Criteria for Inclusion/Exclusion

Subjects must present with a chronic balance deficit due to mild-to-moderate Traumatic Brain Injury (TBI). However, other potentially related symptoms, such as gait disturbance, mild to moderate recurrent headaches, sleep, memory, attention, or cognitive deficits, will be noted on the data collection form at screening and each subsequent evaluation.

Inclusion Criteria

Subjects must meet **all** of the following criteria to be included in the study:

1. Male or female, 18 to 65 years of age, inclusive, at the time of screening.
3. Documentation on the history of a qualifying TBI, mild to moderate in severity. For reference, the Armed Services Health Surveillance Branch (AFHSB) definitions of mild and moderate TBI will be used. The definitions are as follows:
   - Mild TBI: Confused or disoriented state which lasts less than 24 hours; or loss of consciousness for up to 30 minutes; or memory loss lasting less than 24 hours. Excludes penetrating TBI.
   - Moderate TBI: Confused or disoriented state which lasts more than 24 hours; or loss of consciousness for more than 30 minutes, but less than 24 hours; or memory loss lasting greater than 24 hours but less than seven days; or meets criteria for Mild TBI except an abnormal CT scan is present. Excludes penetrating TBI.

   The study investigator will ascertain whether the prior medical records are sufficiently detailed to support the classification of the TBI.
5. If female, the subject is not pregnant, not breastfeeding and has a negative pregnancy test prior to receipt of the PoNS™ device
   Note: Pregnancy testing will be repeated at end-of-study (EOS) (i.e., end of at-home period).
6. If female of childbearing potential, the subject agrees to use adequate contraception from screening and throughout the study period. A female of non-childbearing potential is defined as a subject who is postmenopausal (continuous amenorrhea for 12 months) or surgically sterile (defined as bilateral tubal ligation, bilateral oophorectomy, or hysterectomy).
7. Balance disorder (NeuroCom® Sensory Organization Test (SOT)) composite score at least 16 points below normal [adjusted for age and height, based on normative data] due to a mild-to-moderate traumatic brain injury (TBI), without any concomitant pathologies or etiologies, such as balance or gait deficits due to lower extremity injury or neurological condition other than TBI.
8. At least 1 year post most recent TBI at the time of screening.

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Caution: Investigational Device.
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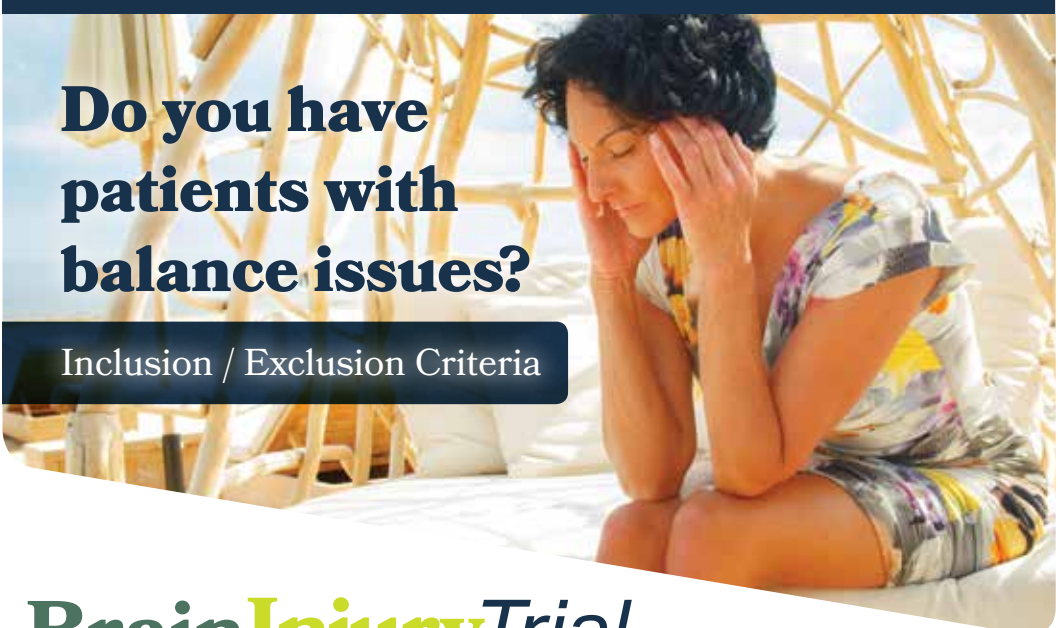

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9. Stable neurologic status, as determined from subject's medical records and the study physician's opinion based on no new or changing symptoms. If available, the most recent neuroradiologic reports will be entered into the data collection form. For all subjects an MRI will be obtained with thin (1 mm) cuts in order to rule out any incidental findings prior to inclusion and the study investigator may exclude subjects based on any concerns of health or safety.
10. All candidates will have participated in a focused physical rehabilitation program for their TBI and have been deemed by their treating clinician/themselves to have reached a plateau.
11. Ambulatory and able to walk continuously on a treadmill for 20 minutes, level grade (no inclination) and at any speed, with support, if needed.
12. Access to a treadmill and commitment to utilize this for the at-home portion of the study.
    Note: Access is defined as the availability of a treadmill for that portion of the balance training at (1) the subject's own home, (2) the home of a relative/friend, (3) a gym or fitness center, or (4) a wellness facility associated with the clinical site.
13. Able to understand the study procedures and give informed consent.
14. Willing and able to adhere to the study schedule.
15. Willing to complete a neuropsychological evaluation prior to inclusion in the study. Should the presence of severe anxiety and/or depression be suggested by the scores on the Beck Anxiety and Depression Inventories (BAI and BDI-II), the subject will be excluded from the study.

Exclusion Criteria

Subjects meeting **any** of the following criteria will be excluded from the study:

1. Medical findings from screening history and physical examination that the study investigator deems clinically significant or that would otherwise impact patient safety or data integrity.
2. Medical finding from prior neuroradiologic study or recent MRI (e.g., tumor or space occupying lesion) that the study investigator deems significant or that would otherwise impact patient safety or data integrity.
3. Planned use or use of any investigational product (i.e., not approved by the FDA), pharmaceutical or device, within 30 days preceding receipt of the PoNS™ device and during the entire study period.
4. Balance or gait deficits due to lower extremity injury or neurological condition other than TBI.
5. Severe TBI defined as an injury with a confused or disoriented state which lasts more than 24 hours; or loss of consciousness for more than 24 hours; or memory loss for more than seven days. Excludes a penetrating brain injury, refractory subdural hematoma, or craniotomy unrelated to the resolution of qualifying traumatic brain injury. Investigator discretion may be exercised on an individual case where surgery was performed that did not remove or significantly alter brain tissue (e.g., to treat a brain aneurysm). Surgery must have been performed at least 6 months prior to screening and a CT scan must be provided to demonstrate no large residual lesions.
6. Oral health problems active at the time of recruitment.
7. Any history of oral health problems (e.g., gum disease or cankers) will be noted on the data collection form.
8. Oral surgery within 3 months of screening.
9. History of oral cancer.
10. Non-removable metal orthodontic devices (e.g., braces) or oral cavity piercings that could interfere with PoNS™ use.
11. Presence of metallic implant or other MRI-incompatible device.
12. Blood pressure abnormalities considered clinically significant by the study physician. If the subject has a systolic blood pressure of <100 mmHg, they will be evaluated for orthostatic hypotension and if the study investigator deems this a risk for the subject's health or safety they will be excluded. If systolic blood pressure >160 mm Hg (average of 3 measurements) at screening and the subject is on medications, the subject will be referred back to their family doctor for review and control but can be re-evaluated once the treating physician deems them to have stable blood pressure. *Note: BP should be measured seated, legs uncrossed, after resting for 5 minutes, with measurements taken 2 minutes apart. If the first two readings differ by >5 mm Hg, additional measurements should be taken and averaged.*
13. Use of Coumadin or any other anticoagulant other than aspirin in the last six months.
14. Untreated or undiagnosed diabetes – the subject will be referred to their family physician and may be re-evaluated at a later date. Undiagnosed diabetes is defined as an HbA1C taken during screening above the upper limit of normal at the study site.
15. Diabetic neuropathy.
16. Active or recent (within 1 year) treatment for any cancer, excluding basal cell carcinoma.
17. Neurological disorders other than those attributed to the primary diagnosis, (e.g., neurodegenerative diseases such as Multiple Sclerosis (MS), Parkinson's Disease (PD), Alzheimer's Disease (AD) or other dementia, Amyotrophic Lateral Sclerosis (ALS).
18. History of epileptic or other seizure disorders.
19. Known ischemic heart disease (angina, stent, history of myocardial infarction, >70% stenosis or cardiovascular imaging) and/or history or atrial or ventricular arrhythmias with or without syncope. Any abnormality on the screening ECG will be referred to the subject's family physician for evaluation and clearance and then the subject can be re-evaluated for inclusion in the study.
20. Any other untreated or unstable acute or chronic, clinically significant medical condition for which the subject is currently undergoing treatment (e.g., autoimmune or immunodeficient disorders) and that the study investigator deems unsuitable for inclusion.
21. Use of a lower extremity biomechanical prosthetic with the exception of a splint to address foot drop.
22. Females who are breastfeeding, pregnant as determined by a pregnancy test, or planning to become pregnant during the study.
23. Chronic use of any potentially interfering drug such as a neuroactive (ototoxic, anti-seizure, anti-convulsive) medication, or chronic/PRN use of any medication that would, in the opinion of the investigator, compromise the subject's ability to function or perform the study activities.
24. Addition of and/or major change in type or dosage of any prescription medication within 3 months prior to receipt of the PoNS™ device at the time of screening, subject to physician discretion.
25. Active alcoholism documented with standardized tools (e.g., CAGE). The study investigator will have the right to exclude subject participation if, in their opinion, the subject seems intoxicated at time of screening and/or during any study appointment.
26. History of drug abuse will be assessed with standardized tools including the CAGE - AID. The study investigator will have the right to exclude subject participation if, in their opinion, the subject seems intoxicated at time of screening or presentation for treatment
27. Recent (6 months) history of smokeless tobacco use (i.e., chewing tobacco, oral tobacco, spit or spitting tobacco, dip, chew, snuff*) (*NCI definition) *Note: Cigarette, cigar, pipe, and/or e-cigarette use is not exclusionary*
28. Any reason, considered by the principal investigator or designee to preclude subject enrollment in the study that might represent a threat to health or safety.
29. Subject is incompatible with the device.
30. Any finding in the neuropsychological evaluation that, in the opinion of the study investigator renders the subject unsuitable for inclusion. Those with severe depression and/or anxiety as suggested by their scores on the BDI-II (above 30) and BAI (above 26) will be excluded.