Title: The Effect of Binasal Occlusion on Balance Following a Concussion: a Randomized Controlled Trial Protocol

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Universitéd'Ottawa
Faculté des sciences de la santé
École des sciences de la réadaptation

University of Ottawa
Faculty of Health Sciences
School of Rehabilitation Sciences

Consent form

Title of the study: The effects of binasal occlusion glasses on balance following a concussion

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Invitation to Participate: You are invited to participate in the abovementioned research study conducted by Dr. Sveistrup, Jacquie van Ierssel, Elizabeth Legace, Jennifer O'Neil, and Coralie Rochefort.

Purpose of the Study: The purpose of this study is to learn more about the recovery of balance following a concussion. We are interested in learning if wearing a pair of glasses that partially blocks vision can improve an individual's balance after they have had a concussion.

Participation: If you decide to participate in this study, you will be asked to complete one 60-minute balance testing session. You will complete this session at the Action Potential Rehabilitation clinic or at the Core Sports & Manual Physiotherapy clinic. At the beginning of the session, we will ask you to complete four questionnaires asking you about specific symptoms, your work history, and previous head injuries. You will then be asked to complete a series of balance tasks while standing on a BTrackS Balance Board. You will be asked to stand on two feet with your eyes open and with your eyes closed. You will also be asked to complete a cognitive task while standing on the BTrackS Balance Board. For the cognitive task, you will be asked to do a timed reading test. While you complete these balance tasks, a headband that measures the movements of your head will be placed around your head, a strap that measures the movements of your torso will be placed around your torso and you will be asked to wear a pair of glasses that video records eye movements and your environment.A part of your vision will be blocked while you complete some of these tasks.

Risks: There is very little risk in participating in this study. At most, you may become tired while completing the balance tests. However, you may request to take a rest at any time.

Benefits: You will not get any personal benefit from being part of this study.

Confidentiality and anonymity: The information that you share will remain strictly confidential. The contents will be used only for generalized data (i.e. not participant-specific)and your confidentiality and anonymity will be protected through the use of participant codes.

Conservation of data: The data collected (hard copies and electronic data) will be kept in a secure manner. All hard copies will be kept in a locked file cabinet in a locked office. The master list of codes and signed informed consent forms will be stored separately in a locked file cabinet. All electronic data will be stored on a laboratory computer and will be password protected.

Compensation: If you decide to participate, you will receive one $10 Tim Horton's gift card. We will also reimburse any costs associated with parking.

Voluntary Participation: Participation is voluntary and if you choose to participate, you can withdraw from the study at any time and/or refuse to answer any questions, without suffering any negative consequences. If you choose to withdraw, your treatment will not be affected, and all data gathered until the time of withdrawal will be destroyed.

Acceptance: I, _____ agree to participate in the above research study conducted by Dr Sveistrup of the School of Human Kinetics, Faculty of Health Sciences.

If you have any questions about the study, you may contact Dr Heidi Sveistrup, Coralie Rochefort, Jennifer O'Neil, Jacquie van Ierssel, or Elizabeth Legace at 613-562-5800 ext 7099.
If you have any questions regarding the ethical conduct of this study, you may contact the Protocol Officer for Ethics in Research, University of Ottawa, Tabaret Hall, 550 Cumberland Street, Room 154, Ottawa, ON K1N 6N5
Tel.: (613) 562-5387
Email: ethics@uottawa.ca

There are two copies of the consent form, one of which is yours to keep.

_____	_____	_____
Signature of Participant	**Name of Participant**	**Date**

_____	_____	_____
Signature of person obtaining informed consent	**Name of person obtaining informed consent**	**Date**