

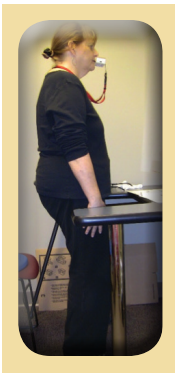


Tactile Communication and Neurorehabilitation Lab
 455 Science Drive, Suite 165
 Madison, WI 53711
 www.tcnl.labs.wisc.edu
 T 608.265.3757



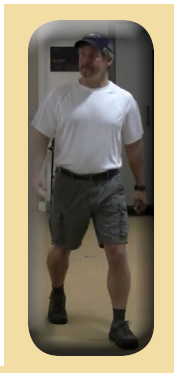
Traumatic Brain Injury Study Recruiting Subjects

- Mild to moderate TBI with balance and walking difficulty
- No loss of consciousness greater than 24 hours
- 26 week study
- Compensation available
- Must meet additional eligibility requirements
- Please see website for details: go.wisc.edu/i24mx8



The structure of the study, with its expert staff and focus on physical therapy, offered me additional layers of balance and movement exercises, as well as meditation. I was part of a team, and TCNL was just as committed to teach me and learn from me as I was committed to the study. I knew I would yield positive results, regardless if I had the "real device." My balance has rapidly and consistently improved, and I have unexpectedly seen improvement with other TBI residuals. The lessons and benefits from the study have been life-changing and life-lasting. My trust in the process and the people was most assuredly in the right place.

~ Dena Taylor



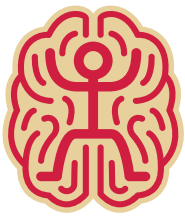
I am very thankful to TCNL for their hard work in developing the PoNS device. They have given me a better quality of life through the study I participated in. I believe that given the opportunity this system will change lives worldwide. I look forward to the day I can continue its use.

~ Andrew Elkins



Prior to participating in the TCNL study at UW, my TBI treatment consisted of different kinds of therapies concentrating on specific symptoms. Most gave me some relief but not a lot of gain. The real change and results in my balance that I got from the PoNS therapy gave me back something huge that I had lost after my injury. Hope! Belief in recovery! Great, caring people with invaluable expertise and a life changing program!

~ Lisa Poehlman



TCNL

Tactile Communication and
Neurorehabilitation Laboratory

2015 UPDATE

From the Directors

On July 1, 2015, TCNL became part of the UW-Madison Department of Kinesiology. Chair Dorothy Farrar-Edwards welcomed TCNL with these words in the Department's newsletter *On the Move*: "We are thrilled to have them. They are making some incredibly interesting progress in finding answers to very serious problems for which there currently are not a lot of great treatments." Our new affiliation will enhance opportunities for collaboration with faculty, staff, and students having interests in human movement, exercise physiology, and sensory/motor control and behavior.

In 2015, we achieved great progress in our academic research and practical clinical applications in many important directions. One collaborative study (detailed in Research Highlights) is the first to demonstrate improved brain function in subjects with Multiple Sclerosis (MS) as measured by functional magnetic resonance imaging (fMRI). Separate collaborative pilot studies in Saint Petersburg, Russia, further extended the spectrum of potential Cranial Nerve-Non-Invasive NeuroModulation (CN-NINM) clinical applications to recovery of hearing loss and tinnitus suppression, and recovery of movement control in pediatric patients with cerebral palsy. Results of these preliminary case studies are very promising. Last year was also challenging for TCNL and created even greater challenges for 2016 (detailed on page 3).

Future directions include extending traumatic brain injury (TBI) rehabilitation to address additional symptoms such as tinnitus, headache, sleep, and post traumatic stress disorder (PTSD), as these are crucial for the rehabilitation of wounded warriors. We are also developing plans for a project surrounding the assessment and training for oculomotor control. The human body has three independent, highly sophisticated movement control systems for body, head and eye movements. Any neurological disorder can affect one or all of these systems. Our current CN-NINM intervention is for recovery of head and body movement control, including posture, balance, and gait. We have preliminary evidence that shows we can recover the missing part — eye movement control — which depends on precise tuning and synchronization of at least six different complex functional networks, and affects everyday activities such as reading, driving, and climbing stairs.

We want to thank all the people, organizations, and foundations who help us to continue to move this cutting edge rehabilitation forward.

"If at first the idea does not seem absurd, then there is no hope for it."

- Albert Einstein



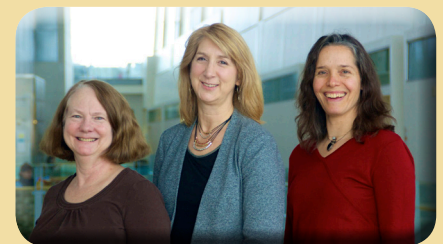
Kurt Kaczmarek, Yuri Danilov, and Mitch Tyler

From the Therapy Team

This has been an exciting year for our therapy team. After the launch of the traumatic brain injury controlled study in 2014, we deployed our training program to three external sites. Now, therapists outside of our lab can use our training for research in their clinics. Once the PoNS technology is commercially available in the market, they will be a ready source of training for new users.

The complexity of our in-lab training made transfer a challenge, and to streamline training transfer we introduced the concept of modules. We defined each training module by its goal. For the TBI study, modules include balance training, gait training, breathing and awareness training (BAT), and movement control exercises. In other studies, we have used a cognitive training module, and experimented with a speech training module. This modular approach makes CN-NINM training easier to perform for both patients and therapists, and helps therapists specifically address areas of most concern to patients.

In the future, we anticipate developing modules in other areas, such as eye movement, tremor, and spasticity. Within each module we will develop training guidelines for that specific purpose, incorporating PoNS use. This will help us create a comprehensive CN-NINM training program that addresses a variety of issues for people affected by neurological dysfunction.



**Janet Ruhland, Kim Skinner,
and Georgia Corner**

2015 Research Highlights

Traumatic Brain Injury Seven subjects have completed and eight are actively participating in TCNL's first randomized controlled trial investigating the reduction of balance and gait impairments caused by TBI. We seek qualified subjects for the remaining 29 subjects and have contracted the services of a professional patient recruitment agency. Please share our information with anyone interested in participating in this study (see back page). Because this is a controlled trial, results will be reported at study conclusion. This study is supported by both the US Army and generous gifts to the TCNL Fund.

We have coordinated the launch of a separate three-site external study (co-sponsored by the US Army) at the Orlando Regional Health Center, Oregon Health Sciences University/ Portland Veterans Administration Hospital, and the Montreal Neurological Institute. While the TCNL trial focuses on acquiring more extensive and longer-term data, this multisite trial is aimed at rigorous testing of our best therapeutic practices and methods using a short and concise protocol.

Multiple Sclerosis Our advanced or "wheelchair-stage" MS study has three active subjects; three have already completed the 18-month protocol. Because subjects present with very different symptoms, we consider this a case series aimed at feasibility of our methods with this population as well as development of the best assessment tools. While requiring great effort and motivation from both subjects and therapists, the protocol may become one of the few effective methods for reducing symptoms of more-advanced MS. While data collection is still in progress, we continue to observe functional improvements

which tend to depend on initial severity of symptoms. A journal manuscript is in preparation for submission.

A separate moderate-stage (cane/walker) pilot study at the Montreal Neurological Institute using TCNL methods showed a statistically-significant improvement in balance in the treatment group but not in the control group. Functional magnetic resonance imaging (fMRI) data did exhibit statistically significant changes in blood perfusion and metabolism in brain structures involved in movement control and memory. This is welcome independent evidence of CN-NINM induced neuroplasticity.

Stroke Based on encouraging results to date, we plan a two-part expansion of our stroke research. In the first stage we hope to acquire data on five individuals using our existing protocol, which considers a variety of stroke-related symptoms. These results will inform the design of a second study with a more focused set of symptoms and measurements (balance and gait) with a goal of acquiring enough data to design a randomized controlled trial. Generous gifts have provided partial support for the first stage; we seek additional funding to enable us to launch this stage and plan for the second stage.

Publications and presentations We presented results of our eye movement studies at six conferences in the US, Canada, and Portugal. Please visit our website for a comprehensive listing, <https://tcnl.labs.wisc.edu/library> and check out Mitch's recorded interview on the Larry Meiller Show, <https://tcnl.labs.wisc.edu/laboratory/news/mitch-tyler-wpr-larry-meiller-show>.

Students and Interns



Kaitlyn

Students are helping in the development of methods for eye movement analysis, physiological data recording, documentation of study results, and instrumentation testing.



Swapnil



Isaac

Two engineering students performed electromyography (EMG) for the TBI Study: **Samuel Acuña** who is pursuing a PhD In Mechanical Engineering and Kristen Rasske who graduated in December with an MS in Biomedical Engineering.

Isaac Loegering is a biomedical engineering undergraduate and has significantly contributed to the modification and maintenance of the lab's database used for the storage of all study data.

Swapnil Deshpande is pursuing a MS in Economics, and works closely with senior scientists to design new programs for the contextualization and visualization of research data.

Michelle Chiang was accepted into the biomedical engineering graduate program at UW and looks forward to delving deeper into eye movement analysis and medical instrumentation.

Dafna Paltin is a recent Temple University graduate and joins the TCNL team as an Intern to support the ongoing research into the efficacy of non-invasive neuromodulation stimulation via the cranial nerves to enhance gait and postural balance in adults with varying neurological conditions.

TCNL welcomed a new opportunity to participate in a practicum program for Kinesiology students. Two students, **Kaitlyn Shaughnessy** and **Chloe Smith**, assisted with the physical therapy components of both the TBI and MS studies.

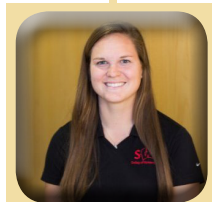
TCNL said goodbye to former students **Nick, Alex, Mike** and **Shekina**. Their contributions were greatly appreciated and we wish them all luck in their future endeavors.



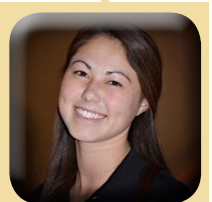
Chloe



Sam



Kristen



Michelle



Dafna

Your Contribution Matters

2016 Challenges

Since 1992, TCNL has been a leader in neuromodulation research, developing and testing new therapies for persons with sensory and neurological disorders using Cranial Nerve-Non-Invasive NeuroModulation (CN-NINM) technology. Our research has resulted in sensory aids for persons with visual and balance disorders, and promising new methods to alleviate symptoms of movement disorders.

TCNL research has been primarily funded by individual donors and private foundations who appreciate the value of disruptive research — doing what shouldn't be possible.

With this support TCNL has developed a multidimensional 10-member research staff with expertise in neuroscience, neurorehabilitation, engineering, electrophysiology, instrumentation, physical therapy, and clinical trials. Supporting this stellar team, along with lab operating expenses, requires nearly \$1 million/year, a cost that TCNL, as a “soft-money” lab, must raise.

This year we may not be able to reach this goal. In 2015, several circumstances brought us to this point. All fundraising efforts were suspended during our administrative move to Kinesiology. We were not able to resume these efforts until fall. We are grateful for those who contributed to our research despite the hurdles. Special thanks go to Neil and Tammy Barry for again hosting a wonderful fundraiser and to Pamela and George Hamel for their continued generosity. Thank you to all our old and new friends who supported us in 2015.

In January 2015, the UW implemented new administrative fees on specific awards – this essentially reduced our available funding from the Army. Finally, we did not have the resources to collaborate with the diverse groups interested in our work due to our focused efforts on the TBI study. Even though we were unable to initiate new collaborations, this was purposeful as the results of the TBI study will move our device and methods forward toward FDA approval and will provide a springboard for application to other disorders.

Coming into 2016, we carry a small balance forward with the Army providing \$263K to complete the TBI study (one-third of last year's support). Unfortunately, US Government support is increasingly difficult to obtain, a situation affecting many research programs across the UW-Madison campus and elsewhere. The US Army, in particular, has substantially cut its research funding due to new congressionally mandated budget reductions.

TCNL is actively exploring alternative funding options, but the fruition of these efforts may come too late for current needs.

TCNL urgently seeks your support. Without additional funding, staff layoffs are imminent, affecting or eliminating potential projects seeking better treatments for symptoms of TBI, stroke, Parkinson's disease, MS, and the range of movement, sensory, and cognitive symptoms accompanying these and other neurological disorders.

Your support has helped us get this far. We need your support to continue our work. Be assured that 100% of TCNL Fund gifts donated through the UW Foundation support TCNL operations, including salaries, student support, research, equipment, travel, symposia, workshops and other functions as they directly relate to the TCNL.

Please contact us to donate or learn more about the lab. We would love to talk to you, host a personal visit, or assist you in hosting a fundraising event. Please spread the word, we can only do this with your help.

Please visit <https://tcnl.labs.wisc.edu/donate> or call (608) 265-3757 for more information on our lab and how to donate.

Thank You!

Please note that as a research lab and not a clinic or health care facility, TCNL does not and cannot charge for participation in research studies. The purpose of our studies is to better understand new treatment methods, not deliver health care. Study participants may or may not realize any benefit from participation, and may be exposed to risks associated with experimental methods. Knowledge acquired from such participation helps TCNL to advance the state of the art in neurorehabilitation and bring hope for those with presently intractable conditions. TCNL devices are not available except as part of experimental protocols approved by the University of Wisconsin-Madison Health Sciences Institutional Review Board.