PARTICIPANT INFORMATION LETTER

PROJECT TITLE: Improving walking stability in people with Parkinson's disease using real-time feedback

APPLICATION NUMBER:	**(2018-196H)**
PRINCIPAL INVESTIGATORS:	Dr Mark Creaby
	Dr Michael Cole
STUDENT RESEARCHER:	Kate McMaster
STUDENT'S DEGREE:	Bachelor of Exercise and Sport Science (Honours)

Dear Participant,

You are invited to participate in the research project described below.

What is the project about?
This research project aims to investigate how feedback during walking may assist with improving walking stability in people with Parkinson's disease (PD). Most falls experienced by individuals with PD occur during walking and those who fall are more likely to fall exhibit different walking patterns. In this study we will investigate whether training to change walking patterns can improve walking stability in people with PD who have a history of falling. By analysing the responses to the training we will be better able to understand potential paths for future research and interventions that may be able to prevent falls in this population.

Who is undertaking the project?
This project is being conducted by Kate McMaster and will form the basis for her Honours degree in Exercise and Sport Science at Australian Catholic University under the supervision of Drs Mark Creaby and Michael Cole. Dr Mark Creaby is a biomechanist and Senior Lecturer at ACU, with experience in movement training research. Dr Michael Cole, also a biomechanist and Senior Lecturer at ACU, has extensive experience in working with people with Parkinson's through a range of research studies.

Are there any risks associated with participating in this project?
The risks associated with participating in this project are considered to be low. However, as with any study involving exercise there is always a slight risk of injury. To minimise this risk you will only be able to participate in this study if you are able to walk without assistance, and are under the age of 80 years and have normal or corrected to normal vision. Fatigue and feeling unstable may also be issues when participating in this study, however we will allow as many rest breaks as needed with chairs placed at either end of the walkway. Prior to the experiment you will be given time to familiarise with the laboratory to ensure you are comfortable with the different tests and walking in the laboratory. The tasks involved in this study are similar to common activities of daily life and, hence, are considered to pose no greater risk than these activities.

In the unlikely event of a fall, first aid officers will be available to provide assistance, and if necessary emergency services will be contacted.

What will I be asked to do?

If you agree to participate in this study you will be required to attend two sessions, one week apart. These assessments will take place in the biomechanics laboratory, on the Brisbane campus of Australian Catholic University.

Session 1 (up to 2.5 hours)

We will assess your vision, cognition, and the symptoms of your Parkinson's disease through a series of tests, which include answering questions and completing tasks such as identifying shapes and memory recall. You will also be asked to complete a written questionnaire based on your previous falls history.

Following these assessments, we will place a series of motion sensors on your skin, to track your movements as your walk in the laboratory. For these to work, you will be required to wear short shorts and for females to wear a sports bra or crop top and males to be shirtless. If you do not feel comfortable being shirtless, you may choose to wear a singlet that we have designed to cover your chest and stomach whilst holes in the singlet will allow for the placement of the sensors. Example photos of some body wearing the markers are shown on the separate sheet.

Throughout each walking assessment your movements will be captured using a multi-camera 3D motion analysis system. Please note that the motion analysis system does not capture your physical image, just the position of the markers in space as you move.

You will be asked to walking under the following three conditions:

i) Baseline Walking: You will be asked to walk along a 35-metre indoor/outdoor sealed walkway approximately 5 times at your own comfortable speed.
ii) Intervention: You will receive feedback on a walking parameter, and you will be asked to respond to this feedback whilst walking. This will take approximately 10-20 minutes.
iii) Post-intervention: Another walking trial will require you to walk 10-metres approximately 5 times.

At the conclusion of each condition you will be asked a few questions regarding the difficulty of the task and how confident you felt while completing the task.

Session 2: (up to 1.5 hours)

(This session will take place 6 to 8 days after session 1.)

In this session, we will assess your walking patterns again, to evaluate if there have been any longer-term changes in your walking patterns. We will place the motion sensors on your skin, the same as in Session 1, and as Session 1, shorts and singlets will be provided. Only your normal comfortable speed walking will be assessed in this session. You will be required to walk 10-metres approximately 5 times. At the conclusion of the task, you will be asked a few questions regarding the difficulty of the task and how confident you felt while completing the task.

What are the benefits of the research project?

There are no immediate benefits from participating in this study. However, all participants who participate will be contributing to further understanding the potential for movement training in people with Parkinson's disease. In general, the findings we receive from this study will be able to assist us in designing future research that may help in reducing the risk of falls in PD.

Can I withdraw from the study?
Participation in this study is completely voluntary. You are not under any obligation to participate. If you agree to participate, you can withdraw from the study at any time without adverse consequences. If you decide to withdraw from the study, you can elect to have any data collected prior to your withdrawal excluded from the final analysis and deleted.

Will anyone else know the results of the project?
In order to maintain your confidentiality, your data will be de-identified using a numeric code only known to the investigators. Aggregate results from this study may be presented at scientific conferences and/or published in a scientific journal.

Will I be able to find out the results of the project?
Given the nature of this research, each participant's personal data is not likely to be meaningful without comparison to the data collected for other participants. As such, participant's individual data will not be provided, but interested individuals are encouraged to sign up to receive a summary of the results as soon as the project is completed.

Who do I contact if I have questions about the project?
If you have any questions about this project do not hesitate to contact either Kate McMaster, or Dr Mark Creaby. Contact details are found at the bottom of this information letter.

What if I have a complaint or any concerns?
The study has been reviewed by the Human Research Ethics Committee at Australian Catholic University (review number 2018-196H). If you have any complaints or concerns about the conduct of the project, you may write to the Manager of the Human Research Ethics and Integrity Committee care of the Office of the Deputy Vice Chancellor (Research).

Manager, Ethics and Integrity
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Any complaint or concern will be treated in confidence and fully investigated. You will be informed of the outcome.

I want to participate! How do I sign up?

If you agree to participate in this project, please contact Kate McMaster (details provided below) to indicate your interest in participating. All participants will be required to complete an informed consent form prior to participation.

Thank you for taking the time to consider this information and we look forward to discussing this research with you soon.

Yours sincerely,

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