Departments of Anatomy and Medicine,
Dunedin,University of Otago

Principal Investigators:
Professor John Reynolds, Dept of Anatomy
Dr Ben Brockway, Respiratory Physician, Dept of Medicine
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PARTICIPANT INFORMATION SHEET

Detecting changes in habits in rapid eye movement sleep behaviour disorder (RBD): a pilot study.

Locality:	**Dunedin**	Ethics ref.: 19/STH/219	
Lead investigator:	**Prof John Reynolds**	Contact phone number:	**Dunedin 03 479 5781**

You are invited to take part in a study on automatic movements and a particular kind of sleep problem called Rapid eye movement sleep Behaviour Disorder or RBD. Whether or not you take part is your choice. If you don't want to take part, you don't have to give a reason, and it won't affect the care you receive. If you do want to take part now, but change your mind later, you can pull out of the study at any time.

This Participant Information Sheet will help you decide if you'd like to take part. It sets out why we are doing the study, what your participation would involve, what the benefits and risks to you might be, and what would happen after the study ends. We will go through this information with you and answer any questions you may have. You do not have to decide today whether or not you will participate in this study. Before you decide you may want to talk about the study with other people, such as 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.

This document is 7 pages long, including the Consent Form. Please make sure you have read and understood all the pages.

What is the purpose of the study?

Rapid eye movement sleep behaviour disorder (RBD) is a sleep problem where people act out their dreams with vocal sounds and sudden, often dramatic arm and leg movements. RBD is related to Parkinson's disease (PD) but receiving one diagnosis does not necessarily means an individual will receive the other. The aim of this project is to investigate if people with RBD show disruption of the automatic control of movements and if this is related to the risk to develop PD. The results obtained in the present study will help us to confirm if the malfunctioning of automatic movements is specific for people diagnosed with Parkinson's disease (PD) or, if it is also present in other neurological conditions such as RBD. This knowledge would help us understand better these neurological conditions and maybe allow us to diagnose them earlier.

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The present study is funded by the Otago Medical Research Foundation and it has been granted ethical approval by the Southern Health and Disability Ethics Committee. The investigators involved in this study and their affiliations in Dunedin are:

Prof. John Reynolds. Professor of Neuroscience, Dept. of Anatomy, Otago University.
Dr Mariana Leriche Vazquez. Assistant Research Fellow, Dept. of Anatomy, Otago University.
Dr Nick Cutfield. Neurologist, Dept of Medicine, Southern District Health Board, Dunedin Public Hospital.
Dr Ben Brockway. Consultant and Senior Lecturer in Respiratory Medicine, Department of Medicine, Dunedin School of Medicine. University of Otago.

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.

Why I've been chosen/invited to participate?

Because you fulfil the characteristics required to volunteer as part of our group of healthy participants or participants with RBD. The characteristics we are looking for are:

1. Men or women, aged between 30 and 90 years old.
2. With normal thinking and memory skills for their age.
3. Without any sleep condition or diagnosed with RBD, as well as people who answer yes to the following question: "Have you ever been told, or suspected yourself, that you seem to 'act out your dreams' while asleep (for example, punching, flailing your arms in the air, making running movements, etc.)?"

Some people cannot be considered for the study since it would affect the interpretation of the results. Those include: people with a diagnosed neurological condition causing slowness of movement and tremor and/or rigid arms or legs and people taking certain medications intended to control those symptoms. A researcher on the study will check your medications.

What will my participation in the study involve?

If you decide to take part, we would like you to attend to Dunedin Hospital at 201 Great King Street, Dunedin Central. The study requires only one visit of approximately 1 hour and a half. We would like you to agree to have an examination to measure your mobility, complete a couple of tasks on the computer and reply to some questions asked by the researcher as well as filling out a separate questionnaire. Some health information will be asked among these questions. Some of these commonly asked questions about your health you might find sensitive, specifically the questions about obsessive behaviour, urinary and constipation problems and the use of certain medications and/or

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drugs. You may wish to decline to answer some of these questions - this will not affect your ability to partake in the remainder of the study.
We will calculate your probability to develop PD with the data available. You will be asked if you want to be informed or not of this result at the end of this document.

For detailed step by step description of the procedures please read the following paragraph in italics:
After signing the consent form, we would measure the mobility of your neck, arms and legs. Next you would complete 2 tasks on the computer:

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 1 min each).*

Then, the researcher will:

- *Ask you some general questions (age, education, etc.) and assess your thinking and memory skills.*
- *Ask you some questions about aspects of experiences of daily living, and finally, you will complete a short questionnaire.*

What are the possible benefits and risks of this study?

Participation on this study may not provide any direct benefit to you personally. Similarly, we do not foresee any side effects or physical risks of taking part in this study. However, disclosure of risk of future development of PD could have some psychological cost: we calculate your probability based on the information you provide and in accordance with a threshold proposed by experts in the field, allowing us to supposedly identify people with high probability to develop PD opposed to those who doesn't. This information is generally used only for research purposes and often fails as a predictor for individuals (for example, in a large study with 650 participants 5 of them where identified with a high probability but only 2 of them developed PD).

Before deciding if you want to know your result you may consider the possible consequences:
Disadvantages:

1. The results may lack accurate predictive value
2. If you happen to be classified in the high risk group, knowing this information could trigger negative psychological effects
3. Currently, there is no drug to cure or slow down the progression of PD

And advantages:

1. If you are in the high risk group, you may be diagnosed earlier and be proactive in making future decisions.

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 incur from participating in the assessment appointment i.e. travel expenses to attend appointments will be reimbursed with petrol vouchers.

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What if something goes wrong?

If you were injured 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 private health or life insurance, you may wish to check with your insurer that taking part in this study won't affect your cover.

What are my rights?

It is entirely up to you to decide if you want to take part in this study, you are free to decline to participate or to withdraw from the research at any time, without experiencing any disadvantage. If you decide to participate, you have the right to access the information we have collected about you. You also have the right to decide if you do or do not want to know if we find out any information that could have some impact on your health.

The information/results of our computer tests will be collected with an identification code. These will be kept in the Race4PD database or a computer under password protection. The researcher testing the participants (Dr Leriche) would assign the participant an identification code which will be also kept in a password protected computer. The information we collect will be kept de-identified and confidential.

What happens after the study ?

The results of this study will be published in an international scientific journal. The data included in that 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 available once all the data is analysed, 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, 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.

Who do I contact for more information or if I have concerns?

If you have any questions, concerns or complaints about the study at any stage, you can contact:
Professor John Reynolds, Dept. of Anatomy
Telephone number: 03 479 5781 (or leave a message for Professor Reynolds with the Dept. of Anatomy, 03 479 7362)
Email: john.reynolds@otago.ac.nz

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If you want to talk to someone who isn't involved with the study, you can contact an independent health and disability advocate on:

Phone: 0800 555 050
Fax: 0800 2 SUPPORT (0800 2787 7678)
Email: advocacy@advocacy.org.nz
Website: https://www.advocacy.org.nz/

Māori health support.
To ensure ongoing cultural safety, the Southern District Health Board encourage those who identify as Māori, and who are participating in health research or clinical trials, to seek cultural support and advice from their own Kaumātua or Whaea in the first instance, or please contact Te Ara Hauora Māori Liaison Service in the Southern DHB:

Wendi Raumati
Kaiāwhina
Te Ara Hauora - Māori Health Liaison Service
Dunedin Hospital
Phone 4740 999 ext 58649

You can also contact the health and disability ethics committee (HDEC) that approved this study on:

Phone: 0800 4 ETHICS
Email: hdecs@moh.govt.nz

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CONSENT FORM FOR PARTICIPANTS

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Please tick to indicate you consent to the following

I have read, or have had read to me in my first language, and I understand the Participant Information Sheet.		
I have been given sufficient time to consider whether or not to participate in this study.		
I have had the opportunity to use a legal representative, whanau/ family support or a friend to help me ask questions and understand the study.		
I am satisfied with the answers I have been given regarding the study and I have a copy of this consent form and information sheet.		
I understand that taking part in this study is voluntary (my choice) and that I may withdraw from the study at any time without this affecting my medical care.		
I consent to the research staff collecting and processing my information, including information about my health.		
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 processed.		
I wish to be informed of my probability to develop Parkinson's disease calculated in the study. If yes, you will be contacted at the end of the study (December 2020 or later) to reconsent to receiving this information.	Yes ☐	No ☐
Only reply if you answered YES to the previous question. I consent to my GP or current provider being informed about my participation in the study and of any significant abnormal results obtained during the study. If yes please provide their contact number/email here:	Yes ☐	No ☐

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I agree to an approved auditor appointed by the New Zealand Health and Disability Ethic Committees, or any relevant regulatory authority or their approved representative reviewing my relevant medical records for the sole purpose of checking the accuracy of the information recorded for the study.	
I understand that my participation in this study is confidential and that no material, which could identify me personally, will be used in any reports on this study.	
I understand the compensation provisions in case of injury during the study.	
I know who to contact if I have any questions about the study in general.	
I understand my responsibilities as a study participant.	
I wish to receive a summary of the results from the study.	Yes ☐ No ☐

Declaration by participant:
I hereby consent to take part in this study.

Participant's name:

Signature: Date:

Declaration by member of research team:

I have given a verbal explanation of the research project to the participant, and have answered the participant's questions about it.

I believe that the participant understands the study and has given informed consent to participate.

Researcher's name:

Signature: Date: