

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

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# **THE EFFECT OF BINASAL OCCLUSION ON BALANCE FOLLOWING A CONCUSSION: A RANDOMIZED CONTROLLED TRIAL PROTOCOL**

## **ABSTRACT**

### **Introduction**

While most individuals will recover within the first month after concussion, a significant number will continue to experience dizziness, balance problems, cognitive deficits, and vision problems. Single-task measures of static balance may not be sensitive enough to capture mild postural changes still associated with incomplete recovery. Increasingly there is an interest in dual-task paradigms of balance assessment as a more accurate representation of functional postural control associated with activities of daily living and sport participation. Binasal occlusion (BNO) has been proposed as a means of providing visual stabilization to improve postural control in individuals with vision-related balance problems following a concussion. The purpose of this study is to assess the efficacy of BNO during the performance of both single and dual-task conditions in adults who continue to experience dizziness one month or longer following a concussion. It is hypothesized that BNO will improve balance and saccadic eye function, and reduce symptoms. This article presents the research protocol for this study.

### **Methods and analysis**

This study is a randomized crossover design balanced with respect to first-order effects. Participants will be recruited and randomly assigned to one of two treatment sequences, binasal occlusion (BNO) or non-occluded vision. Both groups will perform the same static balance tasks, including quiet stance performed during target-focused vision and a visually based cognitive dual-task. Following a short washout period, participants will repeat the balance tasks under the alternate treatment condition. The primary outcome measure is centre of pressure (COP) velocity in both the medial-lateral (M/L) and anterior-posterior (A/P) planes and 95% ellipse. Secondary outcome measures include saccadic eye function and self-report measures of symptoms and disability (neck and dizziness related).

### **Ethics and dissemination:**

Results of this randomized controlled trial (RCT) will allow clinicians to make evidence-informed decisions regarding the management of persistent balance problems post-concussion. Ethics has been obtained through the University of Ottawa Research Ethics Board (REB #H06-17-20). Results will be disseminated at professional conferences and in manuscripts to peer-reviewed journals.

## INTRODUCTION

Concussion is defined as a traumatic brain injury induced by biomechanical forces that can result in a transient neurologic impairments (McCrorry et al., 2017). While most individuals recover within the first month after injury (McCrorry et al., 2017), up to 30% will continue to experience persistent post-concussion symptoms beyond the expected period of normal recovery (Zemek, Farion, Sampson, & McGahern, 2013). A significant number of these individuals will experience dizziness, balance problems, cognitive deficits, and vision problems after concussion, which have been associated with prolonged recovery (Lau, Kontos, Collins, Mucha, & Lovell, 2011; Lovell et al., 2006; McCrorry et al., 2017). The pathophysiologic process underlying prolonged recovery is not yet clearly defined.

As such, a multimodal assessment representing the multiple systems involved in the injury is recommended, including symptoms, cognition, balance and a clinical exam. Most research investigates the impact of concussion on these measures independently. While each of these objective measures is an integral component in the acute diagnosis of concussion, they may not independently demonstrate sufficient sensitivity to monitor recovery from the injury. A growing body of evidence suggests that physiologic recovery extends beyond current measures of clinical recovery (Kamins et al., 2017; Levac, DeMatteo, Hanna, & Wishart, 2008). This suggests that single-task measures of static balance may not be sensitive enough, however, to capture the complex demands of integrating cognition with postural strategies associated with sporting activities and functional daily tasks. Therefore, testing balance alone may not be sensitive enough to mild postural changes still associated with incomplete recovery. Increasingly there is an interest

### **Article Summary**

#### *Article focus*

- This article describes the protocol for an RCT to measure the effect of BNO on balance in adults with persistent balance problems one month or more following a concussion.

#### *Key messages*

- Disturbed balance is common post-concussion, and associated with prolonged recovery.
- High quality evidence for the use of BNO does not exist for patients with persistent balance deficits post-concussion.

#### *Strengths and limitations of study*

- This is the first RCT to examine the effect of BNO in this population.
- The results of this study will allow clinicians to make evidence-informed decisions regarding the management of persistent balance problems post-concussion.
- Other pathophysiologic mechanisms responsible for balance deficits post-concussion may affect the generalizability of results.

in dual-task paradigms of balance assessment as a more accurate representation of functional postural control. Dual-task is defined as the simultaneous performance of cognitive and a motor task, such as balance. Higher-level cognitive effort required in dual-task performance is thought to divert attention away from postural strategies, resulting in postural sway changes. This is of clinical significance, given that return to clinically normal balance is considered a prerequisite prior to returning to sports participation (McCrorry et al., 2017), which typically demands the simultaneous integration of cognitive and postural tasks. While studies on concussed athletes have demonstrated a reduction in cognitive and/or static balance tasks using dual-task paradigms (Broglio, Tomporowski, & Ferrara, 2005; Rochefort et al., 2017), these paradigms are not widely used in the clinical decision-making process for return to sport.

Within both the clinical and research setting, measurement of balance provides valuable information. Force plates are considered the “gold standard” for assessing balance by measuring centre of pressure (COP) generated from foot pressure during stance (O’Connor, Baweja, & Goble, 2016). Centre of pressure is considered a proxy measure for postural sway, a common strategy for maintaining balance. Studies of postural control in individuals 3 months or more post-concussion demonstrate a significant increase in COP displacement compared with controls (Degani et al., 2017). These changes in COP during quiet stance are primarily reflective of the vestibulospinal reflex, which relies heavily on proprioceptive input. This may not be an adequate representation of demands placed on the postural system during activities of daily living and sport, since maintenance of balance requires the complex interaction between the proprioceptive, vestibular, and visual systems.

Given that approximately half of the brain’s pathways are linked to vision (Galetta, Morganroth, et al., 2015; Rizzo et al., 2016), it’s not surprising that there has been increasing interest in assessing vision pathways to further our understanding of the pathophysiology of concussion. Research has identified impairments in oculomotor function, including saccades, in individual immediately after concussion and up to 3 months and more post-injury (Master et al., 2016). Saccades, the ability of the eyes to move rapidly and accurately between two targets, such as when reading, is typically measured objectively using video-oculography (VOG) or using clinical tests of rapid eye movement. Knowledge of the number of saccades generated or pathology in saccadic characteristics would contribute to our understanding of the underlying mechanism of prolonged reading times (Rizzo et al., 2016). This is possible by capturing objective metrics of eye movement obtained through infrared-based video-oculography.

Vision problems are common post-concussion, including subjective complaints of double or blurred vision, oculomotor problems, visual information processing, and visual attention (Yadav, Thiagarajan, & Ciuffreda, 2014). Clinical tests of oculomotor function, have been recently identified as an important component of the initial screening exam in the acute diagnosis of concussion (McCrorry et al., 2017; Patricios et al., 2017). According to a recent systematic review on oculomotor assessment in

mild traumatic brain injury, saccadic eye movements are most frequently investigated (Hunt, Mah, Reed, Engel, & Keightley, 2016). Among measures of oculomotor vision, the King-Devick Test (KDT) has become a popular sideline screening tool for concussion, due to its ability to tap into the domain of oculomotor function not otherwise assessed by best practice diagnostic tools, such as the Standardized Concussion Assessment Tool-5 (SCAT5). The KDT is a reading test of rapid number naming speed that assesses saccadic eye movement, attention, and cognitive function. In addition to its ability to diagnose an acute concussion with high sensitivity and specificity (Galetta, Liu, et al., 2015), emerging evidence supports the use of the KDT as an indicator of recovery in patients with persistent post-concussion symptoms (Rizzo et al., 2016; Subotic, Ting, & Cusimano, 2017). Previous studies have shown that the KDT test times correlate with complex cognitive processes, providing evidence of convergent validity (Subotic et al., 2017). This supports its use in a dual-task paradigm to assess balance in a concussed population.

Vision therapy is commonly prescribed for oculomotor problems prevalent following a concussion. Binasal occlusion is a safe and minimally invasive technique that has been proposed in the symptomatic management of vision-related problems, including dizziness (Ciuffreda, Yadav, & Ludlam, 2017; Gallop, 2014; Proctor, 2009). However, little is known regarding the efficacy of binasal occlusion (BNO) in vision therapy for the management of persistent balance problems in this population. The application of BNO involves blocking the middle of the binocular visual field by placing narrow strips of opaque occlusive material on the nasal portion of both lenses of a pair of glasses (Ciuffreda, 2014, Gallop 1998). The width of the tape may vary according to the individual, angled nasally inferiorly, with the width between the inner canthi recommended as a sufficient distance to provoke a subtle, yet effective response, without disrupting functional vision (Gallop, 2014).

Potential mechanisms for the effect of BNO on symptoms and subjective balance have been proposed, including stabilizing one's sense of orientation by providing a "visual anchor", improving the ability to filter out irrelevant visual information and suppress visual motion, increasing the use of ambient vision, and improving visual attention by reducing the integration of information between the two central visual fields (Ciuffreda, Yadav, & Ludlam, 2017; Gallop, 2014; Padula, Capo-Aponte, Padula, Singman, & Jenness, 2017). Visual attention in the visual cortex using visual-evoked potentials (VEP) has been shown to be impaired post-concussion (Yadav et al., 2014). Thus, improvements in visual attention and stability with BNO may allow an individual to allocate more attention to postural control. Evidence of this would be seen as improved balance during visually-based cognitive dual-task conditions.

High quality studies in the field of vision therapy in the management of concussion are lacking, as research has been limited to case studies and extrapolations from other pathologies (Ciuffreda, Yadav, & Ludlam, 2013; Ciuffreda et al., 2017; Gallop, 1998, 2014; Proctor, 2009). These studies suffer from methodological limitations such as lack of randomization and comparison groups, small sample sizes, and lack

of standardized protocols. While some of these studies did report an immediate and significant improvement in subjective symptoms and functional balance during gait, objective measures of postural sway and oculomotor function were not investigated.

Studies have compared single- with dual-task performance on COP post-concussion, (Degani et al., 2017) or the presence of saccadic dysfunction post-concussion, using visually-based cognitive dual-tasks (Rizzo et al., 2016; Subotic et al., 2017). However, to date, no study has directly compared the effect BNO as an intervention on measures of COP velocity, objective metrics of saccadic eye movement, and symptoms during the performance of single- and visually-based cognitive dual-task balance conditions in a concussion population. This makes it difficult for clinicians to make evidence-informed choices in the management of individuals who experience persistent balance deficits beyond the expected period of normal recovery following a concussion. This study aims to address this gap by assessing the efficacy of a BNO intervention trial in adults with persistent post-concussion balance problems compared with a control condition using both single and visually-based cognitive dual-task balance paradigms. The study is designed as a randomized controlled crossover test with a sample size calculated a priori to ensure the contribution of high quality evidence to a nascent body of literature.

## **OBJECTIVES**

### **Purpose**

The overarching research question is the following: What is the effect of BNO compared with no binasal occlusion on measures of static balance, saccadic eye movement functions, and symptoms in adults who continue to experience dizziness one month or longer following a concussion? The specific objectives of this study are (1) to measure the effect of BNO on postural sway, compared with non-occluded vision during quiet stance on a force plate; (2) to examine the impact of BNO on postural sway while performing a visually based cognitive dual-task compared with target-focused vision, as measured during quiet stance on a force plate; (3) to compare the effect of BNO on saccadic eye function, compared with non-occluded vision during a timed reading task. Saccadic eye function will be quantified as time to completion during the KDT and the total number of saccades; (4) to determine the relationship between a rapid number naming task and observable saccadic eye function; (5) measure the association between self-reported symptoms, disability, and objective measures of balance in adults who continue to experience dizziness longer than one month after concussion.

It is hypothesized that BNO will improve postural sway during a visually based cognitive dual-task more than during quiet stance. We also hypothesize that time to completion of a timed reading task will correlate positively with saccadic eye function, and that both will show improvement with BNO. It is further hypothesized that perceived disability due to dizziness and neck pain would be greater in

individuals with increased postural sway. This article presents the research protocol for this study.

## **METHODS**

### **Design**

This cross-sectional study will examine the effect of BNO on balance in adults aged 18-65 years who continue to experience symptoms one month or more following a concussion. A 2-task, 2-period, 2 treatment condition randomized crossover study design will be used in order to be balanced with respect to first-order effects, as each condition will precede the other condition only once. Potential participants will be screened for eligibility during a telephone interview. Following enrollment, they will be randomized to one of two condition sequences and act as their own control group. Participants will perform two different balance tasks repeated under both treatment (BNO) and control (no BNO) conditions. The treatment/control conditions will be the same for each participant with only the order of each treatment/control sequence randomized. Post-concussion syndrome is considered chronic and stable, and thus suitable for a crossover study design. Likewise, the application of BNO is intended to improve immediate functional balance and saccadic eye movement, rather than cure the concussion. No evidence of the effect time of BNO has been reported in the literature. Based on clinical experience of two of the authors, the treatment effect is limited to the time of application, so there should be no carryover effect between conditions and a negligible washout period between trials is considered sufficient. To minimize any risk of potential carryover effects, patients will also be asked to wait the greater of 1 minute, or until all symptoms return to their pre-test baseline before performing the subsequent task. A summary of the study design is available in Figure 1. All study procedures will be conducted at one of two private rehabilitation clinics in Ottawa, Canada.

### **Participants**

#### *Patient selection*

Participants will be recruited by advertisement posters placed in a visible location within citywide multidisciplinary medical and rehabilitation centres. All recruitment materials will direct individuals interested in participating to contact the research coordinator directly to provide further details about the study and to screen for eligibility by a telephone interview.

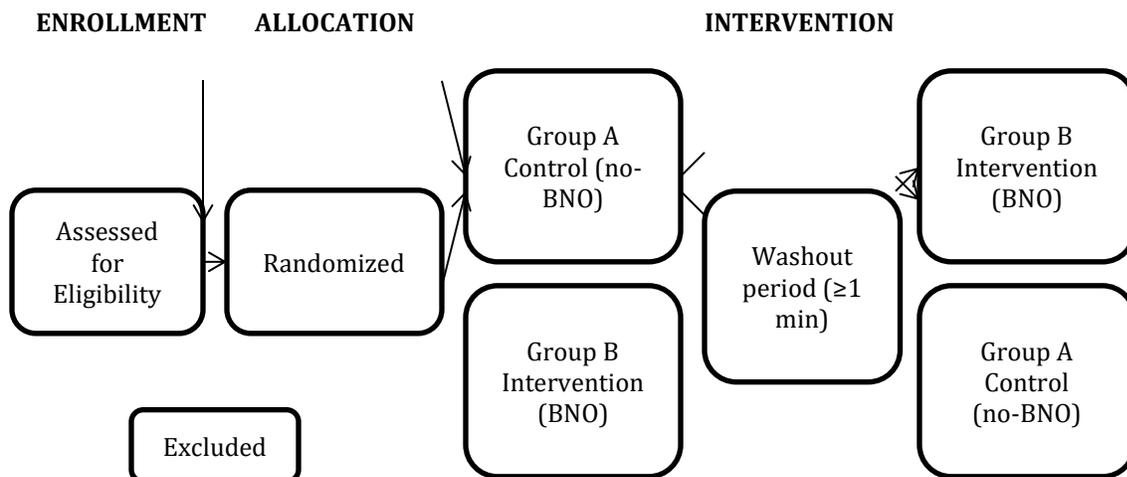
#### *Inclusion criteria*

Forty adults with persistent symptoms one month or more following a concussion will be recruited for the study. Individuals will be considered eligible if they have been diagnosed with a concussion as defined in the 2016 Berlin consensus statement (McCroory et al., 2017) as a traumatic brain injury induced by biomechanics forces, which was caused by either a direct or indirect blow to the head, face, neck or elsewhere on the body with an impulsive force transmitted to the head, which may or may not have involved loss of consciousness, and included one or more of the following clinical domains:

- Symptoms (e.g. headache, nausea, fatigue, feeling like in a fog, difficulty concentrating or remembering, and/or emotional lability)
- Physical signs (e.g. loss of consciousness, amnesia, neurological deficit);
- Balance impairment (e.g. gait unsteadiness)
- Behavioural changes (e.g. irritability)
- Cognitive impairment (e.g. slowed reaction times)
- Sleep/wake disturbance (e.g. somnolence, drowsiness)

Participants must also meet the following inclusion criteria: (1) aged 18-65 years; (2) sustained the concussion 4 or more weeks ago; (3) report persistent dizziness or balance problems not accounted for by a pre-existing musculoskeletal, neurological, or vestibular condition; (4) have normal vision or visual impairments that can be corrected with contact lenses; (5) are proficient in English or French; (6) are able to provide informed consent.

**Figure 1.** Study design



### **Informed consent**

During a telephone screening interview, potential participants will speak with a member of the research team to confirm study eligibility, to review details of the study protocol, and to enroll in the study if deemed suitable. During this discussion, potential participants will be given the opportunity to request an electronic copy of the informed consent form to review prior to meeting with the study team. Once enrolled, participants will attend an in-person testing session at one of the two trial locations. At this session, the research team will review: (1) the purpose of the study; (2) how the randomization process works; (3) a general overview of the testing conditions, and the self-report outcome measures. A thorough discussion of potential risks and benefits associated with participation in the study will then take place, as well as the assurance that participants may withdraw from the study or request a rest at any time during the study without consequence or without effect on the medical care that they receive. Each participant will be given a hard copy of

the informed consent form for signature and an extra copy to take home. Participants will be given as much time as required to re-read and complete the informed consent form, as well as the opportunity to ask for and receive clarification for questions as necessary.

### **Sample size**

40 participants will be recruited for the present study. A power analysis based on COP excursion using a force plate with adults following a concussion has been calculated to determine the number of participants that need to be recruited for the present study. A change in COP excursion by more than 5cm will be considered to be significant, as this represents the minimal detectable change with a 90% confidence interval (Goble, Manyak, Abdenour, Rauh, & Bawega, 2016). A two-tailed analysis will be made with alpha level set at 0.05 and power set at 80%. Due to the nature of this crossover design, loss to follow-up is not expected, and therefore not accounted for in the sample size determination.

### **Randomization**

Participants will be randomly assigned to one of two groups for a crossover study design. Each group will complete both arms of the study, randomized to sequence, starting with either the control condition or the intervention condition. The intervention condition consists of performing the identical balance tasks while wearing glasses overlaid with BNO. Researchers performing the intervention will not be blinded to group allocation due to the crossover design.

## **OUTCOME MEASURES**

For each arm of the study, participants will complete two trials of static balance while standing on a force plate that will record movement of the center of pressure (COP) under their feet. Sensors from an electromagnetic tracking system will also be attached to each participant at the base of the skull, T5, and L5 along the spine, collecting acceleration of movements, angular velocity of movements, and angular rotation of the earth. The sensors will record accelerations of movements, angular velocities, and angular rotations. Throughout each trial condition, Tobii™ eye tracker glasses will be worn to measure and record saccadic eye movements and time to task completion.

### **Primary outcome**

#### *Balance – COP*

Measurement of postural sway as an indicator of persistent balance impairment post-concussion builds upon previous studies demonstrating increased postural sway in the acute period following a concussion (Goble et al., 2016). The primary outcome of interest is the mean M/L and A/P velocity of COP, in addition to the 95% ellipse during different conditions of static balance. The minimal clinical difference

considered to demonstrate a change in postural sway is 5cm based on a previous validation study in a concussed population (Goble et al., 2016).

Postural stability will be assessed using the BTrackS (BTS) Balance Plate and Explore Balance software (BTrackS, Balance Tracking Systems Inc., San Diego, CA, USA) that is easily portable. The BTS Balance Plate is an FDA registered Class 1 Medical Device designed to measure static balance by calculating the centre of pressure (COP) excursion and velocity of an individual during quiet stance (Goble et al., 2016). Centre of pressure is a proxy measure for postural sway, which is a common measure of balance impairment following concussion (Chang, Levy, Seay, & Goble, 2014; Goble et al., 2016; Kleffeldgaard, Roe, Soberg, & Bergland, 2012; Rochefort et al., 2017). Decreased COP displacement can be used as an indicator of recovery or improved postural strategies used to maintain balance after a concussion. The BTS Balance Plate calculates COP using four-sensor technology within a lightweight (<7kg), 0.4m by 0.6 m rectangular platform that is highly accurate and reliable compared with a laboratory-grade force plate (O'Connor et al., 2016).

The Explore Balance software is an application-based program that will be customized to the current study protocol. All balance testing will be performed by members of the research team trained in BTS technology.

### ***Secondary outcomes***

Prior to postural sway data collection, participants will be asked to complete 4 questionnaires, including a participant demographic questionnaire, the post-concussion symptom scale (PCSS), the dizziness handicap inventory (DHI), and the neck disability index (NDI).

### ***Baseline Patient Characteristics***

Baseline patient characteristics will be collected on pre-prepared data collection forms, and will include age, gender, height, weight, race, marital status, level of education, employment status, mechanism of concussion, and previous history of concussion.

### ***The Post-Concussion Symptom Scale (PCSS)***

The use of symptom scales plays an important role in the diagnosis of concussion and in monitoring recovery. International consensus statements (McCroory et al., 2017), position papers (McCrea, Nelson, & Guskiewicz, 2017), and clinical guidelines (Marshall et al., 2015) recommend symptoms as part of a multimodal assessment that includes measures of neurocognitive status, balance, and cranial nerve function. Clinical best-practice standards recommending the complete resolution of symptoms prior to medical clearance for return to sport highlight the importance symptom evaluation in the management of concussion.

The PCSS is a standardized and easily administered 22-item self-report symptom scale that measures the severity of each symptom experienced that day (Lovell et al., 2006). Symptoms are reported on a 7-point Likert scale, with 0 and 6 representing

anchoring points from the absence of symptoms to the presence of severe symptoms. Results are conveyed as the total symptom score and range from 0-132, with a higher score associated with a higher level of symptoms. Total scores demonstrate high internal consistency in a concussion population ( $\alpha=0.93$ ), with a 6.8 point change ( $CI_{80}$ ) associated with a clinical change in symptoms (Lovell et al., 2006).

#### *The Dizziness Handicap Inventory (DHI)*

Dizziness is commonly reported post-concussion (Rochefort et al., 2017), and associated with prolonged recovery (Lau et al., 2011). The presence of dizziness has the ability to significantly impact an individual's quality of life by limiting an individual's activities and raising their anxiety. Developed as a standardized measure to evaluate the self-perceived impact of dizziness on everyday life (Jacobson & Newman, 1990), the DHI is a self-report scale that represents the functional, physical, and emotional domains. Internal consistency is high for total scores ( $\alpha = 0.89$ ) and satisfactory for the three subscales ( $\alpha = 0.72$  to  $0.85$ ). The presence of dizziness-related disability is scored as no (0), sometimes (2), or yes (4). Scores range from 0-100, with a higher score reflecting a greater disability associated with dizziness. Cut-off scores exist for mild (16-34), moderate (36-52), and severe (54+) disability, with an 18-point change in score considered clinically meaningful (Jacobson & Newman, 1990).

#### *The Neck Disability Index (NDI)*

A force to the head or body that results in a concussion is of sufficient force to injure the soft tissue and joints of the cervical spine. Altered proprioception from injured cervical spine structures can contribute to symptoms of dizziness commonly associated with concussion. The NDI is the most commonly used self-report outcome measure for neck pain (MacDermid et al., 2009). The index is a simple and quickly administered 10-item questionnaire measured on a 6-point Likert scale from 0=no disability to 5 = full disability. Scores range from 0-50, with 50 representing the highest level of disability. Psychometric properties of scores demonstrate highly stable test-retest reliability ( $r=0.94-0.95$ ) in patients with neck pain longer than 3 weeks (MacDermid et al., 2009). Clinically important differences have been reported with a 5-7 point change in score depending on whether the pain was of musculoskeletal or neural origin (MacDermid et al., 2009).

#### *Saccadic eye function*

Saccadic eye function will be assessed with two measures, a Tobii™ Pro wearable eye tracker and the KDT. Tobii™ Pro wearable eye tracker uses infrared video-oculography to analyze patterns of eye movement in terms of fixations and saccades ([www.tobii.com](http://www.tobii.com)). Longer, more complicated visual tasks, such as rapid number naming, require longer processing times. The number of saccades completed during each balance condition will be recorded by the Tobii™ Pro. The KDT is a vision-based test of rapid number naming speed that acts as a proxy measure for saccadic eye movement (Galetta, Liu, et al., 2015). The KDT consists of

a demonstration card, plus a series of 3 increasingly more difficult test cards of variably spaced single digit numbers (Subotic et al., 2017). Following completion of the demonstration card, participants are asked to read each test card from left to right, top to bottom, as quickly as possible without errors. A summary score of the test is recorded as the total time to complete all 3 test cards, measured in seconds. Time to completion for the KDT will be recorded by the Tobii™ Pro. A meta-analysis demonstrated high test-retest reliability (ICC=0.92; CI<sub>95%</sub>: 0.91, 0.94) in baseline trials (Galetta, Liu, et al., 2015).

**Table 2:** Outcome measures

Domain	Measure	Outcome of Interest		
		Baseline Disability	Primary	Secondary
Cervical spine	Neck Disability Index	X		
Dizziness	Dizziness Handicap Inventory	X		
Postural sway	M/L COP excursion		X	
	A/P COP excursion		X	
	95% ellipse COP		X	
Eye tracking	Saccades			X
	King Devick Test			X
Symptoms	Post-Concussion Symptom Scale			X

(M/L=medial/lateral; A/P= anterior/posterior; COP,=centre of pressure)

## Interventions

### *Balance Testing Protocol*

All participants will be asked to perform a repeated measure of 2 different balance tasks under 2 different treatment conditions as outlined below. Each trial of balance will take 2 min to administer, and will be performed with the participant wearing socks. Before and after each trial, participants will be asked to rate if they are experiencing any headache, dizziness, nausea, or foginess on a scale of 0 to 10. Following each trial, a washout period will be given as the greater of a minimum of 1 minute of rest or until symptoms aggravated by the task return to their pretrial baseline. A time period of two minutes was chosen as a sufficient interval over

which to collect stable COP data according to the International Society for Posture and Gait Research (Scoppa, Capra, Gallamini, & Shiffer, 2013), while aligning with time required to complete the KDT.

For balance task A, participants will be asked to stand with their feet shoulder width apart on the BTS with their hands placed on their hips. They will be asked to hold this position for two minutes with their eyes open, vision fixed on a small target (dot), and to focus on standing as still as possible.

For balance task B, participants will be asked to stand shoulder width apart on the BTS with their hands on their hips. Participants will be asked to complete a cognitive task while they maintain their balance. The visually based cognitive dual-task will involve the participants performing the King-Devick Test (KDT). Test cards will be fixed to a wall and positioned 12 inches from the participant's face at eye level. Participants will be asked to read the numbers out loud as quickly and as accurately as possible, from left to right, beginning at the top left corner of each test card. The total time to read all 3 test cards and the total number of errors committed will be recorded. If a participant makes an error, they will be asked to restart the test. The test usually takes less than two minutes to complete. Participants who complete the KDT in less than 2 minutes will be asked to restart the test from the beginning and continue reading for the remainder of the test period. Those individuals who require more than the allotted 2 minutes to complete the KDT will continue with the rapid number naming task until completion, and COP data will stop being collected at 2 min.

Throughout each trial, participants will be fitted with a pair of Tobii™ eye tracking glasses that will record their eye movements.

*Control condition: normal vision*

During the control arm of the trials, the eye tracking glasses will remain unobstructed and vision will not be occluded.

*Experimental intervention: BNO*

During the intervention arm of the trials, strips of occlusive material will be placed on the medial portion of each lens of the Tobii™ eye tracking glasses to occlude central integrated vision.

**Planned statistical analyses**

Baseline characteristics for participants will be compared with descriptive statistics (mean, SD, n, %).

The primary objective, the effect of BNO on postural sway, will be addressed by using a dependent t-test to compare differences between treatment conditions for each COP variable. A similar analysis using a dependent t-test (group<sup>x</sup>KDT<sub>time to completion</sub>) will be performed to assess the secondary objective, the effect of BNO on reading. Additionally, a Wilcoxon Signed Rank test will be used to determine if there is a significant difference in the number of saccades completed on the KDT between

the control and intervention conditions. Finally, correlations among self-report measures of disability (DHI and NDI) and symptoms (PCSS), and the 3 dependent measures will be calculated using Spearman's rho for non-parametric data.

### **Ethics and Dissemination**

The possibility of fatigue, an increase in post-concussion symptoms, and problems with balance while completing the trials of balance will be disclosed to potential participants. Participating in this study is very low risk and does not constitute more as compared with usual care that a patient would receive. Participants will be required to provide informed consent, and may withdraw from the study at any time without explanation.

Results from this study will be shared with healthcare professionals and academics at professional conferences and through manuscripts to peer-reviewed journals. Publication topics include the efficacy of BNO on postural sway and saccadic eye function; the impact of a cognitive dual-task on balance; the relationship between KDT time and observable saccadic eye function; and the association between self-reported measures of symptoms, disability, and objective measures of balance.

### **Conclusion: Impact on clinical practice**

The assessment and treatment of vision related issues has been identified as an integral part of the rehabilitation of patients who have suffered a concussion. The efficacy of BNO as a treatment modality in the management of individuals with post-concussion syndrome is currently poorly understood. This article describes the protocol for a randomized controlled trial that tests the efficacy of BNO on static balance for adults with persistent dizziness and balance problems one month or more after concussion. Results from primary and secondary outcome measures will contribute to our understanding of the efficacy of BNO in relation to postural sway, saccadic eye function, symptoms, and disability. This study will begin to fill in the gaps with respect to evidence-based vision therapy to manage persistent dizziness post-concussion.

### **Current Study Status**

This trial is set to begin recruitment in November 2017.

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