Departments of Anatomy and of Medicine, Dunedin,
and Department of Medicine, Christchurch (UOC)
University of Otago

Principal Investigators:
Professor John Reynolds, Dept of Anatomy
Professor Tim Anderson, Dept of Medicine (UOC)
Dr Nick Cutfield, Neurologist, Dept of Medicine
Dr Mariana Leriche Vazquez, Dept of Anatomy
Dr Toni Pitcher, Dept of Medicine (UOC)

PARTICIPANT INFORMATION SHEET

Failure of the habit system as a biomarker of Parkinson's disease.

Locality:	**Dunedin**	Ethics committee ref.:	
Lead investigators:	**Prof John Reynolds / Prof Tim Anderson (UOC)**	Contact phone number:	**Dunedin 03 479 5781 Christchurch 03 378 6075**

Thank you for showing an interest in this project. Please read this information sheet carefully before deciding whether or not it is appropriate for you to take part. Your participation is entirely voluntary. If you decide not to take part, you don't have to give a reason, and it will not affect any future care or treatment. If you do agree to take part in the study, you are free to withdraw at any time without having to give a reason and this will in no way affect any future health care.

This Patient Information Sheet provides information about the study that will help you decide if you'd like to take part. Before making your decision you may want to talk about the study with other people, such as your legal representative, family, whānau, friends, or healthcare providers. Feel free to do this.

If you agree to take part in this study, you will be asked to sign the Consent Form on the last page of this document. You will be given a copy of both the Participant Information Sheet and the Consent Form to keep.

What is the Aim of the Project?

This research project aims to validate a computer-based test for the detection of Parkinson's Disease (PD). The computer-based test is designed to detect changes in habitual responding (i.e., the movements we do automatically). Evidence suggests that PD initially damages the brain areas controlling habits. This research will hopefully help us in the future to increase our accuracy in diagnosing PD and to identify patients with PD at earlier stages of the disease than is currently possible.

What will Participants be Asked to Do?

If you decide to take part, we would like you to attend our Research Facility in Dunedin at the University of Otago, Wellcome building, corner of Great King St. and Frederick St., only once. We would like you to agree to have an examination to measure your motor function and perform a couple of tasks, twice during that visit, separated by 1.5 hours. The tasks are:

1. Pressing 2 keys on your keyboard during 30 seconds with each hand and
2. Play a simple computer car game (4 times for approximately 1min each).

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What Type of Participants are we looking for?

- Men and women aged between 30 and 90 years old, diagnosed with PD in the last 5 years, with normal cognition (PD group) AND
- Men and women aged between 30 and 90 years old, who are **NOT** diagnosed with PD, with normal cognition (control group).

Please make sure that you inform the study staff if any of the following criteria apply to you. This may make you ineligible for participation in this study:

1. A first-degree relative with PD (parents, sibling and/or children).
2. Having received a diagnosis of 'Rapid eye movement sleep behavioural disorder' (RBD) of unknown cause. RBD is associated with enacting behaviours and movements while asleep and dreaming.
3. Having received a diagnosis of cognitive impairment.

What Are The Side Effects And Risks?

We do not foresee any side effects or risks of taking part in this study.

Will I be paid for my participation on this project?

No, you will not be paid to participate in this study. However, we will reimburse any out-of-pocket expenses that you or your support person incur from participating in the assessment appointments e.g. travel expenses to attend appointments.

Will there be any costs for my participation on this project?

No. There will be no costs for you regarding this project.

Can Participants Change their Mind and Withdraw from the Project?

You may withdraw from this project at any time and without any disadvantage of any kind. In addition, the study staff may decide to withdraw you from the study if you have any unexpected side effects from the treatment or if they have any other concerns.

What Information will be Collected and What Use will be Made of it?

We will ask you to complete a questionnaire to gather the following information: gender, ethnicity, date of birth, family history of PD, the presence of any symptoms that might have some association with the later development of PD, exercise habits, handedness, education and computer game experience.

The results of this study will be published in an international scientific journal. The data included in this publication will in no way be linked to any specific person and your identity will not be recorded with the data. If you want access to your personal data later you will need to record the identification number used for your particular tests. You are most welcome to request a copy of the results of the project should you wish. These will be

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available once all the data is analysed, two years following the commencement of the study, nominally in early 2021.

The data collected will be securely stored in such a way that only those involved in the research program will be able to gain access to it. At the end of the project any personal information will be destroyed immediately except that, as required by the University's research policy, any raw data on which the results of the project depend will be retained in secure storage for ten years, after which it will be destroyed.

What if you have any Questions?

If you have any questions about our project, either now or in the future, please feel free to contact us via:

Dr Mariana Leriche Vazquez, Dept. of Anatomy, 03 479 73 73 or email mariana.lerichevazquez@otago.ac.nz.

Professor John Reynolds, Dept. of Anatomy, 03 479 5781 or leave a message with the Dept of Anatomy, 03 479 7362.

ACC statement

In the unlikely event of a physical injury as a result of your participation in this study, you would be eligible to apply for compensation from ACC just as you would be if you were injured in an accident at work or at home. This does not mean that your claim will automatically be accepted. You will have to lodge a claim with ACC, which may take some time to assess. If your claim is accepted, you will receive funding to assist in your recovery.

If you have any questions about ACC please feel free to ask the researcher for more information before you agree to take part in this trial. If you have private health or life insurance, you may wish to check with your insurer that taking part in this study won't affect your cover.

Health and Disability Statement

If you have any queries or concerns about your rights as a participant in this study you may wish to contact a Health and Disability Services Consumer Advocate, telephone: (03) 479 0265 or freephone 0800 37 77 66 or freefax 0800 2787 7678 (0800 2 SUPPORT) or email advocacy@hdc.org.nz. If there is a specific Maori issue/concern please contact Linda Grennell at 0800 377 766.

This project has been reviewed and approved by the Health and Disability Ethics Committee (Ref:).

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CONSENT FORM FOR PARTICIPANTS AND SUPPORT PERSON(S)

Failure of the habit system as a biomarker of Parkinson's disease.

I have read the Participant Information Sheet concerning this project. All my questions have been answered to my satisfaction. I understand that I am free to request further information at any stage.

Interpreters may be available on request. Please make the study staff aware if you would like an interpreter to be available.

1. I have read and I understand the information sheet dated 30/04/18 for volunteers taking part in the study designed to validate a computer-based test for detection of Parkinson's disease. I have had the opportunity to discuss this study. I am satisfied with the answers I have been given.
2. I have had the opportunity to use whānau support or a friend and/or legal representative to help me ask questions and understand the study.
3. I understand that taking part in this study is voluntary (my choice), and that I may withdraw from the study at any time, and this will in no way affect my future health care.
4. I understand that my participation in this study is confidential and that no material that could identify me will be used in any reports on this study.
5. I understand that the test will be stopped if it should appear harmful to me.
6. I understand the compensation provisions for this study.
7. I have had time to consider whether to take part in the study.
8. I know who to contact if I have any side effects from the study.
9. I know who to contact if I have any questions about the treatment used in this study or about the study in general.
10. If I decide to withdraw from the study, I agree that the information collected about me up to the point when I withdraw may continue to be used. Y N
11. I agree to my GP or other current provider being informed of my participation in this study and of any new findings that may require follow up. Y N

I _____ hereby consent to take part in this study.

Participant Signature: | |

Date: | |

_____

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Full name of researcher obtaining consent:	
Project role:	
Signature:	
Date:	

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