Translingual Neural Stimulation in Patients with Multiple Sclerosis

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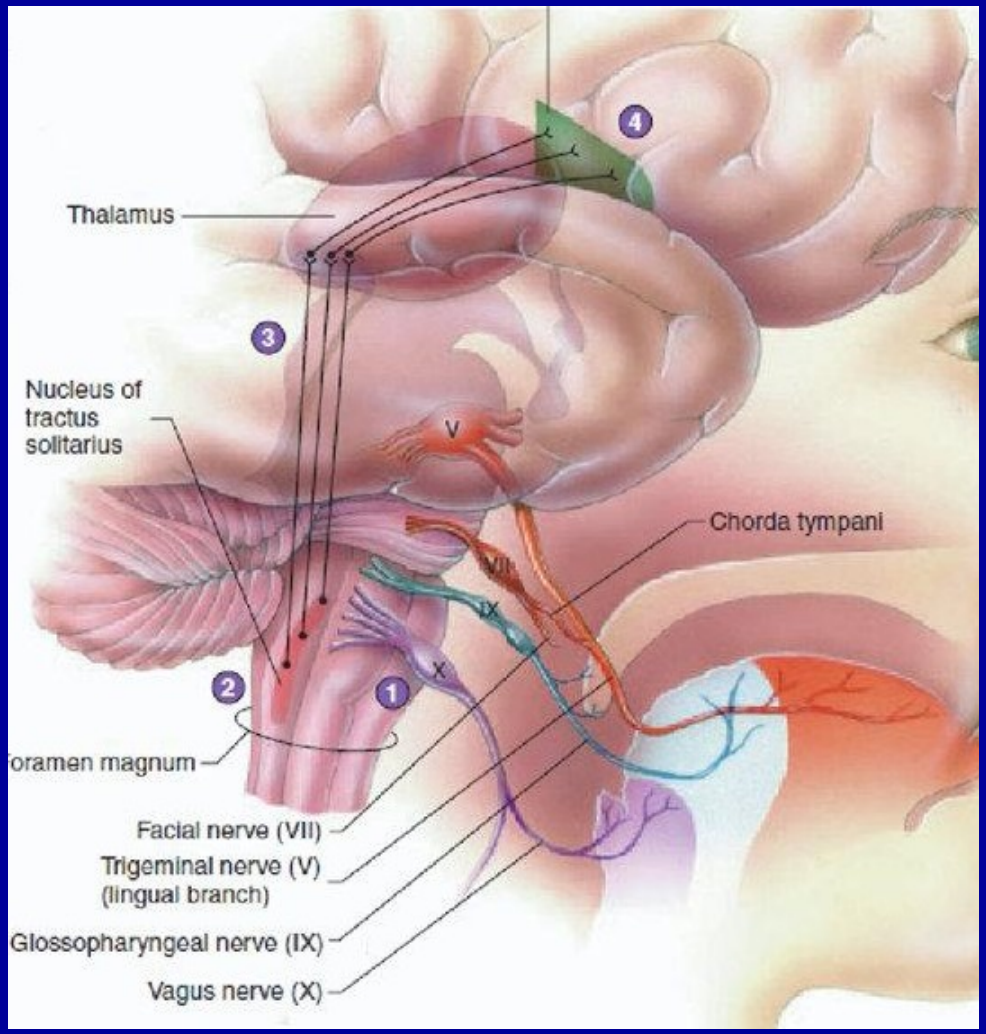
Translingual Neural Stimulation

- Translingual Neural stimulation or Cranial Nerve Non-invasive Neuromodulation (CN-NINM) is a non-invasive portable system that stimulates the cranial nerves in the tongue.

- These cranial nerves have direct connections to the brainstem with additional connections to the cerebellum and other brain regions.

The tongue as a means for non-invasive electrotactile stimulation.

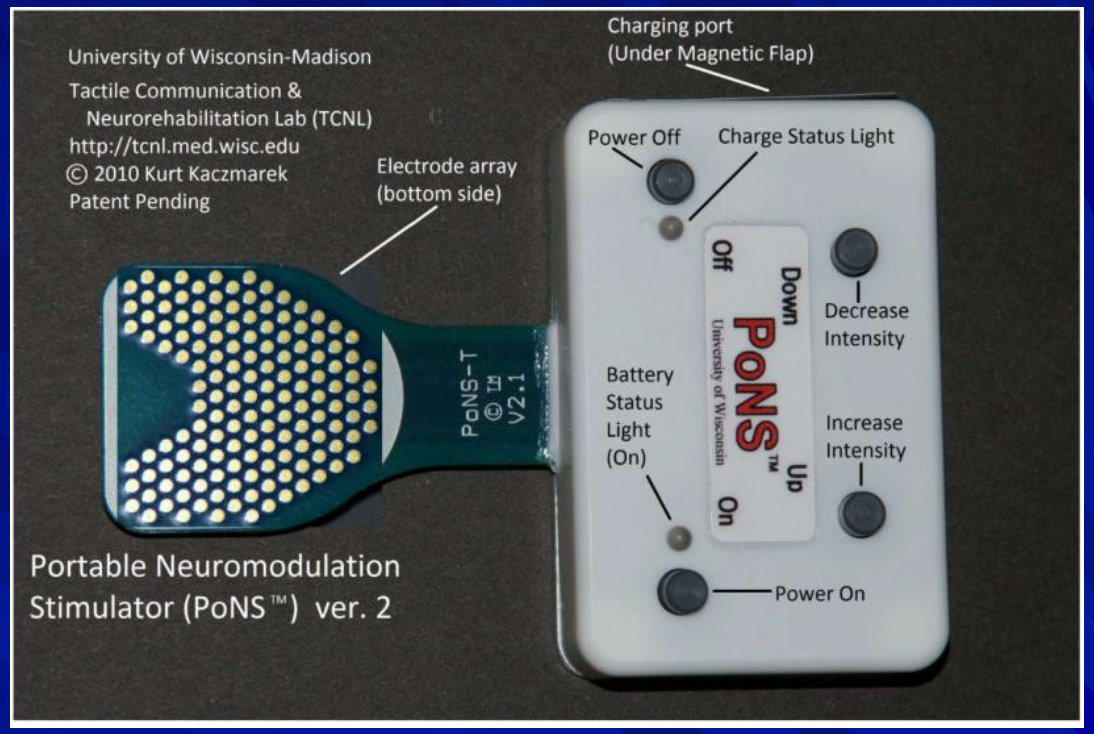


- The anterior aspect of the tongue is innervated by two cranial nerves (CN): the ***lingual*** branch of the ***trigeminal nerve*** (CN-V), and the ***chorda tympani*** branch of the ***facial nerve*** (CN-VII).
- CN-NINM intervention uses controlled, sequenced patterns of mild electrical stimulation on the tongue that are subsequently transmitted as action potentials to key regions in the brainstem (specifically the pons & medulla), and the cerebellum mainly via the 5th and 7th cranial nerves (CN-V & CN-VII).

- The Portable Neuromodulation Stimulator (PoNS™) system (ver. 2) delivers 19-V pulses to the top surface of the tongue.

- While the voltage and pulse timing to each electrode is programmed in the device and cannot be altered, the subject can adjust the stimulus intensity by manipulating a pair of intensity buttons.

- This form of tongue stimulation has been used in our research for the last 15 years under multiple UW Health Sciences - IRB protocols for studies in balance, vision, and sensory substitution studies.



Translingual Neural Stimulation

- When applied in conjunction with other therapeutic interventions for sensory and movement control integration, CN-NINM has demonstrated
  - localized functional changes in brain activity levels,
  - resulting in improved balance, posture, gait and limb movement control,
    - providing indirect evidence of functional neurorehabilitation that complement the behavioral changes.
- At UW we have explored CN-NINM intervention on subjects having balance, posture and gait disorders due to Multiple Sclerosis, Chronic balance dysfunction, Stroke, and TBI.

Background

- The three main sensory processes responsible for balance are:
  a. Visual System: Provides information about the location of surroundings and object with respect to the body
  b. Vestibular System: Senses position, linear accelerations, and rotational movements of the head
  c. Proprioception: Provides information about self, or the relative position of different parts of the body.
    - The sensory information from each of these systems is suitably weighted based on the environmental and physiological factors; and subsequently integrated to achieve balance control (Horak, 2006).
    - The brain stem, cerebellum, and the cerebral cortex are the primary neuroanatomical structures that form the posture control system.
- The deterioration of any one of the sensory or motor systems involved in postural control has drastic effects on balance control (Winter et al., 1990).

Background

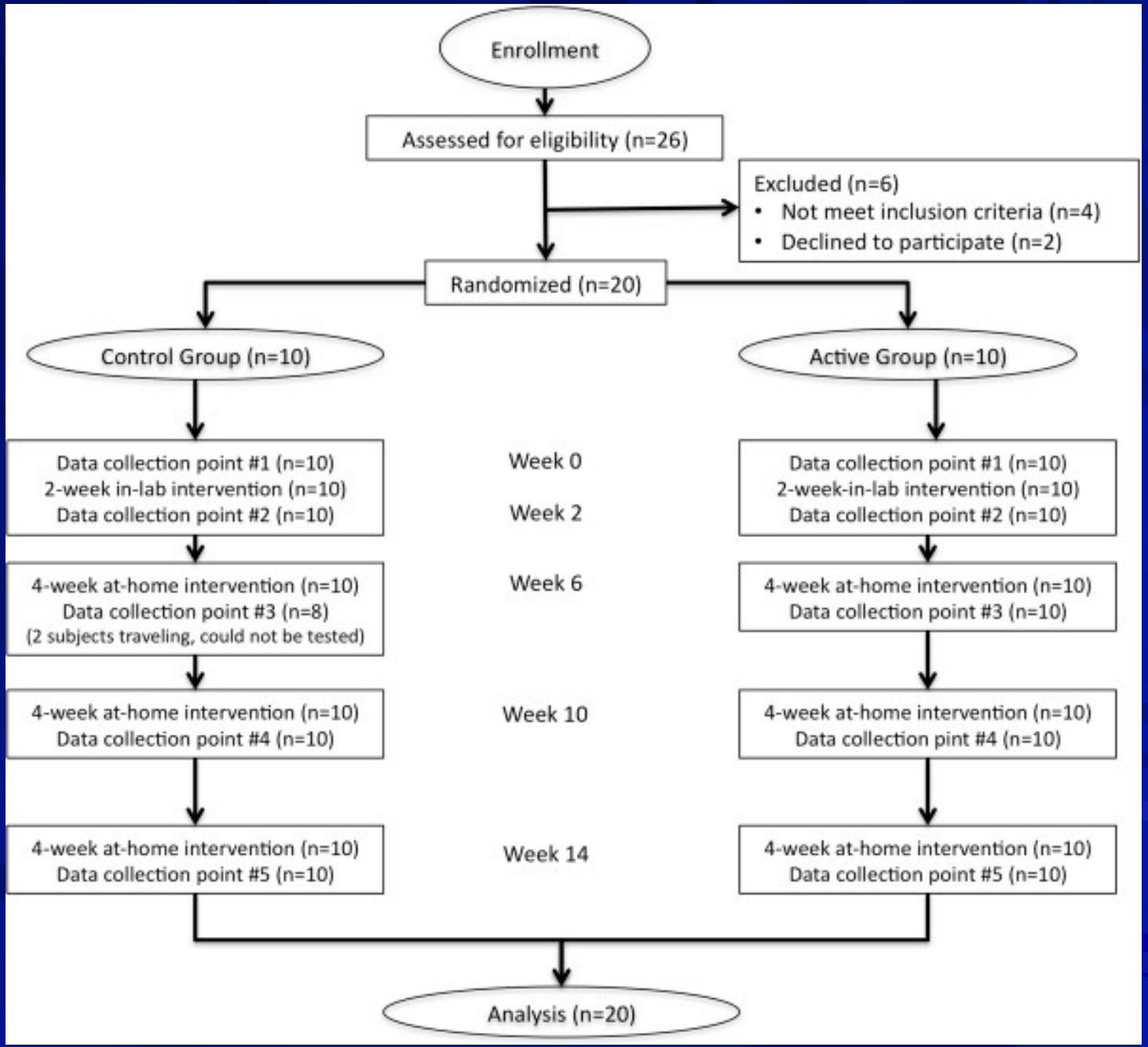
- Existing pharmacological, biological and electrophysiological treatments for gait and balance disorders aim to augment neuroplasticity in patients with neurological disorders (MS, Vestibular disorders, Stroke, TBI).
  - While stimulation of the peripheral nervous system (PNS) and central nervous system (CNS) show positive effects on motor rehabilitation, the overall effect sizes have not been significantly greater than those demonstrated with behavioral therapy alone.
  - Moreover, these treatments are unsuited for widespread clinical application.

Multiple Sclerosis

- Walking impairment most common in patients with MS.
- ~40% of MS patients will need some form of walking assistance within 15 years of disease onset.
- We examined the effect of targeted physical therapy with and without cranial nerve non-invasive neuromodulation (CN-NINM), on the walking ability of people with MS who exhibited a dysfunctional gait.

Multiple Sclerosis

- Inclusion criteria:
  - Relapsing remitting (RRMS), primary progressive (PPMS), or secondary progressive (SPMS) without relapse within 6 months of enrollment in the study;
  - EDSS scores of 3.5 to 6.0; no changes in medication within 3 months of enrollment; and ability to walk 20 minutes on a treadmill (with handrail support as needed) without rest. The EDSS is a rating system used for classifying the condition of people with MS, and emphasizes walking ability. Scores in the range of 3.5 to 6.0 on the EDSS represent people who are ambulatory and have a few functional systems affected to those more significantly affected, requiring intermittent or constant unilateral assistance (e.g., a cane, crutch, or brace) to walk 100 meters with or without resting.
- Exclusion criteria : Major co-morbidities, especially other neurological disorders, uncontrolled pain, hypertension, diabetes, or oral health problems.


Enrollment
Assessed for eligibility (n=26)
Excluded (n=6)
• Not meet inclusion criteria (n=4)
• Declined to participate (n=2)
Randomized (n=20)
Control Group (n=10)
Active Group (n=10)
Data collection point #1 (n=10)
2-week in-lab intervention (n=10)
Data collection point #2 (n=10)
Week 0
Week 2
Data collection point #1 (n=10)
2-week-in-lab intervention (n=10)
Data collection point #2 (n=10)
4-week at-home intervention (n=10)
Data collection point #3 (n=8)
(2 subjects traveling, could not be tested)
Week 6
4-week at-home intervention (n=10)
Data collection point #3 (n=10)
4-week at-home intervention (n=10)
Data collection point #4 (n=10)
Week 10
4-week at-home intervention (n=10)
Data collection pint #4 (n=10)
4-week at-home intervention (n=10)
Data collection point #5 (n=10)
Week 14
4-week at-home intervention (n=10)
Data collection point #5 (n=10)
Analysis (n=20)

Multiple Sclerosis

- The in-lab training consisted of two appointments per day.
  - Within each appointment, subjects performed movement isolation exercises without the device (e.g., chin circles, shoulder circles, and hip circles), 20 minutes of gait training (treadmill) with the device, 20 minutes of balance training with the device, and 20 minutes of relaxation training with the device.

Multiple Sclerosis

Subject characteristics at baseline

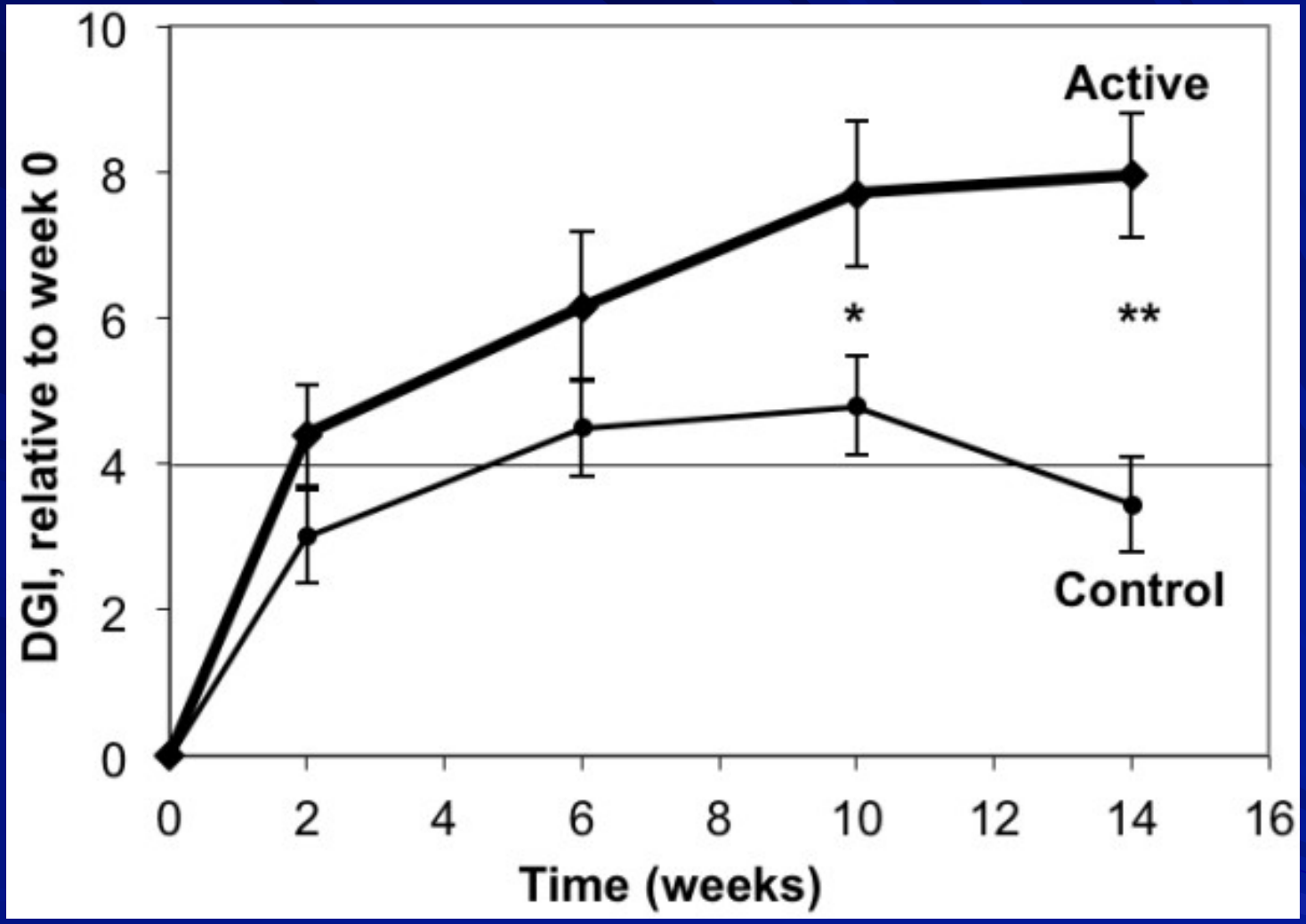
	Active		Control		
Subjects	**10**		**10**		
Men/Women	**4/6**		**2/8**		
	Mean	**SD**	**Mean**	**SD**	***p***
Age	55.40	8.73	51.90	9.31	0.40
Years with MS	24.10	11.03	13.10	6.72	0.01*
EDSS	5.25	0.98	4.60	1.05	0.17
DGI	8.90	2.85	11.95	4.04	0.07

*Indicates significant difference.

EDSS, Expanded Disability Status Scale, DGI = Dynamic Gait Index.

Multiple sclerosis subgroups

	Active (10)	Control (10)
Relapsing Remitting	5	8
Male/Female	1/4	2/6
Secondary Progressive	5	1
Male/Female	3/2	0/1
Primary Progressive	0	1
Male/Female	0/0	0/1



Plot of Change in DGI score versus time. The X-axis represents data acquisition time: 0 weeks is study entry (baseline), 2 weeks is end of lab training, and 6, 10, and 14 weeks are end of each 4-week home training period. The Y-axis represents the change in DGI relative to the baseline DGI value. Error bars are ± 1 SE; * indicates $p < 0.05$, ** indicates $p < .005$.

Patients with Chronic balance dysfunction

- Functional magnetic resonance imaging (BOLD-fMRI) study of patients with Chronic balance dysfunction to measure changes in neural activity due to CN-NINM.
- We used optical flow videos to activate vestibular processing areas of the central nervous system while patients remained motionless in the MRI scanner.
- Patients underwent an initial MRI scan before the first CN-NINM therapy session and a second after one week of therapy.

Patients with Chronic balance dysfunction

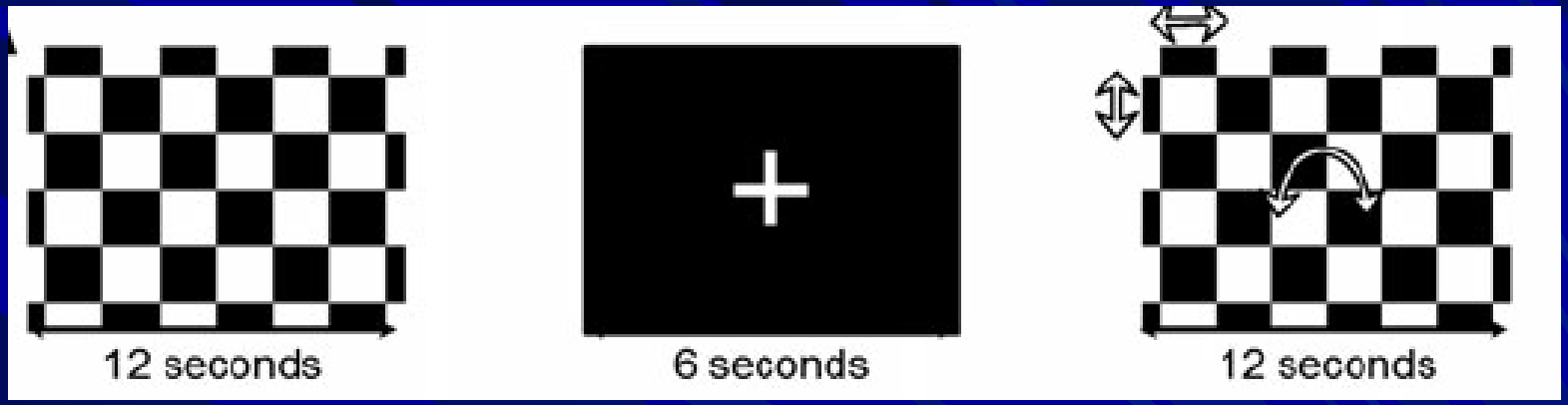
- Inclusion criteria: The inclusion criteria for the balance subjects were very broad. These criteria included anyone with a chronic, stable balance dysfunction that encompassed deficits of balance, posture, and gait.
- Exclusion criteria: The Exclusion criteria, for both balance subjects and controls, were pregnancy, mental health problems, corrected vision below 20/40, myasthenia gravis, Charcot-Marie Tooth disease, post-polio syndrome, Guillan-Barré, fibromyalgia, chronic fatigue syndrome, herniated disc and osteoarthritis of the spine. Exclusion criteria for balance subjects also included communicable diseases (HIV, TB, hepatitis, etc.), oral health problems (open sores in the mouth or tongue), and tongue neuropathies. Subjects were also excluded for the presence of MRI-incompatible metallic implants.

Patients with Chronic balance dysfunction

- 6 women and 5 men (range 38 to 73 years, mean 49.6 ± 8.8 years) with various balance etiologies underwent one week of therapy with CN-NINM.
- Stimulation to the tongue was delivered via a 12x12 electrode array placed on the anterior portion of the tongue. Patients underwent five days of therapy sessions with CN-NINM.

Patients with Chronic balance dysfunction

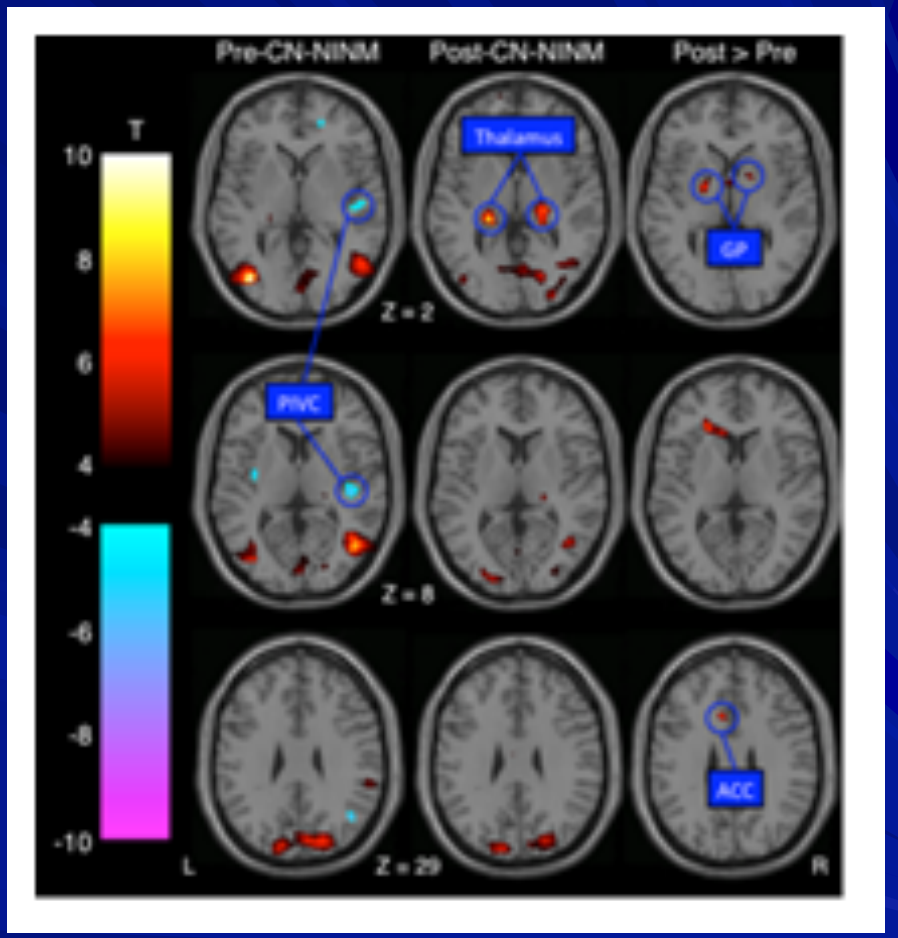
Subject	Gender	Age	Clinical diagnosis
A	M	56	Central Vestibular Disorder
B	F	47	Migraine-related Balance Disorder
C	M	46	Traumatic Brain Injury
D	F	46	Chronic Ménière's Disease
E	M	38	Spinocerebellar Ataxia
F	F	66	Gentamicin Ototoxicity
G	M	64	Idiopathic Cerebellar Ataxia
H	F	43	Spinocerebellar Ataxia
I	M	44	Peripheral Vestibular Disorder
J	F	55	Peripheral Vestibular Disorder
K	F	51	Idiopathic Vestibular Disorder
J	M	73	Cerebellar Infarction



fMRI task

- The vestibular system was stimulated with motion in the visual field (optical flow) (Kikuchi et al., 2009).
- Three visual stimuli were used – a static checkerboard, a checkerboard that appeared to advance/recess, and a checkerboard that advanced/recessed and rotated.
- 12 seconds of visual stimuli alternated with 6 seconds of fixation in a block-design paradigm

- Significant activations in the primary visual cortex and visual association areas and in the PIVC of patients before therapy with CN-NINM that are absent/reduced after therapy.
- Significant activations of the posterior thalamus in patients after therapy with CN-NINM.
- Significant activation of the anterior cingulate cortex (ACC) and areas of the basal ganglia after therapy with CN-NINM. .

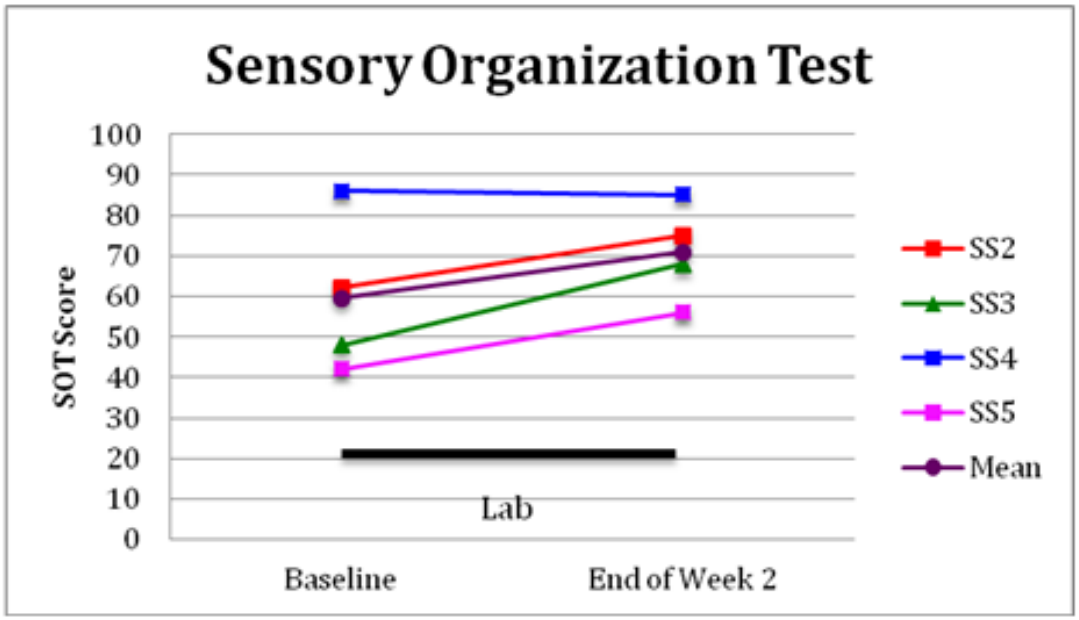


Possible mechanism

- fMRI study in individuals with balance impairments found that neuromodulation training using electrical stimulation of the tongue, combined with movement exercises in balance-impaired individuals, induces *activity of the cerebellum and brainstem nuclei,* structures of the brain that process balance and movement .
  - CN-NINM induces neuroplasticity by noninvasive stimulation of two major cranial nerves: trigeminal, CN-V, and facial, CN-VII. *This stimulation excites a flow of action potentials (AP's) to the brainstem (pons varolli and medulla) and cerebellum via the lingual branch of the cranial nerve (CN-Vc), and chorda tympani branch of CN-VII.*

Stroke

CN-NINM aims to directly reduce symptoms of stroke by enhancing the brain's ability to functionally compensate for neural tissues damaged or compromised during the stroke.



Individual and mean scores on the SOT for 4 patients.

All 4 subjects improved in dynamic balance after the two-week lab intervention.

Four ischemic stroke patients performed optimized sensory-motor conditioning exercises while they received PoNS tongue stimulation.

They also received training to improve cognition, memory, and attention using a PC-based program.

All subjects received 2 weeks of lab intervention.

- The underlying neurological mechanisms of the neurorehabilitation process in stroke:
  - Evidence from animal research - promising strategy of trigeminal nerve stimulation in TBI symptom management.
  - In a rat model of stroke, infarction volume was decreased after trigeminal nerve stimulation via the forehead; changes comparable to a diving response, which can have a neuroprotective component and potential therapeutic benefit,(Shiflett et al., 2015) were also elicited.
  - In related animal research, direct stimulation of the trigeminal nerve induced a pressor response and improved cerebral blood flow by causing cerebrovasodilation through activation of the trigemino-cerebrovascular system and trigemino-parasympathetic reflex (Chiluwal et al., 2017); beneficial effects included increased cerebral perfusion and reduction in edema, blood–brain barrier disruption, and lesion volume.

TBI research

- Traumatic brain injury (TBI) is a leading cause of injury-induced death and physical disability.
- Millions of people experience TBI every year.
- An estimated 5.3 million people are living with TBI-related disabilities:
  - up to 57% of patients with TBI experiencing balance disorders.
  - Mild-to-moderate traumatic brain injury (mmTBI) encompasses most of TBI cases (83%).

TBI

- 26-week, randomized, double-blind phase 1/2 study (NCT02158494) in the United States between 2014 to 2017 with 3 stages:

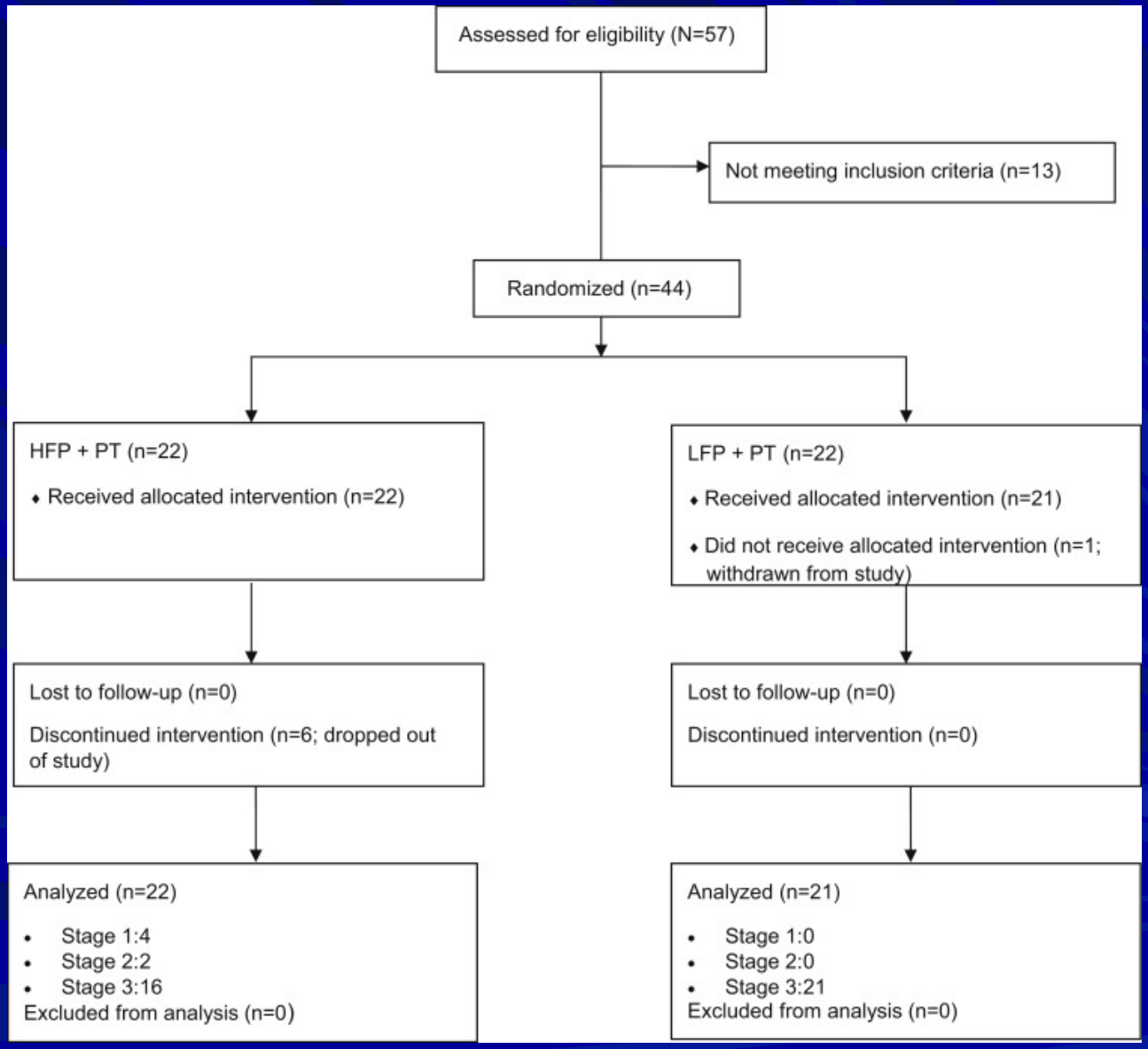
1) Twice-daily in-clinic training program (ITP) for 2 weeks (with at-home training during the intervening weekend),
2) 12-week home training program,
3) 12 weeks with no treatment and a return to normal activities.

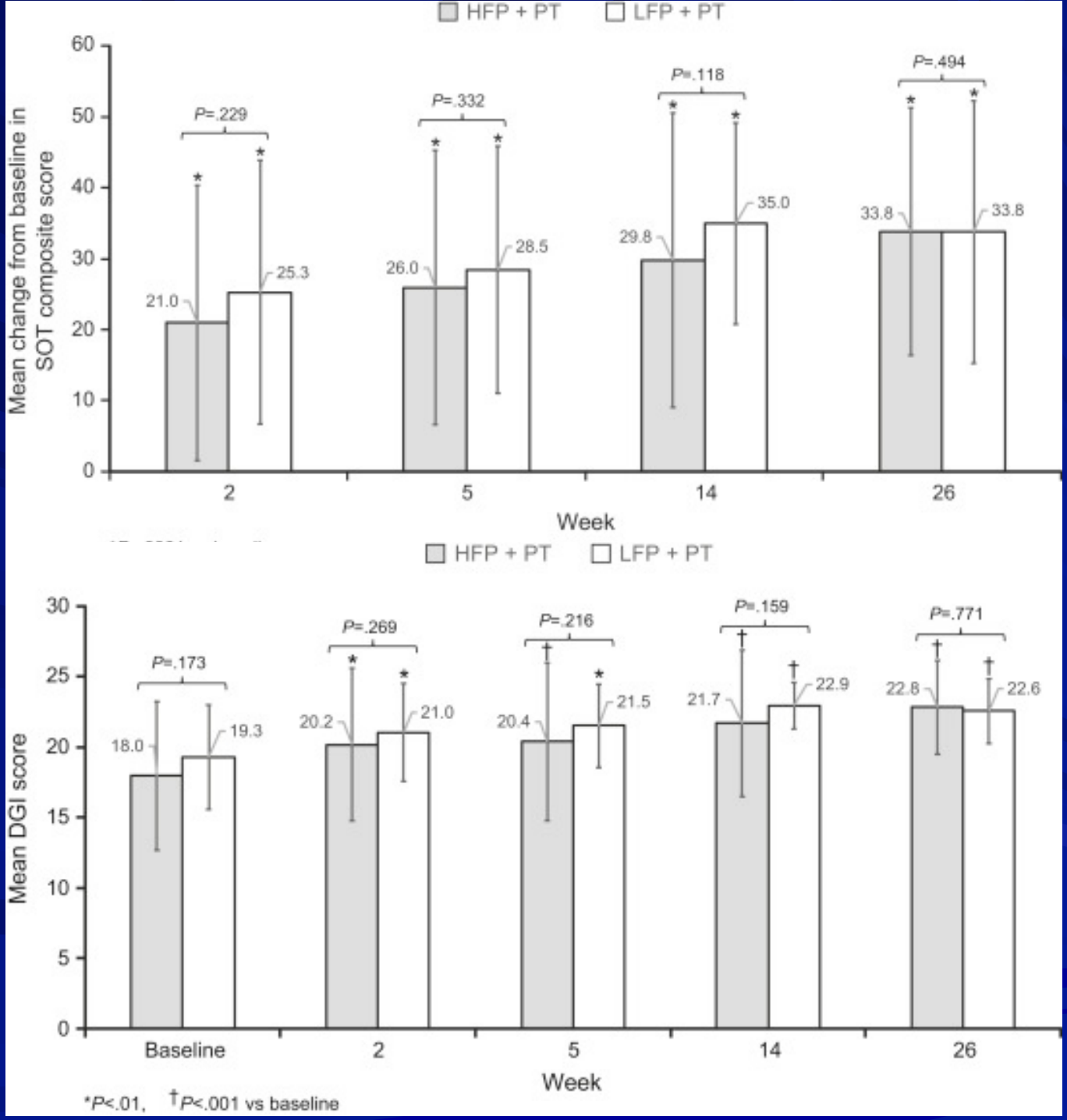
TBI

- Inclusion criteria:
  - Participants were required to have mmTBI that occurred ≥1 year before enrollment,
  - reached a functional plateau in their recovery (as defined by a discharge note from their physical therapist),
  - a NeuroComa Sensory Organization Test (SOT) composite score ≥16 points below normal after adjustment for age.

TBI

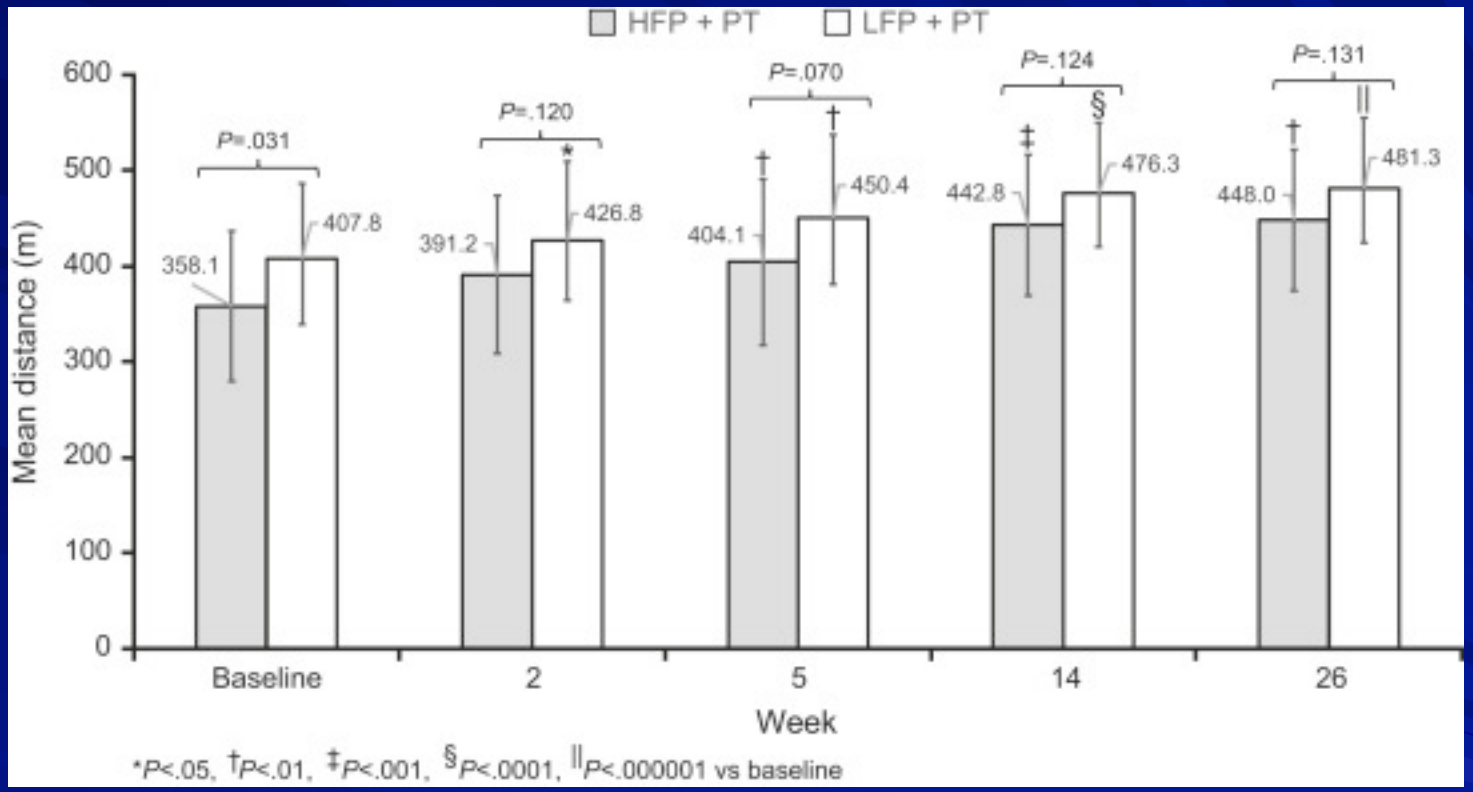
- The primary endpoint was the change in composite SOT score from baseline to week 14.
- The SOT score was also determined at the end of each stage and every 3 weeks during stages 2 and 3.
- Key secondary endpoints were the 6-minute walk test (6MWT) and the Dynamic Gait Index (DGI).


Assessed for eligibility (N=57)
Not meeting inclusion criteria (n=13)
Randomized (n=44)
HFP + PT (n=22)
♦ Received allocated intervention (n=22)
LFP + PT (n=22)
♦ Received allocated intervention (n=21)
♦ Did not receive allocated intervention (n=1; withdrawn from study)
Lost to follow-up (n=0)
Discontinued intervention (n=6; dropped out of study)
Lost to follow-up (n=0)
Discontinued intervention (n=0)
Analyzed (n=22)
• Stage 1:4
• Stage 2:2
• Stage 3:16
Excluded from analysis (n=0)
Analyzed (n=21)
• Stage 1:0
• Stage 2:0
• Stage 3:21
Excluded from analysis (n=0)


HFP + PT
LFP + PT
Mean change from baseline in SOT composite score
60
50
40
30
20
10
0
P=.229
P=.332
P=.118
P=.494
21.0
25.3
26.0
28.5
29.8
35.0
33.8
33.8
2
5
14
26
Week
HFP + PT
LFP + PT
Mean DGI score
30
25
20
15
10
5
0
P=.173
P=.269
P=.216
P=.159
P=.771
18.0
19.3
20.2
21.0
20.4
21.5
21.7
22.9
22.8
22.6
Baseline
2
5
14
26
Week
*P<.01, †P<.001 vs baseline

SOT

DGI


HFP + PT
LFP + PT
Mean distance (m)
600
500
400
300
200
100
0
P=.031
P=.120
P=.070
P=.124
P=.131
358.1
407.8
391.2
426.8
404.1
450.4
442.8
476.3
448.0
481.3
Baseline
2
5
14
26
Week
*P<.05, †P<.01, ‡P<.001, §P<.0001, ‖P<.000001 vs baseline

6MWT

TBI

- Both the HFP+PT and LFP+PT groups had significantly improved balance scores,
  - in SOT scores from baseline at weeks 2, 5, 14 (primary endpoint), and 26.
  - DGI scores had significant improvement (P<.001-.01) from baseline at the same test points;
  - 6MWT evaluations after 2 weeks were significant.
- Importantly, outcomes were sustained for 12 weeks after discontinuing TLNS treatment.
- Results between arms (HFP v LFP) did not significantly differ from each other.

TBI: MRI substudy

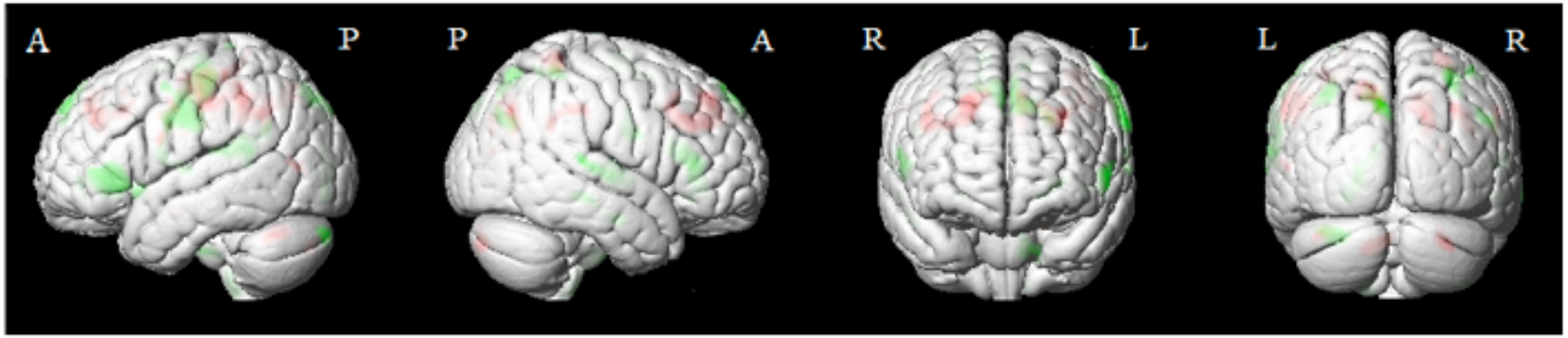
- To better understand the effects of TLNS, a substudy was developed with the primary objective of
  - using structural MRI (sMRI) to evaluate cortical and subcortical changes in the brains of patients before (pre-) and after (post-) treatment.
  - Specifically, the grey matter volume (GMV) results before and after treatment were compared.

TBI: MRI substudy

- sMRI scan (3T MRI GE750 scanner, GE Healthcare, Waukesha, Wisconsin, USA) was performed before the intervention, and immediately after the intervention.
- The preprocessing and statistical analysis for GMV was applied through the toolbox of the CAT12 that works with SPM12.

TBI: MRI substudy

- Significant changes in GMV in specific brain regions when comparing pre- versus post-treatment.



paired t-test of grey matter volume before (pre-) versus after (post-) treatment. Corrected p<0.05, cluster size >212.

Brain regions (BA)	Location	Stereotaxic coordinates (Peak MNI Space)			t-value	Number of voxels
		x	Y	z		
Right hemisphere						
Superior frontal gyrus (9)	Frontal lobe	21.0	42.0	40.5	10.21	1,293
Cuneus (7)	Parietal lobe	18.0	-70.5	36.0	16.97	577
Postcentral gyrus (5)	Parietal lobe	28.5	-45.0	64.5	5.65	271
Superior occipital gyrus (19)	Occipital lobe	34.5	-69.0	39.0	22.93	244
Supplementary motor area (6)	Frontal lobe	49.5	-3.0	25.5	-6.06	285
Supplementary motor area (6)	Frontal lobe	13.5	9.0	55.5	-4.16	398
Middle temporal gyrus (21)	Temporal lobe	52.5	-12.0	-24.0	-4.58	253
Superior temporal gyrus (22)	Temporal lobe	60.0	-30.0	10.5	-17.92	853
Left hemisphere (BA)						
Middle frontal gyrus (9)	Frontal lobe	-27.0	39.0	30.0	6.7	379
Superior medial frontal gyrus (32)	Frontal lobe	-6.0	22.5	40.5	9.8	392
Precuneus (7)	Parietal lobe	-6.0	-70.5	40.5	11.76	541
Inferior parietal lobule (40)	Parietal lobe	-61.5	-42.0	39.0	7.47	603
Postcentral gyrus (4)	Parietal lobe	-31.5	-33.0	57.0	11.64	1,759
Superior frontal gyrus (9)	Frontal lobe	-9.0	55.5	42.0	-3.67	561
Postcentral gyrus (6)	Frontal lobe	-63.0	-1.5	33.0	-4.77	718
Pars triangularis (45)	Inferior frontal gyrus	-57.0	33.0	4.5.0	-4.7	1,632
Superior temporal gyrus (22)	Temporal lobe	-63.0	-49.5	19.5	-4.46	213
Superior occipital gyrus (19)	Occipital lobe	-7.5	-87.0	45.0	-9.36	818
Cuneus (18)	Middle occipital gyrus	-12.0	-90.0	13.5	-5.09	278
Cerebellum	Cerebellum posterior lobe	-15.0	-19.5	-45.0	-24.71	438

	Brain regions (BA)	$r_{(9)}$	p
SOT			
	Right superior frontal gyrus	-0.67	0.05
	Right supplementary motor area	-0.67	0.05
	Right supplementary motor area	-0.68	0.04
	Left superior medial frontal gyrus	-0.72	0.03
DGI			
	Right superior frontal gyrus	-0.69	0.04
	Right cuneus	-0.66	0.05
	Left superior medial frontal gyrus	-0.64	0.06

Correlations between grey matter volume (post- minus pre-) and behavior testing (post- minus pre-).

TBI: MRI substudy

- CN-NINM can produce brain plasticity changes leading to changes in functional assessments with brain-behavioral correlations.
- CN-NINM delivered in conjunction with physical therapy, is a safe, effective, and integrative way to treat TBI.

Overall Conclusions

- CN-NINM may activate a neural network associated with the targeted activities, which then reaches a sensory threshold and activates a neural network.
- The significant increases from baseline in the outcome (e.g., SOT, DGI) composite scores suggest improvements in somatosensory, visual, and vestibular systems that contribute to postural control and balance.

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