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Hospital and Health Service
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i-PROGNOSIS

Participant Information Sheet and Consent

TITLE:	i-PROGNOSIS (Intelligent Parkinson early detection guiding novel supportive interventions)
Project ID:	41562 HREC/18/QPCH/266
SPONSOR:	Sunshine Coast Hospital and Health Service, in collaboration with King's College London
PRINCIPAL INVESTIGATOR:	Dr. Sanjay Gangadharan Sunshine Coast Hospital and Health Service
CHIEF INVESTIGATOR:	Professor K Ray Chaudhuri Neurology Department, King's College Hospital
CONTACT:	Dr. Sanjay Gangadharan E-mail: kch-tr.PDresearch@nhs.net

Dear participant,

Parkinson's is a slow progressive condition, generally starting in middle to older age. Parkinson's 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). Parkinson's 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 Parkinson's when the early symptoms and signs (prodromal) symptoms develop.

The i-PROGNOSIS project is funded by European Horizon 2020 research grant and sponsored by King's College London. It aims to collect data from a wide participant group including healthy volunteers and patients with Parkinson's in order to develop tests for early detection of Parkinson's. This research focuses on identification of specific symptoms (movement and non-motor) which can aid a future diagnosis of Parkinson's disease in clinic. This will also help identify and enrich the sample of early Parkinson's as soon as at neuroprotective treatment is available.

Furthermore, the project will develop strategies to help improve and maintain health related quality of life of patients with Parkinson's.

We would like to obtain data from the interaction of healthy controls as well as Parkinson's patients with their smartphone. This data, namely GData (general data), comprises of analyses of speech, movement, non-motor symptoms like mood. This data was identified based on our existing knowledge of movement and non-motor symptoms in Parkinson's. The GData will be collected by a mobile application. In order to participate as project participant you will need to download the i-PROGNOSIS app via the (phone application centre on phone) Google Play Store on your Android smartphone which is free of cost. Firstly, you will be asked to provide electronic informed consent on the phone app in order to participate in this project. Following this, the i-PROGNOSIS app will run on your smartphone silently in the background and will capture your use and interaction with your smartphone during daily activities. This allows the project to collect data of your daily interactions with your smartphone and possible changes. This will not interfere with how you would normally use your phone or its daily functioning.

What is the purpose of the project?

The aim of the i-PROGNOSIS project is to investigate whether the iPrognosis app can identify differences in the patterns of participant phone use which may be associated with already known movement and non-motor symptoms of Parkinson's. This study is part of a larger project which is hoping to develop a smartphone application which can identify early onset of Parkinson's. The first step of this study is to see if we can develop computer algorithms that can tell the difference between smartphone use in the general population and those who show Parkinson's type symptoms.

In order to do this, this study will need to collect a large enough amount of participant data to see if any identifiable differences between participant phone use can be detected.

Furthermore, the data gathered from this project will also help to optimise the app and corresponding computer programs to better recognise changes in participant behaviour which are related to movement and non-motor symptoms, which might correlate with early Parkinson symptoms.

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 Parkinson's between the age of 40 and 90. We expect that approximately 250 people across Australia will take part.

Do I have to take part?

No. It is up to you to decide whether or not to take part and you can withdraw from the project at any time without giving any explanation. If you decide to take part you will be asked to sign an electronic consent form with which you agree to participate in the project. You can receive further information via the application and the i-PROGNOSIS website (http://www.i-prognosis.eu/?page_id=1772). This website link takes you directly to the GData study where you can find all the relevant information. If you have questions that are not clarified by the information provided, you can contact the i-PROGNOSIS helpdesk via email (info@i-prognosis.eu). This service is available 24 hours a day.

In case you have any remaining queries please feel free to contact the team at King's College Hospital, on behalf of Dr. Sanjay Gangadharan: Neurology Department, King's College Hospital, email: kch-tr.PDresearch@nhs.net.

What will happen to me if I take part?

As GData collection is performed by the i-PROGNOSIS application, you can participate at any time by downloading the application from (applications storage on phone) the Google Play Store. For the application to be functional, you need to provide electronic informed consent for the GData collection project. When you use the app for the first time you will be asked to provide some clinical information to capture if you are using the app as a healthy volunteer or a person with Parkinson's. This information includes age, date of birth, gender, personal health status state, family history (and whether a diagnosis of Parkinson's is known or not known in your family), education and how long you have been using a smartphone for. GData is collected in an unobtrusive way during your interaction with your smartphone when performing daily tasks. The data captured will include characteristics of your speech when making a phone call (this will not capture the personal content of your call), of your typing when writing a text message, your facial expression and elements only in 'selfies' (will not store any identifiable image features or data) and your movements when holding the smart phone.

What data will be collected?

The first time you use the app, we will ask you if you are healthy, have a family history of Parkinson's or if you have been diagnosed with Parkinson's. We will also ask you for your age, date of birth, your gender, your level of education and how long you use a smartphone. Thereafter, the GData captured in the background by the iPrognosis app include:

- Characteristics of your voice when making a phone call. The personal content of your call is never stored.
- How steady you hold your phone during calls or typing, using device sensors, such as the accelerometer.

- Keystrokes-related data when you type using the i-PROGNOSIS Keyboard. What you type is never recorded.
- The distance you covered each day, if you have location services activated and carry your phone around.
- Emotional content from your stored text messages. The content of your messages is not stored.
- Facial expressions from your stored photos. Photos never leave your device.

Where and for how long will my data be stored?

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.

Who is responsible for data protection?

Microsoft Innovation Center Greece is responsible for the data protection and the maintenance of good practice. Further, Aristotle University (Greece) has relevant contracts in place with Microsoft Azure to ensure the data management is compliant with EU law. All i-PROGNOSIS collaborators are responsible for keeping all coded information safe and secure once downloaded to local sites.

What are the possible benefits of taking part?

By participating in this project you will be contributing to a European Horizon 2020 project which may help to develop an app in the future. This app may be able to help assist in the early detection of Parkinson's.

What are the possible disadvantages and risks of taking part?

There are no foreseen disadvantages or risks in taking part in this project.

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 sponsored by European Commission Horizon 2020.

In Australia, the study is led by Dr. Sanjay Gangadharan (Sunshine Coast Hospital and Health Service), in collaboration with Professor K Ray Chaudhuri and his

research team at King's College London. 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). This 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 a Horizon 2020 grant which is awarded by the European Union. 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 Australia 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 the The Prince Charles Hospital Human Research Ethics Committee.

What will happen if I don't want to carry on with the project?

You can withdraw your consent at any point in time and stop participation and further data collection by selecting the "Withdraw option" in the app. By uninstalling the application, further data collection will cease, but any information that you have already provided in the project will be kept. This data will still remain anonymous.

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). This service is available 24 hours a day.

In case you have any remaining queries please feel free to contact the team at King's College Hospital, on behalf of Dr. Sanjay Gangadharan:

Neurology Department, King's College Hospital
Email: kch-tr.PDresearch@nhs.net.

Will my taking part be kept confidential?

Certainly, your clinical data as well as your GData 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 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.

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, on behalf of Dr. Sanjay Gangadharan:

Neurology Department
King's College Hospital
Email: kch-tr.PDresearch@nhs.net

CONSENT

I have read the information and have therefore understood the content and consequences of the study as well as the necessary requirements for participation.

I was provided with the contact information to clarify any remaining questions and this was for me understandable and satisfactory. I have had enough time to decide about my participation in this study.

I authorise the collection, processing, use and disclosure of my pseudo-anonymised data in electronic database(s) for use in research as indicated in the "Will my data be kept confidential?" Section and based on my preferences configured through the app Settings.

As my participation in this study is voluntary, I can withdraw my consent at any time without giving reasons and without any implications.

YOUR SIGNATURE INDICATES THAT YOU HAVE READ AND UNDERSTAND THE ABOVE INFORMATION AND THAT YOU HAVE DECIDED TO PARTICIPATE BASED ON THE INFORMATION PROVIDED. A COPY OF THIS FORM WILL BE AVAILABLE TO DOWNLOAD THROUGH THE "CONSENT" SECTION OF THE APPLICATION.

☐ AGREE ☐ DISAGREE

Name Date Country