MOVEMENT DISORDERS RESEARCH AND REHABILITATION CENTRE
WILFRID LAURIER UNIVERSITY

INFORMED CONSENT STATEMENT

Can Virtual reality technology be used to improve dynamic balance reducing falls in those with PD?

INFORMATION

You are invited to participate in a research study at the Sun Life Financial Movement Disorders Research and Rehabilitation Centre at Wilfrid Laurier University. The purpose of my thesis is twofold. Firstly, I aim to expand on previous literature and its limitations by assessing the effectiveness of virtual reality and its ability to improve balance. Providing researchers and individuals with Parkinson's with more reliable and significant data, on the basis, that virtual reality improves balance. Secondly, I aim to take virtual reality testing further by utilizing a full immersion virtual reality simulation. This study will be conducted by Luke Simpson with the supervision of Professor Quincy Almeida from the Department of Kinesiology and Physical Education, and Director of the Sun Life Financial Movement Disorders Research and Rehabilitation Centre at Wilfrid Laurier University.

This study will include 36 participants who have been diagnosed with idiopathic Parkinson's disease and will last 12 weeks. You will be randomly assigned to one of three groups. You will be asked to complete all testing and intervention protocol/sessions on your regular dopaminergic medication, prescribed for Parkinson's disease. The first session will occur one week before the start of the trial and will last approximately 1 hour and 45 minutes. During this session, Professor Almeida (PhD) will assess your disease severity using a clinical scale called Unified Parkinson's Disease Rating Scale (UPDRS), you will also be scored on the timed up and go test, the sensory organization test (on the Biodex System^{TM} SD), and your gait parameters will be assessed (walking on the Zeno Walkway^{TM}). You will also be asked to complete the PDQ-39 questionnaire, the activities-specific balance confidence (ABC) scale survey and the falls efficacy scale survey (FES). You will be given a practice trial before the start of the TUG, SOT and walking tests. You will also be asked two questions, the first, "Have you fallen recently?" and the second, "how many times?"

Starting one week later, you will begin the intervention training which occurs three times per week. Where you will be completing your experimental protocol, depending on the group that you have been randomly assigned to. At the end of every week you will be asked two questions, the first, "Have you fallen recently?" and the second, "how many times?" After the experimental protocol is complete (three months later) you will be post tested. These tests will be the same as the pre-tests highlighted above. The testing procedure will be repeated one month later as a follow up, to identify any retained learning.

RISKS

Virtual Reality Intervention: Due to the increased visual input from full immersion in the virtual reality system, there is a chance that you may become dizzy or feel sick (simulator sickness). In this scenario please notify the researcher so that he can remove the apparatus and have you rest. You will be allowed to rest until ready to continue.

PDSAFEX Intervention: This part of the experiment requires you to follow an exercise protocol guided by trained individuals. As a result, you may become fatigued and/or feel unsteady while walking. There is also an inherent risk of falling while completing the experimental conditions, mainly when performing the task without vision. However, there will be spotters walking beside you in every task in case you need any assistance. If you feel fatigued please notify the researcher and a volunteer so they can assist you into a comfortable position where you can rest until you feel able to continue. The researcher can give as much time as you want for resting. The tasks to be performed in this study may challenge you. Therefore, we ask you do not worry if you think you are not performing the way you think you should. Try to complete the tasks as best as you can and we will offer any constructive critiques to technique both individually and as a group. However, please, inform any discomfort, at any time, so the researcher can take the necessary action to ensure the discomfort is reduced or removed.
If at any point, you feel that you are unable to continue, you can withdraw yourself from the study at any time by notifying the researchers.

BENEFITS
There are multiple benefits to this study. There are some direct and indirect benefits to the participants. Participants could be directly affected by the virtual reality intervention in that, they see improved dynamic balance, decreased falls and an increased quality of life. Furthermore, the Parkinson's disease society can be impacted indirectly, as a whole. This research aims to provide quantitative data on the effectiveness of VR in improving balance. The data could strengthen previous literature and/or set a new standard for rehabilitative techniques used to address balance in those individuals with Parkinson's.

CONFIDENTIALITY
All participants in the database at the Sun Life Financial Movement Disorders Research and Rehabilitation Centre have been assigned a letter code for identification. In the present study, you will be assigned an identification number. Only the primary researcher Luke Simpson will be aware of the association between the coding system, your identification number, your personal information given, and the experimental data collected. The informed consent forms will be stored separately from experimental data. Informed consent forms will be stored in an alarm secured, locked room at the MDRC. All experimental data will be kept on a secure, password locked computer in which all files are encrypted. Results will be reported as group effects. If the need arises in which an outlier must be acknowledged, participants will only be identified by their identification number. You will never be identified in any presentations or publications of the research study.

CONTACT
If you have questions at any time about the study or the procedures, (or you experience adverse effects as a result of participating in this study) you may contact the researcher, Luke Simpson, at 66 Hickory West, and 519-884-0710 x 3924, or by email at simp0290@mylaurier.ca. This project has been reviewed and approved by the Wilfrid Laurier University Research Ethics Board. If you feel you have not been treated according to the descriptions in this form, or your rights as a participant in research have been violated during the course of this project, you may contact Prof. Robert Basso, Chair, University Research Ethics Board, Wilfrid Laurier University, (519) 884-1970, extension 4994 or rbasso@wlu.ca.

PARTICIPATION
Your participation in this study is voluntary; you may decline to participate without penalty. Participation in this study will not affect your affiliation or participation in other studies going on at the centre. If you decide to participate, you may withdraw from the study at any time without penalty and without loss of benefits to which you are otherwise entitled. If you withdraw from the study, every attempt will be made to remove your data from the study, and have it destroyed. You have the right to omit any question(s)/procedure(s) you choose.

FEEDBACK AND PUBLICATION
The study's results may be presented in conferences, workshops, classes, or published as an article in a scientific journal. You will also receive an updated summary of the findings from this study by way of an annual handout or luncheon event from the MDRC that will update the participants on all of the research being conducted at the Sun Life Financial Movement Disorders Research and Rehabilitation Centre. Additionally, you are welcomed to visit the MDRC and view hung posters that summarize findings of each study conducted at the MDRC.

CONSENT
I have read and understand the above information. I understand that the results uncovered by this research will be presented in journal articles and conference presentations. I have received a copy of this form. I was informed that I may withdraw my consent at any time without penalty by advising the researcher. I agree to participate in this study.

I wish to be contacted for future research at the Movement Disorder Research and Rehabilitation Centre.

_____ **Yes** _____ **No**

Participant's name _____ Date _____

Participant's signature _____ Date _____

Investigator's name _____ Date _____

Investigator's signature _____ Date _____