PROTOCOL TITLE:

Effectiveness of Sensorimotor Multi-axis Automated Rotational Therapy (SMART) for Post- Concussion Syndrome Rehabilitation

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Primary Investigator:
Nichole Siebert, MS, LAT, ATC
GyroStim provider, records and data collection, study oversight
Neuroscience Group
920-725-9373 x3812
Nichole.siebert@neurosciencegroup.com

Sub-Investigators:
Benjamin Siebert, MD, FAAPMR
Patient provider, informed consent for study, and medical oversight
Neuroscience Group
920-725-9373 x5801
Benjamin.siebert@neurosciencegroup.com

Taylor Weuve, MBA, LAT, ATC
GyroStim provider, records and data collection
Neuroscience Group
920-725-9373 x5602
Taylor.weuve@neurosciencegroup.com

Research Assistant:
Gemma Hodgkiss
Medical Student, Medical College of Wisconsin
Data collection and entry
920-221-6621
ghodgkiss@mcw.edu

Consultants and study roles:

Christine McGee, DNP, APNP, NP-BC
Patient provider and informed consent for study
Neuroscience Group
920-725-9373 x5806
Christine.mcgee@nurosciencegroup.com

Steffany Di Biase, APNP, FNP-C
Patient provider and informed consent for study
Neuroscience Group
920-725-9373 x5806
steffany.dibiase@neurosciencegroup.com

Kevin Maher
GyroStim inventor, manufacturer and study design consultant
UltraThera Technologies
719-685-7883, ext. 102
kmaher@ultrathera.com

Courtney Hall, Ph.D.
Study design consultant, data analysis
Professor Emeritus
Eastern Tennessee State University
423-926-1171, ext. 7518
hallcd1@etsu.edu

Jill Diedrich, MSHA, CMA
Study design consultant
Neuroscience Group
920-725-9373, x8003
Jill.diedrich@neurosciencegroup.com

Nicole Shafran, SLP
Study design consultant
608-547-7362
nicole.shafran@thedacare.org

Standard Care Providers: These providers will be caring for and treating subjects in their respective fields. The standard testing they do will provide data for this study. These providers also helped input on the study design, with respect to their standard of care guidelines and practices. See sections 13, 14 and 15 for details on therapies and testing.

Katie Walters, DPT
Physical Therapist
Neuroscience Group
920-725-9373 x3811
Katie.walters@neurosciencegroup.com

Maria Joseph, DPT
Physical Therapist
Neuroscience Group
920-725-9373 x3805
Maria.joseph@neurosciencegroup.com

Jenna Kadlec, PT
Physical Therapist
Neuroscience Group
920-725-9373 x3802
Jenna.kadlec@neurosciencegroup.com

Lisa Truttschel, DPT
Physical Therapist
Neuroscience Group
920-725-9373 x3804
Lisa.truttschel@neurosciencegroup.com

Rachel Haugley, DPT
Physical Therapist
Neuroscience Group
920-725-9373 x3814
Rachel.haugly@neuosciencegroup.com

Caitlin Ryan, SLP
Speech Therapist
Neuroscience Group
920-725-9373 x3809
Caitlin.ryan@neurosciencegroup.com

VERSION NUMBER/DATE:

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REVISION HISTORY

Revision #	Version Date	Summary of Changes	Consent Change?
1	2/11/26	Frequency of GyroStim visits; new assistant; additional dx for inclusion	
2	5/19/26	Removal of PHQ-4 from inclusion/exclusion criteria; retrospective data date range	

NOTE: Leave this section blank for the initial submission. The revision history should be documented for modifications to approved studies.

TABLE OF CONTENTS

1. Study Summary

Study Title	Effectiveness of Sensorimotor Multi-axis Automated Rotational Therapy (SMART) for Post-Concussion Syndrome
Brief Summary	This study evaluates the effectiveness of SMART on the reduction of symptoms for patients with post-concussion syndrome. We hypothesize SMART is effective for reducing persistent symptoms of mild traumatic brain injury (mTBI).
Number of study sites	1
Primary Study Design	Prospective Cohort Study
Secondary Study Design	Retrospective Data Analysis
Primary Objective	To evaluate the effectiveness of SMART in the treatment of patients with persistent post-concussion syndrome.
Secondary Objective(s)	To evaluate the effectiveness of SMART to treat patients with chronic post-concussion syndrome who have plateaued in their recovery with standard of care (SOC) strategies.
Research Intervention(s)/ Investigational Agent(s)	Study will evaluate the effectiveness of SMART treatment, 2-4 treatment sessions per week, 10 sessions total to be completed within 5 weeks.
Drugs/devices used on study (including any IND/IDE #)	GyroStim - FDA Number: K220231
Study Population	18 year and older adult patients with a history of mTBI and diagnosed with post-concussion syndrome
Sample Size	116 required, recruit 128 – Prospective; 40-60 retrospective
Study Duration for individual participants	6 weeks
Study Specific Abbreviations/ Definitions	Sensorimotor Multi-axis Automated Rotational Therapy (SMART), Traumatic Brain Injury (TBI), Mild Traumatic Brain Injury (mTBI), Physical Therapy (PT), Speech Therapy (ST), Cognitive Rehabilitation Therapy (CRT), Occupational Therapy (OT), Post Concussion Symptom Scale (PCSS), Dizziness Handicap Inventory (DHI), Neck Disability Index (NDI), Functional Gait Assessment (FGA) and Modified Clinical Test of Sensory Interaction in Balance (CTSIB-m), Headache Impact Severity Level (Hit-6), Repeatable Battery for the Assessment of Neuropsychological Status (RBANS), Post-concussion syndrome (PCS), standard of care (SOC), Centers for Disease Control (CDC), Attention-Deficit/ Hyperactivity Disorder (ADHD), Food and Drug Administration (FDA), magnetic resonance imaging (MRI), computed tomography (CT), Optokinetic Nystagmus (OKN), Department of Defense (DOD), Electrical Muscle Stimulation (EMS), loss of consciousness (LOC), Sport Concussion Assessment Tool 5 (SCAT 5), indication for use (IFU), vestibular rehabilitation therapy (VRT), Vestibular Ocular Motor Screening (VOMS), Neuroscience Group (NSG), American Association of Neurological Surgeons (AANS), scheduling, information technology (IT), human relations (HR), ICD-10 (International Classification of Diseases 10th Revision)

2. Background

Concussion is a significant problem in the United States, contributing to 75% of the estimated 1.5 million traumatic brain injuries that occur each year (Permenter et al., 2022). However, the Centers for Disease Control (CDC) estimates that between outpatient cases and the many that go unreported, it is between 1.4 and 3.8 million concussions per year (Ferry & DeCastro, 2023). While the initial symptoms can be problematic and should be given appropriate consideration, concussions are generally self-limiting with a good prognosis. Around 90% of symptoms related to concussion are resolved within 10-14 days (Permenter et al., 2022). However, for some, symptoms can linger for weeks, months and even years (Suleiman et al., 2019). While definitions and criteria for these lingering symptoms vary in literature, a diagnosis of post-concussion syndrome (PCS) is given for those with symptoms lasting for greater than 4 -12 weeks post injury (Permenter et al., 2022, Suleiman et al., 2019, Patricios et al., 2023). Unfortunately, clearly defined, comprehensive, and evidence-based treatments and rehabilitation for those suffering from PCS is lacking.

The term concussion is often used interchangeably with mild traumatic brain injury (mTBI). According to the American Association of Neurological Surgeons (AANS), concussion “is defined as a clinical syndrome characterized by immediate and transient alteration in brain function, including alteration of mental status or level of consciousness, that results from mechanical force or trauma (Agarwal et al., 2024).” The trauma causing a concussion may be a direct or indirect blow to the head, or may result from rapid acceleration, deceleration, or rotational movements of the head (Ferry & DeCastro, 2023, Agarwal et al., 2024). It is recognized that while traditional magnetic resonance imaging (MRI) and computed tomography (CT) imaging does not show noted structural changes for those with concussion, at the functional, metabolic and blood flow

levels, changes may be noted (Patricios et al., 2023). This is due to the neurometabolic cascade that occurs at the time of injury. This cascade causes many changes at the cellular and biochemical levels including ionic shifts and changes in neurotransmission, connectivity, and metabolism. These changes lead to neuronal dysfunction and can cause axonal injuries and changes in blood flow (Ferry & DeCastro, 2023, Patricios et al., 2023, Giza & Hovda, 2001).

The American Congress of Rehabilitation Medicine (ACRM) lists 6 criteria for a concussion (Silverberg et al., 2023):

1. A plausible mechanism of injury
2. One or more clinical signs including loss of consciousness, altered mental status, amnesia, or other acute neurologic signs.
3. 2 or more acute symptoms including subjective altered mental status, physical symptoms, cognitive symptoms, and/or emotional symptoms.
4. Clinical examination and laboratory findings, including cognitive, balance or oculomotor impairment or blood biomarkers indicative of intracranial injury.
5. While not required, abnormal neuroimaging is considered.
6. Signs and symptoms cannot be better accounted for by confounding factors.

The types and severity of symptoms of concussion can vary from individuals, but they may include memory and/or concentration deficits, emotional or behavioral changes, headaches, confusion, dizziness and imbalance, visual disturbances and sensitivity, tinnitus, nausea and/or vomiting, insomnia and fatigue (Permenter et al., 2022, Agarwal et al., 2024). While factors such as age, sex and preinjury status and health complications can impact recovery from concussion, the majority of adults have resolved symptoms within 7-10 days with proper post-injury management. The literature demonstrates variability in the percentage of adult athletes that do not recover in the

expected time frame (Ellis et al., 2016). Those with symptoms that persist past 3 months is estimated to be around 15%. However, due to reporting variability amongst healthcare providers, difficulty with accurately documenting impaired cognitive function of patients and limited diagnostic tools, it is believed to be higher than 15% (Permenter et al., 2022). PCS symptoms are those symptoms that remain unresolved from initial injury resulting in concussion, and they can be debilitating affecting an individual's physical, emotional and social lives. Many symptoms such as headache, dizziness, depression, and fatigue overlap with many other health problems. Because of this, getting accurate patient history related to their head injury and previous medical history are extremely important. Studies show that women, a history of Attention-Deficit/ Hyperactivity Disorder (ADHD) or other mood disorders, and a history of previous concussion are more likely to have lingering symptoms. There is mixed evidence that severity of injury or symptoms are correlated with PCS (Permenter et al., 2022, Ellis et al., 2016).

Those that suffer from PCS can have long lasting cognitive and autonomic nervous system dysfunction due to damage that can affect the sympathetic and parasympathetic nervous systems. This damage can manifest itself in symptoms such as depression, headaches, dizziness, confusion and concentration difficulties, and even orthostatic intolerance (Permenter et al., 2022). It is also well documented that the vestibular system is greatly impacted from damage, which can affect balance and cause vertigo, syncope, and other symptoms. While the vestibular system is often recognized, chronic visual dysfunction after a concussion is often overlooked or underappreciated by many health professionals. This exists despite the well-established connection between the vestibular and ocular systems (Suleiman et al., 2019).

Treating the vast constellation of symptoms that exist for those with PCS is challenging, and little evidence-based, comprehensive research has been done to

address caring for these patients. The recent 6th Consensus Statement on Concussion in sport notes that rehabilitation for specific symptoms, combinations of rehabilitation, timing, and accounting for modifying factors such as sex and age are not well established. However, rather than do nothing for athletes with lingering symptoms they recommend vestibular and/or cervicovestibular rehabilitation to help facilitate recovery (Patricios et al., 2023). The Clinical Practice Guidelines for Physical Therapy Evaluation and Treatment After Concussion/Mild Traumatic Brain Injury discuss symptom-based interventions. These interventions include addressing possible movement related and motor function impairments, cervical and musculoskeletal impairments, vestibular and oculomotor impairments, as well as exertional and exercise intolerance (Quatman-Yates et al., 2020). One particular report focused “on the early identification and targeted treatment of the pathophysiological mechanisms governing persistent concussion symptoms… [and] also outlines the qualified roles and responsibilities of healthcare professionals that can help contribute to the multi-disciplinary managements of this unique patient population” (Ellis et al., 2016). This report classified PCS into subcategories of physiological, vestibulo-ocular, and cervico-genic PCS, and recommended interventions based on these groups. They also recommended neuropsychological testing and interventions for those with cognitive dysfunction and pharmacologic intervention for headaches (Ellis et al., 2016).

Unfortunately, a 2021 systematic review of Nonpharmacologic Treatments of Persistent Post-concussion Symptoms in Adults, found very low evidence for treating PCS symptoms with commonly recommended interventions such as vestibular rehabilitation, graded physical exercise, manual therapy, psychological treatments, oculomotor vision treatment, or psychological intervention. They stressed the need for further research on interventions for those with PCS (Rytter et al., 2021).

2.1 Potential Solution

Given the need for improved treatments for patients that suffer from PCS, this study will collect data from clinical use of Sensorimotor Multi-axis Automated Rotational Therapy (SMART) to present to the Food and Drug Administration (FDA) as evidence of efficacy for an improved therapeutic treatment for PCS.

SMART has been in use for fifteen years and is recognized as an effective intervention for therapeutic treatment of vestibular dysfunction resulting directly from mTBI. GyroStim is FDA cleared and has been designated by the FDA as a Breakthrough Medical Device for the treatment of vestibular dysfunction. SMART is used to stimulate, challenge, and improve the functional performance of the human sensorimotor system. GyroStim is a medical device designed specifically to provide SMART, and it will be utilized in this study.

In 2022-23, a retrospective data collection was done at Heyser Chiropractic Neurology @ the Brain Center in Tallahassee, Florida. This was completed by Bill Heyser, DC. The data compares the results of two separate groups that suffered from a concussion, one group was subject to standard of care (SOC) treatment and the other group was subject to all SOC treatment plus SMART intervention with GyroStim.

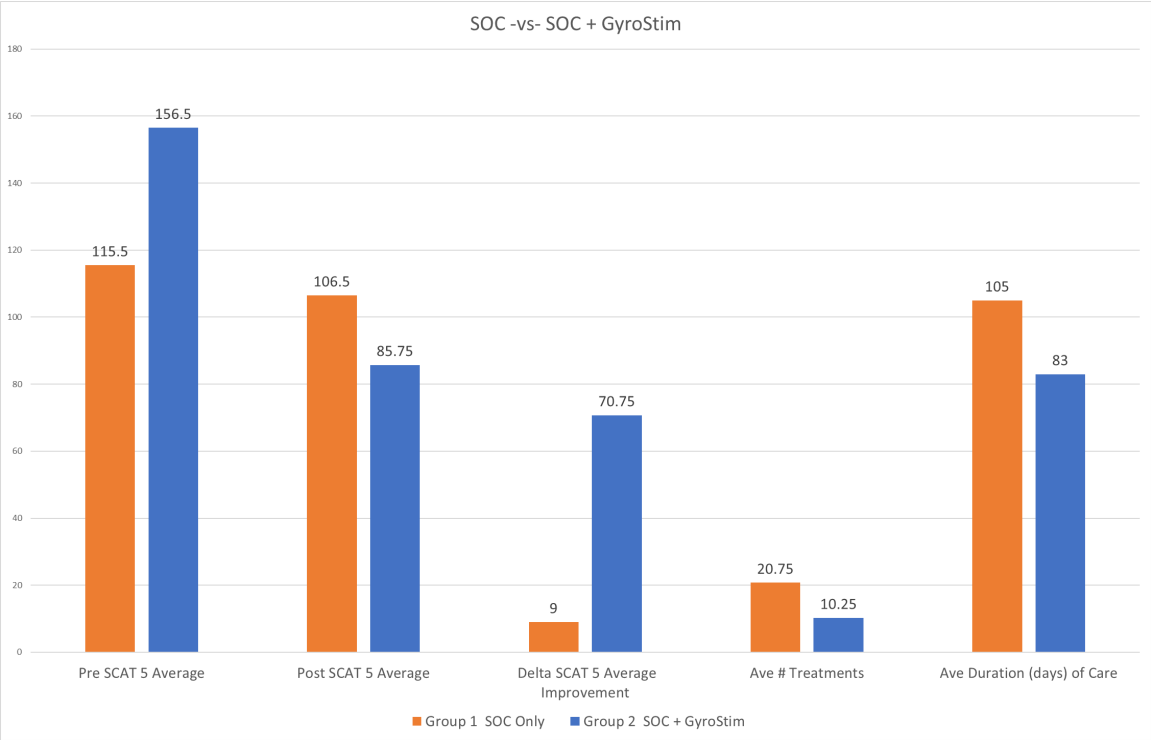
Standard of care treatment included the following interventions:

- Neurosensory Integrator for multi-modal therapy including balance and rhythmic stabilization, motor/ sensory coordination, neurological rehab, improving reaction time, visual therapy including saccades and Optokinetic Nystagmus (OKN), and cognitive challenge.
- Visual therapy to improve convergence, saccadic, and pursuit activity to integrate with motor/sensory and cognitive activity. Integrate visual,

auditory, sequential programming. Gaze stabilizing exercises

- Cognitive therapy to improve memory, visual and auditory processing, such as memory exercises, Stroop exercises, mixed number-word exercises, etc.
- Motor/sensory challenges with hand/eye coordination and memory/ sequential processing
- Exercise bike to increase heart rate and oxygenation with visual or cognitive challenge, such as saccadic exercises using Hart charts for scanning, reading, word finding, and near/far saccades
- Acupuncture, including neuro-acupuncture (scalp acupuncture) per Department of Defense (DOD) protocols
- Chiropractic Manipulative therapy to establish and maintain normal biomechanics, especially of the cervical spine
- Nutritional supplementation for metabolic support
- Hyperbaric to increase oxygen saturation
- Pain management consult for nerve block to decrease headache symptoms
- Electrical Muscle Stimulation (EMS) to increase afferentation to brainstem
- Cold laser for photomodulation effects to various tissues and organs
- Gait training and exercises

The subjects in the study are concussion patients with loss of consciousness (LOC)<30mins. The chart compares data collected using Sport Concussion Assessment Tool 5 (SCAT 5) for the assessment of symptom recovery over time. Group 1 patients were treated with Standard of Care (SOC) only. Group 2 patients were treated exactly as patients in Group 1, except this group of patients was also treated with SMART.



The data shows patients in Group 2 who received SOC plus SMART experienced an average of approximately 6X greater improvement on their SCAT 5 score than patients in Group 1 who were treated with SOC alone. Additionally, Group 2 gains occurred with an average of 1/2 the number of treatment sessions than patients in Group 1.

Since its first clinical use for concussion in 2010, GyroStim has helped thousands of patients achieve successful recoveries, offering real-world validation of its effectiveness for vestibular dysfunction and other complications of mild traumatic brain injury (mTBI). Despite the large number of successful patient outcomes reported, and from pilot studies such as the one presented above, there are no scientifically valid studies for demonstrating efficacy of SMART. The purpose of this study is to generate and gather scientifically valid clinical data that formally documents and supports the claims of these outcomes, so mTBI/PCS may be specifically included in GyroStim's

indication for use (IFU). The current Indications for Use (IFU) include the general indication for treatment of balance disorders and vestibular dysfunction, which supports GyroStim's clinical application across a broad spectrum of neurological conditions known to benefit from vestibular rehabilitation therapy (VRT). This scope inherently encompasses patients with mTBI/PCS-induced vestibular dysfunction. However, to reduce confusion in the marketplace and ensure clarity, UltraThera intends to amend the IFU to explicitly state: "...and treatment for mTBI/PCS."

GyroStim is a computer-controlled multi-axis rotational chair. During treatment, the patient is safely and comfortably secured in the chair with a 5-point torso harness, an interlocked lap belt, and an interlocked ankle restraint. The rotational chair is surrounded by a safety perimeter and is accessible through an interlocked entrance door. The circular safety perimeter has a steel frame and is fitted with clear polycarbonate panels mounted around the structure.

The GyroStim operator has complete control of all movements of the rotational chair via the user interface computer. The operator can select prewritten motion profiles from a library within the software. Profiles can be selected in a strategic sequence that gradually increases a patient's movements in degrees of motion, rotational speed, and in short durations from 15-60 seconds, each time being called a "run." A typical therapy session will be comprised of 3 to 10 runs and will last approximately 30-40 minutes. Treatment typically begins with motion profiles that generate low levels of therapeutic stimulation that have slow rotation rates and move in minimal degrees of motion. The operator, working closely with the patient, can incrementally increase the intensity of the profiles as needed throughout the course of therapy.

GyroStim also has 4 laser-detecting targets that are positioned around the chair.

The patient will be asked to use a handheld laser pointer to aim at and hit the targets during each run. The laser targets will transmit each laser hit back to the GyroStim computer where the hits will be counted and expressed in a value of hits-per-minute. Each run is followed by a rest period, and the patient is monitored for changes in symptoms using the Vestibular Ocular Motor Screening (VOMS) test scale. The VOMS scale is used in combination with the hits-per-minute score. Together they allow clinicians to administer data-driven therapy sessions that are individualized, providing safe and effective therapy progression while protecting the patient from overstimulation.

Chronic post-concussion symptoms manifest and may persist as vestibular and cognitive dysfunction. SMART provides a means to address these symptoms, thereby a means to potentially address and resolve persistent post-concussion syndrome, providing relief for millions of patients.

2.2 This Study

The purpose of this study is to collect both retrospective and prospective clinical data for a statistical analysis of the effectiveness of GyroStim/SMART as a therapeutic intervention for post-concussion syndrome, both in terms of how it effects the rate of recovery and the extent of recovery.

3. Study Objectives and Endpoints

3.1 The objective of this study is to collect clinical data, both retrospective and prospective to document and statistically analyze the effectiveness of SMART in the treatment of patients with post-concussion syndrome.

3.2 We hypothesize that patients who include SMART therapy as part of their treatment regimen will improve faster than patients who do not include SMART treatment.

3.3 We hypothesize that patients whose treatment approach includes SMART will improve to a greater extent in their primary outcome measures than patients whose treatment approach did not include SMART.

3.4 The primary study endpoints are Post Concussion Symptom Scale [(PCSS) see Appendix B] Headache Impact Severity [(HIT-6) see Appendix C], [(NDI) see Appendix D], Dizziness Handicap Inventory [(DHI)see Appendix E], Neck Disability Index Functional Gait Assessment [(FGA) see appendix F], Modified Clinical Test of Sensory Interaction in Balance [(CTSIB-m) see Appendix G], Repeatable Battery for the Assessment of Neuropsychological Status [(RBANS) see Appendix H], and the Rivermeade Post-Concussion Symptom Questionnaire (see Appendix I). These assessments will be performed before, midway, and after intervention. There are no secondary end points to be evaluated.

3.5 Safety endpoints include improvements in symptoms related to those primary endpoint measures. This includes improvements in headache, dizziness, balance, nausea, and cognitive function.

3.6 Stopping rules include serious adverse events, such as injury or significantly worsened symptoms in one or more participants that would require other medical or emergent intervention. The study may also be stopped should interim data analysis reveal overall worsening of subjects in the SMART group, as compared to the control group. Other possible stopping rules would include unforeseen and unlikely events such as significant equipment problems with the GyroStim machine or computer that cannot be easily fixed, or major facility or personnel issues that cannot be easily or quickly rectified. Other possible rules would include the inability to recruit an adequate number of patients to complete the study.

4. Number of Participants

4.1 The prospective portion of this study will include 128 participants treated at the same location. We anticipate screening approximately 200 potential participants to reach our enrollment goal.

4.2 Analysis requires 116 participants with 54 in each group. 128 will be enrolled, allowing for 64 in each group.

4.3 Participants who leave the study early will be replaced, if we fall below the 116 participants needed.

4.4 The retrospective portion of this study will include clinical data from all patients that began SMART for treatment of symptoms related to a PCS diagnosis from 9/1/23 through 12/31/25, which is between 40-50 patients.

5. Inclusion and Exclusion Criteria

5.1 Participants will be screened in person by a clinic physician or nurse practitioner.

5.2 A history of closed head injury and a current diagnosis of mTBI with persistent symptoms (≥ 4 weeks) consistent with persistent post-concussion syndrome (PPCS) or post-concussion syndrome (PCS) is the primary criteria for inclusion into the study. Subjects must also have a diagnosis of imbalance, dizziness or other relevant vestibular dysfunction. A diagnosis of relevant cognitive deficits or difficulties is required to qualify for ST/CRT. Any cognitive deficits or difficulties must be related to mTBI/concussion and must not be to the extent that would negate a subject's ability to consent themselves. Subjects must be at least 18 years of age and able to communicate verbally and be competent to consent.

5.2.1 Subjects may have received care for their concussion and related symptoms from other providers prior to seeking care at Neuroscience Group. Providing they meet the above criteria, they will not be excluded from participation, as long as they are not doing PT or ST/CRT concurrently or have previously done SMART elsewhere for the treatment of this head injury.

5.3 Exclusion criteria include those patients under 18 years of age, those not competent to consent, those with a concussion that occurred less than 4 weeks prior to initial visit, weighing greater than 400lbs, greater than 7ft tall, those unable to communicate verbally, pregnant, less than 12 weeks post-partum, active benign paroxysmal positional vertigo (BPPV), severe claustrophobia, uncontrolled hypertension, uncontrolled seizures, ankylosing spondylitis, concern for postural cardiac issues, active cervical radiculopathy or active cauda equina symptoms, Chiari malformation Type II-IV, detached retina, or severe limitations with cervical range of motion. Other exclusions include those with neurological disorders including multiple sclerosis and Parkinson's, severe depression or anxiety, those with hearing impairments, and significant vision dysfunction, and recent upper extremity injury.

5.3.1 As pregnancy is an exclusion, medical staff will have potential female subjects fill out a pregnancy questionnaire (see Appendix K) to determine if pregnancy is a possibility. If it is possible, the subject will be given a form (see Appendix L) and provided with a home pregnancy test and package instructions (or they may use their own), which will need to be filled out and returned at the beginning of their first therapy visit. The home pregnancy test will need to be done within 3 days of their first visit. They will also be advised to continue with proper contraception or abstinence, and they will also be informed that should they become pregnant, they will need to notify a

member of our medical staff at Neuroscience Group as soon as possible.

5.4 Exclusions with special consideration and approval from provider may include post-surgical patients (must be greater than 8-12 weeks post-op to participate and may request approval from surgeon). Patients that receive care prior to the 4 week date post-concussion, may potentially still participate, depending on the care received. This will be up to the discretion of our physician or nurse practitioner, if they feel it has significantly altered their expected prognosis or recovery timeline that could affect the study results.

5.5 Prescription anticoagulant medication use such as warfarin, heparin, lovenox and others will exclude a patient from participation. Over the counter aspirin use will not exclude a patient. Vitals including blood pressure, SpO2 and heart rate are taken prior to participating in GyroStim to help screen for potential issues. As always, the well-being of our patients is primary concern, and if the physician or nurse practitioners feel participation in this study due to medications is an unnecessary risk, the patient will be excluded from consideration.

5.6 Retrospective participants are nearly identical in the above inclusion and exclusion criteria.

6. Special Populations

6.1 This study will not enroll or use data from any special populations.

7. Recruitment Methods for Prospective Study

7.1 Participants will be new patients or current Neuroscience Group (NSG) patients who are newly diagnosed with PCS.

7.2 Participants will be recruited from the patient population within two possible clinic sites. They will be screened from their initial appointment with either Benjamin Siebert, MD, Christine McGee, DNP, APNP, NP-BC, or Steffany Di Biase, APNP, FNP-C for a diagnosis of post-concussion syndrome. All patients will be treated according to their symptoms, findings, and medical and rehabilitation needs, and those that qualify for the study will be asked if they will volunteer for the research study. All necessary medical records will be accessed through EPIC, by those involved in the care and management of these patients.

7.3 Patients will be asked to consider participation during their initial evaluation for post-concussion complications. If they are unsure, they will have two

business days to determine their participation. They will need to let our scheduler know their participation status at the time of their initial call.

7.4 There will be no formal materials used for recruitment, as the proposed study is in line with our current options and plan of care for our concussion patients. No additional materials or forms will be provided to potential subjects, other than the informed consent and pregnancy questionnaire and possible test form for potential female subjects. Should a patient desire to see GyroStim and how it works prior to deciding to participate, that can be arranged. The providers will explain their treatment options, and if they are qualified candidates, they will be asked if they would be willing to participate in the research. If they are not willing, they will not be denied SOC treatment or have their treatment plan altered in any way. Treatment options would include physical therapy, speech therapy, and GyroStim. Other options may include medications for headache management and sleep, vision therapy, optometry referrals, counseling or behavioral health referrals, further treatment for pain management, and referrals to other specialties, such as neurology.

7.5 There will be no compensation for participants in either Group.

8. Consent/Assent Process

8.1 Informed consent for Prospective Study:

- Informed consent will be obtained by our physician or one of the nurse practitioners (see 5.2).
- The consent process will take place onsite at Neuroscience Group, in one of the private clinic exam rooms.
- The consent process will be conducted face-to-face, in person.
- If a patient is unsure about wanting to participate, their provider will still go through the consent form and answer all questions. Our scheduler will contact the patient within approximately 2 business days and inquire about their decision to participate in the study or not. If they choose to proceed with participating, they will be asked to bring the consent form to their first PT or ST/CRT visit and sign it in the presence of their provider. If they would like more time to decide on participating, they can arrange a follow-up phone call with our scheduler.
- All participants have the right to stop treatment or withdraw from the study at any time. At the start of each PT session, ST/CRT session and SMART treatment session, and during those sessions, participants are frequently asked about their consent to proceed.

8.2 Informed Consent for Retrospective Study

- No informed consent will be utilized for the collection of retrospective data.

9. Process to Document Consent in Writing

9.1 All signed informed consents will be copied and given to the participants for their records. Signed copies will be kept in a folder to be retrieved by one of the investigators to then document and store in a locked cabinet.

10. Setting

10.1 All data collection and related patient care will be performed in-clinic at Neuroscience Group. Initial provider exams will be performed in traditional, private exam rooms. SMART sessions will be conducted in-clinic, in a private room that is designed specifically for the GyroStim equipment. Speech therapy (ST) or Cognitive Rehabilitation Therapy or CRT) will be performed in-clinic in a private room that is appropriately set up for evaluations and therapy. Physical therapy will take place in clinic with some exams and manual therapy being performed in a private room, and some exercises being done in a common physical therapy gym.

10.2 This is a large, private medical clinic with 2 main locations in Appleton and Neenah, Wisconsin. We have 58 licensed providers and 140 additional care team personnel and staff to assist with reception, phone calls, billing, scheduling, information technology (IT), human relations (HR), public relations, management, etc. The Appleton location has approximately 31,225 square feet, including 41 exam/treatment rooms. The physical therapy gym at the Appleton clinic is approximately 1,600 square feet and is appropriately equipped. The Neenah location has approximately 38,920 square feet with 58 exam/treatment rooms. All exam/treatment rooms are appropriately equipped to care for our patient population. There is an appropriately equipped physical therapy gym that will be utilized at the Appleton location that is approximately 1,269 square feet.

11. Study Intervention

11.1 The study intervention is a therapeutic treatment for persistent post-concussion symptoms following mTBI. The therapy will be administered with a therapeutic medical device called GyroStim. GyroStim is FDA cleared and has been designated by the FDA as a breakthrough medical device (FDA number K220231). The intervention therapy produced by GyroStim is sensorimotor multi-axis automated rotational therapy, or

SMART, and is the primary intervention of this study. SMART is used to stimulate, challenge, and improve the functional performance of the human sensorimotor system. SMART is administered with a methodology that presents incremental challenge to regions of the sensorimotor system that may have become dysfunctional as a result of mTBI. GyroStim offers technological advantages that allow it to produce a wide range of precisely controlled and complex therapy intensities, or "dosage of intensity," with greater precision, control, and intensity than can be produced with manual PT techniques. GyroStim software provides the GyroStim operator with real-time objective and subjective patient response data that is used by the operator to individualize and optimize each therapy session. The real-time data is also used by the clinician for monitoring and protecting the patient from overstimulation that can occur during therapeutic treatment of mTBI. GyroStim software has capabilities to manage basic patient data, as well as treatment/run data. GyroStim software allows the clinician to select and run specific, individual programs in a series of runs that present incrementally increasing intensity, duration, and cognitive challenge to help promote functional gains and achieve patient rehabilitation. The intervention device, GyroStim, consists of a circular safety perimeter that has a steel framework with a safety interlocked entry door. The entire perimeter is paneled with transparent polycarbonate sheets to allow the GyroStim operator to maintain constant visual observation of the patient during therapy. GyroStim is a multi-axis rotational device consisting of two rotational frames, with the first frame rotating in the yaw axis (clockwise and counterclockwise) and the second frame mounted on top of the first frame and rotates in the pitch axis (forward and backward). The rotational frames are attached to powerful and precise electrical motors that provide motion in their respective axis. Each frame can rotate about its axis through 360 degrees continuously, either one axis at a time, or both axes simultaneously, if desired. The patient chair is mounted within the pitch frame. It has clear polycarbonate safety shielding on both sides and overhead and is open at the front of the chair for patient access. The chair has an adjustable 5-point patient harness for securing the patient during rotation, the seatback height is adjustable, and the chair has an adjustable height footrest. There is an electronically interlocked safety belt for securing across the patient's lap, as well as an electronically interlocked belt that goes across the patient's ankles. Both yaw and pitch motors receive motion commands from the user interface computer. The motors work collectively to rotate the chair specifically as directed by the prewritten therapeutic program that has been selected by the clinician. The GyroStim software has a library of prewritten programs that provide quick and easy access to all 30 levels of therapeutic

intensity. There are 4 laser-detecting targets that are mounted on the safety perimeter, with approximately 90 degrees separation between each laser target. While rotating in the chair, the patient may be directed by the clinician to use a hand-held laser pointer in their right hand, left hand, or both hands to try and hit the targets. Each time the patient hits a target, the target will illuminate and beep. Additionally, the target will transmit a "hit" signal to the user interface computer for data processing and collection. Patient safety is continuously maintained via numerous hardware and software safety interlocks. Each interlock must be in a safe state, or the device will not operate, i.e., door must be shut, step must be down, all safety belts must be latched, door must be closed, etc. There are patient activated STOP buttons located at the end of each hand hold which allows the patient to terminate the therapy run at any time. The operator has access to a STOP RUN button on the user interface screen that will terminate the run and bring the patient back to the HOME position. There is a large emergency stop button that is position near the operator that when pushed removes all power from the automation motors in the event of an emergency.

11.2 *Drug/Device Handling:* The device being used, GyroStim, is a large, computer-controlled machine that cannot be moved to another room or location. It is also only run by two people within the clinic, with one person being the primary provider.

12. Prospective Study Timelines

12.1 An individual participant's average study time is 6 weeks.

12.2 It is anticipated to take approximately 18 months to complete the study of 116 participants.

12.3 It is estimated to take approximately 18 months from IRB approval to complete the study.

SMART Research Study Schedule

Group	Week 1	Weeks 2-5	Week 6
SOC Only Group	PT & ST/CRT baseline testing during 1st visits	PT & ST/CRT once per week each	PT & ST/CRT follow-up testing
GyroStim Group A	• PT & ST/CRT baseline testing during first visit • Begin GyroStim visits after testing, up to 2 times per week	• PT & ST/CRT once per week each • Complete up to 2 GyroStim visits per week.	PT & ST/CRT follow-up testing after completing GyroStim visits
GyroStim Group B	• PT & ST/CRT baseline testing during first visit • Begin GyroStim visits after testing with visits up to 3 times per week	• PT & ST/CRT once per week each • Complete up to 3 GyroStim visits per week.	PT & ST/CRT follow-up testing after completing GyroStim visits
GyroStim Group C	• PT & ST/CRT baseline testing during first visit • Begin GyroStim visits after testing with visits up to 4 times per week	• PT & ST/CRT once per week each • Complete up to 4 GyroStim visits per week.	PT & ST/CRT follow-up testing after completing GyroStim visits

13. Prospective Study Procedures Involved

13.1 Participants will self-select into Control Group, or GyroStim Group. All Groups will have the same experience during the intake process, and they will have the same training for at-home daily exercise routines. Each group will contain 64 participants for a total of 128 participants. Control Group participants will be treated with SOC involving one in-clinic targeted physical therapy (PT) session per week, for five weekly SOC sessions total to be completed within 5 weeks. They will also be treated with cognitive rehabilitation therapy/speech therapy (CRT/ST) with one session per week, for 5 weekly sessions, to also be completed within 5 weeks. GyroStim Group participants will be treated the same as Control Group with SOC involving one in-clinic targeted physical therapy session and one cognitive rehabilitation therapy/speech therapy per week. In addition to their PT and ST/CRT each week, GyroStim Group participants

will also complete a total of 10 GyroStim sessions within a timeframe of no longer than 5 consecutive weeks. Preliminary data taken from a retrospective data analysis from patients at AVORA Health in North Carolina, collected by Kim Fox, DPT demonstrates faster rehabilitation times, with higher frequency visits utilizing GyroStim (write-up done by Keving Maher, Ultrathera Technologies and analysis done by Coutney Hall, PhD, Professor Emeritus at Easter Tennessee University; see Appendix M for write up). As such, it is recommended to have patients participate in GyroStim visits up to 4 times a week. However, given patient needs, the study is designed with treatment density per week flexibility, allowing patients to select to participate at treatment density rates of 4, 3, or 2 sessions per week. Outcome data from all participants in both groups will be included in the study outcome data.

13.2 Standard of care for all participants in both groups will include physical therapy and CRT/ST. Other treatments or therapies may also include vision therapy/rehabilitation, vitamin/supplement utilization, medications and interventional treatments for headache management and/or other pain, medication for treatment of sleep disruption, neuro-optometry with eyeglass prescription with or without prism glasses, neuropsychological testing, pain management, and/or behavioral counseling.

13.3 Assessments will occur for all participants in both groups, Control Group and GyroStim Group, based on the following schedule:

- Baseline Test – tests will occur at the beginning of the first visit with PT and with CRT/ST. If the participant is doing GyroStim, they will also begin their session within that week.
- Follow-up – tests will occur at the beginning of the 6th PT and CRT session.

14. Prospective Study Outcome Measures

14.1 Assessments for all participants will include the following:

PT Testing:

- Post Concussion Symptom Scale (PCSS) (Appendix B)
- Headache Impact Severity Level (HIT-6) (Appendix C)
- Neck Disability Index (NDI) (Appendix D)
- Dizziness Handicap Inventory (DHI) (Appendix E) Functional Gait Assessment (FGA) (Appendix F)
- Modified Clinical Test of Sensory Interaction in Balance (CTSIB-m) (Appendix G)

CRT/ST Testing:

- Repeatable Battery for the Assessment of Neuropsychological Status (RBANS)
- Rivermeade Post-concussion Symptom Questionnaire (Appendix I)

15. Prospective Study Intervention

15.1 Control Group: SOC

- Customized Physical Therapy
  - Each participant will follow typical SOC physical therapy that will be individualized to provide targeted therapy strategies for treatment of their specific mTBI symptoms.
    - The treating clinician will create and provide a customized VRT home exercise program (HEP) per standard of care, consisting of gaze stabilization, habituation, balance and gait exercises, and endurance training (Hall et al., 2021). Gaze stabilization exercises (GSE) were developed based on the concepts of VOR adaptation and substitution and involve head movement while maintaining fixation on a target which may be stationary or moving. Gaze stabilization exercises based on the principles of substitution were developed with the goal of promoting compensatory strategies. For example, during eye-head movement between targets, a large eye movement to a target precedes the head turning towards the target, potentially facilitating preprogrammed eye movements. Habituation involves repeated exposure to the stimulus that causes dizziness and over time this systematic repetition of provocative movements leads to symptom reduction. Habituation exercises are chosen based on movements (of self or the visual environment) that provoke symptoms, and the patient performs several repetitions of body or visual motions that cause mild to moderate symptoms. Balance and gait exercises are chosen based on identified impairments and limitations and are performed under challenging sensory and dynamic conditions to optimize functioning of the sensory and motor systems underlying postural control. Balance exercises may include static standing balance with altered base of support, altered visual and somatosensory cues, dynamic weight shifting and reactive balance control training. Gait activities may include walking on uneven terrains, over/around obstacles, and walking with head turns, varied speeds, and with a cognitive or motor dual task. General conditioning, such as a customized graduated walking program for endurance, is frequently an element of VPT because individuals

with dizziness often limit physical activity to avoid symptom provocation.

- Each participant will receive 6 SOC therapy sessions, with testing to be done at the beginning of the 1st and 6th visit. The sessions will be in-clinic with a physical therapist(s), occurring once per week, and all 6 sessions must be completed within 6 weeks.
- Each participant will be given training and instructions for performing at-home therapy exercises during the intervention period.
- Each participant will be encouraged to maintain proper hydration and nutrition, optimize sleep, reduce stressors, and comply with other directed clinical therapies/treatments, if indicated, during the 6-week program.

- Cognitive Rehabilitation Therapy/Speech Therapy
  - Each participant will also follow typical SOC CRT/ST that will be individualized to provide targeted therapy strategies for treatment of their specific cognitive symptoms related to mTBI/PCS.
  - Each patient will be evaluated at their initial CRT/ST appointment and undergo RBANS testing. They will be seen weekly for ongoing therapy. This may include education, energy management, memory, attention, reasoning, executive function, processing, and word retrieval tasks, as well as strategies to help aid in memory and attention at home, such as organizational and system suggestions to aid in maintaining schedules and functional tasks related to daily life. Patients are also assigned tasks to do at home which may include continued work on reading, puzzles, games, cards, etc.
  - Each participant will receive 6 SOC CRT sessions, with testing to be done at the beginning of the 1st and 6th visit. The sessions will be in-clinic with a speech therapist, occurring once per week, and all 6 sessions must be completed within 6 weeks.

15.2 GyroStim Group: SOC combined with GyroStim / SMART Therapy

- GyroStim therapy in addition to SOC targeted PT and CRT/ST
  - In addition to the intervention protocol described above for Control Group, participants in GyroStim Group will receive 10 SMART treatment sessions with GyroStim, with each session duration of less than 40 minutes. The in-clinic sessions will occur twice per week, will occur during the same week, but not on the same days

as their once per week visits each for PT and CRT/ST. All 10 GyroStim sessions will be completed within 5 weeks. Each SMART session will follow the GyroStim Run-to-Run Progression Strategy, with clinical decision making by a licensed athletic trainer (LAT) to help determine progression.

16. Schedule of Prospective Study Procedures

16.1

SMART Research Study Schedule

Group	Week 1	Weeks 2-5	Week 6
SOC Only Group	PT & ST/CRT baseline testing during 1st visits	PT & ST/CRT once per week each	PT & ST/CRT follow-up testing
GyroStim Group A	• PT & ST/CRT baseline testing during first visit • Begin GyroStim visits after testing, up to 2 times per week	• PT & ST/CRT once per week each • Complete up to 2 GyroStim visits per week. PT & ST/CRT follow-up testing after completing GyroStim visits	
GyroStim Group B	• PT & ST/CRT baseline testing during first visit • Begin GyroStim visits after testing with visits up to 3 times per week	• PT & ST/CRT once per week each • Complete up to 3 GyroStim visits per week. PT & ST/CRT follow-up testing after completing GyroStim visits	
GyroStim Group C	• PT & ST/CRT baseline testing during first visit • Begin GyroStim visits after testing with visits up to 4 times per week	• PT & ST/CRT once per week each • Complete up to 4 GyroStim visits per week. PT & ST/CRT follow-up testing after completing GyroStim visits	

- GyroStim is the device that will be used to produce the SMART therapeutic intervention being investigated.

- PT evaluated FGA and mCTSIB scores, patient reported CGS, HIT-6, NDI and DHI scores (see Appendices), and ST evaluated RBANS and Rivermeade Post-Concussion Symptom Questionnaire scores.
- Other noted interventions for patients may include other treatment, such as vision therapy, counseling, optometry, and headache management medications. However, unless significant trends appear within participant groups, there is no plan to investigate these further.
- Epic medical records may be used to collect information about the participants.

16.2 While participants may continue medical care, no additional long-term data will be collected for the study.

16.3 GyroStim is an FDA cleared medical device for the treatment of balance disorders and vestibular dysfunction. As vestibular dysfunction is often a symptom of post-concussion syndrome, it is being investigated as a treatment for PCS. All participants in this study have been diagnosed with either a balance disorder or vestibular dysfunction. There exists a large body of anecdotal evidence and patient testimony that patients experience significant reduction, and in many cases complete recovery from persistent symptoms from mTBI. This study aims to collect clinical data to assess whether this intervention produces statistically significant findings in this patient population.

16.4 GyroStim is safe to use up to 4 times per week in this study.
Based on cumulative clinical experience, published data, and device safeguards, use at a frequency of up to four times per week in the proposed study is supported as safe within established protocols.

16.4.1 Long-Term Clinical Use

GyroStim has been in clinical use since 2010, representing over 16 years of operational experience without reported serious adverse events attributable to treatment frequency. In clinical practice, treatment frequency has varied based on patient need, including higher-intensity schedules for traveling patients.

When patients travel long distances, typical protocols may include one to two sessions per day over five consecutive days without incident, demonstrating tolerance at frequencies exceeding four times per week.

16.4.2 Published Data

The Fox study (see Appendix M) included seven participants treated between four and ten times per week, with no reported adverse events.

While the sample size is limited, it provides direct evidence of tolerability at frequencies above four sessions weekly.

16.4.3 Standard of Care Context

Conventional vestibular rehabilitation therapy (VRT) commonly involves habituation exercises performed up to three times daily. GyroStim provides vestibular stimulation within a controlled, clinician-supervised environment, aligning with accepted therapeutic paradigms for vestibular habituation and adaptation.

16.4.4 Regulatory Status

GyroStim is cleared by the U.S. Food and Drug Administration for providing vestibular stimulation for symptoms of vestibular dysfunction. The FDA clearance does not specify limitations regarding frequency, intensity, or duration of treatment.

16.4.5 Built-In Safety Controls

The treatment protocol incorporates multiple safeguards:

- Symptom assessments between each run, comparing baseline and post-run status
- Data-driven decision-making (DDDM) is built into the software to prevent overstimulation
- Patient-controlled stop buttons on both handholds
- Controlled deceleration and automatic return to upright HOME position, if the patient presses the Stop button
- These mechanisms provide continuous monitoring and immediate intervention capability during treatment.

16.4.6 Conclusion

Considering:

- 16+ years of clinical use without frequency-related incidents
- Documented tolerability at frequencies exceeding four sessions per week
- Alignment with conventional vestibular therapy dosing paradigms
- FDA clearance without frequency restrictions
- Structured procedural safeguards and patient control features

Use of GyroStim at up to four times per week is supported as safe within the defined study protocol and standard operating procedures.

17. Comparison of Usual Care and Study Procedures

17.1 SOC for participants, with or without SMART, is available to all patients, without participating in the study. This may include all or none of the following: physical therapy, speech therapy, vision therapy, referrals for optometry, counseling, headache management medications, and other medically necessary referrals. All prescribed treatments are based on medical need and patient consent.

17.2 Testing procedures and therapy visits for participants in the study are the same as the testing procedures and therapy visits for patients who choose not to participate in the study. However, it is noted that participants in the study will be more stringently scheduled, as compared to non-participants, to improve statistical validity and reliability.

17.3 Great care was taken to design the study to fit the typical SOC for our patients. If it is in the best interest of the patient to alter their care in a manner that conflicts with the study design, the patient may be removed from the study and proceed with care as prescribed and recommended by their provider.

18. Withdrawal of Participants

18.1 Anticipated reasons for patient withdrawal without their consent include excessive rescheduling that alters testing timelines, illness, or other/additional injuries. Other possibilities include patient intolerance to SMART, although it is anticipated most of these patients will elect to self-terminate.

18.2 Orderly termination, as with any service, treatment, or therapy that is halted, will be discussed with the patient. It is this clinic's primary focus to treat and work with our patients, regardless of research status. Their SOC will continue, in ways to best accommodate the patient.

19. Data Management and Confidentiality

19.1 To prevent a loss of confidentiality, all paper study records will be stored in a locked cabinet in a locked room in room 1430 at the Neuroscience Group building at 445 W. Calumet Appleton, WI 54915. We will code study data with a study identifier (not participant's name) and keep coded data separate from personal information such as name and contact information. Study data (using only the study identifier) will be maintained in an electronic computer file on a secure server at Neuroscience Group. Only approved study staff will have access to any of the data. The results

of this study may be published and/or presented at meetings without identifying individual subjects.

19.2 All data and participant information will be secured in compliance with electronic medical records standards and will be treated according to all necessary HIPPA standards, as would any other medical data within the clinic. All providers undergo yearly HIPAA compliance training, as required by law for a medical practice. Any compiled data in spreadsheet form will/ be kept under secure electronic storage that is not connected to the internet. Any transmission of data will be through secure medical records software or secured email, which is used by the medical providers participating in this study. All de-identified study data will be kept for 3 years.

Select all that apply:

- x Data will be coded, and the "key" linking identities to codes will be kept separately from the data.
- ☐ Data will be coded, and the "key" linking identities to codes will be kept on paper only. The study data will be stored electronically and labeled only with codes.
- ☐ Only those listed as key personnel will have access to the "key."
- x Access to the "key" will be limited to the following persons (e.g., PI): Nichole Siebert, MS, LAT, ATC, Taylor Weuve, MBA, LAT, ATC, Benjamin Siebert, MD
- ☐ This study is funded by the National Institutes of Health and is covered by a Certificate of Confidentiality.
- ☐ This study is NOT funded by the National Institutes of Health but because it will collect sensitive information, the research team will apply for a Certificate of Confidentiality to protect data from being requested without the subject's consent as part of a legal proceeding.
- ☐ Other: _____

19.3 Describe how and where data and/or specimens will be stored and maintained. The following list is provided for convenience but is not an exhaustive list. Select all that apply:

- ☐ Online Collaborative Research Environment (OnCore) Biospecimen Management
- ☐ Research Electronic Data Capture (REDCap) *Specify which instance you will be using (e.g., ICTR's, Department of Medicine's)*: _____
- **x** Other software option that will be stored on departmental server. *Specify*: electronic file on secure server.

- **x** Locked filing cabinet or drawer inside a locked room. Specify the building: _Neuroscience Group 445 W. Calumet, Appleton, WI 54915, GyroStim room #1430._____
- **x** Other (describe): see 16.2 description_____
- **x** Data will not be stored or accessed on portable devices.
- ☐ Portable devices will be used to access secure web-based data collection sites such as ICTR's REDCap. No data will be stored locally on the device.
- ☐ Data stored on portable devices will be coded with the key stored separately. No identifiers will be stored on portable devices.
- ☐ Data stored on portable devices and therefore only encrypted devices will be used.

19.4 Management of Identifiers: Explain whether there will be a unique code on the specimen/dataset that can be used to LINK to a participant's identity, but will not, by itself, reveal who the participant is. If you will create and maintain a "key" linking identities to codes, explain where this key will be stored. Define when identifiers (such as names) or the "key" linking codes to identifiers will be destroyed, if known. Please modify the common options below as needed.

- ☐ Identifiers will be destroyed after all data has been collected.
- ☐ Identifiers will be destroyed at study closure.
- x Identifiers will be destroyed at study closure or at the time of publication.

20. Provisions to Protect the Privacy Interests of Participants

20.1 Where appropriate and possible, procedures will be performed in a private area where others cannot see the procedures being performed or overhear the conversation between subjects and researchers. The exception is the common physical therapy gym, but this is typical of PT gyms.

20.2 All members of the clinical study team are up to date on their institutional HIPAA training.

20.3 The study is not collecting information that could pose legal or reputational risks to participants.

20.4 Patients will have treatments and procedures explained thoroughly, prior to beginning the therapy. Patients are also encouraged to ask questions, and care is taken to assist patients in feeling comfortable.

Therapy is not initiated, carried out, or progressed without patient consent and acknowledgement.

20.5 All EMR data is accessed by authorized personnel only. Any data shared will be in coded, spreadsheet or document format, without patient names.

21. Sharing of Results

21.1 Depending on patients' other care providers' access to EMR, they may be able to see their care and treatments, but this would not differ from other normal medical care.

21.2 The results of the study will be shared with UltraThera Technologies for clinical evidence and in the FDA 510(k) application process for GyroStim. The de-identified data will likely be shared with insurance companies for consideration of treatment reimbursement, with peered reviewed journals for publication consideration, and with CMS for new CPT coding. UltraThera may present the de-identified clinical data to medical professionals, and anyone interested in considering SMART for treatment of PCS.

21.3 De-identified data will also be shared with Courtney Hall, PhD, Professor Emeritus at Eastern Tennessee State University for statistical analysis.

21.4 All de-identified data will be transmitted through secure, electronic means, such as EMR or secure e-mail.

21.5 As much as possible, any patient identifiers will be withheld/masked and only codes will be used.

21.6 The results of this study may be published and/or presented at meetings without identifying individual subjects.

22. Data and Specimen Banking

22.1 While we do not currently have plans to conduct further research after the completion of this study, it is possible the deidentified data maybe retained for further studies to be conducted at Neuroscience Group or distributed to other entities for further research.

23. Prospective Study Analysis

23.1 Statistical Hypotheses*: State the formal and testable null and alternative hypotheses for primary and key secondary endpoints, specifying the type of comparison (e.g., superiority, equivalence or non-inferiority, dose response) and time period for which each endpoint will be analyzed.*

H_1: We hypothesize that the group with SMART as part of their treatment regimen will improve faster than patients who do not include SMART treatment.

H_0: We hypothesize that the group with SMART as part of their treatment regimen will improve at the same rate as patients who do not include SMART treatment.

H_1: We hypothesize that the group with SMART as part of their treatment regimen will improve to a greater extent in their primary outcome measures from baseline to discharge than patients whose treatment approach did not include GyroStim.

H_0: We hypothesize that the group with SMART as part of their treatment regimen will improve to the same extent in their primary outcome measures from baseline to discharge than patients whose treatment approach did not include GyroStim.

23.2 Sample Size Justification:

A power analysis was performed with an alpha value of 0.05 and power of 0.95 with an estimated large effect size of 0.80, and a sample size 116 total (58 in each group) was determined to have the power to show a 2-tailed difference between these two groups given a matched paired design. The power analysis was performed using G*Power. To account for disqualification or dropouts, an additional 12 participants (10% attrition rate) will be recruited for a total of 128 participants.

23.3 Statistical Methods:

Descriptive statistics, including means/standard deviations and frequency/proportion as appropriate, will be calculated for demographic variables (e.g., age, gender, time from onset) and for the outcome measures at baseline and discharge. Group differences between the Standard and SMART groups for each of the outcome measures will be analyzed using Repeated Measures ANOVAs.

Statistical Power:
The primary objective and statistical analysis of the study remain unchanged; therefore, there is no need to reassess statistical power. The primary analysis will continue to compare **Group 1 versus Group 2**, as outlined in the original hypotheses. All patients in Group 2 will be combined for comparison to Group 1.

Treatment Frequency Selection:
The request to allow participant self-selection into 2, 3, or 4 sessions per week does not alter the primary endpoint or the primary Group 1 versus Group 2 analysis. The statistical structure of the study remains unchanged. Allowing this range of treatment frequency better reflects real-world clinical application of GyroStim. In routine practice, patients may be treated as infrequently as once per week or as frequently as ten times per week (e.g., twice daily), depending on clinical indication and tolerance. Systematically capturing treatment frequency data will permit exploratory analyses to evaluate potential dose–response relationships (as observed in the Fox study) between treatment frequency and clinical outcomes. These data may inform optimization of future protocols and guide study design aimed at improving therapeutic efficiency and patient outcomes.

23.4 Planned Interim Analysis:
Per the test schedule chart below, participants will be tested at the beginning and end of the study.

SMART Research Study Schedule			
Group	**Week 1**	**Weeks 2-5**	**Week 6**
SOC Only Group	PT & ST/CRT baseline testing during 1st visits	PT & ST/CRT once per week each	PT & ST/CRT follow-up testing
GyroStim Group A	• PT & ST/CRT baseline testing during first visit • Begin GyroStim visits after testing, up to 2 times per week	• PT & ST/CRT once per week each • Complete up to 2 GyroStim visits per week. PT & ST/CRT follow-up testing after completing GyroStim visits	
GyroStim Group B	• PT & ST/CRT baseline testing during first visit • Begin GyroStim visits after testing with visits up to 3 times per week	• PT & ST/CRT once per week each • Complete up to 3 GyroStim visits per week. PT & ST/CRT follow-up testing after completing GyroStim visits	
GyroStim Group C	• PT & ST/CRT baseline testing during first visit • Begin GyroStim visits after testing with visits up to 4 times per week	• PT & ST/CRT once per week each • Complete up to 4 GyroStim visits per week. PT & ST/CRT follow-up testing after completing GyroStim visits	

23.5 Handling of Missing Data:

An "intention to treat analysis" will be utilized and missing data will be imputed with the most recent data collected.

24. Potential Benefits to Participants

24.1 For patients that elect to proceed in the GyroStim Group that includes treatment with SMART, preliminary studies have shown benefit to patients with vestibular dysfunction and balance disorders. As PCS symptoms often include dizziness, imbalance, and symptoms of vestibular dysfunction, participants in this group will likely benefit with improved balance, reduced dizziness, and a reduction in other symptoms of vestibular dysfunction. Anecdotal evidence and patient testimonies suggest that participants in GyroStim Group may also experience improvement in cognitive function, reduction of headaches, reduction of sensitivity to motion, bright light, and loud sounds, improved sleep, and other persistent symptoms from mTBI.

25. Risks to Participants

25.1 The reasonable, foreseeable risks for patients that elect to proceed in either the Control Group or the GyroStim Group, are the same. An increase in any therapeutic activity level can produce a temporary exacerbation in symptoms such as a presentation or temporary worsening of headache, light-sensitivity, dizziness, vertigo, disorientation, nausea, brain fog, difficulty with attention, memory and/or concentration, fatigue, neck pain, insomnia, emotional dysregulation and other symptoms of mTBI. It is expected that the emergence or worsening of mTBI related symptoms are temporary and should resolve/reduce to previous baseline within a few hours to a few days. While unexpected, it is possible that worsened symptoms could last longer or become chronic.

25.2 Risk from withdrawing or delaying treatment involved in the study are minimal and may include the lack of resolution of symptoms that may have resulted from engaging in therapeutic treatment for mTBI. Data from patients who deviate from study timeline requirements will not be included in the study.

25.3 If a patient becomes pregnant, they will be removed from the study. They may still receive standard of care treatment for their symptoms, as deemed best by their medical providers.

25.4 The preliminary screening by a physician or nurse practitioner and following established inclusion and exclusion criteria provides a significant reduction in the risk of harm to participants. The criteria were designed to avoid risks that exist for certain patients that may be susceptible to more serious injuries or problems. It is anticipated that only minor patient discomfort will be experienced by some patients, and that will be sufficiently addressed with rest periods, slowing of therapy progression, or temporary halting of treatment. Additionally, the SMART run-to-run progression protocol, see Appendix A, and the GyroStim software combine to provide the patient with protection from overstimulation. The GyroStim collects subjective and objective patient response to each therapy run that can be used by the GyroStim operator to assess patient comfort, patient progress, and for making informed decisions for whether to decrease, repeat, or increase the therapy intensity on the next run.

26. Provisions to Monitor the Data to Ensure the Safety of Participants

26.1 The investigator and sub-investigators will be checking the data at least weekly, if not more frequently. Should any concerning patterns or data

arise, discussions will be held to address these immediately. Patients are under continual care and monitored while at our facility(ies) undergoing various treatments and therapies. Adverse events or concerns for patient safety will be reported immediately to the principal investigator or sub-investigators.

26.2 Should a subject's symptoms worsen and not reduce prior to continuing their next SMART, PT or ST/CRT, the providers will discuss with the patient the extent of their worsened symptoms and how to best proceed in the best interest of the patient. Two possibilities may then happen. First, treatment and therapy will continue as scheduled, with a slower or less demanding treatment plan of progress, i.e. few runs or slower speeds in GyroStim or fewer or less strenuous exercises or activities in PT. The second possibility is to alter the patient's care plan in their best interest, with fewer visits, extended time between visits, or stopping treatment or therapy all together. Should this occur, the subject will be removed from the study, and they will continue treatment as most appropriate for their current status and condition.

26.3 Should a patient worsen beyond what is expected, or develop new, unexpected symptoms, they will be removed from the study and the principal investigator should be notified as soon as possible. Any development serious enough to warrant emergency room or urgent care visits will be reported to the IRB. Also, any unexpected symptoms that develop that are not related to a known, current health condition of the patient will also be reported to the IRB. These will be reported as soon as possible, typically within the next business day.

26.4 Development of concerning data or patterns will also be relayed to the IRB and participating and potential subjects as necessary and required.

27. Economic Burden to Participants

27.1 This study is not sponsored by outside entities or funded by a grant. Patients will incur normal medical costs, depending on their insurance coverage or self-pay means. SMART treatment is not currently covered by insurance among payors in the region served by Neuroscience Group, and as such is a self-pay (cash pay) treatment. For those that choose to participate in the SMART intervention group, the cost is $149 per session for the first 9 sessions. The 10th session will be free. This brings the total out of pocket cost to $1341 for GyroStim Group participants. We understand that the out-of-pocket cost may be a hindrance for participation, and it does economically limit the number of patients that are able to participate in the SMART arm of the study. However, current cost-analysis for Neuroscience Group, our cost per patient is $1331.06 for 10 sessions. This is based on current average patient load, space, equipment, depreciation, and staff costs for all aspects of GyroStim care.

For reference, specialized PT self-pay cost averages $125 per visit, with minimal specialized equipment.

GYROSTIM AVERAGE COST/VISIT				
Direct Cost	**Average Hourly Pay**	**Minutes/Visit**	**Cost/Visit**	**Notes**
Nursing	$ 37.60	5 (1x order entry)	$ 0.31	1x order entry
Intake	$ 23.90	2	$ 0.80	
Billing	$ 26.50	2	$ 0.88	
Athletic Trainer	$ 33.28	52	$ 28.84	20 min prep for New Patient 40 min for appointment 10 min follow-up - data entry or care coordination
			$ 30.84	
Other Costs	**Annual Cost**	**Annual Visit Volume**		
Rent	$ 5,640.00	400	$ 14.10	
Depreciation	$ 35,268.00	400	$ 88.17	
			$ 102.27	
			$ 133.11	
		Cost to NSG for 10 visits (no NSG margin)	$ 1,331.06	
		Cost to patient	$ 1,341.00	

28. Resources Available

28.1 This is a private medical practice with a specific and advertised concussion program. In 2024, nearly 530 new concussion patients were seen at Neuroscience Group. This clinic has had the GyroStim equipment and SMART treatment available since Q3 of 2023, and to date have completed treatment for approximately 50 patients, with more in progress. This treatment program has been gradually introduced to the public. Given the inclusion and exclusion criteria, we believe we will be able to recruit adequate numbers of patients for both groups.

28.2 As study participants are also patients, they will be treated as necessary. We anticipate approximately 3-4 hours each week on average, per patient.

28.3 This is a large, private medical clinic with 2 main locations in Appleton and Neenah, Wisconsin. We have 58 licensed providers and 140 additional care team personnel and staff to assist with reception, phone calls, billing, IT, HR, public relations, etc. The Appleton location has approximately 31,225 square feet, including 41 exam/treatment rooms. The Neenah location has approximately 38,920 square feet with 58 exam/treatment rooms. All exam/treatment rooms are appropriately equipped to care for our patient population. There is an appropriately equipped physical therapy

gym that will be utilized at the Appleton location that is approximately 1,269 square feet.

28.4 As appropriate and necessary, patients will be treated in-house if medical or psychological (we have a licensed social worker on staff) issues arise. If a medical emergency arises, protocols and licensed personnel are in place to deal with the emergency until 911 emergency personnel arrive to take the patient to the hospital ER. No significant medical or psychological issues are anticipated to arise, as our SOC is well-established for treatment, and GyroStim is a non-significant risk device.

29. Multi-Site Research

29.1 All research will be conducted at one of the Neuroscience Group clinics, one located in Neenah, WI and the other located in Appleton, WI. The two locations are approximately 10 minutes apart, and providers and supporting clinical staff travel between the two locations, depending on the day. Recruitment will occur at both locations, as well as speech therapy. All physical therapy will occur at the Appleton location. Participants' schedules will determine their new patient visit location and speech therapy location.

30. Retrospective Study

30.1 Retrospective data will be collected on all patients 18 years and older that started SMART (GyroStim) at Neuroscience Group between 9/1/2023 and 12/31/2025, with a diagnosis of post-concussion syndrome.

30.1.1 These patients will be identified using the GyroStim software to generate a report on all patients that are under the "concussion" group, and then further evaluated using patient records available in EPIC from there to see if they fit the inclusion and exclusion criteria as listed in section 5.

30.2 All data will be de-identified, i.e. name, date of birth, address, email, phone number, or medical record number. No identifying data will transmitted or shared. This information will only be in a secured Key document, linking randomly generated ID numbers with patient identifying data. Only the PI and sub-investigators will have access to this Key document, which will be destroyed once the study is complete.

30.3 Data collected to be analyzed will include age, gender, date of concussion, history of previous concussion if known, any pre- and post-testing done to include PCSS, Hit-6, FGA, NDI, DHI, mCTSIB, when post-testing was done, if patient completed SMART, if there was a reason given for stopping, if the patient continued with more than 10 sessions, and if patient was doing additional therapies for concussion, what those therapies were and if they were completed prior, during or after SMART.

30.4 All data will be grouped and analyzed, assessing for SMART therapy effectiveness as an intervention for PCS, timing of utilizing SMART after injury, impact of other therapies, and patterns of patient compliance and tolerance. Data will be shared with Courtney Hall, PhD, Professor Emeritus at Eastern Tennessee State University for statistical analysis. Specific statistical testing is yet to be determined, and will be dependent on the data that is gathered.

30.4.1 This data will be used to inform and improve patient care using SMART for the treatment of PCS. We hope to use the data to determine if there is an optimal timing for utilizing SMART, if there are patient sub-groups (age, gender, other therapies, etc.) that this therapy is more or less beneficial for, and if there is benefit to more or less sessions of SMART. We will look to see if there are other conclusions that can be gleaned from the data that may determine how we approach using SMART for patients. Thus, it may be shared with other providers that utilize SMART for their patient care. It will likely be used by UltraThera Technologies to approach CMS for seeking an ICD-10 (International Classification of Diseases 10th Revision) code for SMART and used by providers to assist with negotiating insurance reimbursement, if appropriate.

31. Statement on Ethical Considerations

31.1 Study will be conducted according to ethical principles stated in the Declaration of Helsinki (2024), and ethics approval will be obtained prior to conducting this study from Pearl IRB.

31.2 All participants will be provided with comprehensive information about the study, procedures, purpose, benefits and risks. Written informed consent will be obtained from all participants and will take into consideration the well-being and freewill of all participants, voluntary participation and withdrawal for any reason without penalty, and the respect of privacy. Participants will remain anonymous in any and all publications, and all personal data will remain confidential and secure. Personal, identifying data will be removed from data sets prior to analysis and distribution.

31.3 Careful consideration was taken to in the study design and potential harms were assessed, with care was taken to minimize risks to ensure participant safety and wellbeing.

References

Agarwal, N., MD, Thakkar, R., & Than, K., MD, FAANS (2024, April 29). *Concussion*. American Association of Neurological Surgeons. Retrieved September 10, 2024, from https://www.aans.org/patients/conditions-treatments/concussion/#:~:text=also%20be%20absent.-,Symptoms,before%20or%20after%20the%20injury .

Ellis, M. J., Leddy, J., & Willer, B. (2016). Multi-Disciplinary Management of Athletes with Post-Concussion Syndrome: An Evolving Pathophysiological Approach. *Frontiers In Neurology*, *7*, 136. https://doi.org/10.3389/fneur.2016.00136

Ferry, B., & DeCastro, A. (2023, January 9). *Concussion*. NCBI Bookshelf. Retrieved November 30, 2023, from https://www.ncbi.nlm.nih.gov/books/NBK537017/

Giza, C. C., & Hovda, D. A. (2001). The Neurometabolic Cascade of Concussion. *Journal of Athletic Training*, *July-Sep; 36*(3), 228-235. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC155411/

Hall CD, Herdman SJ, Whitney SL, et al. Vestibular rehabilitation for peripheral vestibular hypofunction: updated clinical practice guideline from the APTA. J Neurol Phys Ther. 2022;46(2):118-177.

Hallock H, Mantwill M, Vajkoczy P, Wolfarth B, Reinsberger C, Lampit A, Finke C. Sport-Related Concussion: A Cognitive Perspective. Neurol Clin Pract. 2023 Apr;13(2):e200123. doi: 10.1212/CPJ.0000000000200123. Epub 2023 Feb 21. PMID: 36891462; PMCID: PMC9987206.

Harmon KG, Drezner JA, Gammons M, et al.. American Medical Society for Sports Medicine position statement: concussion in sport. Br J Sports Med. 2013;47(1):15-26. doi. 10.1136/bjsports-2012-091941.

Heyser, B (2023). [Unpublished data collection from retrospective study utilizing GyroStim patients with concussion; collected by Bill Heyser, DC at Heyser Chiropractic Neurology @ the Brain Center in Tallahassee, FL]

Hoffer ME, Balaban C, Gottshall K, Balough BJ, Maddox MR, Penta JR. Blast exposure: vestibular consequences and associated characteristics. Otol Neurotol. 2010;31(2):232-236.

Laborey M, Masson F, Ribéreau-Gayon R, Zongo D, Salmi LR, Lagarde E. Specificity of postconcussion symptoms at 3 months after mild traumatic brain injury: Results from a comparative cohort study. J Head Trauma Rehabil. 2014;29(1):E28-36.

Maher, K, Hall, C (2026) *Comparative Clinical Outcomes of Physical Therapy Versus Physical Therapy Combined With GyroStim for Treatment of Post-Concussion Syndrome: A Retrospective Case Series.*[Unpublished write-up from a retrospective data analysis done at ANOVA Healthcare in North Carolina; data collected by Kim Fox, DPT].

Management and Rehabilitation of Post-Acute mild Traumatic Brain Injury Work Group. VA/DoD Clinical Practice Guideline for the Management and Rehabilitation of Post-Acute Mild Traumatic Brain Injury. Version 3.0. https://www.healthquality.va.gov/guidelines/rehab/mtbi. Published June 2021.Accessed August 31, 2021.

Murray DA, Meldrum D, Lennon O. Can vestibular rehabilitation exercises help patients with concussion? A systematic review of efficacy, prescription and progression patterns. Br J Sports Med. 2017;51(5):442-451.

Patricios, J. S., Schneider, K. J., Dvorak, J., Ahmed, O. H., Blauwet, C., Cantu, R. C., Davis, G. A., Echemendia, R. J., Makdissi, M., McNamee, M., Broglio, S., Emery, C. A., Feddermann-Demont, N., Fuller, G. W., Giza, C. C., Guskiewicz, K. M., Hainline, B., Iverson, G. L., Kutcher, J. S., . . . Meuwisse, W. (2023). Consensus statement on concussion in sport: 6th International Conference on Concussion in Sport - Amsterdam, October 2022. *British Journal of Sports Medicine*, *June 2023; 57*(3), 695-711. https://doi.org/10.1136/bjsports-2023-106898

Permenter, C. M., Fernandez-de Thomas, R. J., & Sherman, A. I. (2022, August 29). *Postconcussive Syndrome*. NCBI Bookshelf. Retrieved November 1, 2023, from https://www.ncbi.nlm.nih.gov/books/NBK534786/

Quatman-Yates, C. C., PT, DPT, PhD, Hunter-Giordano, A., PT, DPT, Shimamura, K. K., PT, DPT, NCS, OCS, CSCS, FAAOMPT, Landel, R., PT, DPT, FAPTA, Alsalaheen, B. A., PT, PhD, Hanke, T. A., PT, PhD, & McCulloch, K. L., PT, PhD, FAPTA (2020). Physical Therapy Evaluation and Treatment after Concussion/ Mild Traumatic Brain Injury - Clinical Practice Guidelines Linked to the International Classification of Functioning, Disability and Health From the Academy of Orthopaedic Physical Therapy, American Academy of Sports Physical Therapy, Academy of Neurologic Physical Therapy, and Academy of Pediatric Physical Therapy of the American Physical Therapy Association. *Journal of Orthopaedic & Sports Physical Therapy*, *50*(4), CPG1-CPG73. https://doi.org/10.2519/jospt.2020.0301

Rytter, H., PhD, Graff, H. J., PhD, & Henriksen, H. K., PT (2021). Nonpharmacological Treatment of Persistent Postconcussion Symptoms in Adults - A Systematic Review and Meta-analysis and Guideline Recommendation. *JAMA Network Open*, *2021;4*(11), e2132221. https://doi.org/10.1001/jamanetworkopen.2021.32221

Shirley Ryan (2016, November 9) *Functional Gait Assessment*. Shirley Ryan Ability Lab. Retrieved September 6, 2024, from https://www.sralab.org/rehabilitation-measures/functional-gait-assessment

Shirley Ryan (2013, May 20). *Modified Clinical Test of Sensory Interaction in Balance*. Shirley Ryan Ability Lab. Retrieved September 6, 2024, from https://www.sralab.org/rehabilitation-measures/modified-clinical-test-sensory-interaction-balance

Silverberg, N. D., PhD, Iverson, G. L., PhD, Cogan, A., PhD, OTR/L, Dams-O-Connor, K., PhD, Delmonico, R., PhD, Graf, M. J. P., MD, Iaccarino, M. A., MD, Kajankova, M., PhD, Kamins, J., MD, McCulloch, K. L., PhD, McKinney, G., DHSc, Nagele, D., PsyD, Panenka, W. J., MD, Rabinowitz, A. R., PhD, Reed, N., PhD, Wethe, J. V., PhD, Whitehair, V., MD, Anderson, V., PhD, Arciniegas, D., MD, . . . Manley, G. T., MD, PhD (2023). The American Congress of Rehabilitation Medicine Diagnostic Criteria for Mild Traumatic Brain Injury. *Archives of Physical Medicine and Rehabilitation*, (104), 1343-55. https://doi.org/10.1013/japmr.2023.03.036

Suleiman, A., Lithgow, B. J., Anssari, N., Ashiri, M., Moussavi, Z., & Mansouri, B. (2019). Correlation between Ocular and Vestibular Abnormalities and Convergence Insufficiency in Post-Concussion Syndrome.

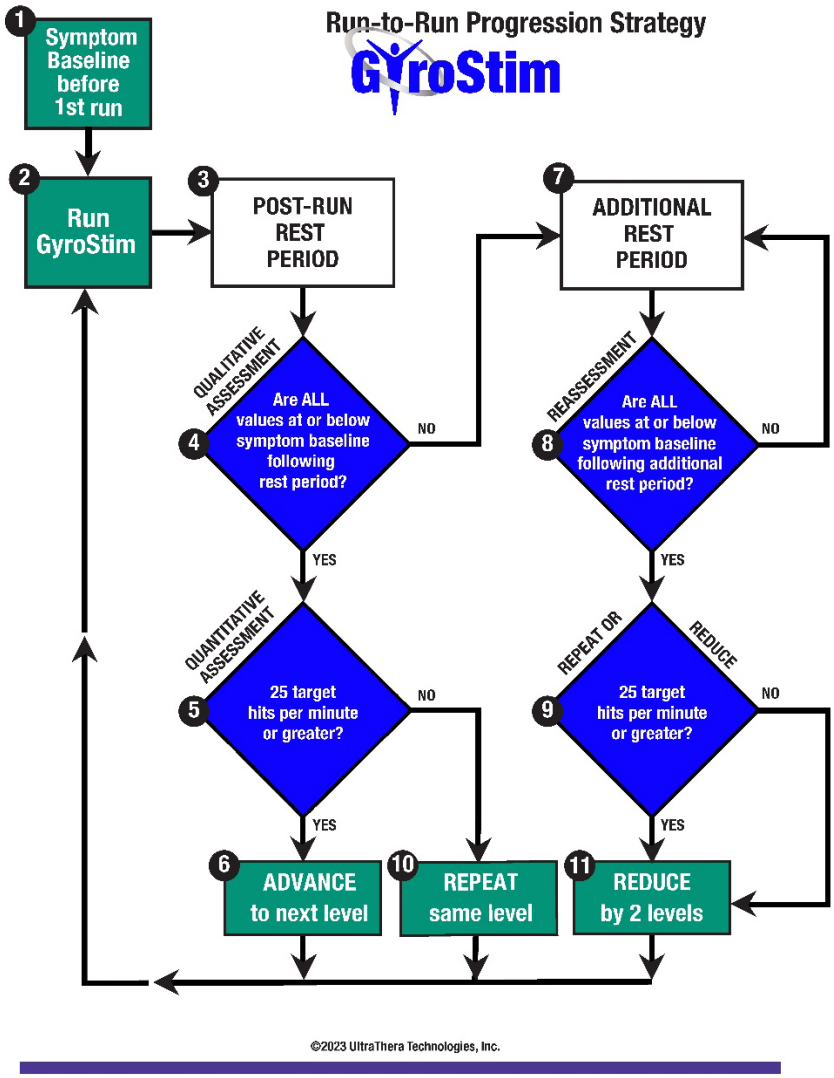
Neuroopthalmology, *2020 June 40*(3), 157-167. https://doi.org/10.1080/01658107.2019.1653325

Yang CC, Tu YK, Hua MS, Huang SJ. The association between the post-concussion symptoms and clinical outcomes for patients with mild traumatic brain injury. J Trauma. 2007;62(3): 657-663.

32. Appendices

A. GyroStim Run-to-Run Progression Flow Chart
B. Post-Concussion Symptoms Scale (PCSS)
C. Headache Impact Test (Hit-6)
D. Neck Disability Index (NDI)
E. Dizziness Handicap Inventory (DHI)
F. Functional Gait Assessment (FGA) (2016)
G. Modified Clinical Test of Sensory Interaction in Balance (CTSIB-m) (2013)
H. Repeatable Battery for the Assessment of Neuropsychological Status (RBANS)
I. Rivermeade Post-Concussion Symptom Questionnaire
J. Pregnancy Questionnaire for potential female research subjects
K. Pregnancy Test Results for potential female research subjects
L. Comparative Clinical Outcomes of Physical Therapy Versus Physical Therapy Combined With GyroStim for Treatment of Post-Concussion Syndrome: A Retrospective Case Series

Appendix A


Run-to-Run Progression Strategy
GyroStim
1 Symptom Baseline before 1st run
2 Run GyroStim
3 POST-RUN REST PERIOD
7 ADDITIONAL REST PERIOD
QUALITATIVE ASSESSMENT
4 Are ALL values at or below symptom baseline following rest period?
NO
YES
REASSESSMENT
8 Are ALL values at or below symptom baseline following additional rest period?
NO
YES
QUANTITATIVE ASSESSMENT
5 25 target hits per minute or greater?
NO
YES
REPEAT OR
REDUCE
9 25 target hits per minute or greater?
NO
YES
6 ADVANCE to next level
10 REPEAT same level
11 REDUCE by 2 levels
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Appendix B

Concussion Grading Scale

Directions: After reading each symptom, please circle the number that best describes the way you have been feeling today. A rating of 0 means you have not experienced this symptom(s) today. A rating of 6 means you have experienced severe problems with this symptom today.

Date of last known concussion: _____
Date of previous of concussion if more than one: _____

Symptoms	None	Mild		Moderate		Severe	
Headache	0	1	2	3	4	5	6
Nausea	0	1	2	3	4	5	6
Vomiting	0	1	2	3	4	5	6
Balance Problems	0	1	2	3	4	5	6
Dizziness	0	1	2	3	4	5	6
Fatigue	0	1	2	3	4	5	6
Trouble Falling Asleep	0	1	2	3	4	5	6
Sleeping More Than Usual	0	1	2	3	4	5	6
Sleeping Less Than Usual	0	1	2	3	4	5	6
Drowsiness	0	1	2	3	4	5	6
Sensitivity to Light	0	1	2	3	4	5	6
Sensitivity to Noise	0	1	2	3	4	5	6
Irritability	0	1	2	3	4	5	6
Sadness	0	1	2	3	4	5	6
Nervousness	0	1	2	3	4	5	6
Feeling More Emotional	0	1	2	3	4	5	6
Numbness or Tingling	0	1	2	3	4	5	6
Feeling Slowed Down	0	1	2	3	4	5	6
Feeling Mentally "Foggy"	0	1	2	3	4	5	6
Difficulty Concentrating	0	1	2	3	4	5	6
Difficulty Remembering	0	1	2	3	4	5	6
Visual Problems (double vision, blurred vision, etc.)	0	1	2	3	4	5	6
Total Symptom Score:							
Total of ALL Symptoms:							

Appendix C

To complete, please circle one answer for each question.

When you have headaches, how often is the pain severe?

Never Rarely Sometimes Very Often Always

How often do headaches limit your ability to do usual daily activities including household work, work, school, or social activities?

Never Rarely Sometimes Very Often Always

When you have a headache, how often do you wish you could lie down?

Never Rarely Sometimes Very Often Always

In the past 4 weeks, how often have you felt too tired to do work or daily activities because of your headaches?

Never Rarely Sometimes Very Often Always

In the past 4 weeks, how often have you felt fed up or irritated because of your headaches?

Never Rarely Sometimes Very Often Always

In the past 4 weeks, how often did headaches limit your ability to concentrate on work or daily activities?

Never Rarely Sometimes Very Often Always

To score, add points for answers in each column:

Column 1 : Never 6 points each	+	Column 2: Rarely 11 points each	+	Column 3: Sometimes 10 points each	+	Column 4: Very Often 11 points each	+	Column 5: Always 13 points each
☐		☐		☐		☐		☐

If your HIT-6 is 50 or higher:
You should share your results with your provider. Headaches that stop you from your daily activities could be a migraine.

TOTAL SCORE ☐

Appendix D

Neck Disability Index

This questionnaire has been designed to give us information as to how your neck has affected your ability to manage in everyday life. PLEASE ANSWER EVERY SECTION AND SELECT THE ANSWER IN EACH SECTION THAT APPLIES TO YOU. We realize you may consider that two or more statements in any one section relate to you, but please just select the answer that most closely describes your problem.

Pain Intensity ☐ I have no pain at this moment. ☐ The pain is very mild at the moment. ☐ The pain is moderate at the moment. ☐ The pain is fairly severe at the moment. ☐ The pain is very severe at the moment. ☐ The pain is the worst imaginable at the moment.	**Concentration** ☐ I can concentrate fully when I want to with no difficulty. ☐ I can concentrate fully when I want to with slight difficulty. ☐ I have a fair degree of difficulty in concentrating when I want to. ☐ I have a lot of difficulty in concentrating when I want to. ☐ I have a great deal of difficulty in concentrating when I want to. ☐ I cannot concentrate at all.
Personal Care (washing, dressing, etc.) ☐ I can look after myself normally without causing extra pain. ☐ I can look after myself normally, but it causes extra pain. ☐ It is painful to look after myself and I am slow and careful. ☐ I need some help but can manage most of my personal care. ☐ I need help every day in most aspects of my personal care. ☐ I do not get dressed, I wash with difficulty and stay in bed.	**Work** ☐ I can do as much work as I want to. ☐ I can only do my usual work, but no more. ☐ I can only do most of my usual work, but no more. ☐ I cannot do my usual work. ☐ I can hardly do any work at all. ☐ I can't do any work at all.
Lifting ☐ I can lift heavy items without extra pain. ☐ I can lift heavy items, but it gives me extra pain. ☐ Pain prevents me from lifting heavy items off the floor, but I can manage if they are conveniently placed, e.g., on a table. ☐ Pain prevents me from lifting heavy items, but I can manage light to medium weights if they are conveniently positioned. ☐ I can only lift very light items. ☐ I cannot lift or carry anything at all.	**Driving** ☐ I can drive my car without any neck pain. ☐ I can drive my car as long as I want with slight pain in my neck. ☐ I can drive my car as long as I want with moderate pain in my neck. ☐ I can't drive my car as long as I want because of moderate pain in my neck. ☐ I can hardly drive at all because of severe pain in my neck. ☐ I can't drive my car at all.
Reading ☐ I can read as much as I want to with no pain in my neck. ☐ I can read as much as I want to with slight pain in my neck. ☐ I can read as much as I want to with moderate pain in my neck. ☐ I can't read as much as I want to because of moderate pain in my neck. ☐ I can hardly read at all because of severe pain in my neck. ☐ I cannot read at all.	**Sleeping** ☐ I have no trouble sleeping. ☐ My sleep is slightly disturbed (less than 1 hour sleepless). ☐ My sleep is mildly disturbed (1-2 hours sleepless). ☐ My sleep is moderately disturbed (2-3 hours sleepless). ☐ My sleep is greatly disturbed (3-5 hours sleepless). ☐ My sleep is completely disturbed (5-7 hours sleepless).
Headaches ☐ I have no headaches at all. ☐ I have slight headaches, which come infrequently. ☐ I have moderate headaches, which come frequently. ☐ I have moderate headaches, which come frequently. ☐ I have severe headaches, which come frequently. ☐ I have headaches almost all the time.	**Recreation** ☐ I am able to engage in all my recreation activities with no neck pain at all. ☐ I am able to engage in all my recreation activities, with some pain in my neck. ☐ I am able to engage in most, but not all of my usual recreation activities because of pain in my neck. ☐ I am able to engage in a few of my usual recreation activities because of pain in my neck. ☐ I can hardly do any recreation activities because of pain in my neck. ☐ I can't do any recreation activities at all.

Appendix E

Dizziness Handicap Inventory

Instructions: The purpose of this scale is to identify difficulties that you may be experiencing because of your dizziness. Please circle "always", OR "no" OR "sometimes" to each question. Answer each question only as it pertains to your dizziness problem.

1.	Does looking up increase your problem?	Always	Sometimes	No
2.	Because of your problem, do you feel frustrated?	Always	Sometimes	No
3.	Because of your problem, do you restrict your travel for business or pleasure?	Always	Sometimes	No
4.	Does walking down the aisle of a supermarket increase your problem?	Always	Sometimes	No
5.	Because of your problem, do you have difficulty getting into or out of bed?	Always	Sometimes	No
6.	Does your problem significantly restrict your participation in social activities, such as going out to dinner, going to movies, dancing or to parties?	Always	Sometimes	No
7.	Because of your problem, do you have difficulty reading?	Always	Sometimes	No
8.	Does performing more ambitious activities like sports, dancing, and household chores, such as sweeping or putting dishes away; increase your problem?	Always	Sometimes	No
9.	Because of your problem, are you afraid to leave your home without having someone accompany you?	Always	Sometimes	No
10.	Because of your problem, have you been embarrassed in front of others?	Always	Sometimes	No
11.	Do quick movements of your head increase your problem?	Always	Sometimes	No
12.	Because of your problem, do you avoid heights?	Always	Sometimes	No
13.	Does turning over in bed increase your problem?	Always	Sometimes	No
14.	Because of your problem, is it difficult for you to do strenuous housework or yardwork?	Always	Sometimes	No
15.	Because of your problem, are you afraid people may think you are intoxicated?	Always	Sometimes	No
16.	Because of your problem, is it difficult for you to go for a walk by yourself?	Always	Sometimes	No
17.	Does walking down a sidewalk increase your problem?	Always	Sometimes	No
18.	Because of your problem, is it difficult for you to concentrate?	Always	Sometimes	No
19.	Because of your problem, is it difficult for you to walk around your house in the dark?	Always	Sometimes	No
20.	Because of your problem, are you afraid to stay home alone?	Always	Sometimes	No
21.	Because of your problem, do you feel handicapped?	Always	Sometimes	No
22.	Has your problem placed stress on your relationship with members of your family or friends?	Always	Sometimes	No
23.	Because of your problem, are you depressed?	Always	Sometimes	No
24.	Does your problem interfere with your job or household responsibilities?	Always	Sometimes	No
25.	Does bending over increase your problem?	Always	Sometimes	No

Appendix F

Appendix.

Functional Gait Assessment[a]

Requirements: A marked 6-m (20-ft) walkway that is marked with a 30.48-cm (12-in) width.

_____1. GAIT LEVEL SURFACE

Instructions: *Walk at your normal speed from here to the next mark (6 m [20 ft]).*

Grading: Mark the highest category that applies.

(3) Normal—Walks 6 m (20 ft) in less than 5.5 seconds, no assistive devices, good speed, no evidence for imbalance, normal gait pattern, deviates no more than 15.24 cm (6 in) outside of the 30.48-cm (12-in) walkway width.

(2) Mild impairment—Walks 6 m (20 ft) in less than 7 seconds but greater than 5.5 seconds, uses assistive device, slower speed, mild gait deviations, or deviates 15.24–25.4 cm (6–10 in) outside of the 30.48-cm (12-in) walkway width.

(1) Moderate impairment—Walks 6 m (20 ft), slow speed, abnormal gait pattern, evidence for imbalance, or deviates 25.4–38.1 cm (10–15 in) outside of the 30.48-cm (12-in) walkway width. Requires more than 7 seconds to ambulate 6 m (20 ft).

(0) Severe impairment—Cannot walk 6 m (20 ft) without assistance, severe gait deviations or imbalance, deviates greater than 38.1 cm (15 in) outside of the 30.48-cm (12-in) walkway width or reaches and touches the wall.

_____2. CHANGE IN GAIT SPEED

Instructions: *Begin walking at your normal pace (for 1.5 m [5 ft]). When I tell you "go," walk as fast as you can (for 1.5 m [5 ft]). When I tell you "slow," walk as slowly as you can (for 1.5 m [5 ft]).*

Grading: Mark the highest category that applies.

(3) Normal—Able to smoothly change walking speed without loss of balance or gait deviation. Shows a significant difference in walking speeds between normal, fast, and slow speeds. Deviates no more than 15.24 cm (6 in) outside of the 30.48-cm (12-in) walkway width.

(2) Mild impairment—Is able to change speed but demonstrates mild gait deviations, deviates 15.24–25.4 cm (6–10 in) outside of the 30.48-cm (12-in) walkway width, or no gait deviations but unable to achieve a significant change in velocity, or uses an assistive device.

(1) Moderate impairment—Makes only minor adjustments to walking speed, or accomplishes a change in speed with significant gait deviations, deviates 25.4–38.1 cm (10–15 in) outside the 30.48-cm (12-in) walkway width, or changes speed but loses balance but is able to recover and continue walking.

(0) Severe impairment—Cannot change speeds, deviates greater than 38.1 cm (15 in) outside 30.48-cm (12-in) walkway width, or loses balance and has to reach for wall or be caught.

_____3. GAIT WITH HORIZONTAL HEAD TURNS

Instructions: *Walk from here to the next mark 6 m (20 ft) away. Begin walking at your normal pace. Keep walking straight; after 3 steps, turn your head to the right and keep walking straight while looking to the right. After 3 more steps, turn your head to the left and keep walking straight while looking left. Continue alternating looking right and left every 3 steps until you have completed 2 repetitions in each direction.*

Grading: Mark the highest category that applies.

(3) Normal—Performs head turns smoothly with no change in gait. Deviates no more than 15.24 cm (6 in) outside 30.48-cm (12-in) walkway width.

(2) Mild impairment—Performs head turns smoothly with slight change in gait velocity (eg, minor disruption to smooth gait path), deviates 15.24–25.4 cm (6–10 in) outside 30.48-cm (12-in) walkway width, or uses an assistive device.

(1) Moderate impairment—Performs head turns with moderate change in gait velocity, slows down, deviates 25.4–38.1 cm (10–15 in) outside 30.48-cm (12-in) walkway width but recovers, can continue to walk.

(0) Severe impairment—Performs task with severe disruption of gait (eg, staggers 38.1 cm [15 in] outside 30.48-cm (12-in) walkway width, loses balance, stops, or reaches for wall).

_____4. GAIT WITH VERTICAL HEAD TURNS

Instructions: *Walk from here to the next mark (6 m [20 ft]). Begin walking at your normal pace. Keep walking straight; after 3 steps, tip your head up and keep walking straight while looking up. After 3 more steps, tip your head down, keep walking straight while looking down. Continue alternating looking up and down every 3 steps until you have completed 2 repetitions in each direction.*

Grading: Mark the highest category that applies.

(3) Normal—Performs head turns with no change in gait. Deviates no more than 15.24 cm (6 in) outside 30.48-cm (12-in) walkway width.

(2) Mild impairment—Performs task with slight change in gait velocity (eg, minor disruption to smooth gait path), deviates 15.24–25.4 cm (6–10 in) outside 30.48-cm (12-in) walkway width or uses assistive device.

(1) Moderate impairment—Performs task with moderate change in gait velocity, slows down, deviates 25.4–38.1 cm (10–15 in) outside 30.48-cm (12-in) walkway width but recovers, can continue to walk.

(0) Severe impairment—Performs task with severe disruption of gait (eg, staggers 38.1 cm [15 in] outside 30.48-cm (12-in) walkway width, loses balance, stops, reaches for wall).

_____5. GAIT AND PIVOT TURN

Instructions: *Begin with walking at your normal pace. When I tell you, "turn and stop," turn as quickly as you can to face the opposite direction and stop.*

Grading: Mark the highest category that applies.

(3) Normal—Pivot turns safely within 3 seconds and stops quickly with no loss of balance.

(2) Mild impairment—Pivot turns safely in >3 seconds and stops with no loss of balance, or pivot turns safely within 3 seconds and stops with mild imbalance, requires small steps to catch balance.

(1) Moderate impairment—Turns slowly, requires verbal cueing, or requires several small steps to catch balance following turn and stop.

(0) Severe impairment—Cannot turn safely, requires assistance to turn and stop.

_____6. STEP OVER OBSTACLE

Instructions: *Begin walking at your normal speed. When you come to the shoe box, step over it, not around it, and keep walking.*

Grading: Mark the highest category that applies.

(3) Normal—Is able to step over 2 stacked shoe boxes taped together (22.86 cm [9 in] total height) without changing gait speed; no evidence of imbalance.

(2) Mild impairment—Is able to step over one shoe box (11.43 cm [4.5 in] total height) without changing gait speed; no evidence of imbalance.

(1) Moderate impairment—Is able to step over one shoe box (11.43 cm [4.5 in] total height) but must slow down and adjust steps to clear box safely. May require verbal cueing.

(0) Severe impairment—Cannot perform without assistance.

(Continued)

Appendix.
Continued

_____7. GAIT WITH NARROW BASE OF SUPPORT

Instructions: *Walk on the floor with arms folded across the chest, feet aligned heel to toe in tandem for a distance of 3.6 m [12 ft]. The number of steps taken in a straight line are counted for a maximum of 10 steps.*
Grading: Mark the highest category that applies.
(3) Normal—Is able to ambulate for 10 steps heel to toe with no staggering.
(2) Mild impairment—Ambulates 7–9 steps.
(1) Moderate impairment—Ambulates 4–7 steps.
(0) Severe impairment—Ambulates less than 4 steps heel to toe or cannot perform without assistance.

_____8. GAIT WITH EYES CLOSED

Instructions: *Walk at your normal speed from here to the next mark (6 m [20 ft]) with your eyes closed.*
Grading: Mark the highest category that applies.
(3) Normal—Walks 6 m (20 ft), no assistive devices, good speed, no evidence of imbalance, normal gait pattern, deviates no more than 15.24 cm (6 in) outside 30.48-cm (12-in) walkway width. Ambulates 6 m (20 ft) in less than 7 seconds.
(2) Mild impairment—Walks 6 m (20 ft), uses assistive device, slower speed, mild gait deviations, deviates 15.24–25.4 cm (6–10 in) outside 30.48-cm (12-in) walkway width. Ambulates 6 m (20 ft) in less than 9 seconds but greater than 7 seconds.
(1) Moderate impairment—Walks 6 m (20 ft), slow speed, abnormal gait pattern, evidence for imbalance, deviates 25.4–38.1 cm (10–15 in) outside 30.48-cm (12-in) walkway width. Requires more than 9 seconds to ambulate 6 m (20 ft).
(0) Severe impairment—Cannot walk 6 m (20 ft) without assistance, severe gait deviations or imbalance, deviates greater than 38.1 cm (15 in) outside 30.48-cm (12-in) walkway width or will not attempt task.

_____9. AMBULATING BACKWARDS

Instructions: *Walk backwards until I tell you to stop.*
Grading: Mark the highest category that applies.
(3) Normal—Walks 6 m (20 ft), no assistive devices, good speed, no evidence for imbalance, normal gait pattern, deviates no more than 15.24 cm (6 in) outside 30.48-cm (12-in) walkway width.
(2) Mild impairment—Walks 6 m (20 ft), uses assistive device, slower speed, mild gait deviations, deviates 15.24–25.4 cm (6–10 in) outside 30.48-cm (12-in) walkway width.
(1) Moderate impairment—Walks 6 m (20 ft), slow speed, abnormal gait pattern, evidence for imbalance, deviates 25.4–38.1 cm (10–15 in) outside 30.48-cm (12-in) walkway width.
(0) Severe impairment—Cannot walk 6 m (20 ft) without assistance, severe gait deviations or imbalance, deviates greater than 38.1 cm (15 in) outside 30.48-cm (12-in) walkway width or will not attempt task.

_____10. STEPS

Instructions: *Walk up these stairs as you would at home (ie, using the rail if necessary). At the top turn around and walk down.*
Grading: Mark the highest category that applies.
(3) Normal—Alternating feet, no rail.
(2) Mild impairment—Alternating feet, must use rail.
(1) Moderate impairment—Two feet to a stair; must use rail.
(0) Severe impairment—Cannot do safely.

TOTAL SCORE: _____ MAXIMUM SCORE 30

[a] Adapted from Dynamic Gait Index.[1] Modified and reprinted with permission of authors and Lippincott Williams & Wilkins (http://lww.com).

Appendix G

FALL PROOF PROGRAM: CENTER FOR SUCCESSFUL AGING, CAL STATE FULLERTON

Modified Clinical Test of Sensory Interaction in Balance (CTSIB-M)

*Administer only one trial per condition if participant able to complete first trial without loss of balance.

Condition One:	*Eyes Open, Firm Surface*			
	Trial One	Total Time:	_____ /	30 sec
	Trial Two	Total Time:	_____ /	30 sec
	Trial Three	Total Time:	_____ /	30 sec
Condition Two:	*Eyes Closed, Firm Surface*			
	Trial One	Total Time:	_____ /	30 sec
	Trial Two	Total Time:	_____ /	30 sec
	Trial Three	Total Time:	_____ /	30 sec
Condition Three:	*Eyes Open, Foam Surface*			
	Trial One	Total Time:	_____ /	30 sec
	Trial Two	Total Time:	_____ /	30 sec
	Trial Three	Total Time:	_____ /	30 sec
Condition Four:	*Eyes Closed, Foam Surface*			
	Trial One	Total Time:	_____ /	30 sec
	Trial Two	Total Time:	_____ /	30 sec
	Trial Three	Total Time:	_____ /	30 sec
		TOTAL:	_____ /	**120 sec**

Purpose of Test:

This test is designed to assess how well an older adult is using sensory inputs when one or more sensory systems are compromised. In condition one, all sensory systems (i.e., vision, somatosensory, and vestibular) are available for maintaining balance. In condition two, vision has been removed and the older adult must rely on the somatosensory and vestibular systems to balance. In condition three, the somatosensory system has been compromised and the older adults must use vision and the vestibular system to balance. In condition four, vision has been removed and the somatosensory system has been compromised. The older adults must not rely primarily on the vestibular inputs to balance.

Begin timing each trial using a stopwatch. The trial is over when (a) the participant opens his/her eyes in an eyes closed condition, (b) raises arms from sides, (c) loses balance and requires manual assistance to prevent a fall.

This test provides some insight into whether each of the sensory system available for balance are being used effectively. Failure to maintain balance in condition two indicates that the older adults is visually dependent. They are not using somatosensory inputs to maintain balance when eyes are closed. Failure to maintain balance in conditions 3 and 4 indicate that the visual and/or vestibular system is not being used to maintain balance. Poor performance on this test would suggest the need for multisensory training if the medial history does not indicate that

FALL PROOF PROGRAM: CENTER FOR SUCCESSFUL AGING, CAL STATE FULLERTON

an actual problem(s) exists (e.g., peripheral neuropathy will affect our ability to use somatosensory inputs, etc.). Check medical history to determine whether the participants has a history of inner ear infections or an inner ear disorder (e.g., meniere's disease, acoustic neuroma, etc.)

Appendix H

RBANS Benefits & Features

Benefits

- Covers five domains: Immediate Memory, Visuospatial/Constructional, Language, Attention, and Delayed Memory.
- Track recovery during rehabilitation and progression of neurological disorders.
- Use as a neuropsychological "screen battery" when lengthier standardization assessments are either impractical or inappropriate
- Repeat evaluations when an alternate form is needed to control for content practice effects.
- Identify inclusion/exclusion criteria as well as efficacy and cognitive side effects in Clinical Trials.

Features

RBANS Update provides significant improvements and is ideal for measuring change over time. It can serve as a neuropsychological "screen battery" when lengthier standardization assessments are either impractical or inappropriate.

- Four parallel forms: Form A offers a single set of norms based on age, gender, race, education, and geographic region, with equating studies and adjustments for Forms B-D

Appendix I

Appendix 1.5

The Rivermead Post Concussion Symptoms Questionnaire*

After a head injury or accident some people experience symptoms which can cause worry or nuisance. We would like to know if you now suffer from any of the symptoms given below. As many of these symptoms occur normally, we would like you to compare yourself now with before the accident. For each one, please circle the number closest to your answer.

0 = Not experienced at all
1 = No more of a problem
2 = A mild problem
3 = A moderate problem
4 = A severe problem

Compared with before the accident, do you now (i.e., over the last 24 hours) suffer from:

Headaches	0	1	2	3	4
Feelings of dizziness	0	1	2	3	4
Nausea and/or vomiting	0	1	2	3	4
Noise sensitivity, easily upset by loud noise	0	1	2	3	4
Sleep disturbance	0	1	2	3	4
Fatigue, tiring more easily	0	1	2	3	4
Being irritable, easily angered	0	1	2	3	4
Feeling depressed or tearful	0	1	2	3	4
Feeling frustrated or impatient	0	1	2	3	4
Forgetfulness, poor memory	0	1	2	3	4
Poor concentration	0	1	2	3	4
Taking longer to think	0	1	2	3	4
Blurred vision	0	1	2	3	4
Light sensitivity, easily upset by bright light	0	1	2	3	4
Double vision	0	1	2	3	4
Restlessness	0	1	2	3	4

Are you experiencing any other difficulties?

1._____	0	1	2	3	4
2._____	0	1	2	3	4

* *King N, Crawford S, Wenden F, Moss N, Wade D. The Rivermead Post Concussion Symptoms Questionnaire: A measure of symptoms commonly experienced after head injury and its reliability.* Journal of Neurology. *1995;242:587-592.*

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Appendix J

Pregnancy Questionnaire

for potential female research subjects

Name:_____ Date of Birth:_____

Date of last menstrual period? _____

Could you be pregnant? ____Yes ____No

If no, please select why pregnancy is not possible:

____No intercourse

____ No intercourse since last period

____hysterectomy

____menopause

____sterilization procedure:_____ date_____

____partner is sterile/had vasectomy date: _____ with follow up confirmation of sterility? ___ Yes ___ No

____always use contraception correctly

____ postpartum/recent delivery Date:_____

Breastfeeding/pumping constantly? ___ Yes ____ No

Have you had a period since delivering? ___ Yes ___ No

____ other:_____

If you could be pregnant, do not always use contraception correctly, you had a sterilization procedure done less than 3 months ago, or a recent delivery more than 4 weeks ago without constant breastfeeding, a pregnancy test will be required to participate in this study. You may use your own, or one will be provided for you. The test will need to be

PROTOCOL TITLE: Sensorimotor Multi-axis Automated Rotational Therapy (SMART) for Post-Concussion Syndrome

Appendix K

Pregnancy Test Results

for potential female research subjects

Please initial below:

_____ Pregnancy test was done as directed, within 3 days of my first therapy visit

Date of test: _____ Date of first visit: _____

Results:

_____ positive _____ negative

By signing below, you agree that the above information provided is truthful and accurate. If the results are positive, you will still receive all appropriate care, but you may not participate in research or utilize GyroStim. If the results are negative, you may continue to participate as a research subject, and you will need to maintain use of contraception. You also agree to notify your provider should you become pregnant during the time you are a subject for this study.

_____ _____

Signature Date

_____ _____

Printed Name Date of Birth

Please return this form to your provider at the beginning of your first visit.

Appendix L

Comparative Clinical Outcomes of Physical Therapy Versus Physical Therapy Combined With GyroStim for Treatment of Post-Concussion Syndrome: A Retrospective Case Series

Introduction

A targeted, multidisciplinary, symptom-specific rehabilitation regimen is currently regarded as the standard of care (SOC) for individuals experiencing persistent symptoms following mild traumatic brain injury (mTBI) or concussion. This retrospective case series evaluates comparative outcome data from patients treated with SOC alone versus SOC supplemented with multimodal neurorehabilitation delivered via GyroStim (GyroStim). The objective of this analysis is to evaluate whether GyroStim is associated with differences in rehabilitation rates in patients with post-concussive symptoms.

Methods

This comparison utilized retrospective clinical chart review data from adult patients with a documented history of mild traumatic brain injury (mTBI) and a confirmed diagnosis of post-concussion syndrome. Due to the retrospective design, small SOC sample size, lack of randomization, and unequal group sizes, findings should be interpreted as associative rather than causal.

Outcome Measures

Vestibular dysfunction is a common sequela of mTBI, therefore outcomes were evaluated using the Dizziness Handicap Inventory (DHI), a validated patient-reported measure of vestibular-related symptom severity and functional impact. Baseline and discharge DHI scores were collected to quantify change over the course of treatment and to calculate therapeutic dose–response (change in DHI divided by the treatment duration (weeks)).

Standard of Care

All patients underwent similar intake protocols, received balance education, and were prescribed standardized home exercise programs. All patients completed standardized pre- and post-intervention testing using the DHI assessment. All patients received SOC consisting of therapy programs designed to address identified concussion-related impairments, including individualized and targeted physical, vestibular, and vision therapies.

GyroStim Intervention

GyroStim is a computer-controlled, multi-axis rotational chair designed to deliver multimodal neurorehabilitation protocols. It is an FDA-cleared medical device with Breakthrough Device designation for balance disorders and vestibular dysfunction indications.

A subset of all patients received GyroStim multimodal neurorehabilitation treatment in addition to SOC (GyroStim). Half of the GyroStim group received High-Density GyroStim treatment defined as ≥4 sessions per week, and the other half received Low-Density GyroStim treatment defined as <4 sessions per week.

Data Analysis

Patient data was analyzed in three different ways as described and documented below.

1. DHI Outcome Comparison

Data collected from the patient charts was analyzed to look at DHI outcomes for all patients and to compare differences between patients who were treated with SOC alone versus patients who were treated with GyroStim in addition to SOC.

Table 1. Dizziness Handicap Inventory (DHI) outcomes for All Patients and Groups

Variable	All patients (n=19)	GyroStim + SOC (n=15)	SOC* (n=4)	Significance** (p-value)
Baseline DHI (/100)	46 ± 20	48 ± 21	36 ± 13	0.29
Discharge DHI (/100)	30 ± 24	35 ± 25	14 ± 12	0.14
Change in DHI (/100)	15 ± 18	14 ± 19	22 ± 13	0.45
Number of PT visits	8.3 ± 5.6	6.9 ± 5.5	13.5 ± 2.4	0.03
Treatment duration (wks)	8.1 ± 6.4	6.7 ± 6.3	13.0 ± 4.2	0.08

* Interpret group comparisons cautiously due to small SOC sample size
** Group differences between GyroStim + SOC compared to SOC

Key Findings

- All patients, GyroStim and SOC groups, showed a significant improvement in DHI (means ± SD: pre-therapy DHI = 46 ± 20, post-therapy DHI = 30 ± 24; p = 0.003).
- There were significant group differences in the number of PT visits (GyroStim: 6.9 ± 5.5 vs. SOC: 13.5 ± 2.4; p = 0.03).
- There was a trend for differences in treatment duration (GyroStim: 6.7 ± 6.3 weeks vs. SOC: 13.0 ± 4.2 weeks; p = 0.08).

2. GyroStim Treatment Density & Therapeutic Dose-Response

Data collected from the patient charts was analyzed to evaluate the relationship between GyroStim treatment density and therapeutic dose-response.

Table 2. Low-Density GyroStim Therapy (<4 sessions/week) vs. High-Density GyroStim therapy (≥4 sessions/week)

Variable	Low-Density (n=8)	High-Density* (n=7)	Significance** (p-value)
Baseline DHI (/100)	48 ± 26	48 ± 17	0.99
Discharge DHI (/100)	36 ± 30	33 ± 19	0.78
Change in DHI (/100)	12 ± 18	16 ± 21	0.72
Number of PT visits	4.1 ± 2.6	9.2 ± 6.3	0.07
# GyroStim sessions (n)	12.3 ± 4.3	13.2 ± 7.7	0.77
Treatment duration (wks)	11.5 ± 4.8	1.3 ± 0.5	< 0.001
Therapeutic Dose-Response † (in DHI units)	0.8 ± 2.1	12.9 ± 13.4	0.025

† Therapeutic Dose-Response = Change in DHI/Treatment duration in DHI units

*High-Density protocols involved up to two sessions per day delivered over consecutive days

** Group differences between Low-Density (<4 sessions/week) compared to High-Density (≥4 sessions/week) GyroStim

Key Findings

- For the GyroStim group, there was a significant correlation (p = 0.03) between treatment density (# sessions/week) and TDR (TDR; r = 0.57; moderate to good strength of correlation). For the SOC group, there was a moderate to good correlation (r = 0.56) between # PT visits and TDR.
- Based on the correlation between treatment density and TDR, patients receiving GyroStim treatment were grouped into Low-Density (< 4 sessions/week) and High-Density (≥ 4 sessions/week) for comparison.
- Between these two groups, there were no significant group differences in terms of Pre-therapy DHI, Post-therapy DHI and DHI Change (p > 0.05).
- There were significant group differences for treatment duration (Low-Density: 11.5 ± 4.8 weeks vs. High-Density: 1.3 ± 0.5 weeks; p < 0.001) and TDR (Low-Density: 0.81 ± 2.1 DHI units/week vs. High-Density: 12.9 ± 13.4 DHI units/week; p = 0.025).

3. High-Density GyroStim Treatment vs SOC

Based on the significant findings in Table 2 that High-Density GyroStim treatment results in substantially greater TDR and faster rate of improvement than Low-Density, Table 3 compares differences between High-Density GyroStim treatment and SOC.

Table 3. High-Density GyroStim Treatment vs SOC

Variable	SOC (n=4)	High-Density (n=7)	Significance* (p-value)
Baseline DHI (/100)	36 ± 13	48 ± 17	0.24
Discharge DHI (/100)	14 ± 12	33 ± 19	0.13
Change in DHI (/100)	22 ± 13	16 ± 21	0.63
Number of PT visits	13.5 ± 2.4	9.2 ± 6.3	< 0.001
Treatment duration (wks)	13.0 ± 4.2	1.3 ± 0.5	< 0.001
Therapeutic Dose-Response (in DHI units)	1.6 ± 0.6	12.9 ± 13.4	0.13

* Group differences between High-Density GyroStim treatment compared to SOC

Key Findings

- Comparing High-Density GyroStim treatment to SOC, there was a significant difference in treatment duration (High-Density: 1.3 ± 0.5 weeks vs. SOC: 13.0 ± 4.2 weeks; $p < 0.001$) and number of PT sessions (High-Density: 9.2 ± 6.3 vs. SOC: 13.5 ± 2.4; $p < 0.001$).
- Comparing SOC to High-Density treatment, there is a non-significant trend for differences in TDR (High-Density: 12.9 ± 13.4 DHI units vs. SOC: 1.6 ± 0.6 DHI units; $p = 0.13$).

Summary of Findings

- All patients, GyroStim groups and SOC group, showed a significant reduction in symptoms.
- Total number of treatment sessions was similar between groups: Standard of Care (SOC) and GyroStim groups (≈13 sessions each).
- GyroStim showed trends toward greater treatment efficiency.

- Increased treatment density was significantly associated with faster rate of rehabilitation in the GyroStim group.
- High-Density GyroStim treatment markedly accelerated rate of rehabilitation.
    - No significant differences in baseline, discharge, or total DHI change, indicating similar overall symptom improvement although the High-Density group demonstrated a significantly faster rehabilitation rate.
- High-Density GyroStim demonstrated substantially improved rehabilitation efficiency compared to SOC.

Conclusion

GyroStim Is Associated With Up To 8 Times Faster Rate of Rehabilitation Than Conventional Physical Therapy Alone

This retrospective clinical chart review compares SOC physical therapy alone to GyroStim combined with SOC and reveals substantial differences in the rate of rehabilitation between the groups. Despite similar total numbers of treatment sessions and comparable overall symptom improvement, patients in the High-Density GyroStim treatment group experienced rehabilitation rates an average of 8 times faster, underscoring that GyroStim's primary advantage is the speed and efficiency with which concussion recovery may be achieved.

A statistically significant therapeutic dose-response relationship was observed: increased frequency (density) of GyroStim treatment is associated with faster rehabilitation rates, i.e., increasing treatment density increases efficiency. In practical terms, this suggests that GyroStim does more than enhance SOC rehabilitation; it has the potential to substantially compress recovery timelines, reduce overall treatment duration, and enable patients to return to normal function far sooner than conventional therapy alone.

Collectively, these findings position GyroStim as a high-efficiency neurorehabilitation accelerator, capable of delivering comparable clinical outcomes approximately eight times faster than SOC alone when applied at sufficient treatment density. Within the limitations of small sample size and retrospective design, these results warrant prospective controlled studies and suggest a potential shift in expectations for recovery speed and therapeutic efficiency in post-concussion rehabilitation.