PARTICIPANT INFORMATION STATEMENT AND CONSENT FORM

Treadmill-based gait adaptability: effects of ageing and Parkinson's disease on brain activity
Chief Investigator: Dr Jasmine Menant

1. What is the research study about?

You are invited to take part in this research study. The research study aims to understand how well you can adapt your walking pattern under time constraints when you are walking on a treadmill. For this purpose, we record your brain activity during this task in a non-invasive manner. The data will be compared across groups of young versus older people, and people with Parkinson's disease versus healthy age and sex-matched controls. For older people, the data will also be explored in the context of fall risk.

2. Who is conducting this research?

The study is being carried out by the following researchers:

Role	***Name***	***Organisation***
Chief Investigator	*Dr Jasmine Menant*	*NeuRA*
Co-Investigator/s	*Professor Stephen Lord*	*NeuRA*
	Dr Yoshiro Okubo	*NeuRA*
	A/Prof Juno Kim	*UNSW*
	Mr Cameron Hicks (PhD student)	*NeuRA*
	Dr Paulo Henrique Silva Pelicioni	*NeuRA, UNSW*
	Ms Priscila Nobrega De Sousa (PhD student)	*UNSW*
	Ms Kulvara Lapanan (PhD student)	*UNSW*
	Ms Carly Chaplin	*NeuRA*

3. Inclusion/Exclusion Criteria

Before you decide to participate in this research study, we need to ensure that it is ok for you to take part. The research study is looking recruit people who meet the following criteria:

- Aged 18 years and older.
- Living independently in the community.
- Able to walk for 15 minutes consecutively without an aid (self-reported).
- Able to understand and communicate in English.
- Mini-Mental State Examination (MMSE) score of 24 or above indicating no cognitive impairment.

Participants who meet the following criteria will be excluded from the study:

- History of stroke or transient ischemic attacks (TIA).
- Being colour blind.
- Recent surgery that may affect your ability to walk or recover balance.
- Excessive fear of falling, anxiety disorder or psychological distress that would prevent walking comfortably on a treadmill (please note that prior experience with walking on a treadmill is not required).

In addition, participants are required to fit into **one** of the following inclusion groups:

Group 1 (Healthy Young Adults) and Group 4 (Healthy Controls to match Parkinson's Disease Participants)

- Aged 18 years and over.
- No diagnosis of a progressive neurological or psychiatric condition (e.g. Parkinson's Disease, Multiple Sclerosis).

Group 2 (Older Adults)

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- Aged 70-90 years.
- Sufficient visual & auditory acuity and have a close informant (weekly contact of > 1 hour), preferably.
- No previous diagnosis of dementia.
- No psychotic symptoms or a diagnosis of schizophrenia or bipolar disorder, multiple sclerosis, motor neuron disease, developmental disability, progressive malignancy (active cancer or receiving treatment for cancer, other than non-metastatic prostate and skin cancer).
- No medical or psychological conditions that may prevent them from completing assessments.

Group 3 (Parkinson's Disease)
- Diagnosis of idiopathic PD (UK PD Brain Bank criteria).
- No significant freezing of gait that can impact overground and treadmill walking ability.
- No diagnosis of another progressive neurological or psychiatric condition (e.g. dementia, Multiple Sclerosis).

4. Do I have to take part in this research study?
Participation in this research study is voluntary. If you do not want to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the study at any stage.

If you decide you want to take part in the research study, you will be asked to:
- Read the information carefully (ask questions if necessary).
- Sign and return the consent form if you decide to participate in the study.
- Take a copy of this form with you to keep.

5. What does participation in this research require, and are there any risks involved?
If you agree to participate you will be asked to complete the following research procedures:

Screening: A screening questionnaire asking about components of the inclusion and exclusion criteria will determine if you are eligible to take part. Completion of the screening measures will be administered to you in a telephone call or email. If the screening process shows that you meet the criteria for inclusion, then you will be able to start the research project, and we will organise a time for you to visit our lab. If the screening questionnaire shows that you cannot be in the research project, we will thank you for your time.

If you meet the inclusion criteria and agree to participate, you will be required to attend a one-off assessment conducted at NeuRA (n Randwick). The assessment will take approximately 2 hours including breaks.

Consent: The study will see you meet a researcher from Neuroscience Research Australia (NeuRA, Barker Street, Randwick 2031) who will provide you with a detailed description of the testing procedure/s and answer any questions you may have before asking you to give your written consent.

Assessments: Upon coming to the lab, the assessor will take you through a series of assessments.

Part A – Descriptive Assessments (approximately 45mins)
- *Thinking and attention tasks* – You will be asked to complete a short battery of standard tests to evaluate different aspects of attention, speed of thinking and orientation.
- *Fear of falling* – You will be asked to complete a short survey asking about concern about falls.
- *Falls risk assessment* – You will be asked to undertake measurements of your vision, sensation, leg muscle strength, reaction time and standing balance.
- *Parkinson's disease specific assessments* – If you meet the Group 3 inclusion criteria, you will also be asked to undertake a series of questions and physical tasks related to any dyskinesia symptoms (involuntary, uncontrolled movements) you may have.

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Part B – Main Assessment (approximately 60mins)

- You will be fitted with the fNIRS (functional near-infrared spectroscopy) system to measure brain function while performing walking tasks. You will be required to wear a cap fitted with small optical sensor devices (optodes) and a small backpack holding the recording system. This is a safe and non-invasive method. The process of placing the optodes on your scalp can cause minor discomfort, but this is uncommon.
- You will also be fitted with six sensors attached with tape over your clothes and shoes on the lower back , chest, wrists, and feet to record your movements during walking.
- You will then be fitted with a harness for your safety before being asked to walk on a treadmill. While walking at a self-selected comfortable speed, you will be instructed to step and avoid avoiding stimuli displayed as lit squares (green and red squares) on the surface of the treadmill. There will be three experimental blocks where you will be walking for 2-5 minutes at a time. You will be given rest breaks between blocks.

Part C – Online Questionnaires (approximately 15-20mins)

- If you meet the Group 3 inclusion criteria, you will also be asked to complete a series of online questionnaires about your basic health, physical activity, general lifestyle and falls history.

Additional Costs and Reimbursement: There are no costs associated with participating in this research project and as this project is based on voluntary participation, you will not be paid to take part. However, as a token of our appreciation, you will receive a $30 gift voucher to reimburse you for any reasonable travel, parking and other expenses while completing the assessments.

Study Risks:

- There is minimal risk of muscle strain or a fall as a result of the testing protocol, however the risk is very low.
- There is minimal risk of experiencing discomfort wearing the fNIRS cap as the sensors put slight pressure on the skull with may give rise to a mild headache; this subsides immediately when taking off the cap.
- There is minimal risk of experiencing some nervousness, shortness of breath or other exercise-related discomforts when walking on the treadmill. Appropriate supervision, warm-up exercise and wearing the safety harness will minimise the risks. If you experience discomfort or distress at any time during the assessments and training, please notify a staff member immediately.

To minimise the risks of these harms/discomforts, the study protocol will be carried out by trained research assistants and/or students supervised by the primary investigator, with procedures developed to minimise these risks/discomforts. In the event of a stressful situation or if you feel discomfort wearing the fNIRS cap, assessment will be immediately interrupted, the fNIRS cap taken off, and you will be seated for a break. If necessary, a first aid / medical officer is available on-site at NeuRA.

If participation in the study brings up stress or anxiety, listed below is a suggestion for a free and widely available phone and web-chat counselling service:

Beyond Blue (free 24-hour phone support or web chat 3-12pm AEST).

- Website https://www.beyondblue.org.au/
- Telephone 1300 224 636

The benefits outweigh these potential risks of discomfort/harm because the study outcome will enhance our knowledge of the mechanisms underlying fear of falling in older adults.

6. What are the possible benefits of taking part?

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While there are no direct benefits of participating in this study for you as the participant, findings from this study will improve our understanding on the mechanisms underlying our ability to adapt our walking pattern with time pressure to maintain balance and avoid falling. Results from this project will guide our future research, to investigate if an intervention involving training in this complex walking task might improve efficiency of brain processing and people's ability to deal with perturbations during walking and prevent falls.

You will be able to receive a fall risk assessment report outlining your performance on a variety of sensorimotor assessments, relative to age-matched norms. The report will include information on how to lower your risk of falls. In the event of inadvertent health findings during the research, the test results will be communicated to you and to your general practitioner with your permission.

7. What will happen to information about me?
By signing the consent form, you consent to the research team collecting and using information about you for the research study.

The research team will store the data collected from you for this research project for:
- A minimum of 5 years after the publication of the research results.

The information about you will be stored in a:
- Re-identifiable format where any identifiers such as your name, address, and date of birth will be replaced with a unique code.

You will be asked to provide your consent for the research team the share or use the information collected from you in future research that:
- Will be specific to the aims of this research.

Your information will only be shared in a format that will not identify you.
- Information collected from you in an electronic format stored on a NeuRA password protected Supported Platform, only accessible to the approved research investigators.
- Information collected from you using paper-based measures will be stored at NeuRA in a locked location and only the approved research investigators will have access to this information.

The information you provide is personal information for the purposes of the Privacy and Personal Information Protection Act 1998 (NSW). You have the right of access to personal information held about you by the University, the right to request correction and amendment of it, and the right to make a complaint about a breach of the Information Protection Principles as contained in the PPIP Act. Further information on how the University/NeuRA protects personal information is available in the UNSW Privacy Management Plan and the NeuRA Privacy Policy.

8. How and when will I find out what the results of the research study are?
The research team intend to publish and/ report the results of the research. All Information will be published in a way that will not identify you. If you would like to receive a copy of the results you can let the research team know by inserting your email or mailing address in the consent form. We will only use these details to send you the results of the research.

9. What if I want to withdraw from the research study?
If you do consent to participate, you may withdraw at any time. You can do so by completing the 'Withdrawal of Consent Form' which is provided at the end of this document, or you can ring the research team and tell them you no longer want to participate. Your decision not to participate or to withdraw from the study will not affect your relationship with UNSW Sydney or NeuRA. If you decide to leave the research study, the researchers will not collect additional information from you. You can request that any identifiable information about you be withdrawn from the research project.

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10. What if I have a complaint or any concerns about the research study?
If you suffer any injuries or complications as a result of this research project, you should contact the study team as soon as possible and you will be assisted with arranging appropriate medical treatment.

Complaints Contact
If you have a complaint regarding any aspect of the study or the way it is being conducted, please contact the UNSW Human Ethics Coordinator:

Position	UNSW Human Research Ethics Coordinator
Telephone	+ 61 2 9385 6222
Email	humanethics@unsw.edu.au
HC Reference Number	HC230093

11. What should I do if I have further questions about my involvement in the research study?
The person you may need to contact will depend on the nature of your query. If you require further information regarding this study or if you have any problems which may be related to your involvement in the study, you can contact the following member/s of the research team:

Research Team Contact Details & Chief Investigator

Name	Dr Jasmine Menant
Position	NeuRA Senior Research Fellow
Telephone	+61 9399 1267
Email	j.menant@neura.edu.au

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Consent Form – Participant providing own consent

Declaration by the participant

- ☐ I understand I am being asked to provide consent to participate in this research study;
- ☐ I have read the Participant Information Sheet, or someone has read it to me in a language that I understand;
- ☐ I understand the purposes, study tasks and risks of the research described in the study;
- ☐ I provide my consent for the information collected about me to be used for the purpose of this research study only.
- ☐ I have had an opportunity to ask questions and I am satisfied with the answers I have received;
- ☐ I freely agree to participate in this research study as described and understand that I am free to withdraw at any time during the study and withdrawal will not affect my relationship with any of the named organisations and/or research team members;
- ☐ I understand that I will be given a signed copy of this document to keep.
- ☐ I understand that the results of the research will be made available upon publication.
- ☐ I would like to receive a copy of the study results via email or post, I have provided my details below and ask that they be used for this purpose only.
- ☐ I understand and acknowledge data collected may be used for the purpose of future research and that any personal identifiers will be removed.

Name:_____

Address: _____

Email Address: _____

Optional consent for future research:

- ☐ I provide my consent for my name and contact details to be retained in a register so I can be contacted about other research projects in the future.

Participant Signature

Name of Participant (please print)	
Signature of Research Participant	
Date	

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Declaration by Researcher*

☐ I have given a verbal explanation of the research study; its study activities and risks and I believe that the participant has understood that explanation.

Researcher Signature*

Name of Researcher (please print)	
Signature of Researcher	
Date	

* An appropriately qualified member of the research team must provide the explanation of, and information concerning the research study. All parties signing the consent section must date their own signature.

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Form for Withdrawal of Participation

I wish to **WITHDRAW** my consent to participate in this research study described above and understand that such withdrawal **WILL NOT** affect my relationship with The University of New South Wales and NeuRA.

- ☐ I am withdrawing my consent and I would like any identifiable information collected about me which I have provided for the purpose of this research study withdrawn.

- ☐ I am withdrawing my consent to participate in further components of this research and provide my permission for the research team to retain and/or use information collected about me which I have provided for the purpose of this research.

Participant Signature

Name of Participant (please print)	
Signature of Research Participant	
Date	

The section for Withdrawal of Participation should be forwarded to:

CI Name	Dr Jasmine Menant
Email	j.menant@neura.edu.au
Phone	+61 9399 1267
Postal Address	Neuroscience Research Australia Falls, Balance and Injury Resarch Group Margarete Ainsworth Building Barker Street Randwick 2031 NSW

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