PROTOCOL TITLE:

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

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Title of Project: Sensorimotor Multi-axis Automated Rotational Therapy (SMART) for Post-Concussion Syndrome

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INFORMED CONSENT

This Informed Consent will explain about being a participant in a research study. It is important that you read this material carefully and then decide if you wish to be a participant.

PURPOSE OF THIS RESEARCH STUDY

The purpose of this research study is to gather clinical data that will be collected and analyzed to show the effectiveness of **S**ensorimotor **M**ulti-axis **A**utomated **R**otational **T**herapy (**SMART**), utilizing GyroStim, for post-concussion syndrome rehabilitation. The newly gathered clinical data will be compared to physical therapy (PT) and speech therapy/cognitive rehabilitation therapy (ST/CRT) clinical data. This study is being sponsored and conducted by Neuroscience Group.

If you are asked to participate, your consent will allow us to use clinical data that will be generated from your use of GyroStim and/or PT and ST/CRT during your concussion rehabilitation.

All protected health information used or disclosed will be kept private, and all data will have personally identifiable information such as name, phone number, email address, address and date of birth removed. This de-identified data may be used for several purposes:

1. The de-identified data may be presented in a formal application to the FDA requesting the GyroStim medical device be granted approval for treatment of post-concussion syndrome.
2. The de-identified data may be used in applications for publication in one or more peer reviewed medical journals.
3. The de-identified clinical data may be presented at meetings, conventions, social media, and marketing campaigns.

GYROSTIM INFORMATION

Current GyroStim Regulatory Status

GyroStim received FDA clearance for assisting in the treatment of vestibular dysfunction and balance disorders in 2022. Additionally, the FDA designated GyroStim as a Breakthrough Medical Device in 2021 for demonstrating its ability to provide treatment that is more effective and accessible than the standard of care. GyroStim is investigational and not currently approved for the treatment of post-concussion syndrome. However, results of this research study will be submitted to the FDA in pursuit of that approval.

GyroStim Description

GyroStim is a multi-axis rotational chair that can rotate a patient left and right (yaw) as well as forward and backward (pitch) directions for 360 degrees continuously. The computer-controlled, automated device produces motions with a high degree of precision and control. The chair has a safety harness which safely and comfortably secures the patient. For patient comfort, stop buttons are located at the top of the right and left patient handholds. The patient can press either button at any time to stop the motion of the chair and return to an upright, forward-facing position. The rotational chair is surrounded by a clear shatterproof safety barrier with an inter-locked safety door. A light tower provides visual indication of the active status of the chair. The rotational chair is surrounded by four electronic, light sensitive targets placed in various locations around the safety barrier. The patient may be tasked with holding a low-power laser emitting device (a laser pointer), pointing the beam, and 'hitting' as many of the 4 targets as possible while in motion. When hit with the laser beam, the target will 'beep' and light up and send a signal to the software which will count the number of 'hits per minute' that occurred during the treatment run.

The operational software has a library of 30 different levels of therapy treatment protocols (pre-written programs). The protocols range from very low to very high therapy intensity. Each protocol administers a specific level of therapy intensity that can be reproduced with a very high degree of precision and control. Each protocol can be run for a duration of 15 – 60 seconds. The clinician will use the library to strategically select a series of protocols to present to each patient throughout a therapy session. Each therapy session is data-driven and will progress at a rate that is individualized and optimized for the needs of each individual patient.

The GyroStim medical device will be used by clinicians in this study for administering SMART for the treatment of post-concussion syndrome.

PARTICIPATION EXPECTATIONS

Duration:

Study duration for each participant will be 6 weeks. The participant will complete 6 visits with PT and 6 visits with ST/CRT. These visits will be once per week, with testing during visits 1 and 6. These appointments will last from 45-60 minutes. Participants may also choose to do GyroStim. If the participant chooses to receive GyroStim treatment, they will complete 10 GyroStim sessions, with each session lasting approximately 40 minutes. Participants will complete sessions at a frequency of two, three, or four times a week, for a total of 10 sessions to be completed in 5 weeks, prior to their 6th PT and ST/CRT visits. More information on these visits is provided below. Participating in this study is voluntary, meaning you freely choose to participate, and you may elect to stop treatments at any time.

What to expect:

The purpose of this research study is to collect data that will be gathered from subjective (how you feel) and objective (observable and measurable findings) tests to be performed before and after your treatment sessions. The data will be used to establish the effectiveness of GyroStim for post-concussion syndrome rehabilitation. To collect the necessary data for this study, you will be asked to participate in testing that is typical for physical therapy and speech therapy evaluations for post-concussion syndrome.

Testing will include questionnaires that you fill out, as well as tests administered by your therapist(s). Questionnaires will include the Post Concussion Symptom Scale (PCSS), Neck Disability Index (NDI), Dizziness Handicap Inventory (DHI), and Headache Impact Test (HIT-6). You may have filled out some of these questionnaires for your new patient visit, but you will need to fill them out again to be current for your first physical therapy visit. Tests that will be administered by your physical therapist during your evaluation, which we will use as data for this study, will include a Functional Gait Assessment (FGA)

and the Modified Clinical Test of Sensory Interaction in Balance (CTSIB-m). These tests will help evaluate your balance. Your physical therapist may also do further testing related to your current injury(ies) or status, but these will not be included in this study. These other tests and evaluations may look at neck, spine or joint range of motion and strength, palpation and special testing to evaluate painful or injured areas, oculomotor (eye movement) function testing, positional testing for vertigo, exertion and movement testing to help determine what provokes symptoms, and more. Your physical therapist will use the findings to form a plan to treat and rehabilitate and/or accommodate your injury(ies) and symptoms. Treatment and rehabilitation may include manual myofascial (soft tissue) therapy, therapeutic massage, range of motion exercises and stretching, strengthening exercises, controlled balance and gait training, eye and coordination exercises, maneuvers to treat positional vertigo, breathing and nervous system calming techniques, recommendations of endurance training, home exercise plans and more.

Your speech therapist will administer a test called the Repeatable Battery for the Assessment of Neuropsychological Status (RBANS) which assesses 5 main areas of cognitive functioning. You may also do additional evaluations that will not be used for this study, which may include further formal assessments and subjective information about how you perceive your ability to do certain tasks related to your job and daily life. Your speech therapist will use the findings to form a personalized plan to treat and rehabilitate and/or accommodate your injury(ies) and symptoms. Treatment and rehabilitation may include tasks, exercises, and strategies to improve memory, attention and executive functioning, organizational strategies, home practice and practical applications and recommendations for aiding in return to work.

You may experience increased symptoms such as headache, light-sensitivity, dizziness, vertigo, disorientation, nausea, brain fog, difficulty with attention, memory and/or concentration, fatigue, neck pain, insomnia (difficulty sleeping), and emotional dysregulation (mood swings or less control of emotional responses) from the above testing and evaluations. These increased symptoms are usually temporary and typically reduce/resolve within a few hours to a few days.

PROCEDURES

Prior to the start of the treatment sessions, you will be asked to meet with or speak with via phone call, clinical staff for scheduling all tests and treatment visits. You will be asked to perform a series of pre-tests at your initial evaluations of PT and CRT to generate and collect clinical data to establish your baseline condition prior to the start of the post-concussion rehabilitation treatment. These tests will include several questionnaires. Questionnaires will include the Post Concussion Symptom Scale (PCSS), Neck Disability Index (NDI), Dizziness Handicap Inventory (DHI), and Headache Impact Test (HIT-6). You may have filled out some of these questionnaires for your new patient visit, but you will need to fill them out again to be current for your first physical therapy visit. You will also be evaluated by your physical therapist for your balance. These evaluations will include a Functional Gait Assessment (FGA) and the Modified Clinical Test of Sensory Interaction in Balance (CTSIB-m). Your speech therapist will also conduct a thorough cognitive test called the Repeatable Battery for the Assessment of Neuropsychological Status (RBANS). At the beginning of your 6th visit, you will be asked to repeat these same questionnaires and tests. This will conclude your participation in the study. However, your treatment may continue as your providers recommend.

If during your first PT evaluation, it is determined that SMART is not currently an appropriate treatment for you, you may continue being a research participant but only doing PT and CRT. If you choose to do SMART treatment and you are cleared by PT, you will complete 10 GyroStim sessions, at a frequency of two, three or four times a week. You will choose what frequency you would like to complete your sessions in. Data from another location that utilizes GyroStim from the treatment of concussion has

suggested that a higher frequency of visits may improve rates of rehabilitation. Each session will last approximately 40 minutes, and they will occur during the same weeks as your PT and CRT sessions. Follow up testing will occur after you have completed all 10 GyroStim sessions, and will be conducted during the subsequent PT & CRT visits. All 10 GyroStim sessions must be completed prior to your 6th PT and CRT visits. GyroStim sessions cannot occur on the same days as your PT visits but may occur on the same days as CRT.

If your therapist(s) determine(s) the frequency of visits should be altered to best address your needs, you may be removed as a research participant.

A total of 128 participants will be enrolled. Each group will have 64 participants. Individual results will be available in your medical record, which you may access with MyChart, or you may request your individual results. Final study results will not be formally disclosed to participants.

ALTERNATIVE PROCEDURES/TREATMENTS

Should you choose not to participate in this study, you may continue treatment with PT or CRT, without data being used for the study. Depending on your providers' recommendations, you may also complete vision therapy, headache management, pain management, neurology or see outside referred providers for optometry or neuropsychology. You may follow through with these other treatments, regardless of your participation status.

POSSIBLE RISKS

Possible risks of participating in this study or proceeding with treatment include those that are usual or typical with therapy and treatment of vestibular dysfunction and other symptoms related to post-concussion syndrome. These may include temporary emergence or temporary worsening of symptoms such as headache, light-sensitivity, dizziness, vertigo, imbalance, nausea, brain fog, difficulty with attention, memory and/or concentration, fatigue, neck pain, insomnia, and emotional dysregulation. It is expected that any emergence or worsening of symptoms should be temporary and are expected to resolve/reduce to previous baseline status within a few hours to a few days. While unlikely, there is a possible risk of worsening symptoms becoming chronic. There is also the possibility of risks that are currently unforeseeable.

Over the course of the study, if any new, significant findings emerge that could indicate increased risks or other findings that may relate to your willingness to continue participating, they will be provided to you.

POSSIBLE BENEFITS

Possible benefits of participating in this study or proceeding with treatment include those that are usual or typical with participating in PT, CRT or GyroStim treatment. These may include the reduction or resolution of symptoms including headache, light-sensitivity, dizziness, vertigo, imbalance, nausea, brain fog, difficulty with attention, memory and/or concentration, fatigue, neck pain, insomnia, and emotional dysregulation.

Your participation in this study allows us to use your clinical data to demonstrate the efficacy of GyroStim and SMART for post-concussion syndrome treatment to the FDA. FDA approval for this clinical application may ultimately benefit some of the millions of people each year who suffer from concussion. Sharing your data may not have a direct impact on your health and well-being, but you

may benefit by knowing your participation in this study has potential to help in regulatory approval processes and ultimately may help others have access to this treatment.

COMPENSATION FOR MEDICAL TREATMENT: It is highly unlikely that participation in this study could result in the need for medical treatment. In the event that you sustain an injury related to treatment received as part of this research study, you must notify the Neuroscience Group of such injury and the costs associated with any treatment related to the injury should be billed to your insurance company. Neuroscience Group will pay the cost of any treatment that is a direct result of the treatment you received as part of this study and not covered by your insurance.

COMPENSATION FOR RESEARCH PARTICIPANTS AND FINANCIAL COSTS

There is no compensation in the form of payments for participation in this study. Participants will incur normal medical costs for their care. Claims for physical and speech therapy will be submitted by Neuroscience Group to the participant's insurance company, and the participant should check with their insurance provider if they have questions or concerns about their coverage. GyroStim is not currently covered by insurance, and it is a cash pay service. Participants will be charged $149 per visit for the first 9 visits, and the 10th visit will be free. Total out of pocket cost for GyroStim will be $1341.

VOLUNTARY PARTICIPATION

Your participation in this research program and allowing us to capture and use your data is voluntary. You may choose to not participate in this research study. Should you decide to participate, you can change your mind and withdraw at any time. In all cases, the benefits or treatment to which you are otherwise entitled will not be affected, and you may continue with care from your providers. You may withdraw by notifying any member of your care team at Neuroscience Group or by calling Nichole Siebert at 920-725-9373, x3812.

CONTACT FOR QUESTIONS

If you have any questions or research-related problems at any time, you may call Nichole Siebert at 920-725-9373, x3812. If you have concerns, complaints about this study, to report an injury or illness related to this study or to request additional information about this study, contact Dr. Siebert at 920-725-9373.

If you have questions, concerns or complaints about your rights as a research volunteer or about taking part in this study, or to obtain information or offer input, you may contact Pearl IRB at 317-899-9341.

Pearl IRB
29 East McCarty Street, Suite 100
Indianapolis, IN 46225.

Pearl IRB is a group of people who perform independent review of research studies to protect the rights and welfare of study participants. Although Pearl IRB has approved the information provided in this informed consent form and has approved for the study investigator and overseeing doctor to do the study, this does not mean that Pearl IRB has approved you being in the study, or that the study is without risks. You must consider the information in this consent form for yourself and decide if you want to be in this study.

CONFIDENTIALITY

Every attempt will be made to see that your personal protected health information will be kept private and confidential. A copy of the de-identified records from this study will be stored at Neuroscience Group for at least 3 years after the end of this research. Although your rights and privacy will be maintained in a manner as required by HIPAA, the study staff (which are members of your care team) and employees of Neuroscience Group will have access to your protected health information for obtaining the data for this study, and as is necessary for aiding in your care and treatment, and for billing and financial reasons. The results of this study may be published and/or presented at meetings using only de-identified data. The de-identified data obtained in this study may be used to seek approval from federal organizations to receive reimbursement from Medicare, and/or insurance companies for reimbursement. It may also be utilized for the advertisement and further use of GyroStim equipment for treating patients. As such, use of data may be used for commercial profit, which research subjects will not be entitled to.

A description of this clinical trial will be available on http://www.Clinical Trials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time. The IRB, the FDA, and UltraThera Technologies, Inc. (GyroStim manufacturer), and Courtney Hall, PhD from Eastern Tennessee University will have access to only the de-identified study records, which will omit your name, email address, address, phone number and date of birth. The data will include gender, age, date of injury, adherence to (maintaining) therapy schedule, and results of the above-mentioned physical therapy and speech therapy questionnaires and testing. Your records will be kept completely confidential according to current legal requirements. They will not be revealed unless required by law, or as noted above. While identifying information will be removed from study data, it is possible that the data gathered from this study may be used for future studies by Neuroscience Group, or possibly distributed to other entities for research without obtaining additional informed consent.

If you sign this document, you give permission for the staff at Neuroscience Group to use or disclose (release) your health information that identifies you for the research study as described above. The health information that we may use or disclose (release) for this research incudes: information in your medical records, medical history, results of questionnaires, results of physical therapy and speech therapy testing, and documentation made by your healthcare providers that may be relevant to the study, such as changes in symptoms, need to alter care, etc. The health information listed above may be used by and/or disclosed (released) to: Your nurse practitioner, physical therapist, speech therapist, and to study staff that include Nichole Siebert, MS, LAT, ATC, Taylor Weuve, MBA, LAT, ATC, Gemma Hodgkiss, medical student (research assistant), and Benjamin Siebert, MD, FAAPMR. All of these individuals are employees of Neuroscience Group and members of your healthcare team. Neuroscience Group is required by law to protect your health information. By signing this document, you authorize Neuroscience Group to use and/or disclose (release) your health information for this research. Your authorization will expire at the end of this research study.

By signing this document, you confirm that you have read or had this document read to you. You will be given a signed copy of this informed consent document. You acknowledge that you have been given the chance to ask questions and to discuss your participation with consenting provider and the investigator upon request. You freely and voluntarily choose to give your consent to be in this research project. You are free to take as much time as you need to decide whether to participate in this research study. Our scheduler will contact you in approximately 2 business days. If you would still like more time to decide, please notify our scheduler. We cannot schedule treatment for you, until we are aware of your decision. If you take this form home and decide you would like to participate, please bring this form with you to your first physical therapy or speech therapy visit. You will then sign it with your provider.

_____

SIGNATURE OF PARTICIPANT DATE

_____

PRINTED NAME OF PARTICIPANT DATE

_____

SIGNATURE OF PROVIDER CONSENTING DATE

_____

SIGNATURE OF WITNESSING PROVIDER DATE

_____

SIGNATURE OF INVESTIGATOR DATE

Please select which group you are choosing to participate in:

___ PT & CRT only

___ PT & CRT with GyroStim up to 2 times per week

___ PT & CRT with GyroStim up to 3 times per week

___ PT & CRT with GyroStim up to 4 times per week