Constipation and changes in the gut flora in Parkinson's disease: A Pilot Study

Participant Information Leaflet for potential participants with Parkinson's disease

Lead investigator: Dr Isobel Sleeman

You are invited to take part in a research study. Before you decide whether or not to take part, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully. Discuss the study with others, such as relatives or your General Practitioner (GP), if you wish.

Ask us if there is anything that is not clear or if you would like more information.

Take time to decide whether you wish to take part.

Thank you for reading this.

What is the purpose of the study?

The purpose of this study is to investigate if there is a link between Parkinson's disease and the gut. While Parkinson's is often considered to be a neurological disorder, it is strongly associated with constipation, which often develops years before other symptoms occur. If it can be shown that gut changes precede other Parkinson's symptoms, this may offer insights into the development of the disease. Previous studies have looked at the range and number of bacteria in the gut, but the results have been inconsistent. We plan to recruit participants with a new diagnosis of Parkinson's disease and a healthy member of the same household (e.g., partner or spouse) to act as a comparison (healthy volunteer). We plan to collect stool samples to look for differences in the bacteria, fungi and other species between Parkinson's patients and healthy volunteers.

We would also plan to test if an established technique for measuring body muscle and fat (bio-impedance analysis) is reliable in people with tremor associated with Parkinson's disease.

The study is likely to last six months, however, each individual can expect to be involved for approximately two months.

Why have I been invited to take part?

You have been invited to take part as a you have been newly diagnosed Parkinson's disease.

Do I have to take part?

No, taking part is completely voluntary. We appreciate that you have very recently had a significant diagnosis, and that this is likely to be a difficult time for you and your family. As such, we would like you to have at least three days to think about whether you'd like to take part in the study. During this time and afterwards, you are welcome to contact us to ask questions about the study before you decide if you'd like to take part. The contact email address and phone numbers are at the end of this leaflet.

If you decide to take part, we will ask you to sign a consent form. If you decide not to take part, you do not need to give a reason. Your decision will not affect the care you receive now or in the future. Similarly, if you do start the study, you will be free with withdraw at any time without giving a reason, and your care will be unaffected.

What will happen to me if I take part?

If you decide to take part, you will be invited to the Rowett Institute (part of the University of Aberdeen based at the Foresterhill Health Campus) for two research visits

At your first visit, you will have an opportunity to discuss the study further and if you are happy to proceed, you will be asked to complete a consent form.

During the first visit:

- You will be asked a number of questions about your health and medications
- Undergo a clinical examination to determine the severity of your Parkinson's disease
- You will be asked to complete a number of questionnaires about symptoms of your Parkinson's disease, bowel symptoms, swallowing and day to day activities.
- We will check your weight and height
- We will test your taste sensitivity using standardized taste strips
- We will ask you to drink a small glass of water while you are being videotaped
- We will assess your body composition (of fat, water, muscle etc) using a technique called bio-. This involves having stickers attached to your hand and foot (like you would for an electrocardiogram (known as an ECG)) and a very mild electrical current run between the two. This is painless as the current is too mild to be felt.

The first visit is expected to last approximately an hour.

After the first visit, you will be asked by telephone to recall what you have eaten and drunk over the previous 24 hours, as a way of assessing your dietary intake.

You will also be asked to collect two stool samples at home and post them to the Rowett Institute. Instructions, suitable containers and envelopes for posting will be provided. Stool samples will be disposed of when they have been analysed.

You will be invited to your second visit approximately four weeks later to repeat the bio-impedance and swallowing tests. We will also ask you if there have been any changes to your health or medications between the first and second visit or if you have agreed to participate in any other research studies. The second visit is expected to take less than 20 minutes. We are based at the Foresterhill Health Campus and have a car park specifically for volunteer visits which is very close to the clinical trials centre. Travel expenses will be available for both visits.

Your data will be stored in an anonymised form for six years after the end of the study. They will be stored securely on a University of Aberdeen computer server.

There are no lifestyle or other restrictions for participants of this study.

Study Timeline

What are the possible benefits of taking part?

We do not anticipate that you will directly benefit by being involved in this study. There is the possibility that the information we get from the study may help us to treat patients with Parkinson's disease better, however, it is almost certain that further studies would be needed before treatment could change.

What are the possible disadvantages and risks of taking part?

We don't anticipate any disadvantages or risks with taking part in this study. Like any study, the time commitment may be a disadvantage and some people might consider collecting a stool sample unpleasant.

Can I decide not to carry on with the study?

Yes, you can withdraw at any time without having to give us a reason. However, if you feel comfortable enough to discuss your withdrawal reason with us, we would be interested in hearing your thoughts.

Will my information be kept confidential?

Yes. All information which is collected about you during the course of the research will be kept strictly confidential. Any information about you which leaves the hospital/surgery will have your name and address removed so that you cannot be recognised from it. Any publications will not contain any identifiable information.

Study information including your medical records may be reviewed by people from outside the study team, who have a duty to ensure that we are running it properly. These people are likely to work for the University of Aberdeen or NHS Grampian but may also come from organisations which regulate research.

Identifiable data will be kept separately from the research data (e.g. results of clinical examination, stool sample analysis). We will ask permission to share your anonymised data with other researchers to be used in ethically reviewed and approved future studies.

If you are unable to continue the study because you no longer have the mental ability (capacity) to agree, we will stop collecting information and samples. However, we may use the anonymised data that we have collected up to that point in the analysis with your consent.

With your consent, we will inform your GP of your participation in the study.

We ask your permission to contact your GP if there are any unexpected findings. For example if we find blood in the stool sample or anything else that may require further investigation. If this were to happen, we will discuss it with you and handle the matter with appropriate urgency.

We will ask for your consent to review your medical notes for up to ten years as part of this research project. This would be to determine if there was any correlation between the findings at baseline and future progression of a person's Parkinson's disease. We will ask the same for controls in order to have a comparison.

Finally we will ask for permission to contact you about future ethically reviewed and approved research studies. Your contact details will be stored securely in line with data protection laws for up to ten years if you agree.

How will we use information about you?

We will need to use information from you and from your medical records for this research project.

This information will include your name, NHS number and contact details. 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.

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. 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 www.hra.nhs.uk/information-about-patients/

by asking one of the research team

by sending an email to dpa@abdn.ac.uk, or

by ringing us on 01224 272596

What will happen at the end of the study?

When the results of the study are known, a report will be generated from the study, which may result in presentations and publications. If you wish, we can inform you of the results. We may also organise local events where the general public and people with Parkinson's disease can find out about the results and ask questions.

At the end of the study, the data will be archived in accordance with the policies of the University of Aberdeen and will be destroyed six years after the study is completed.

Who has organised and funded the research?

This study has been funded by both the NHS Grampian Endowment Fund and the Institutional Strategic Support Fund (ISSF), administered by the University of Aberdeen with the funding coming from the Wellcome Trust.

The study is sponsored by the University of Aberdeen.

Who has reviewed the study?

The study has been reviewed by the [North of Scotland] Research Ethics Committee.

What if there is a problem or something goes wrong?

If you have a concern about any aspect of this study, you should ask to speak to the

researchers who will do their best to answer your questions [07980 000016].

Contact details for further information:

Dr Isobel Sleeman

Room 1.127 Polwarth Building,

Foresterhill Health Campus,

University of Aberdeen,

Aberdeen,

AB25 2ZD

[**07980 000016**]

If you are unhappy with the response, you can contact the Research Governance team via 01224 437220 or by emailing researchgovernance@abdn.ac.uk.

Thank you for taking the time to read this.