



Portable Neuromodulation Stimulator (PoNS) Therapy for Gait and Balance Deficits in Chronic Stroke Survivors: A Single Arm Study
Physical Therapy (PT) combined with PoNS as indicated for use in people living with Stroke conducted at Rehabologym in collaboration Helius Medical Inc

REHABOLOGYM is a Neuro-Robotic Rehabilitation Center utilizing state of the art technologies and comprehensive methodologies for Neurological Occupational Therapy (OT), Physical Therapy (PT), Speech Therapy (ST / SLP) and Certified Personal Training to restore & maximize health and overall well-being.

REHABOLOGYM utilizes Robotics & state of the art "cutting edge" technologies that deliver engaging, intensive, repetitious movements which are key principles to movement recovery, cognitive stimulation, health maintenance and improved function. REHABOLOGYM'S methodology is targeted to increase function & independence with daily activities that are important and meaningful.

Overview of PoNS Physical Therapy Stroke Study @ Rehabologym:

Selected individuals with a diagnosis of Stroke, determined by Rehabologym's Principal Investigators, Dr. Jay L. Lombard, DO, Neurologist, Avrielle Peltz, MA, OTR/L & Research Coordinator Deborah Krekeler, DPT, will participate in 5 Comprehensive Physical Therapy Evaluations over a period of 24 weeks; a) before treatment begins, b) intermittently during treatment c) after 12 weeks of Intensive Physical Therapy with use of the on-label PoNS Device delivered by PoNS Certified Neuro Physical Therapists at Rehabologym and d) after a 12 week hiatus. Each Physical Therapy session will be no less than 60 minutes in duration and will be one-on-one with a PoNS Certified Physical Therapist. There will be a total of 26 visits, which include comprehensive Evaluations and Physical Therapy Sessions combined with PoNS treatment, that will consist of both in-clinic participation and Home Exercise Programs customized to each individual.

The focus of the study is to 1) evaluate aspects of safety related to PoNS Therapy; 2) further evaluate the efficacy of PoNS on improving dynamic gait & balance, establishing durability of effect, risk of falling, fall rate and adherence to PoNS utilization; 3) to further explore quality of life to measure physical, mental, behavioral and general health and functional decline (> 30% on gait & balance improvement at endpoint) during the 12 week follow up.

Cost of Participation: FREE of charge for all eligible participants

If you have any questions or would like to be considered for study eligibility, please contact Rehabologym directly at 914-603-8600 or email info@rehabologym.com

Rehabologym

www.rehabologym.com

580 White Plains Rd Suite 120A Tarrytown, NY 10591

Telephone 914-603-8600 Fax 914-603-8601



Sample PoNS Physical Therapy (PT) Stroke Study Schedule:

*Sample schedule is subject to change at clinician discretion based on individual client needs

Pre-Participation Screening Visit: 30 days or less prior to study start
Medical Examination & Screening by Neurologist – 45 minutes
Baseline PT Evaluations, Cognition Screening & Informed Consent – 2 hours

Week 1:

PT PoNS Treatment x3 In-Clinic + PT Evaluation #1
PT PoNS Treatment x1 At Home (Virtual)
Total – 4 SESSIONS (PT Session and Evaluation combined in first session)

Week 2:

PT PoNS Treatment x3 In-Clinic
PT PoNS Treatment x1 At Home (Virtual)
Total – 4 SESSIONS

Week 3:

PT PoNS Treatment x3 In-Clinic
Total – 3 SESSIONS

Week 4:

PT PoNS Treatment x3 In-Clinic + PT Re-Evaluation #2
Total – 3 SESSIONS (PT Session & Re-Evaluation combined on last session of week)

Week 5-7:

PT PoNS Treatment x1 In-Clinic
Total – 1 SESSION (* No Less than 4 days at home exercises using PoNS Device)

Week 8

PT PoNS Treatment x1 In-Clinic + PT Re-Evaluation #3
Total – 1 SESSION (PT Session & Re-Evaluation combined on last session of week - * No Less than 4 days at home exercises using PoNS Device)

Week 9-11

PT PoNS Treatment x1 In-Clinic
Total – 1 SESSION (* No Less than 4 days at home exercises using PoNS Device)

Week 12

PT PoNS Treatment x1 In-Clinic + PT Re-Evaluation #4 **End of Study Participation – Return PoNS Device – Resume Regular daily Exercises & Therapy – 12 WEEK BREAK**
Total – 1 SESSION (PT Session & Re-Evaluation combined on last session of week)

Week 24

Follow up PT Re-Evaluation #5

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Client Name: _____ **Study ID#** _____

Pre-Participation Screening Visit: _____ (Date/Time)

Start Date: _____ **Primary PT Rehabologist(s):** _____

Week 1 PT Sessions – Week of: _____

Day _____ Time _____
Day _____ Time _____
Day _____ Time _____
Day _____ Time _____ (Virtual Home Visit)

Week 2 PT Sessions – Week of: _____

Day _____ Time _____
Day _____ Time _____
Day _____ Time _____
Day _____ Time _____ (Virtual Home Visit)

Week 3 PT Sessions – Week of: _____

Day _____ Time _____
Day _____ Time _____
Day _____ Time _____

Week 4 PT Sessions – Week of: _____

Day _____ Time _____
Day _____ Time _____
Day _____ Time _____ (PT + Re-Evaluation 90 Minutes)

Week 5 PT Session – Week of: _____

Day _____ Time _____

Week 6 PT Session – Week of: _____

Day _____ Time _____



Client Name: _____

Study ID# _____

Week 7 PT Session – Week of: _____

Day _____ Time _____

Week 8 PT Session – Week of: _____

Day _____ Time _____ (PT + Re-Evaluation 90 Minutes)

Week 9 PT Session – Week of: _____

Day _____ Time _____

Week 10 PT Session – Week of: _____

Day _____ Time _____

Week 11 PT Session – Week of: _____

Day _____ Time _____

Week 12 PT Session – Week of: _____

Day _____ Time _____ (PT + Re-Evaluation 90 Minutes)

END OF STUDY Participation – Please Return you PoNS Device to Rehabologym

12 WEEK BREAK – Resume Regular Activities and Therapy

Week 24 Follow Up PT Evaluation: – Week of: _____

Date: _____ Time _____ (Re-Evaluation 60-90 minutes)

CANCELLATIONS / MAKE UP Schedule:

In the event of unforeseen cancellations due to illness, unexpected personal events or inclement weather, please re-schedule make up visits accordingly.

Cancel Date: _____ Make Up Date: _____

Cancel Date: _____ Make Up Date: _____

Cancel Date: _____ Make Up Date: _____

Cancel Date: _____ Make Up Date: _____

Cancel Date: _____ Make Up Date: _____

Cancel Date: _____ Make Up Date: _____

PoNS at REHABOLOGYM

PoNS is an innovative medical device that delivers a mild electrical stimulation to the surface of the tongue triggering a flow of neural impulses to the brain structures.



The PoNS device is indicated for use as a short term treatment of gait and balance deficits due to mild or moderate symptoms from multiple sclerosis and other neurological conditions.

To be used in conjunction with supervised physical therapy.

For more information or to schedule an appointment contact REHABOLOGYM at **914- 603-8600** or email info@rehabologym.com
Visit www.Rehabologym.com to learn more!



580 White Plains Road, Suite 120A



- Rehabology is located in Southern Westchester County in the Hudson Valley Region. Rehabology is in close proximity to the 5 boroughs of NYC, Long Island, Rockland, Orange, Putnam & Dutchess Counties, Connecticut & New Jersey.
- Rehabology is located on ground level with a private entrance for ease of wheelchair accessibility and for individuals who require use of adaptive devices.
- Handicapped parking is available on the side of the building (please see diagram above).
- For those who require public transportation, the bus stop is located at the front of the building entrance (please see diagram above).
- Rehabology provides transportation and lodging resources at discounted rates for Rehabology members, with participating providers for Westchester County residents and out of town clients.
- Metro North Tarrytown Train Station is located only a short 2.2 Miles from Rehabology. Tarrytown Train Station runs on the Metro North Hudson Line. Details regarding train schedules can be found on the Metro North Railroad website <https://new.mta.info/>. Accessible Uber and Taxi options are available for transport from the train station to and from Rehabology.

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