Impact of a paced breathing exercise intervention on autonomic nervous system function and symptom severity in youth post-concussion: a pilot feasibility study

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Introduction: Mild traumatic brain injury (mTBI) or concussion accounts for over two million emergency department visits per year in the US alone [1,2]. People post-concussion often suffer from various symptoms, including physical disturbances (headache, dizziness, nausea, balance difficulties, sleep disturbances) cognitive deficits (attention, memory, executive function) and emotional disorders (anxiety, depression, irritability) [3,4]. Symptoms of concussion generally resolve spontaneously within a few weeks, but can become persistent and chronic (more than three months). A wide variation exists in reports of persistent post-concussion symptoms (PPCS) prevalence, depending on the mechanism of injury and nature of the population sampled. Up to 30% of children and adolescents who suffered sport-related concussions, experience PPCS [5].

There is a wide overlap between symptoms associated with Autonomic Nervous System (ANS) dysfunction and those most commonly reported in concussion patients e.g. dizziness, nausea, fatigue, exercise intolerance, anxiety and sleep disturbances [3,6–9]. Moreover, ANS dysfunction post-concussion is frequently reported, at the acute and chronic stage post-injury [3,6–11]. ANS dysfunction has been proposed as a factor that can contribute to post-concussive symptoms and complaints [3,12,13]. One option for an evidence-based treatment of ANS dysfunction is slow and paced breathing exercises. Slow breathing techniques have been shown to impact peripheral and central ANS activities as well as psychological status in healthy participants [14,15].

Limited studies have investigated the impact of prescribing breathing interventions in individuals' post-concussion. A randomized clinical trial with relatively small sample size, demonstrated improvement in symptoms reported, neuropsychological function and ANS functioning following a 10-weeks program of heart rate variability biofeedback training, using breathing exercises, in adults post mTBI during the acute-subacute stage [16]. In another study, one session of virtual-reality based deep breathing exercise, was found to be safe and to improve symptoms of tension, fatigue and confusion in adolescents and young adults during the chronic stage post-concussion [17]. A meta-analysis evaluated the therapeutic effect of relaxation interventions for PPCS (meditation, yoga and mindfulness), included general breathing exercises, concluded that the existing literature revealed significant improvement of overall symptoms as well as of mental and physical health, cognitive performance and quality of life [4].

The impact of paced breathing exercise intervention program on ANS function and symptoms severity during the acute and sub-acute stage in youth post-concussion was not addressed in these early studies.

Objectives:

1- To assess the feasibility of administering a paced breathing exercise intervention program to children and adolescents in the acute and sub-acute period after concussion
2- Document ANS function, symptom severity (post-concussion symptoms, anxiety, sleep) before and after administration of the intervention.
3- Characterize early autonomic profiles, and examine whether early paced-breathing exercise can accelerate symptom improvement and reduce the risk of persistent post-concussive symptoms (acute cohort)

Methods:

Participants: 20 participants (sub-acute cohort) will participate in the study, 10 in the intervention group and 10 in the control group. Inclusion criteria: 1) aged 9-18 years, 2) seven days-3 months post-concussion, and 3) at least one post-concussion symptom in the Post-concussion Symptom Inventory (PSCI) that is relevant to ANS dysfunction (e.g. dizziness, nausea, fatigue, confusion, anxiety or sleep disturbances). Exclusion criteria: 1) known heart disease, and 2) previous neurological problems other than concussion.

Another 20 participants (acute cohort) will participate in the study, 10 in the intervention group and another 10 in the control group. Inclusion criteria: 1) aged 9-18 years, 2) 0-72 hours post-concussion, and 3) present to the ED with at least one post-concussion symptom in the Post-concussion Symptom Inventory (PSCI) that is relevant to ANS dysfunction (e.g. dizziness, nausea, fatigue, confusion, anxiety or sleep disturbances). Exclusion criteria: 1) known heart disease, and 2) previous neurological problems other than concussion

Study procedure:

Sub-Acute Cohort: Participants will be enrolled from the Montreal Children's Hospital Concussion Clinic at their initial visits. If the participant is eligible according to the inclusion and exclusion criteria, the concussion clinic coordinator will introduce the study. If they agree to hear more about the research, one of the study team will meet with them, explain the project and collect informed consent should they agree to participate.

Consenting children and adolescents will first fill out the PSCI. Eligible participants will then fill out the modified Composite Autonomic Symptom Score 31 (mCOMPASS-31) questionnaire, as well as an anxiety and sleep screening. After which they will wear the Polar H10 chest strap and undergo the ANS assessment. This will be performed in five stages: (1) rest while lying supine for five minutes (2) quiet active standing for five minutes (3) rest while sitting for five minutes (4) a 2-minute paced breathing test (5)

a 2-minutes sustained handgrip test [18–20]. In addition, the systolic and diastolic blood pressure will be measured during the last minute of rest in supine and standing, using a standard blood pressure device.

Before each test, instructions for the test will be reviewed with the participants. If needed, additional rest will be added as per the participant preference.

The assessment will be performed in a quiet environment, in a treatment room without excessive visual stimulation. Subjects will be asked not to eat one hour before the tests, and to go to the bathroom before the assessment begins. In addition, relevant data (demographic, anthropometric, medical, functional and background data) will be retrieved from the Concussion Clinic Database (Montreal Children's Hospital). All participant data will be anonymized to ensure privacy and confidentiality of participants' personal information, with each participant assigned a unique identifier.

Acute Cohort: Participants will be enrolled from the Montreal Children's Hospital Pediatric Emergency Department. Upon arrival to the Montreal Children's Hospital Emergency Department, a member of the research team will screen children for inclusion/exclusion. If the child meets the inclusion criteria and expresses interest in participation, the research team will thoroughly explain the study and answer any questions the parent or child may have. If patient and parent agree to participate, written consent will be obtained. The research team member will then proceed with data collection.

Consenting youth will first fill out the PSCI, followed by the modified Composite Autonomic Symptom Score 31 (mCOMPASS-31) questionnaire and anxiety and sleep screening questionnaires. The research team will also collect relevant data (demographic, anthropometric, medical, functional and background data). All participant data will be anonymized to ensure privacy and confidentiality of participants' personal information, with each participant assigned a unique identifier.

Interventions: In addition to the initial assessment, the intervention group will have up to 10 minutes of paced breathing practice using a device-guided breathing, to learn and experiment the exercise. The paced breathing exercise includes inhale for 4-seconds and exhale for 6-seconds, for a total of 6 breaths per minute. If the participant is unable to reach 6 breaths per minute (e.g. due to their age), they will be asked to try to reach the lowest respiratory rate possible. Following this, and in addition to the standard rehabilitation care post-concussion (relative physical and cognitive rest for 24-48 hours, then a focus on gradually returning to normal activities and school as symptoms improve, individually guided by the clinic team or by following discharge instructions from the Emergency Department), the participants in the intervention group will be instructed to perform a 10-minute daily paced breathing home-exercise program using *Breathe*, a free application for breathing training (Breathe: relax & focus®, by Havabee). The *Breathe* application guides the breathing exercise and records the date and time of the session only, no personal information. The breathing home-exercise program will be performed during the evening after their return from school, or the time they are usually return from school (for the acute cohort), for four-weeks or until full recovery (no symptoms and full return to school and sport). In addition, the participants will document the daily exercises performed on a paper log that will be given to the participants after the initial assessment. For the sub-acute cohort, a weekly phone meeting will be performed with the participants in the intervention group, reviewing exercises, providing specific instructions, and making any necessary adjustments. For the acute cohort, the weekly phone calls include both groups, with follow-up questions inquiring about exercises (intervention group) and the stage of recovery (both groups).

In both cohorts, all participants (intervention and control group) will undergo a second assessment after four weeks following completion of the intervention program. During the second assessment, information regarding time to return to school, return to sport, and clear from medication will be collected as well.

Allocation and randomization: For each of the cohorts, after the initial assessment, participants will be randomized into intervention (n=10) and control groups (n=10).

Computer-generated random group listing will be applied using a 2:2 allocation and permuted blocks. one of the study team will generate the allocation sequence using the WinPepi program [21]. If the participant is allocated to the intervention group, the study team will proceed with the intervention, otherwise, the patient will proceed as per usual procedures (standard rehabilitation usual care).

Measures: Feasibility outcomes will include the number days of practice, the total and daily time of practice, and open questions about the ease, tolerance, and applicability of the exercises for the intervention group participants and their caregivers.

ANS function of the sub-acute cohort will be assessed by Heart rate (HR) and Heart Rate Variability (HRV) using the Polar H10 device [22]. The data collected by the Polar H10 chest strap will be recorded anonymously using the Elite HRV: Wellness & Fitness application, that was downloaded to the lab iPad. The application will record the data anonymously, without any information on the participants. HRV time measures included the SDNN (Standard Deviation of the N-N Interval) and the RMSSD (the square root of the Mean Square Differences of Successive R-R Interval) [4,25]. Frequency measurements of HRV includes band in the range between 0.04-0.15 Hz - low frequency (LF), the band in the range between 0.15-0.4 Hz- High Frequency (HF) and the relationship between LF and HF (HF/LF) [19,23]. HR and HRV of the sub-acute cohort will be assessed during different conditions: (1) basic activity level during five minutes rest in supine and sitting, (2) active standing test (3) Paced breathing test, (4) and the Handgrip test[18–20,24]. In addition, the systolic and diastolic blood pressure will be measured using a standard blood pressure device during the last minute of rest in supine and standing. HRV will not be collected from the acute cohort at this time. ANS dysfunction associated symptoms will be assessed using the Composite Autonomic Symptom Score 31 (COMPASS-31) questionnaire [25,26], which will be modified to report the symptoms in the past week instead of the past year (mCOMPASS-31) for the sub-acute cohort and in the past month for the acute cohort. In addition, post-concussion symptoms will be assessed using Post-concussion Symptom Inventory (PSCI) questionnaire [27]. Anxiety and sleep will be assessed using

the PROMIS® (Patient-Reported Outcomes Measurement Information System) short forms 4a for anxiety, and sleep-related impairment.

(https://www.healthmeasures.net/exploremeasurement- systems/promis).

The total daily time of practice in the intervention group is the primary outcome measure for the first objective. The change in the HRV time measures during five minutes rest in sitting and PSCI total score, are the main outcome measure for the second objective.

Analytical plan: Relevant descriptive statistics will be used, based on the distribution of the data (parametric or nonparametric). Outcome measures will be compared between the intervention and control groups using appropriate statistical tests, along with the appropriate correlation coefficient. A *preliminary* analysis on the primary outcome measures with an alpha value of below 0.050 and a required power of 80% will reveal the minimum sample size for a follow-up study.

Significant impact: This protect is a first step of exploring the impact of paced breathing exercise as a simple and effective rehabilitation strategy in youth post-concussion at the acute and sub-acute stage, for improving ANS function at rest and in response to physical exertion, in addition to improve symptoms severity and recovery. We will also collect feasibility and acceptability data within the context of this project, which can then be used to guide the development of a larger randomized clinical trial for this intervention.

Consistent with current concussion guidance, which discourages prolonged strict rest and instead recommends relative rest for 24–48 hours followed by symptom-limited activity, paced breathing is a low-burden strategy that can be initiated early. Therefore, an ED-based amendment is warranted to evaluate feasibility and safety in the acute stage. In addition, characterize early autonomic profiles, and examine whether early paced-breathing exercise can accelerate symptom improvement and reduce the risk of persistent post-concussive symptoms

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