosis (GData study) app, and who would like to expand their participation in the i-PROGNOSIS Project by participating in the SData Study.
- Group 3: Healthy people and patients with Parkinson`s disease between 40 and 90 years of age (without prior participation in the GData Study), who will be evaluated medically and participate in the SData study.

Why have I been invited?

You have been invited to take part in the project because you are either a healthy volunteer or a patient with PD between the age of 40 and 90. You may or may not have participated in G Data collection study previously. If you have participated in GData study, you may have been invited because your gathered data suggests you may or may not have a higher probability of risk of developing Parkinson’s through substantial data screening and computer learning algorithm system analysis. We expect that approximately 20-30 people across the UK will take part.

Do I have to take part and what will happen if I don't want to carry on with the project?

No. It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the routine clinical care you receive. You will still receive your planned treatment.

What will happen to me if I take part and what data will be collected in the SData Study?

If you are participating in the GData study and receiving automatic notification within the i-Prognosis App, you will be contacting King´s College Hospital for an outpatient appointment. You will be informed about two different options of participation in the SData study.

Firstly, you can just consent to a medical evaluation only (which will be described later). However, if you are interested to further participate in the i-Prognosis project, we would ask you to consent for a medical evaluation, as well as 2 outpatient follow up appointments. If you agree, we would add a smartwatch next to the i-Prognosis App aiming to measure further motor and non-motor symptoms being indicative for PD.

If you are a healthy person or a patient with PD and have not yet participated in the i-Prognosis project, we would like to ask you to download the i-Prognosis App for free from the Google play store and consent for the GData Study as explained in the electronic participant information and electronic consent form (Version 4, 09.08.2017, ethic ID17/L0/0909) in addition to this SData study.

Your participation in the SData study requires your written informed consent. SData study covers a comprehensive medical evaluation which includes clinical neurological examination as well as further evaluation of motor and non-motor symptoms of PD. Cardinal motor symptoms of PD like tremor, brady- and hypokinesia (slow movement), rigidity, gait and balance are measured based on validated scales and questionnaires as well as established diagnostic tests. Medical history, non-motor symptoms (e.g. sleep, mood, cognition), general wellbeing and general quality of life are asked with the help of validated scales and questionnaires. Instrumental diagnostics which consist of standard procedures such as the measurement of height, body weight, lying and standing blood pressure, heart rate and olfactory (smell) test will be performed.

In addition, you will be provided with a smartwatch to capture additional motor and non-motor symptoms being indicative for PD. You will be asked to wear the smartwatch throughout the day to mainly capture physical activity, movements during eating and parameters of sleep. Information about your sleep will be captured by the smartwatch sensors. You will be asked to start the capturing when going to bed and stop it after waking up. Accelerometer data will be recorded for 1 minute after you woke up to detect and evaluate tremor. All data captured with the smartwatch will be stored temporarily on the user's smartphone and they will be uploaded later in pseudo-anonymised form on the Cloud for further analysis. You will be provided instruction on how to operate the devices properly, relevant safety precautions to consider and how to contact the study team at King`s College in case you require further assistance.

The SData study contains a follow up visit that will include medical evaluation and instrumental diagnostics tests between 6-9 months after the first visit. This aims to recognize any change of PD-related motor and non-motor symptoms as well as to capture possibly new symptoms of PD over the time.

Where and for how long will my data be stored?

The data obtained during the medical evaluation will be reported on a paper case report form which will be stored at King`s College Hospital site in a double locked cupboard, fire secured and password protected cupboard. Furthermore the data collected in the paper case report forms will be transferred to electronic data bank, called the Open Clinica platform and this data will be stored on a secure server with restricted access of the Aristotle University of Thessaloniki, Greece. The transfer will take place over Secure Sockets Layer (SSL) connections. All data collected, in the paper case report form as well as in the Open Clinica platform will be pseudo-anonymised. This means that the data will be not connected to your name but by a so-called identifier. The identification of your data is only possible by the local study team principal investigator.

All data obtained by the i-Prognosis App via the smartphone will be transferred and stored as described in the SData Study informed consent

The data obtained by the smartwatch will be handled in the same way as the data obtained by the use of the i-Prognosis App as described in the SData Study informed consent. This means that the pseudo-anonymised data will be sent on secure Microsoft Azure cloud servers of Microsoft data centres located in Europe. The data will be stored there for at least three years. Microsoft Azure platform is one of the most compliant with international and European regulations for data exchange and storage. Whilst cloud storage is used the ultimate destination for the storage of anonymised data is the Aristotle University of Thessaloniki (Greece). At the end of the Azure subscription, data will be downloaded on Aristotle University of Thessaloniki (Greece) secure servers of the Department of Electrical and Computer Engineering and they will be stored there indefinitely.

Who is responsible for data protection?

For the data obtained during the medical evaluation reported on a paper case report forms, the study team of King`s College London is responsible. For the data stored in the electronic data bank and data obtained by the smartwatch, the Microsoft Azure Innovation Center Greece and the Aristotle University of Thessaloniki, Greece, are responsible for the data protection and the monitoring of good practices in terms of data management by the rest of the i-PROGNOSIS members. The all gathered data will be moved to the Aristotle University of Thessaloniki, Greece after 3 years (on completion of the study).

Who has access to my data?

Your data will be coded. This means your most identifiable data, such as your name and date of birth, is replaced by a numerical and alphabetical identifier. Your data will be sent to the secure Microsoft Azure cloud servers, where your consent form and data will be held separately. The data will be stored there for at least three years. The Microsoft Azure platform is one of the most compliant with international and European regulations for data exchange and storage. Cloud storage is a cloud computing model in which data is stored on remote servers accessed from the Internet. Whilst cloud storage is used, the ultimate destination for the storage of coded data is the Aristotle University of Thessaloniki (Greece). At the end of the Azure subscription, data will be downloaded on Aristotle University of Thessaloniki secure servers of the Department of Electrical and Computer Engineering and will be stored there indefinitely.
This study obtained data can be stored on an electronic data storage medium and can be transferred in coded form (without name or initials but instead a number and letter code) to the

following persons:

- The principal investigator and sub investigators of the study as well as specific members of the i-PROGNOSIS consortium for scientific analyses and publication of the results.
- I understand and agree that all of my coded data from this study will be used for future research.

What are the possible benefits of taking part?

By participating in this project, you will be contributing to a European Horizon 2020 project which is likely to optimise an app to help early detection of PD. This could improve the management of Parkinson's and the development of future neuroprotective treatments. This project might also offer wider benefits to society and those with similar conditions.

What you may gain is possibly that unaware movement and non-motor symptoms are recognised by the App and these symptoms will be examined with a comprehensive medical evaluation protocol in an outpatient setting. Symptoms which might be indicative of early Parkinson's disease will be examined and each study participant will be individually advised and evaluated by a movement disorders specialist.

What are the possible disadvantages and risks of taking part?

We do not anticipate any direct disadvantages or risks in taking part. Some participants might experience a psychological burden to undergo further medical evaluation by a medical expert with the risk of being diagnosed with Parkinson`s disease or that any other health related pathological finding that might be obtained. However, by taking part they would be fully supported by the research team and medical expert throughout this process.

Who is organising and funding this project?

The project is led by Professor K Ray Chaudhuri and his research team at King's College London and is being co-sponsored by King's College Hospital in the UK. The i-PROGNOSIS, part of which is this study, is coordinated by Professor Leontios Hadjileontiadis and his research team at Aristotle University of Thessaloniki, Greece. The project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement number No 690494.

How have patients and the public been involved in this project?

This project has been extensively reviewed by patients and members of the public throughout Europe (Greece, France, Germany, Belgium and Sweden). The review in the UK included an evening multidisciplinary team group clinic at King's College Hospital NHS Foundation Trust as well as an expert patient group called 'Community for Research Involvement and Support by people with Parkinson's (CRISP)'.

Who has reviewed this project?

This is Horizon 2020 grant which is one of the most prestigious grant awarded by the European Union. Currently, one in 20 such grant applications are successful. The grant process goes through

a long and vigorous review of the methodology, statistics and aims. There is a stringent security protocol for all data collected.

Furthermore, all research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This project has been reviewed and given favourable opinion by Surrey Borders Research Ethics Committee (18/LO/0074). It has also been approved by the Health Research Authority and each local hospital will also give confirmation that the project can go ahead.

What if there is a problem?

If you have a concern about any aspect of this project, you can contact the i-PROGNOSIS helpdesk via email (info@i-prognosis.eu).

In case you have any remaining queries please feel free to contact our team at King's College Hospital: Professor K Ray Chaudhuri, Neurology Department, King's College Hospital, telephone: 0203 299 8336, email: kch-tr.PDresearch@nhs.net

Will my taking part be kept confidential?

Certainly, your clinical data as well as your SData will be transferred from the application to an electronic data storage medium that contains the project data of all participants. All data is coded to avoid the possibility of linking your consent form (containing your identifiable information) with the data from your everyday smartphone and smartwatch use. Furthermore you can withdraw your consent at any point in time without any implications. The project results will be published without any personally identifiable information.

Your name will not be used in any reports about the project and all data is stored in accordance with the Data Protection Act 1998.

Thank you

Thank you for considering taking part in this project and taking the time to read this information sheet.

Contact for Further Information

Should you want further information about the project please contact:

Professor K Ray Chaudhuri

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