WHITE PAPER

Evaluating the Real-World Impact of PoNS Therapy™ on Return-to-Work Outcomes in Individuals on Long-Term Disability due to Traumatic Brain Injury

Natasha K.J. Campbell
Mathieu Gagnon
Tanja Yardley
Sonia Brodie
Dr. Ryan C.N. D'Arcy

October, 2023

HealthTech Connex Inc.
Unit 1009, City Centre 3, 13761 96th Avenue
Surrey, BC, Canada V3V 0E8

BACKGROUND

In North America, over 6.8 million individuals are living with a disability related to traumatic brain injury (TBI). With an overall return-to-work (RTW) rate of only ~40% in brain injured populations, many of these individuals end up on long-term disability.[1] Two years post injury, those who have not yet returned to work are unlikely to work again.[2] Few resources are provided to this undermanaged and underserved population, despite significant costs related to long-term disability (LTD).

The consequences of a head trauma affect many areas of functioning, including motor, speech and language, cognition, mental health, social participation. Chronic deficiencies in balance and gait are common in people who have experienced TBI or concussion.[3] Rehabilitation therapy (physical therapy, occupational therapy, and vestibular therapy) is the current standard of care. However, the efficacy varies greatly, with 10-40% of patients reaching a functional plateau and/or losing functions gained from standard rehabilitation.[3–5] Chronic balance deficits can have a significant negative impact on functional status, capacity to return to work and quality of life, leading to social isolation and mental health issues.

The Portable Neuromodulation Stimulator (PoNS™) device is a Health Canada licensed, class II (low risk) orally-applied medical device that delivers electrical stimulation to two major cranial nerves. The device (**Figure 1**) stimulates the sensorimotor fibres of the trigeminal and facial nerve branches that innervate the anterior two-thirds of the tongue using a sequenced pattern of superficial electrical stimulation (typically for 20 minutes). Prolonged stimulation has been shown to initiate long-lasting processes of neuronal reorganization with a variety of dramatic results, including the correction of gait/balance impairments resultant from concussions when combined with physical therapy.[4,6] Over time, with consistent engagement of specific neural areas in the brainstem, the brain "learns" to employ compensatory pathways that can modulate functional activity. The process of neurostimulation leads to neuromodulation and, consequently, triggers adaptive changes known as neuroplasticity.

***Figure 1**. The PoNS™ device. The intraoral component of the system has a hexagonally patterned array of 143 gold- plated circular electrodes. This part of the device is held lightly in place by the tongue pressing toward the roof of the mouth, and rests on the anterior, superior part of the tongue. The intraoral unit connects to the controller module, which fits loosely around the neck.*

Clinical trial data shows that 74% of chronic mild-moderate TBI participants who had

plateaued with standard rehabilitation therapy experienced significant and lasting improvement in their balance, gait, and walking endurance after 14 weeks of PoNS Therapy™.[4] Secondary endpoint measures, including headache burden, risk of falls, sleep quality, and concussion symptom severity also improved significantly.

Here we describe the impact of PoNS Therapy™ on specific RTW outcomes in individuals on LTD due to chronic TBI, based on real-world evidence collected in a Canadian clinical setting with insurance provider Pacific Blue Cross (PBC).

OBJECTIVES AND PROGRAM DESIGN

The objective of the current program was to track and report occupational performance and durable return-to-work status for 6+ months in nine (9) LTD Plan members after 14 weeks of PoNS Therapy™. The program candidates represented a selection of challenging cases, for whom RTW was not anticipated for a variety of medical and functional reasons. Furthermore, we describe specific outcomes affecting RTW status including gait and balance, headache, mental health and cognitive performance.

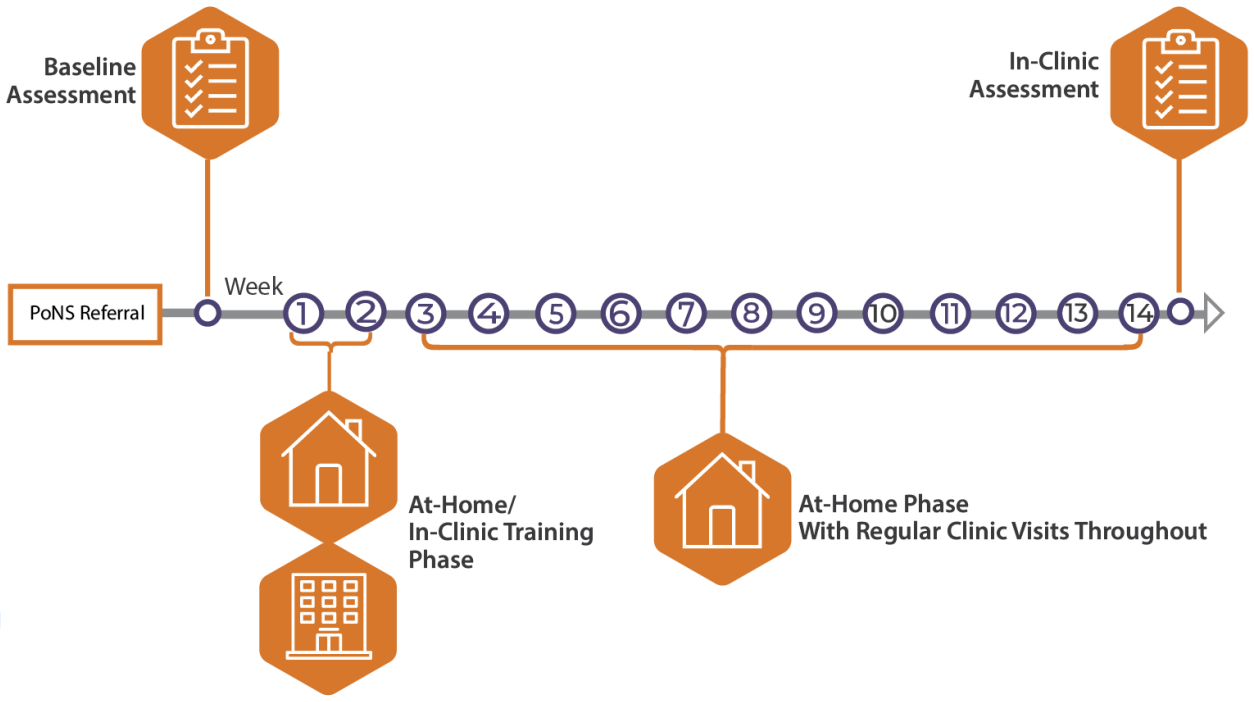

***Figure 2**. Program Design.*

This 14-week program was based on previously published clinical trial designs using the PoNS™ device.[4,7] Program design is outlined in **Figure 2**. The 14-week PoNS Therapy™ protocol consists of a morning and afternoon training session, with a focus on balance and gait training. Breathing and Awareness (BAT) training is also performed twice daily. The first two weeks of the program are spent supervised in-clinic, while the majority of weeks 3-14 are spent at home with weekly check-ins. A sample schedule is outlined in **Figure 3.** The program is therapeutically guided, with the clinician having full clinical judgement based on the plan member's needs and goals. Outcome measures were readministered at the mid and end points.

Daily Training Schedule		
Morning Session	Warm-up Exercises without PoNS	10 min.
	Balance Training with PoNS	20 min.
	Gait Training with PoNS	20 min.
	BAT with PoNS	20 min.
Break		3-4 hours
Afternoon Session	Balance Training with PoNS	20 min.
	Movement Control Exercises without PoNS	20 min.
	Gait Training with PoNS	20 min.
Break		
Evening Session	BAT with PoNS	20 min.

***Figure 3**. Example Daily PoNS Therapy™ Schedule.*

Plan members were between the ages of 19-65 (mean = 38.33 years old) and diagnosed with a mild-moderate traumatic brain injury (at least 2 years post-injury) that did not respond to standard rehabilitation measures. They were all working full-time at the time of injury. All plan members were on longstanding approved disability claims and were expected to be on permanent disability benefits. Of the nine plan members enrolled, five were female. All nine completed the full 14 weeks.

RETURN-TO-WORK OUTCOMES

Return-to-Work Outcomes:

To date, five out of nine Plan members **have returned to work**, or have been deemed work-ready (file closed). Three of those five individuals were female. Given that these individuals were determined to be unlikely to work again, this represented a significant outcome for the stakeholder Pacific Blue Cross.

Durability Outcomes:

Of the five plan members who were deemed work-ready, all are back full time with full duties for **more than six months,** all to their **prior occupations**. The fifth plan member was deemed able to return to employment and their file was closed.

OCCUPATIONAL PERFORMANCE

The Canadian Occupational Performance Measure (COPM) is a well-known tool developed in consultation with the Department of National Health and Welfare and the Canadian Association of Occupational Therapists.[8] It is a client-centered assessment that incorporates a semi-structured interview conducted by a clinician to determine the client's self-perception of performance in everyday living. Individuals are asked to rate the importance of their daily tasks in three areas: self-care, productivity, and leisure. It allows the individual to pick five important occupational performance problems and rate them in terms of satisfaction and performance.

A change of two points or more on the COPM is considered a minimal clinically important difference (MCID)[9]. The mean

67%

increase in points for "occupational performance" and "occupational satisfaction" across the five plan members who returned to work was 3.16 and 3.52, respectively. Three out of those five demonstrated clinically significant improvements (increased by at least two points) on both the "performance" and "satisfaction" scores. Of the remaining two Plan members who returned to work, one had a clinically significant change in "satisfaction" score and a 1.8 score difference in "performance" score. Inversely, the fifth member had a clinically significant change on their "performance" score and a 1.6 score difference on their "satisfaction" score. In other words, all five clients who returned to work reported clinically significant improvements using the COPM on one or more measures.

BALANCE AND GAIT MEASUREMENTS

The NeuroCom® Computerized Dynamic Posturography Sensory Organization Test (SOT) (**Figure 4**) is an objective, automated measure of sensory-motor integration that evaluates the functional contribution of the somatosensory, visual, and vestibular components of balance. A composite score is calculated and compared with a database normalized for age and height. Changes greater than eight points on the composite score are considered a clinically significant improvement.[10]

Six of nine plan members experienced a **clinically significant improvement** in balance and gait, based on their composite SOT score. **Eight plan members said that Balance and Gait was no longer a barrier to return to work.**

Six out of nine plan members moved from below their age-adjusted normative cut-off to above their normative cut-off after 14 weeks (clinically significant). Two out of

nine plan members who did not show clinically significant improvements were above the normative cut-off range prior to the program and maintained a score above their normative cut-off. One plan member scored below their normative cut-off at both intake and discharge; however, their score increased by 49 points, which was still highly clinically significant.

***Figure 4**. The NeuroCom® Computerized Dynamic Posturography Sensory Organization Test.*

HEADACHE DISABILITY INDEX

The Headache Disability Index (HDI)[11] is scale to identify difficulties that a person may be experiencing because of self-reported headache symptoms. The scale rates an individual's perceived headache disability severity based on their total score. Scores range from Mild (10- 28%), Moderate (30-48%), Severe (50-68%) or Complete (72% or more) disability.

Of the nine plan members, six reported that headaches were a barrier to work at the beginning of the program. Of these six, **50%** reported a reduction in their chronic, longstanding headaches at the end of the program. There was a mean **50%** reduction of the severity of headaches self-reported by these three plan members.

Two of the three plan members (**67%**) who reported a reduction in the severity of headaches are back to work.

MENTAL HEALTH SCORES

The Patient Health Questionnaire (PHQ-9)[12] is a short self-report questionnaire measuring the severity of depression. PHQ-9 scores of 5-9, 10-14, 15-19, and 20+ represent mild, moderate, moderately severe, and severe depression, respectively. Determining clinically

significant change recommends a person move from a depressed range (defined as scores greater than or equal to 10) pre-treatment to a non-depressed range (defined as scores less than or equal to nine) post-treatment. Improvement in scores should be 50% or greater of the patients' pretreatment score; a five-point or more change in scores indicates reliable change.

Four out of eight plan members who completed the PHQ-9 at baseline and discharge reduced their scores from either severe to moderate depression or mild to no depression. Three plan members had no change in cut-off score. One plan member's score increased (unrelated to the PoNS™ program), and they were referred to mental health support.

Of the five plan members who returned to work, the mean improvement percentage in PHQ-9 score was 50%. While the current results may not suggest clinically significant improvements for all plan members, the results are trending in the right direction.

The Generalized Anxiety Disorder 7-item scale (GAD-7)[13] is a short self-report questionnaire measuring anxiety symptom severity. GAD-7 scores of 0-4, 5-9, 10-14, and 15+ represent minimal, mild, moderate, and severe anxiety, respectively. Of the eight plan members who completed the GAD-7 questionnaire, three reduced their scores (two from mild to minimal and one from severe to moderate), four remained in the same category, and one plan member reported an increase in anxiety which was unrelated to the PoNS™ program. Importantly, for many of these Plan members, the final mental health screen occurred just prior to the return-to-work phase, capturing some anxiety around the prospect of returning to work successfully.

COGNITIVE PERFORMANCE

Brain vital sign evaluations were extracted from event-related potentials (**ERPs**). ERPs, measured by means of electro-encephalography (**EEG**), are well characterized in medical literature[14] as a physiological measure of brain function. The NeuroCatch® Platform is designed to record and analyze brain vital sign responses using a portable EEG device and providing automated, standardized and clinically intuitive results. Three highly validated[30] ERPs are recorded with this device: the **N100** (linked to auditory sensation), **P300** (linked to basic attention), and the **N400** (linked to cognitive processing). These ERPs have been validated across large samples of healthy individuals recovering from brain injury.[15,16]

Overall, six out of the ten plan members showed improved basic attention and cognitive processing speed, but this was not statistically significant between the return-to-work group and the other plan

members. Although these changes were not significant at a group level, this was a small sample size and small individual-level changes were recorded by the clinicians. In other words, NeuroCatch® results suggest that PoNS Therapy™ can have additional positive impacts on basic attention and cognitive processing, which is consistent with prior published research.[17]

COST ANALYSIS AND IMPACT

According to the Group Long Term Disability Termination study conducted by the Canadian Institute of Actuaries in January of 2019, the **average financial burden of a long-term nervous system claim** is approximately **$486,000 per file**[18].

The total **program costs for this project were** ($18,500 * 9 participants =) **$166,500.** The program costs are calculated as: $10,500 for the PoNS™ device, $7,000 for clinical time (approximately 60 hours), and $1,000 for coordination and administrative costs.

Pacific Blue Cross (PBC), the insurance provider, completed a cost benefit analysis (CBA) for each of the five plan members who returned to work or had their files closed. Without any interventions, these five cases had a projected total cumulative cost of $1.8M to the Insurance provider. By supporting the return to work/file closure of these five individuals, **the insurance provider reported an estimated $1.6M in LTD claim savings**.

While the direct medical cost savings are significant, these exclude indirect cost savings and perhaps the more significant impacts on mental health and overall wellbeing for both the individuals and their families. Anecdotally, one of the cases the team counts as most successful involves a plan member who moved from suicidal to stable and expressed extreme gratitude for what they described as a "lifesaving experience" with the clinical team.

In this report, we tracked occupational performance and return-to-work status in nine (9) LTD Plan members after 14 weeks of PoNS Therapy™. **Five out of nine (56%) returned to work or had their files closed**, and **four of those five (80%) have returned to their prior occupations full-time for more than six months**, providing the insurance provider with an estimated $1.6M in cost savings. Given that these individuals were determined to be unlikely to work again, we consider this project a major success.

REFERENCES

1. Van Velzen JM, Van Bennekom CAM, Edelaar MJA, Sluiter JK, Frings-Dresen MHW. How many people return to work after acquired brain injury?: a systematic review. *Brain Inj*. 2009;23(6):473-488.
2. Kendall E, Muenchberger H, Gee T. Vocational rehabilitation following traumatic brain injury: A quantitative synthesis of outcome studies. *J Vocat Rehabil*. Published online 2006.
3. Kleffelgaard I, Roe C, Soberg HL, Bergland A. Associations among self-reported balance problems, post-concussion symptoms and performance-based tests: a longitudinal follow-up study. *Disabil Rehabil*. 2012;34(9):788-794.
4. Tyler M, Skinner K, Prabhakaran V, Kaczmarek K, Danilov Y. Translingual Neurostimulation for the Treatment of Chronic Symptoms Due to Mild-to-Moderate Traumatic Brain Injury. *Arch Rehabil Res Clin Transl*. 2019;1(3):100026. doi:https://doi.org/10.1016/j.arrct.2019.100026
5. National Center for Injury Prevention and Control; Division of Unintentional Injury Prevention. Brain Injury in the United States: Epidemiology and Rehabilitation. Published 2015. http://www.cdc.gov/traumaticbraininjury/pdf/tbi_report_to_congress_epi_and_rehab-a.pdf
6. Danilov Y, Paltin D. Translingual Neurostimulation (TLNS): Perspective on a Novel Approach to Neurorehabilitation after Brain Injury BT - Pre-Clinical and Clinical Methods in Brain Trauma Research. In: Srivastava AK, Cox CS, eds. Springer New York; 2018:307-327. doi:10.1007/978-1-4939-8564-7_19
7. Leonard G, Lapierre Y, Chen J-K, Wardini R, Crane J, Ptito A. Noninvasive tongue stimulation combined with intensive cognitive and physical rehabilitation induces neuroplastic changes in patients with multiple sclerosis: A multimodal neuroimaging study. *Mult Scler J - Exp Transl Clin*. 2017;3(1):2055217317690561. doi:10.1177/2055217317690561
8. Law M, Baptiste S, McColl M, Opzoomer A, Polatajko H, Pollock N. The Canadian occupational performance measure: an outcome measure for occupational therapy. *Can J Occup Ther*. 1990;57(2):82-87. doi:10.1177/000841749005700207
9. Wressle E, Samuelsson K, Henriksson C. Responsiveness of the Swedish version of the Canadian occupational performance measure. *Scand J Occup Ther*. 1999;6(2):84-89.
10. Wrisley DM, Stephens MJ, Mosley S, Wojnowski A, Duffy J, Burkard R. Learning effects of repetitive administrations of the sensory organization test in healthy young adults. *Arch Phys Med Rehabil*. 2007;88(8):1049-1054.
11. Jacobson GP, Ramadan NM, Aggarwal SK, Newman CW. The Henry Ford hospital headache disability inventory (HDI). *Neurology*. 1994;44(5):837.
12. Kroenke K, Spitzer RL, Williams JBW. The PHQ-9: validity of a brief depression severity measure. *J Gen Intern Med*. 2001;16(9):606-613.
13. Spitzer RL, Kroenke K, Williams JBW, Löwe B. A brief measure for assessing generalized anxiety disorder: the GAD-7. *Arch Intern Med*. 2006;166(10):1092-1097.
14. Luck S. *An Introduction to the Event-Related Potential Technique*. 2nd ed. MIT Press; 2014. citeulike-article-id:472845
15. Sculthorpe-Petley L, Liu C, Ghosh Hajra S, et al. A rapid event-related potential (ERP) method for point-of-care evaluation of brain function: Development of the Halifax Consciousness Scanner. *J Neurosci Methods*. 2015;245:64-72. doi:https://doi.org/10.1016/j.jneumeth.2015.02.008

16. Carrick FR, Pagnacco G, Azzolino SF, et al. Brain Vital Signs in Elite Ice Hockey: Towards Characterizing Objective and Specific Neurophysiological Reference Values for Concussion Management . *Front Neurosci*. 2021;15:952. https://www.frontiersin.org/article/10.3389/fnins.2021.670563

17. Kirby ED, Jones CB, Fickling SD, et al. Real world evidence of improved attention and cognition during physical therapy paired with neuromodulation: a brain vital signs study . *Front Hum Neurosci* . 2023;17. https://www.frontiersin.org/articles/10.3389/fnhum.2023.1209480

18. Canadian Institute of Actuaries, Research Council – Experience Research Committee. Group Long Term Termination Study. Published January 2019.