



Webinar Series

United Spinal Association

Webinar title: Direct Nerve Stimulation

What is it really and what is the potential?

Presenter/presenters:

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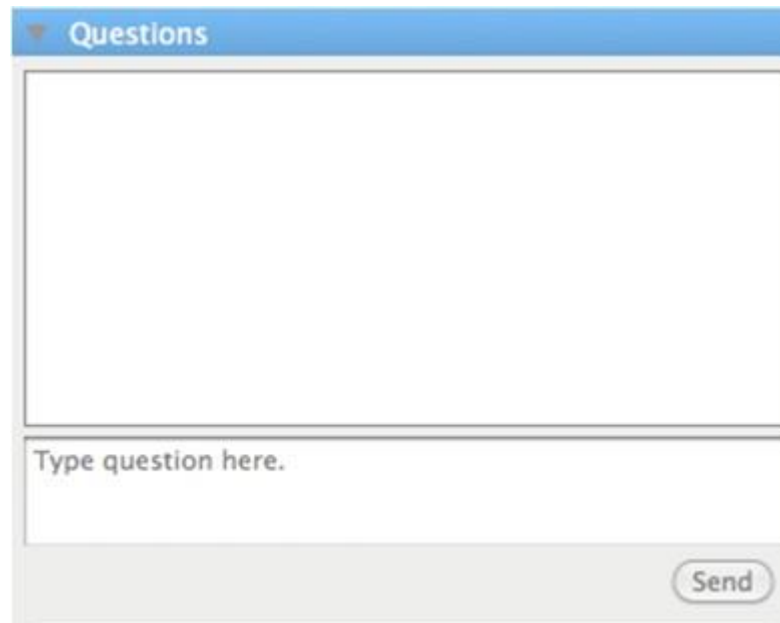
Jennifer French, MBA



Kimberly Anderson-Erisman, PhD



Want to Ask a Question?



A web form titled "Questions" with a blue header bar. Below the header is a large, empty rectangular text area. At the bottom of the form is a smaller text input field containing the placeholder text "Type question here." and a "Send" button.

Disclaimer page

The information presented in this webinar is not meant to replace the advice from a medical professional. You should consult a health care professional familiar with your specific case, concerns and condition.

Neurotech Network and its representatives do not endorse, rate, sell, distribute, prescribe, administer or recommend any products, procedures or services. We highly suggest for you to take information to a trained medical professional familiar with your case to discuss options that are best for you.



www.themiamiproject.org

The Miami Project is dedicated to finding more effective treatments and, ultimately, a cure for paralysis resulting from spinal cord injury.



www.NeurotechNetwork.org

*Helping people regain life thru
neurotechnology*

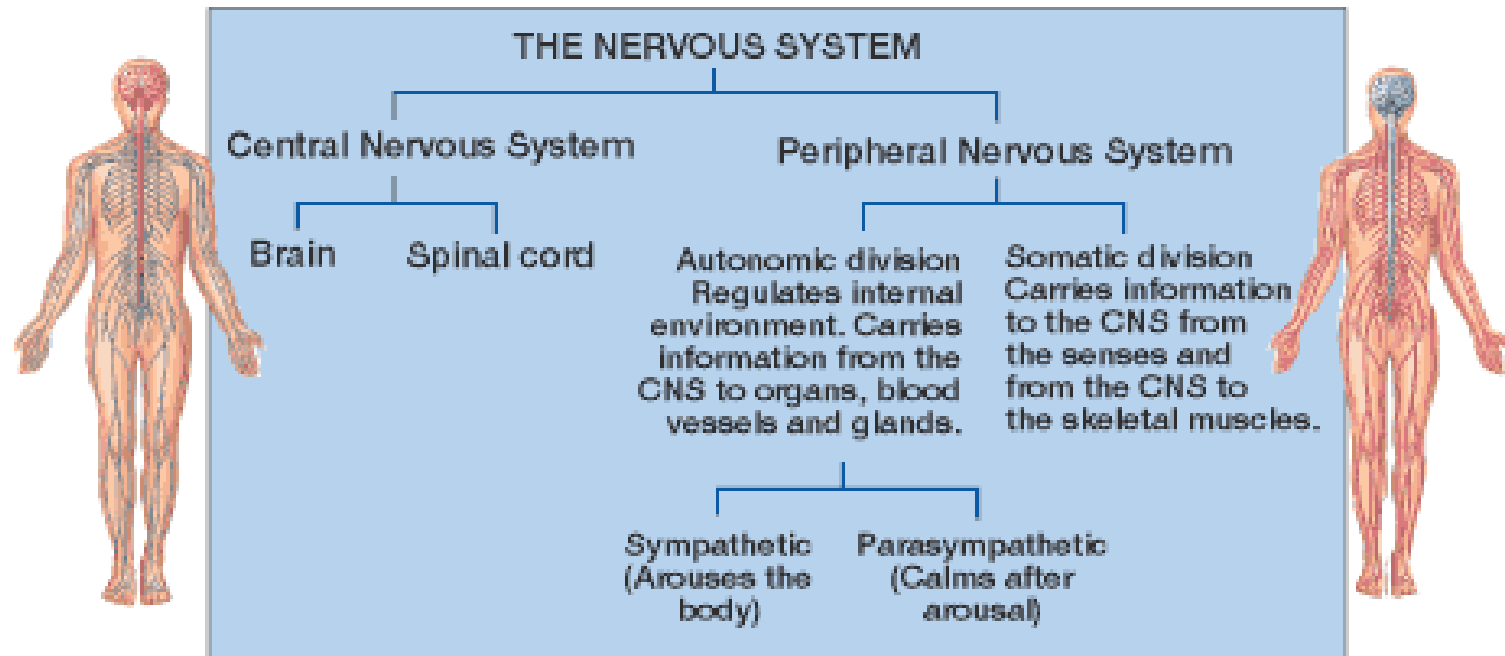
Focusing on education of and advocacy to access neurotechnology devices, therapies and treatments for people living with impairments, their care-givers and medical professionals.



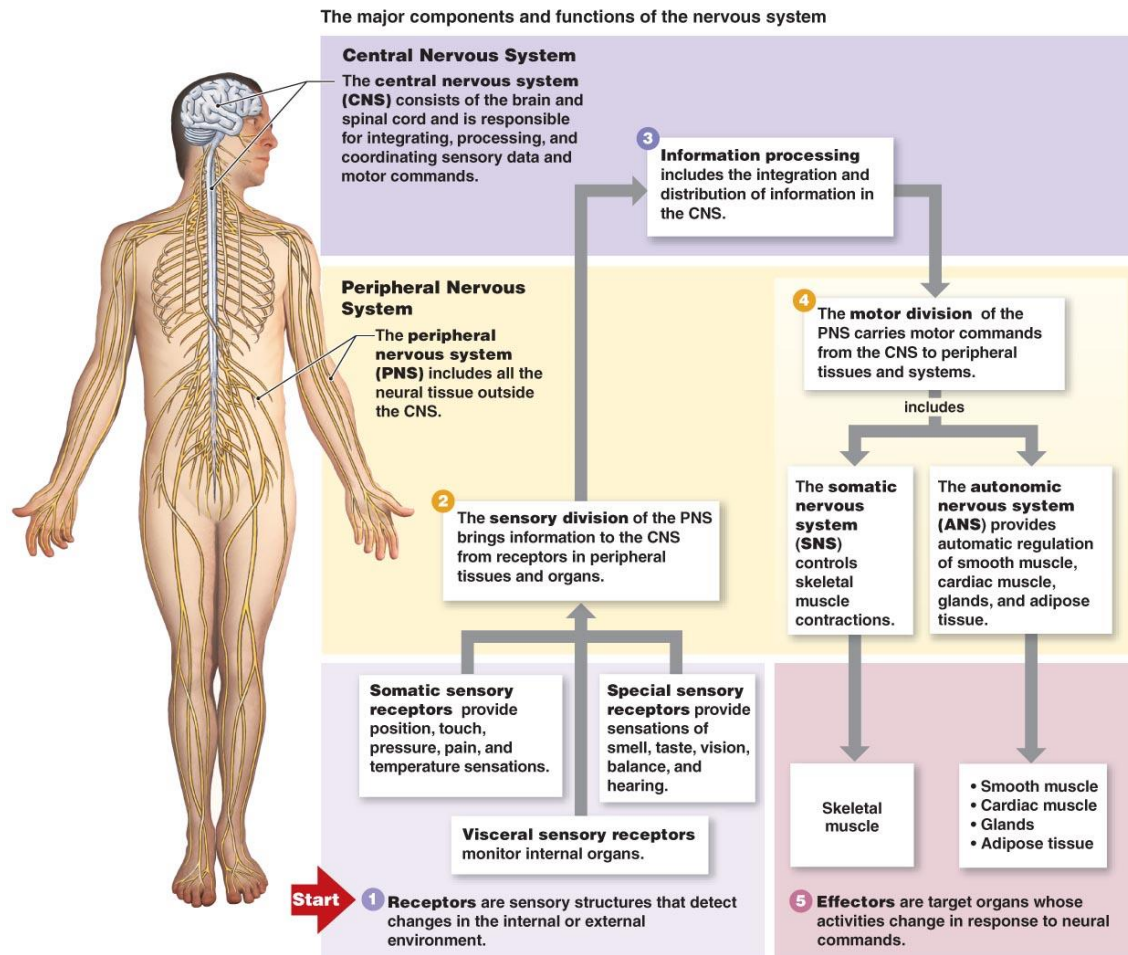
Objectives

- Understanding the Human Nervous System
- Introduce various purposes of stimulation to a nerve
- Differentiate implanted from external stimulation
- Technology applications
 - Peripheral
 - Brain
 - Spinal Cord
- Resources to learn more

The Human Nervous System



The Human Nervous System



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Purposes of Nerve Stimulation

Promote Plasticity

- Peripheral
- Brain
- Spinal Cord

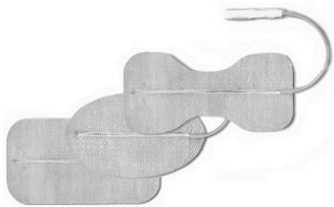
Modulation

- Control Pain
- Suppression tremors or seizures
- Obesity
- Bladder

Movement

- Augment rehabilitation
- FES
- Regulate

Implanted vs External



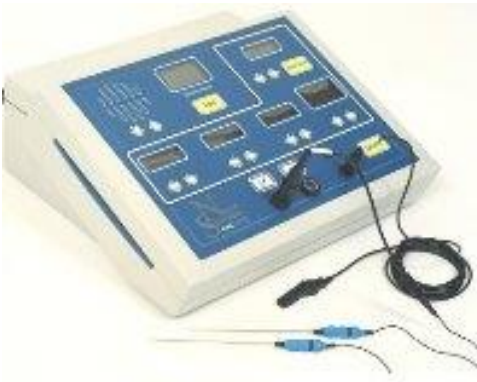
	Benefits	Risks
External Stimulation	<ul style="list-style-type: none">• low clinical risk• easy to implement• lower cost	<ul style="list-style-type: none">• burning of skin• stimulate a large muscle group rather than targeted• difficult to duplicate/compliance
Implanted Stimulation	<ul style="list-style-type: none">• targeted stimulation• Consistency• ease of use• mobile	<ul style="list-style-type: none">• surgery• infection• scar tissue• higher cost• complex

Stimulation of Peripheral Nerves

	Commercial	Investigative
Facial Muscles	X	X
Swallowing	X	X
Sleep Apnea	X	X
Depression		X
Stroke/SCI Recovery Upper Extremity	X	X
Bladder Management	X	X
Nerve Repair*		X
Pain Management*	X	X
Gait for Drop Foot	X	X

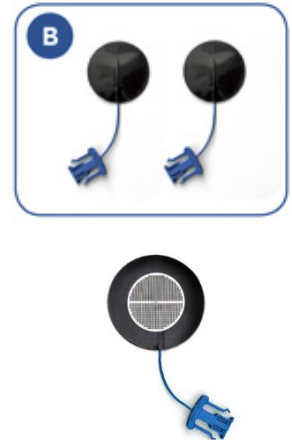
PENS

Percutaneous Neuromodulation Systems



Algotec

www.algotec-ltd.com



Biowave

www.biowave.com



SPR Therapeutics

www.sprtherapeutics.com

Stimulation of the Brain

TMS & rTMS

Transcranial Magnetic Stimulation

DBS

Deep Brain Stimulation



BCI & BMI

Brain Computer Interface
Brain Machine Interface

tDCS

Transcranial Direct Current Stimulation

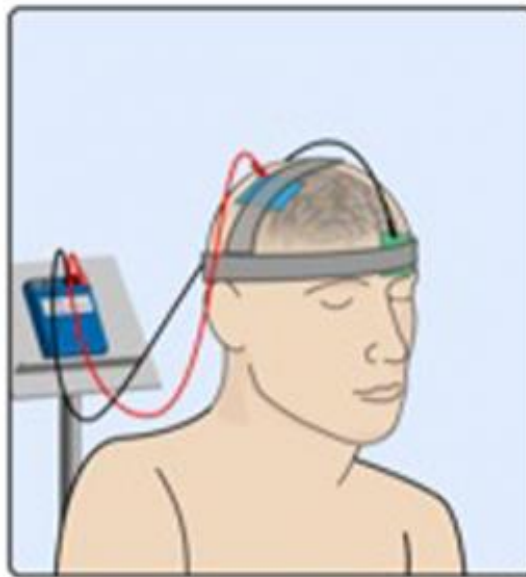
Stimulation of the Brain - External



TMS

TMS — *Transcranial Magnetic Stimulation*

- Magnetic stimulation on outside of brain
- Magnetic pulses produce changes in neuron activity

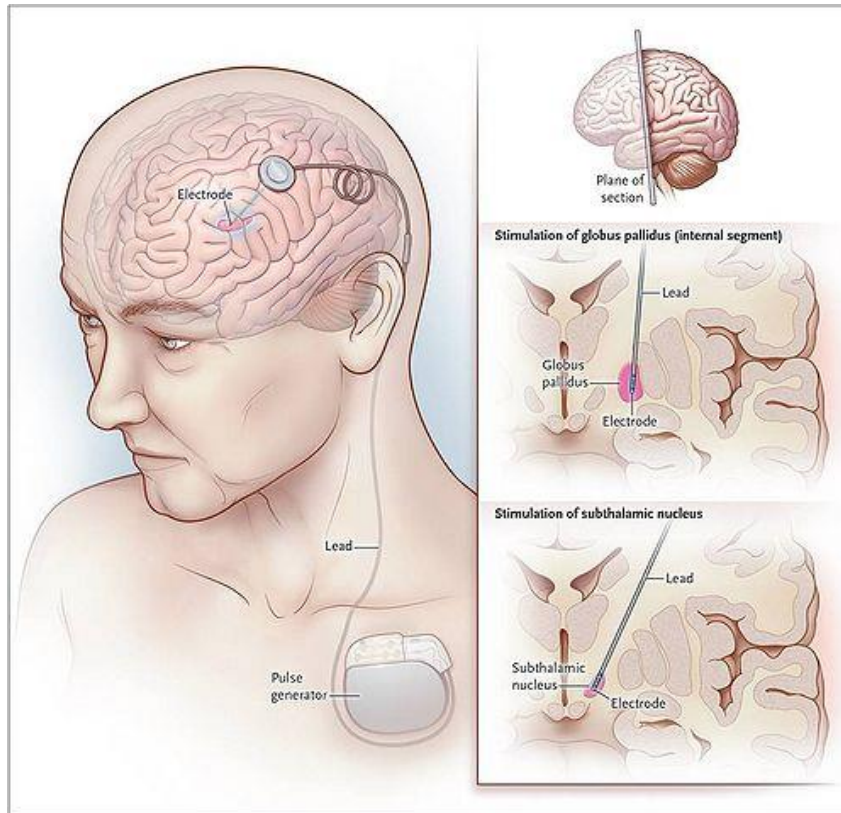


tDCS

tDCS — *Transcranial Direct Current Stimulation*

- Direct Current stimulation on outside of brain
- Low level current between anode & cathode to produce changes in neuron activity

Stimulation of the Brain - Internal

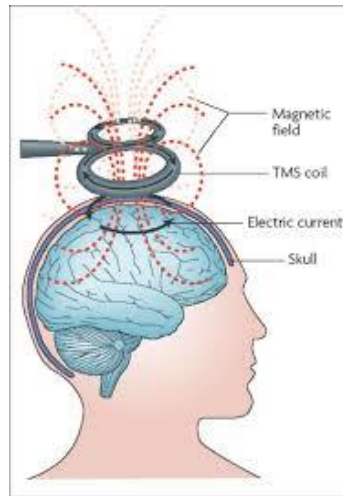


- Implanted electrodes in brain
- Stimulate abnormal signals or affect cells and chemicals in the brain
- Various targets of the brain. Most common is subthalamic nucleus (STN) or globus pallidus interna (GPI)

Stimulation of the Brain: Commercial



- Medtronic Activa DBS - www.medtronic.com
- Boston Scientific Vercise - www.bostonscientific.com
- St. Jude Medical Brio - www.sjm.com
- Aleva Neurotherapeutics – www.aleva-neuro.com



- NeuroStar TMS Therapy® System - www.neuronetics.com
- eNeura: Spring TMS - www.eneura.com
- Magstim - www.magstim.com
- Cefaly - www.cefaly.us
- Nexstim – www.nexstim.com
- Brainsway – www.brainsway.com
- Rio Grand Neurosciences – riograndneuroscience.com



- Fisher Wallace Stimulator- www.fisherwallace.com
- Halo Neuroscience – www.haloneuro.com



Non-FDA Approved:

- TCT Research Ltd www.trans-cranial.com
- Cognitive Kit Cognitivekit.com
- Brain Stimulator theBrainStimulator.net
- Thync – thync.com
- Foc.us – www.foc.us

Stimulation of the Brain: Investigational



Cervel Neurotech rTMS

www.cervel.com



Soterix Medical 1 × 1 tDCS Platforms

www.soterixmedical.com



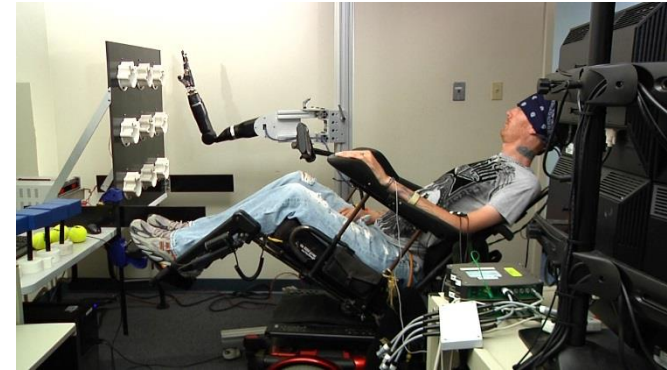
Noted Published Studies

- Stroke Rehabilitation – rTMS, tDCS
- Incomplete SCI rTMS, tDCS
- Parkinson's disease – rTMS
- ALS – rTMS
- Chronic Pain – DBS
- Tourette's – DBS
- Huntington's – DBS
- MS - DBS
- Psychiatric - DBS

Stimulation of the Brain: Investigational



Battelle & Ohio
State University
NeuroBridge
ClinicalTrials.gov
Identifier:
NCT01997125

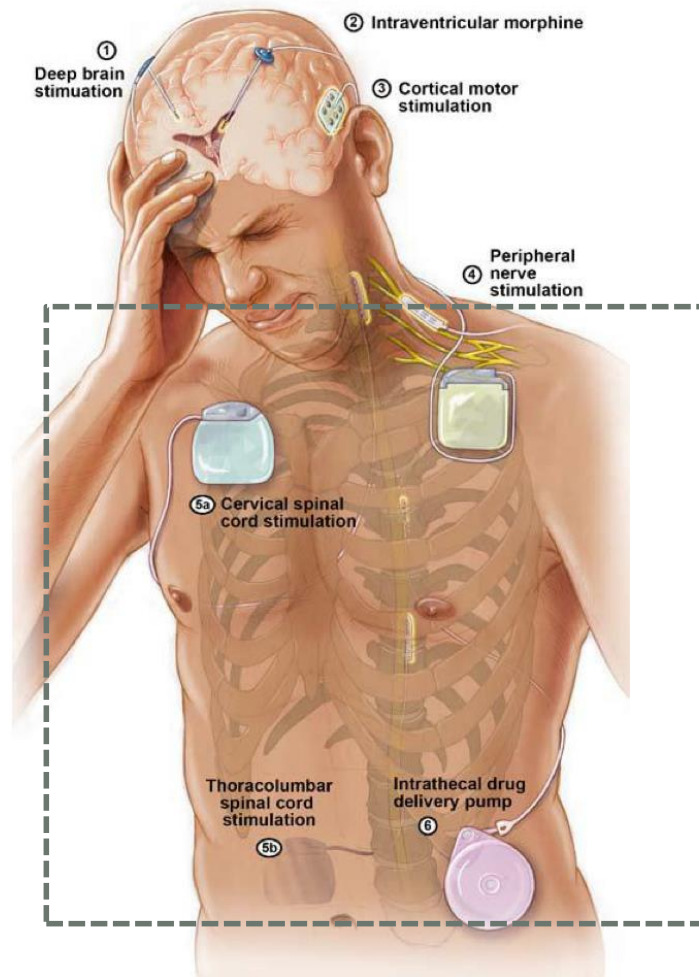


University of
Pittsburgh
ClinicalTrials.gov
Identifier: -
NCT01894802,
NCT01364480



Brain Gate Brown
University
MultiCenter
ClinicalTrials.gov
Identifier: -
NCT00912041

Stimulation of the Spinal Cord



- Cervical spinal cord
- Thoracolumbar spinal cord
- Intrathecal

SCS - Spinal Cord Stimulation



Medtronic:
Restore Sensor

www.tamethepain.com



Boston Scientific:
Precision Spectra

www.controlyourpain.com



St. Jude Medical:
Eon

www.poweroveryourpain.com



StimWave:
Freedom-4

www.stimwave.com



Neuro:
Senza

www.nevro.com



Nuvectra:
Algovita

www.nuvectramed.com

Epidural Stimulation

- 16-electrode array implanted over the L1-S1 spinal cord segments
- Creates sensory input to the spinal cord, which may alter the threshold for motor circuitry activation

Source: Harkema et al 2011, Lancet

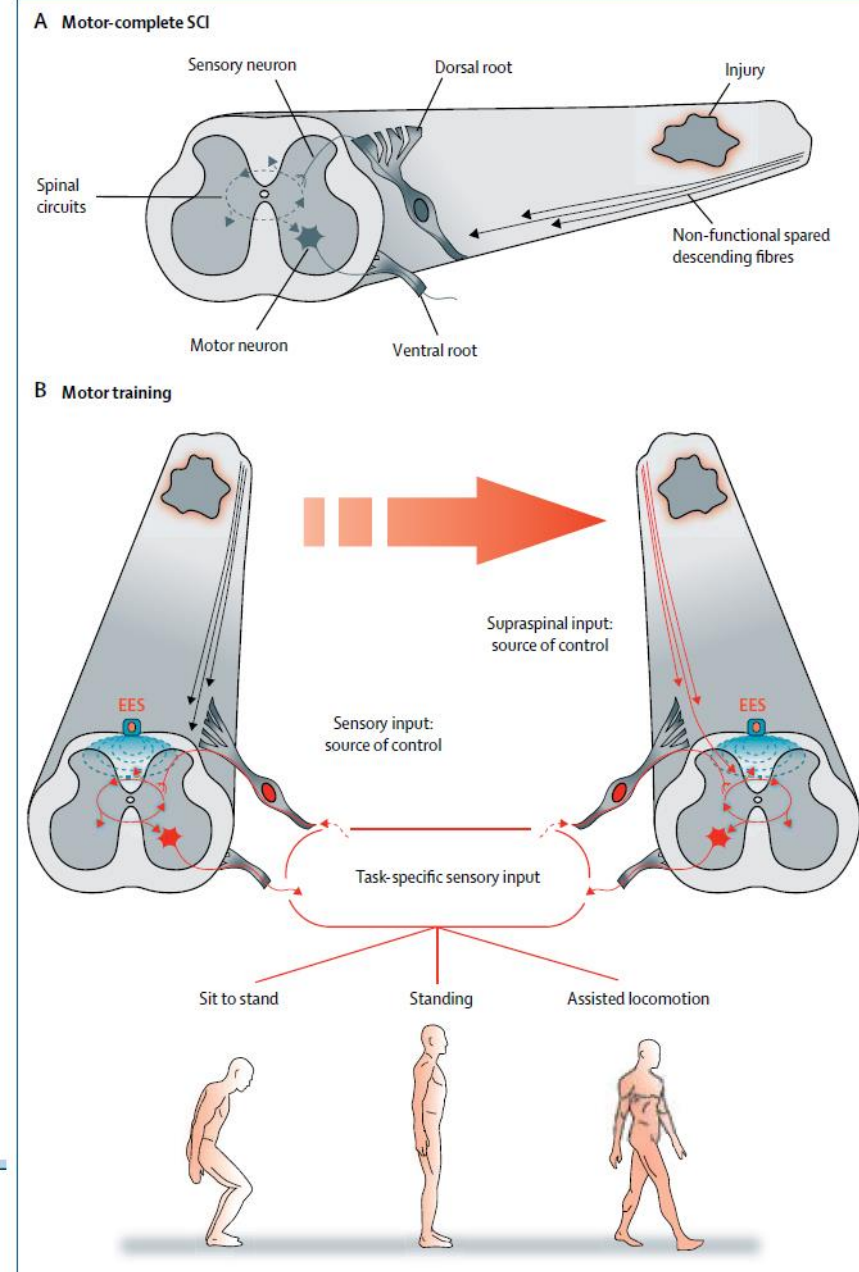


Figure: Electrically enabled motor control and training after SCI
(A) Paralyzing SCIs in human beings are rarely complete, but instead spare tissue bridges that might support functional recovery. (B) Epidural electrical stimulation facilitates processing of task-specific sensory information to produce movement. Training might promote plasticity of spared descending fibres, restoring some supraspinal control when spinal circuitries are tuned with epidural stimulation. SCI=spinal cord injury. EES=epidural electrical stimulation.

Noted Clinical Trials

- **Epi Stim to Facilitate Standing and Stepping,**
NCT02339233
 - The overall aim is to assess whether task specific locomotor training and spinal cord electrical stimulation (SCES) can induce neural reorganization of the functionally isolated human spinal cord to improve standing and stepping in individuals with functionally complete SCI.
 - **Univ. Louisville; Cervical and Thoracic SCI**
- **Epi Stim to Recover Cardiovascular Function,**
NCT02037620
 - This study is designed to use epidural spinal cord stimulation to improve cardiovascular and respiratory function.
 - **Univ. Louisville; Cervical SCI**

Source: www.ClinicalTrials.gov

Noted Clinical Trials

- **Spinal Cord Neuromodulation for SCI, NCT02313194**
 - This study is designed to assess the strategy of using spinal cord stimulation to improve the ability to move arms and hands in spinal cord injured humans.
 - **UCLA; Cervical SCI**
- **Stimulation with Wire Leads to Restore Cough, NCT01659541**
 - The overall aim is to assess the efficacy of spinal cord stimulation to restore effective cough in individuals with chronic cervical SCI.
 - **Case Western Reserve Univ.; Cervical SCI**

Source: www.ClinicalTrials.gov

Noted Clinical Trials – Non-Invasive

- **Transcutaneous Electrical Spinal Stimulation for Lower Limbs, NCT01949285**
 - The aim is to assess whether non-invasive spinal cord electrical stimulation can be used to measure spared function in individuals with non-ambulatory SCI and if it is a useful rehabilitation tool.
 - **UCLA, NeuroEnabling Tech.; Cervical and Thoracic SCI**
- **Restoring Arm and Hand Function with Non-Invasive Spinal Stimulation, NCT01906424**
 - This study is designed to assess the strategy of non-invasive spinal cord stimulation to improve the ability to move arms and hands in spinal cord injured humans.
 - **UCLA, NeuroEnabling Tech.; Cervical SCI**

Source: www.ClinicalTrials.gov

Considerations for Participating in any Clinical Trial

- Know your rights & risks: Informed Consent, Read the fine print
- Understand your commitments
- Manage your expectations
- Beware – of “trials” that are unapproved, even in the US – just because a US doctor is doing it does not mean it is legitimate
- Do your research – get a second or third opinion from a research center or hospital
- Never pay for experimental treatments
- Expect Follow Up
- Refer to ClinicalTrials.gov
(<https://clinicaltrials.gov/ct2/about-studies/learn>)

Additional Resources

- Search Terms ClinicalTrials.gov

- “spinal cord injury”, “tetraplegia”, “paraplegia”

AND

- “stimulation”, “spinal cord stimulation”, “epidural”, “neuromodulation”, “brain interface”, “TMS”, “tDCS”

- Miami Project:

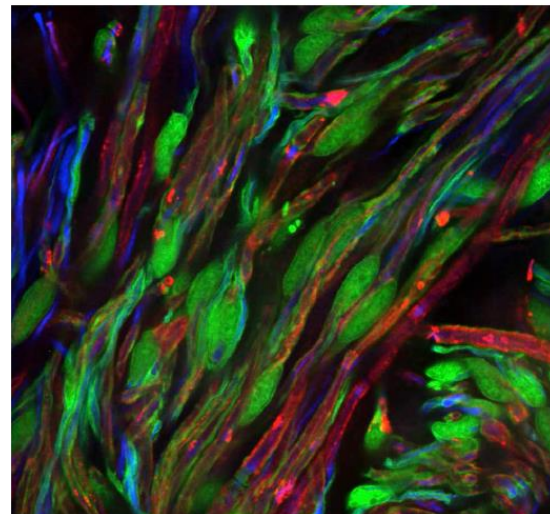
www.themiamiproject.org

- [Link study for treatment of pain & AD for SCI using DBS](#)

- [Neurotech Network Condition Fact Sheets: www.NeurotechNetwork.org](#)

including spinal cord injury, brain injury, stroke, multiple sclerosis, Parkinson’s and more

Experimental treatments for spinal cord injury:
What you should know (Version 2)



A guide for people living with spinal cord injury,
their family, friends and health care professionals

Free Download of this booklet
<http://www.themiamiproject.org/research/participate/research-participation/experimental-treatments/>



Webinar Series

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NEUROTECH NETWORK

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Next Webinar is October 13, 2016: Pain and Spasticity Management