PARTICIPANT INFORMATION SHEET

The progressive effect of relapsing-remitting multiple sclerosis on gait variability using a body-fixed accelerometer

Investigators

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PURPOSE OF THE STUDY:

The purpose of this study is to use a body-fixed motion sensor to investigate the variability (instability) of the stride pattern in people with relapsing-remitting multiple sclerosis, and to compare the results to individuals with different levels of disease progression and to a healthy, age- and sex- matched control group.

BACKGROUND:

Multiple sclerosis (MS) is a degenerative disease of the central nervous system that can cause a variety of debilitating symptoms. Some of these symptoms have been shown to cause changes in gait variability, which can decrease mobility related to quality of life and increase the risk of falling. By studying how gait changes throughout the progression of MS, a better understanding will be developed of how and when motor control changes occur, while quantifying the magnitudes of these changes, which will provide an objective measure for clinical assessment of disease severity and treatment options. Therefore, this study will attempt to answer several questions about gait variability in people with MS using a body-fixed sensor (accelerometer) as a measurement device.

PROCEDURE:

In this study, you will walk for up to 10-minutes around a 200-metre track at a self-selected walking speed. A motion sensor will be placed on your lower back with a strap. This sensor will track your body’s movements as you walk. The recorded movements will be used to assess the variability of your stride using specialized data analysis software.

Prior to the walking trial, we will collect basic demographic information (e.g. height and weight), as well as some information about your history with multiple sclerosis. We will use this information to classify the stage of your MS according to an accepted scale (EDSS), allowing for the comparison of walking data at various stages of the disease. You will also complete a questionnaire: the Modified Fatigue Impact Scale. This questionnaire is a reliable
and valid instrument that will be used to help control for the effects of fatigue on gait, respectively. The session will take approximately 45 minutes.

RISKS:

There are no known risks or side effects associated with participating in this study. The study involves analyzing your stride pattern during normal everyday walking conditions (i.e., preferred speed and flat terrain). You are advised to stop walking if you begin to feel tired or unsteady at any point during the test.

WILL I BENEFIT IF I TAKE PART?

Your participation in this study is on a voluntary basis. You will not receive any direct benefit or compensation for your participation in the study.

CONFIDENTIALITY / FREEDOM TO WITHDRAW:

Individual subject codes (e.g. Subject 1A) will be the only reference to any presentation of individual data. The data will be stored securely with an electronic password or in a locked filing cabinet, where only the investigators will have access to participant information. There are no circumstances that would require the investigator to directly identify any participants of the study. The results of this research study may be used for a Master’s thesis, journal articles, and conference or clinical presentations. You are free to withdraw from the study at any time prior to the release of the published results. The estimated release date of the study results is December 2018.

This project has been approved by the Research Ethics Board of the University of Regina and Regina Qu’Appelle Health Region. If you have any questions or concerns about your rights or treatment as a research participant, you may contact the Chair of the University Research Ethics Board by phone at (306) 585-4774 or by e-mail at research.ethics@uregina.ca.

Should you have any questions or wish to discuss the procedures or objectives of the study, please contact Russell Kohrs via phone (306-450-3531) or e-mail (rakohrs@uregina.ca).