

The Vagus Changes Everything  
FSM can Change the Vagus  
And now there is Data

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# Think about the Nervous System

We know the nervous system responds well to FSM treatment

- We treat concussion, brain fog, stroke
- FSM treats Nerve Pain, Central sensitization
- FSM treats Phantom limb pain
- FSM treats Thalamic stroke pain
- FSM Improves coordination after injury
- FSM treats RSD/CRPS
- FSM treats Fibromyalgia and the Spinal Cord



FSM should be able to change the vagus.

The FSM Vagus protocol showed clinical improvement for the last 8 years

We had no data to prove that it worked.

Until now.

# Vagus Nerve

Connects Body to the Brain

The Brain to the Body

Controls the vocal cords

Controls Digestion

- Stomach acid

- Pancreatic secretions

- GI sphincters

- GI Motility

Regulates Heart rate

Suppresses the immune system

Reduces sugar release from the liver

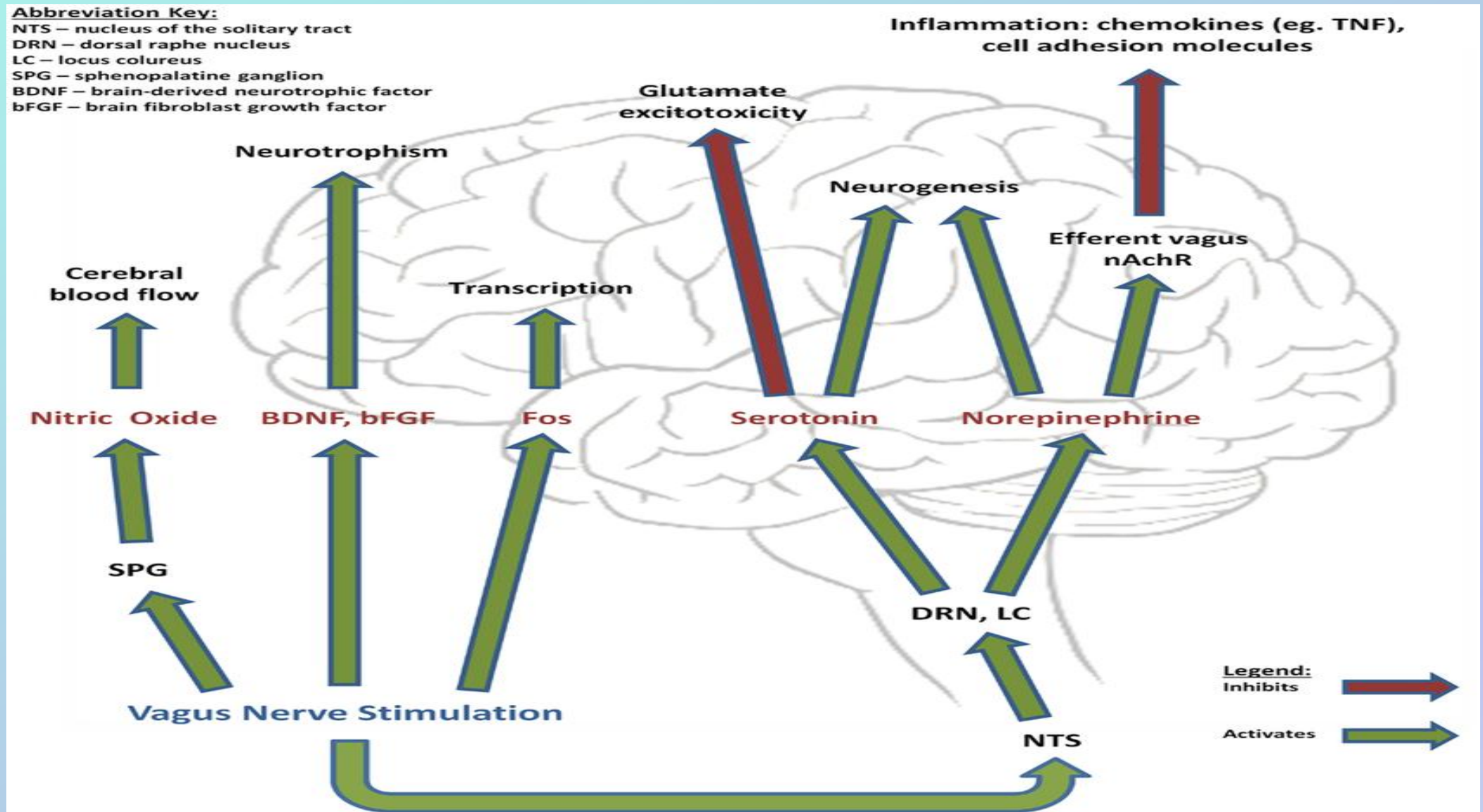
Improves kidney function, blood pressure

Is a pain nerve in the abdomen



# In the Brain

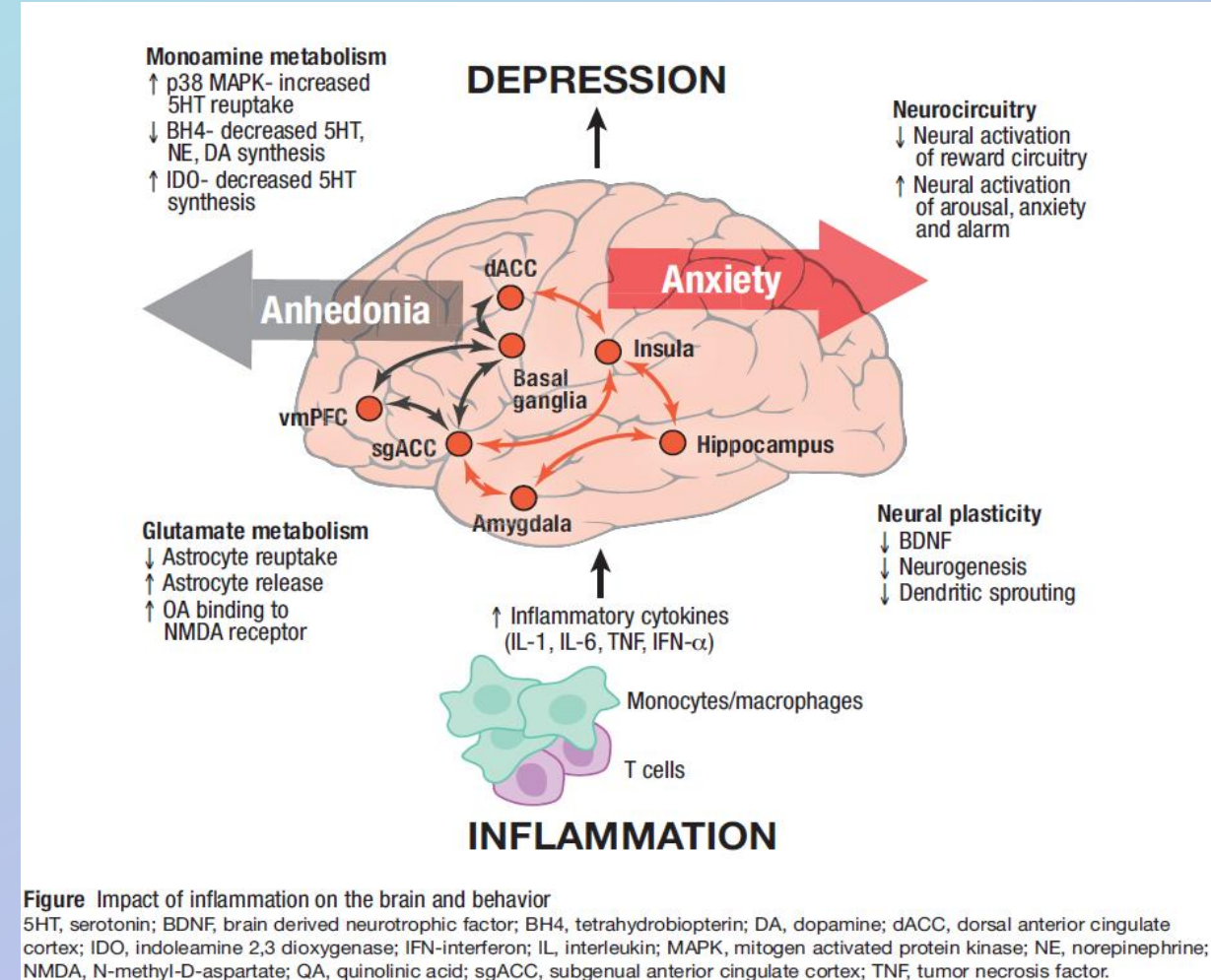
## Vagus Activates Good Things – Inhibits Bad things



# In the Brain

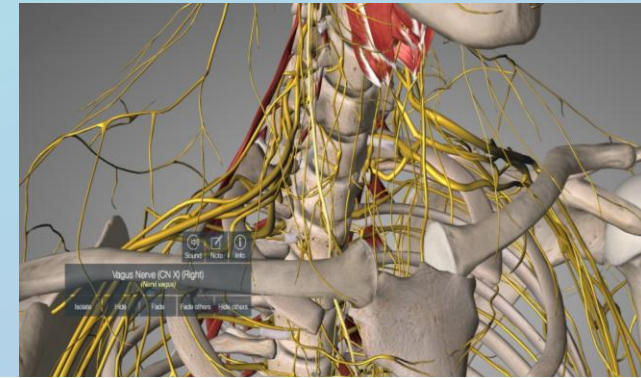
## Vagus Activates Good Things – Inhibits Bad things

- Vagal nerve stimulators used to
  - Treat Depression
  - Treat Anxiety
  - Vagal nerve stimulators improve Alzheimer's symptoms, long term
  - Vagal nerve stimulators are being used to prevent seizures

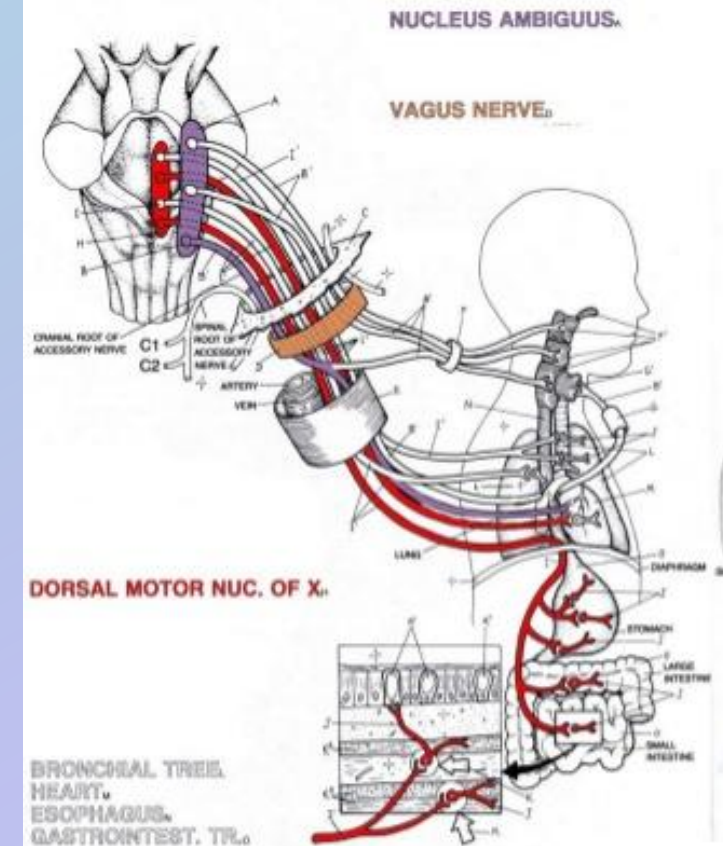


# Vagus Motor Fibers

- **Motor fibers** – start in nucleus ambiguus
  - Skeletal muscles of neck, face
  - Pharyngeal Branch- pharynx, soft palate striate muscles, (part of) tongue
  - Superior laryngeal branch – inferior constrictor and cricothyroid muscles of larynx and the pharyngeal plexus
  - Recurrent laryngeal branch innervates all vocal cord muscles except the one that lets you scream
  - Left recurrent laryngeal branch – under the aorta
  - Right recurrent laryngeal branch - under the subclavian artery
  - Cardiomotor pre-ganglionic neurons

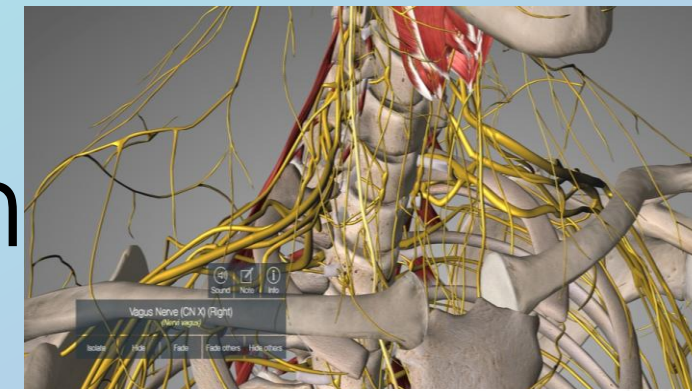


VAGUS (X) NERVE: MOTOR COMPONENT.

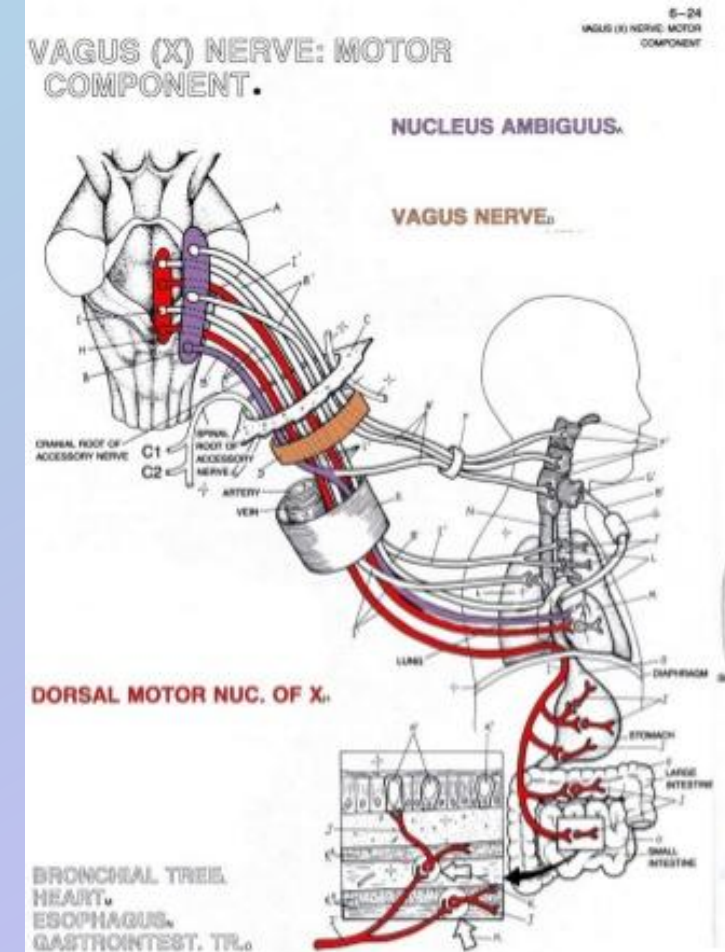


# Vagus Motor fibers

## Pharynx, Esophagus, Duodenum



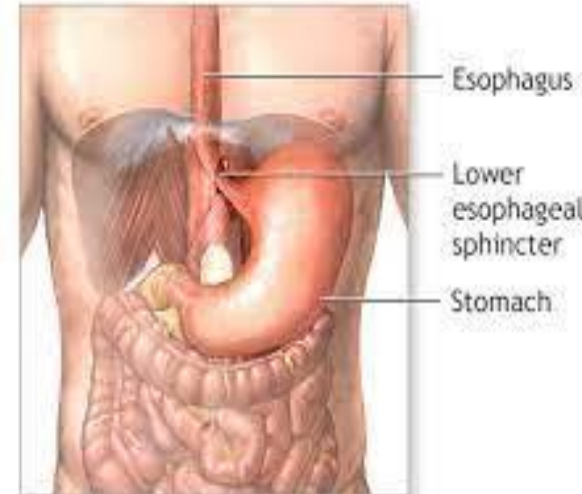
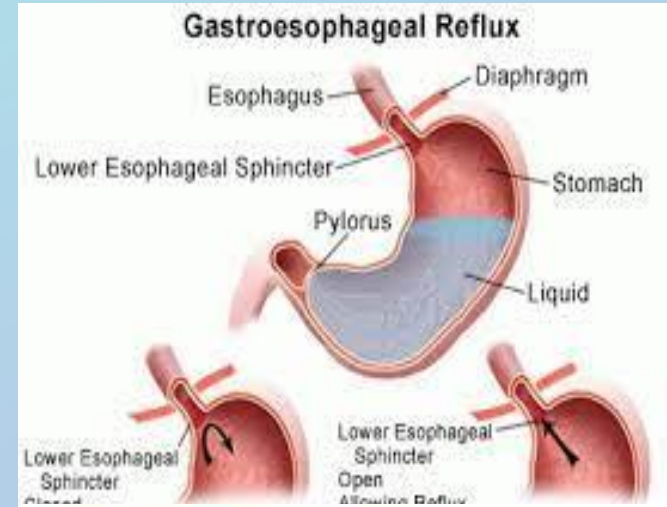
- **Visceral Motor pre-ganglionic fibers** – start in dorsal motor nucleus
  - The vagus is why you have saliva and mucous
    - Provide parasympathetic innervation for cardiopulmonary and gastrointestinal systems, the glands of the pharyngeal and laryngeal mucosa
  - The vagus is why you don't have asthma
    - Pulmonary branches innervate bronchial smooth muscle
  - The vagus is why you can swallow
    - Esophageal plexus innervates smooth muscles along entire length of esophagus
  - Vagal fibers follow esophagus through diaphragm



# Vagus Motor fibers

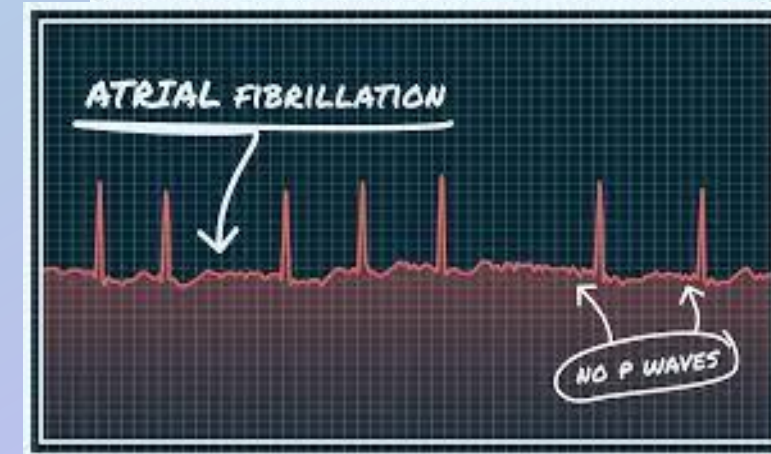
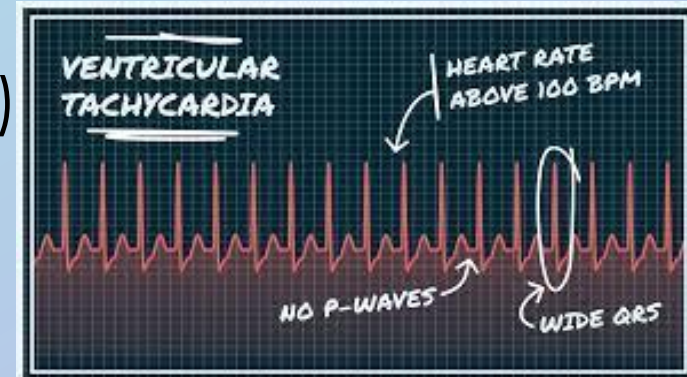
## Pharynx, Esophagus, Duodenum

- The vagus opens the lower esophageal sphincter (LES) for food to go into the stomach
- Then the LES should close and
- The duodenal sphincter should open to let the stomach empty.
- If the vagus is suppressed, the LES stays open, the food stays in the stomach leading to
- Reflux
- Gastroparesis
  - stomach doesn't empty
- Slow transit time / constipation



# Vagus - Motor fibers - Heart

- Cardiac motor branches synapse in end organ
  - Left vagus – AtrioVentricular node – Ventricle (v-Tach)
  - Right vagus – SinoAtrial node – Atria (Atrial Fib)
- The Vagus slows the heart rate
  - Useful clinically in V-Tach and atrial fibrillation
- Compensates for sympathetic drive
- Reduced vagal tone:
  - POTS
  - Elevated resting heart rate

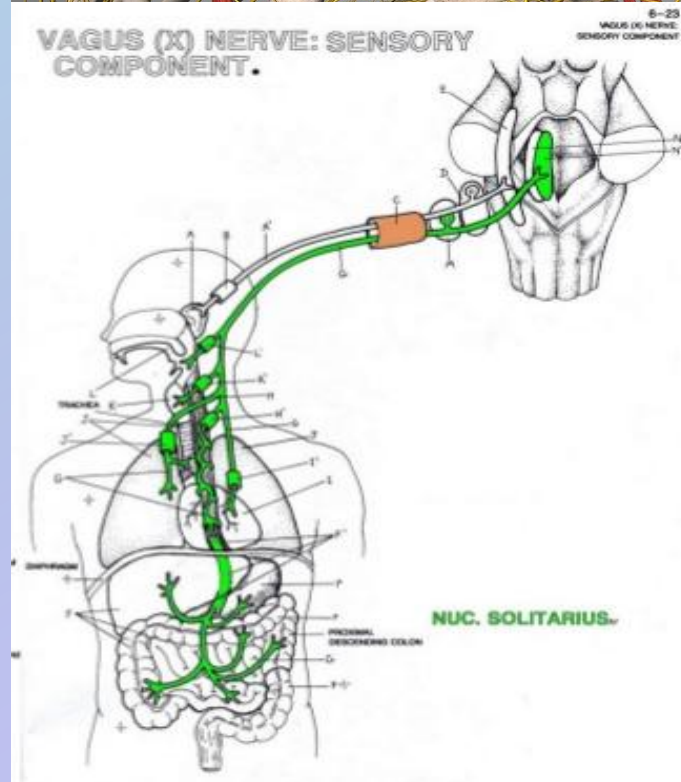


- The Vagus is turned down by infection, stress and trauma

The Vagus is suppressed by  
Infection,  
Stress,  
Trauma

# Vagus Sensory Fibers

- Small unmyelinated afferents from stomach, intestines, liver, pancreas and spleen
- **Stretch receptors** in stomach tell you when you're full
- Unconscious sensations hunger, satiety and nausea
- Pain information from heart, esophagus and trachea
- Vagal afferents from baroreceptors in aortic arch and pulmonary airways (Slows the heart)
- Chemo receptors in upper small intestine - Senses nutrients. Makes you crave what you need

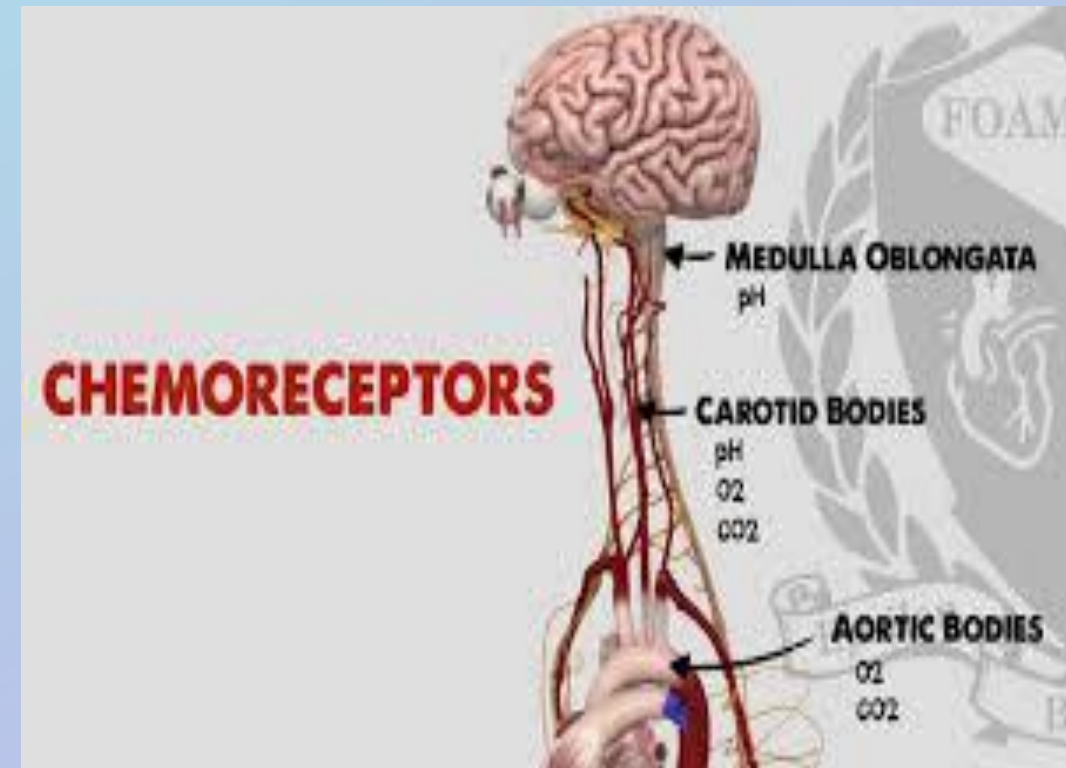


Modified from: Diamond, Scheibel & Elson "The Human Brain Coloring Book" 1985 Harper Collins

# Vagus Sensory Fibers

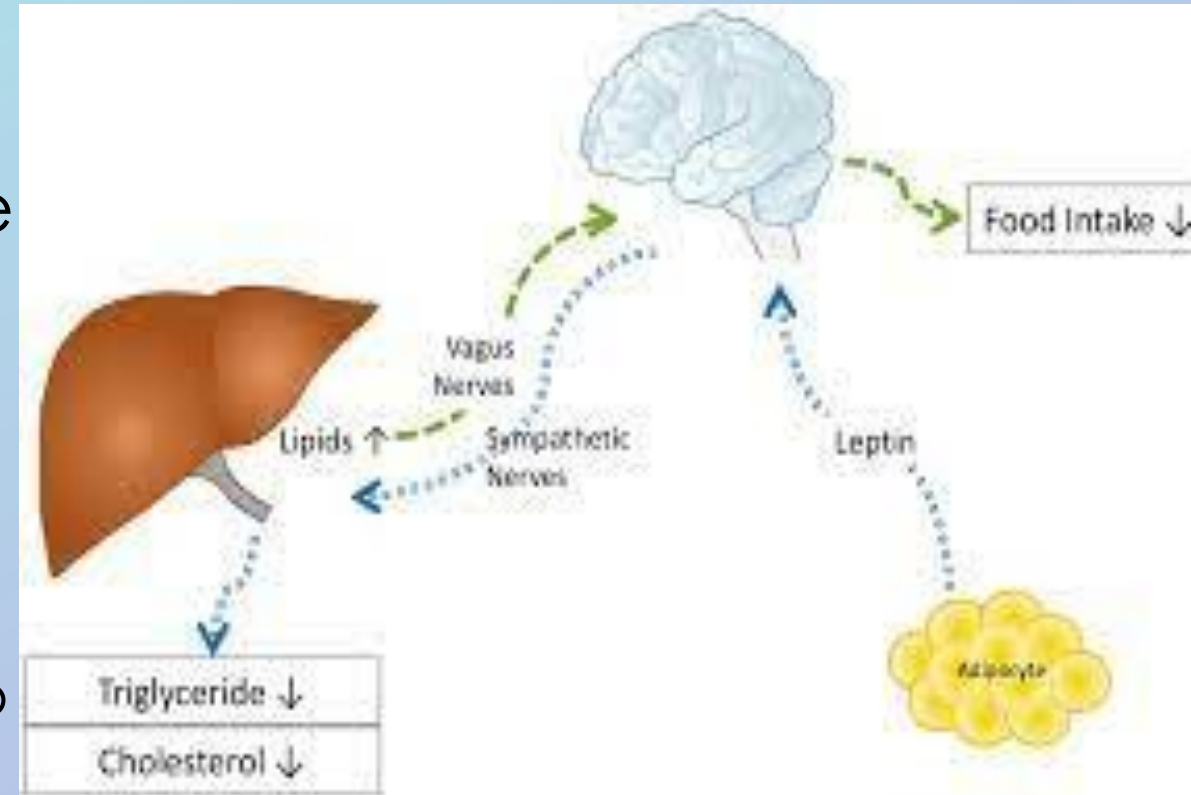
## Chemo-receptors in aorta:

- They respond to significant drops in arterial oxygen levels, increased carbon dioxide levels, and increased acidity or decreased pH in the blood.
- When triggered, these fibers send signals to the cardiorespiratory centers of the medulla.
- This triggers compensatory reflexes:
- increase in the rate and depth of ventilation, to restore proper gas exchange.



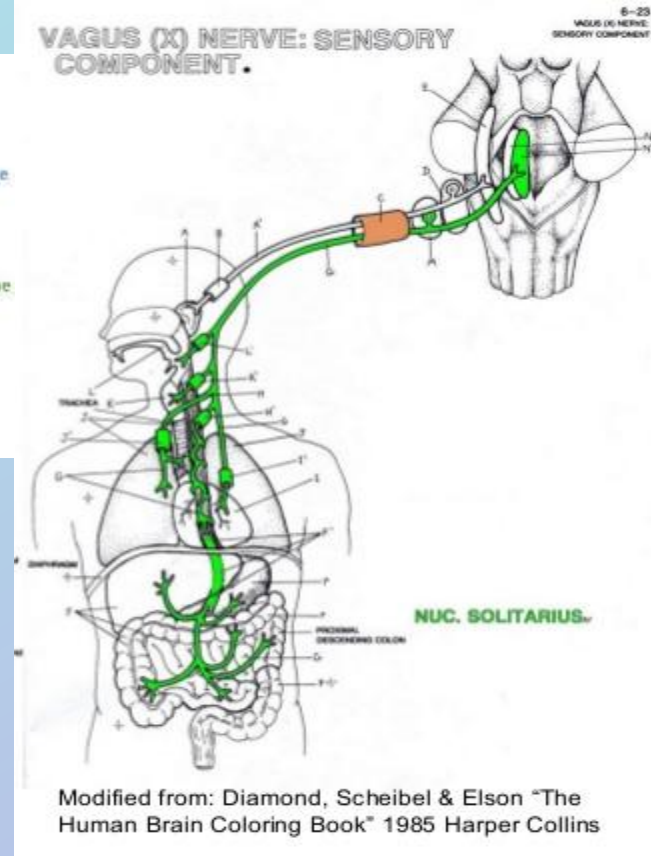
# The Vagus and Blood Sugar

- The hepatic vagus suppresses conversion of glycogen to glucose
- Vagus stimulates the conversion of glycogen stored in the liver to glucose too prevent low blood sugar.
  - Low blood sugar creates stress
  - Stress suppresses the vagus
- When there is threat or stress your muscles need glucose
  - When the vagus is down glucose goes up
- Vagus controls blood sugar by fibers to the liver that stop the liver from converting glycogen to glucose



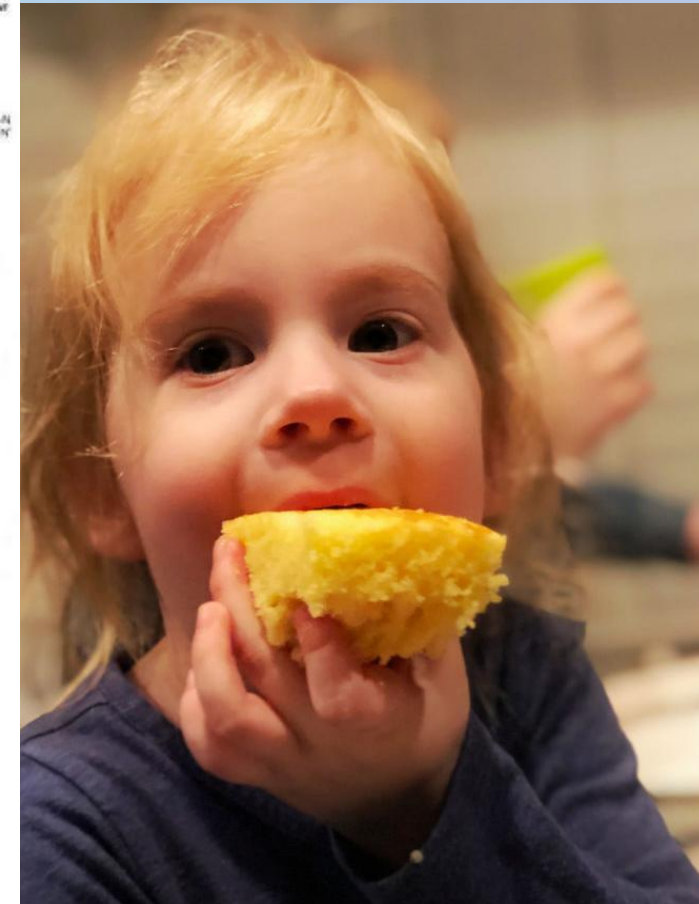
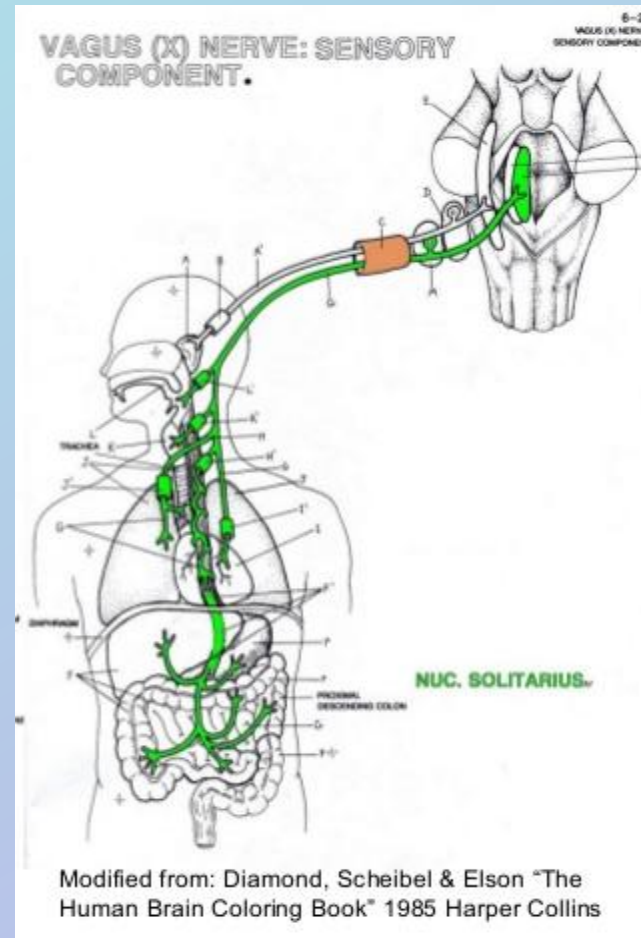
# Vagus Anatomy Sensory and Pain

- General Sensory Fibers
  - Carry **touch, pain and temperature** from ear, pharynx and larynx
  - Auricular branch – pinna, auditory canal then enters superior vagal jugular ganglion
    - Ear sensation from C2-3, Vagus, mandibular branch of V
- General **sensory fibers** from pharynx and larynx join the motor fibers of C3-4-5
- All of the general sensory fibers of the vagus synapse within the spinal nucleus of the trigeminal nerve at the motor nerves of C3-4-5



# Have you ever wondered why you cough on a crumb?

- General sensory fibers of the vagus carry sensation from the pharynx and larynx
- Those sensory fibers synapse within the trigeminal nucleus in the spine at C3-4-5.
- C3-4-5 carry nerves and motor fibers to the diaphragm.
- Sensation from the vagus says cough when it feels the crumb.
- You cough before your sensory cortex knows you need to.

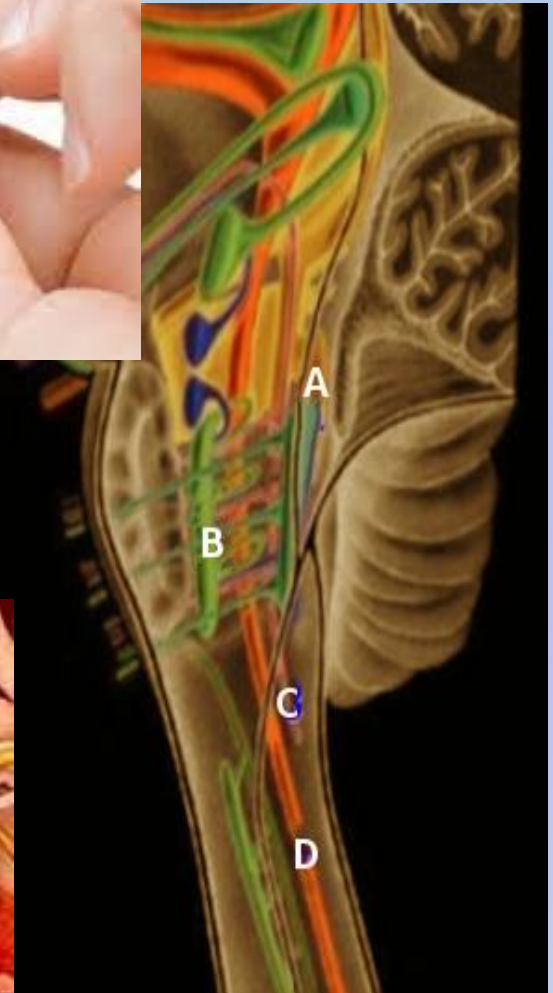


# Have you ever wondered why you cough when you touch your ear drum with a cotton swab?

- General sensory fibers of the vagus carry sensation from the ear canal and ear drum
- Those sensory fibers synapse within the trigeminal nucleus in the spine at C3-4-5.
- C3-4-5 carry nerves and motor fibers to the diaphragm.
- Sensation from the vagus says cough when it feels something on the ear drum.
- You cough before your sensory cortex knows you've touched your ear drum
- So, you won't injure your ear drum



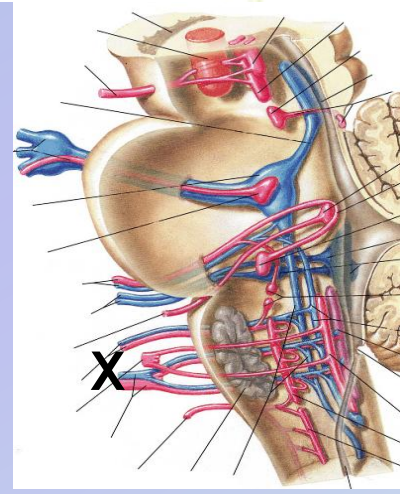
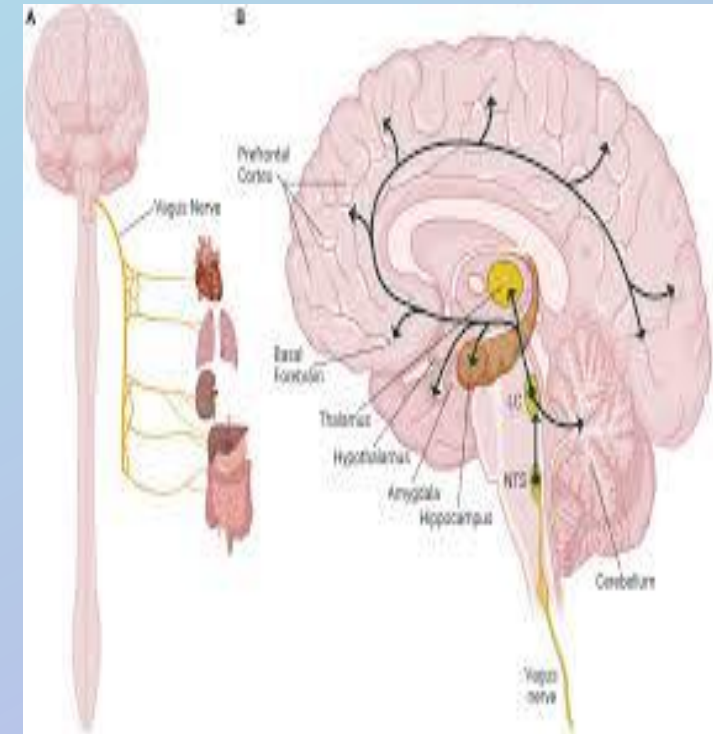
A: Dorsal nucleus of vagus nerve  
B: Nucleus ambiguus  
C: Solitary nucleus  
D: Spinal trigeminal nucleus



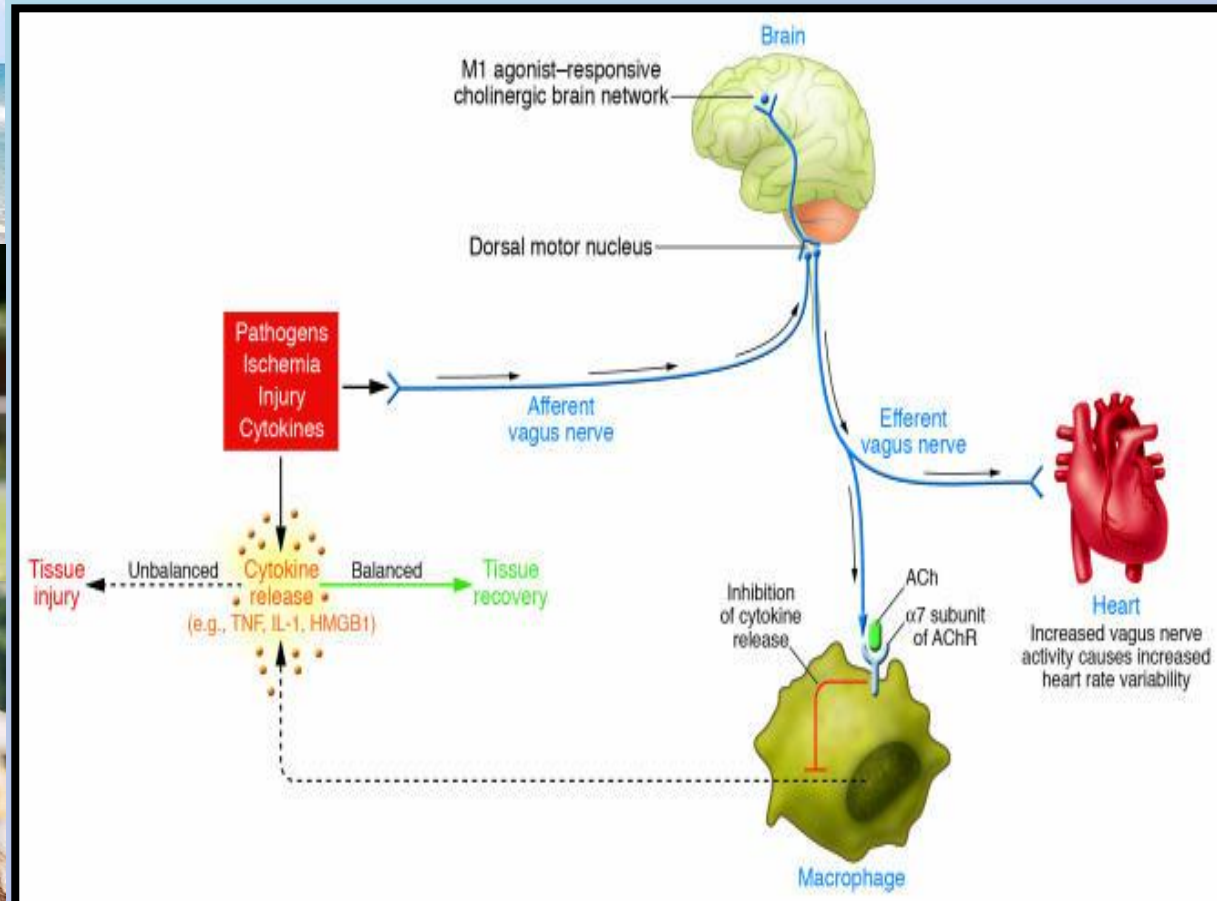
The Vagus is turned down by  
Infection  
Stress  
and  
Trauma

# What causes vagal dysfunction?

- 80% of information from the body to the brain comes from the vagus
- Vagus /109 signals to medulla: Infection, stress, trauma
- Medulla /94 signals to Midbrain, limbic system / 89
- Midbrain /89 signals to turn down Vagus
- Medulla /94 is source of the Vagus /109
  - Vagal nuclei (dorsal and ventral nuclei) localized in the medulla
  - Once the vagus leaves the medulla, there is only one vagus /109
  - Source of sympathetic and parasympathetic autonomies
  - Coordinates the body's autonomic function and stress response

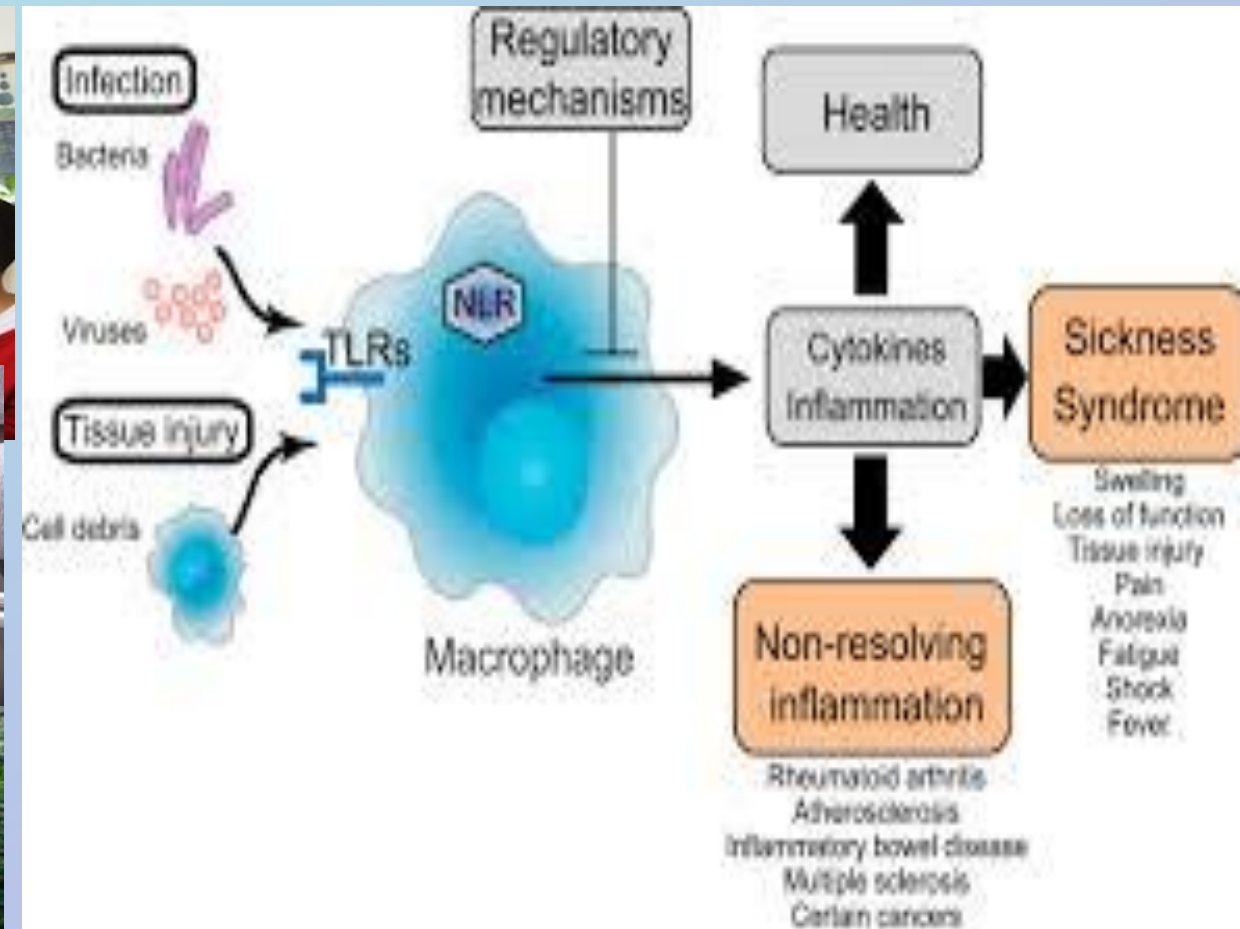
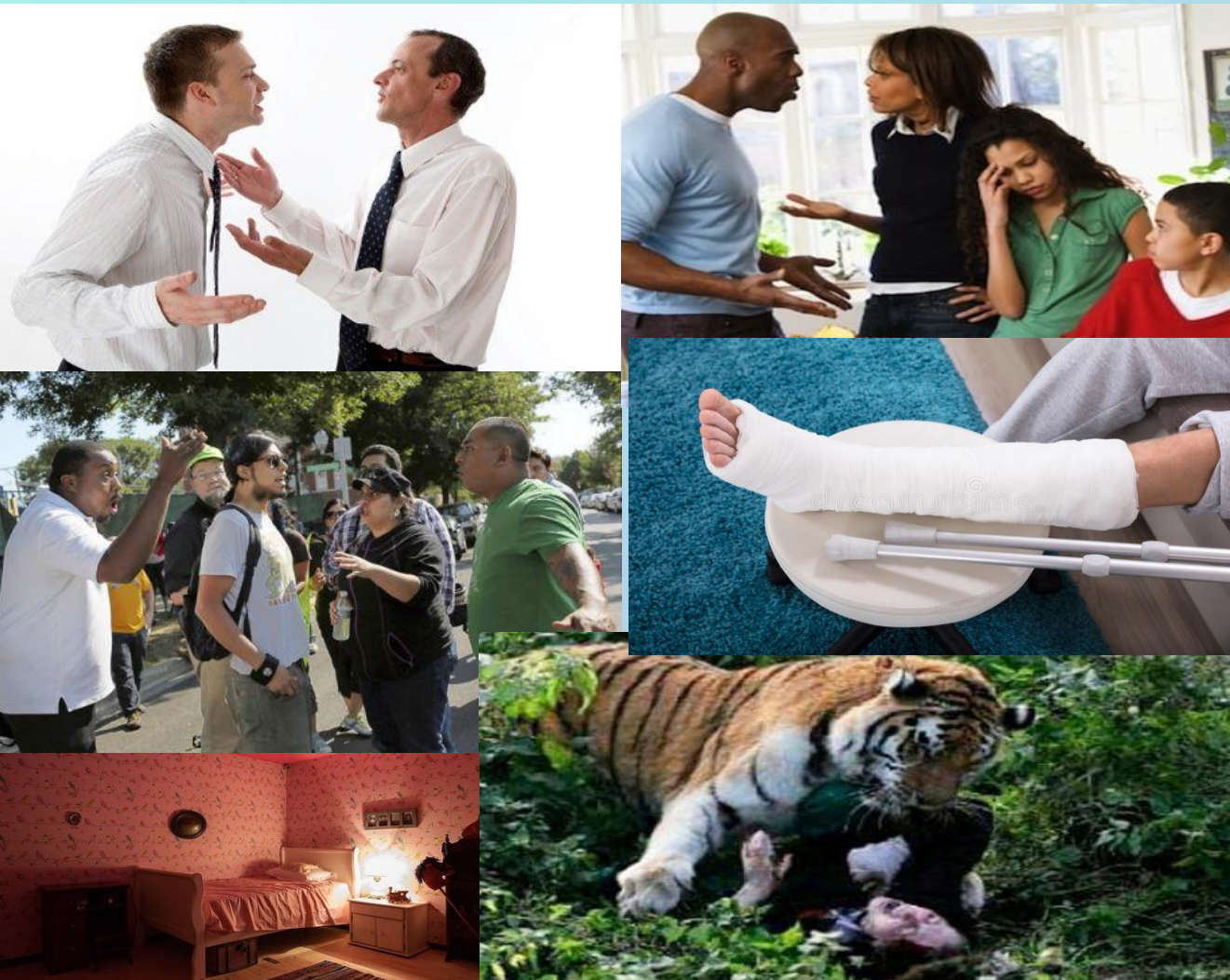


The Vagus slows the heart, reduces inflammation and blood sugar, quiets immune response, and improves digestion. When stress is down and life is good. The vagus creates parasympathetic dominance



Tracey, K. J. (2007). cholinergic anti-inflammatory Physiology and immunology of the pathway. *Journal of Clinical Investigation*, 117(2), 289-296.

The Vagus is turned down during infection, stress, threat and trauma so inflammation, blood sugar, immune response and heart rate can go up and digestion, acid, enzymes and motility can go down.



Tracey, K. J. (2007). Physiology and immunology of the cholinergic anti-inflammatory pathway. *Journal of Clinical Investigation*, 117(2), 289–296

# Same response to ALL stressors

The stress centers, the endocrine and nervous systems react to ALL stress in, more or less, the same way.

Suppress the vagus to  
Increase heart rate  
Suppress digestion  
Increase inflammation  
and SURVIVE



FSM uses the “Vagal Tone” Protocol  
to increase Vagal tone.

# Where should you prove it?

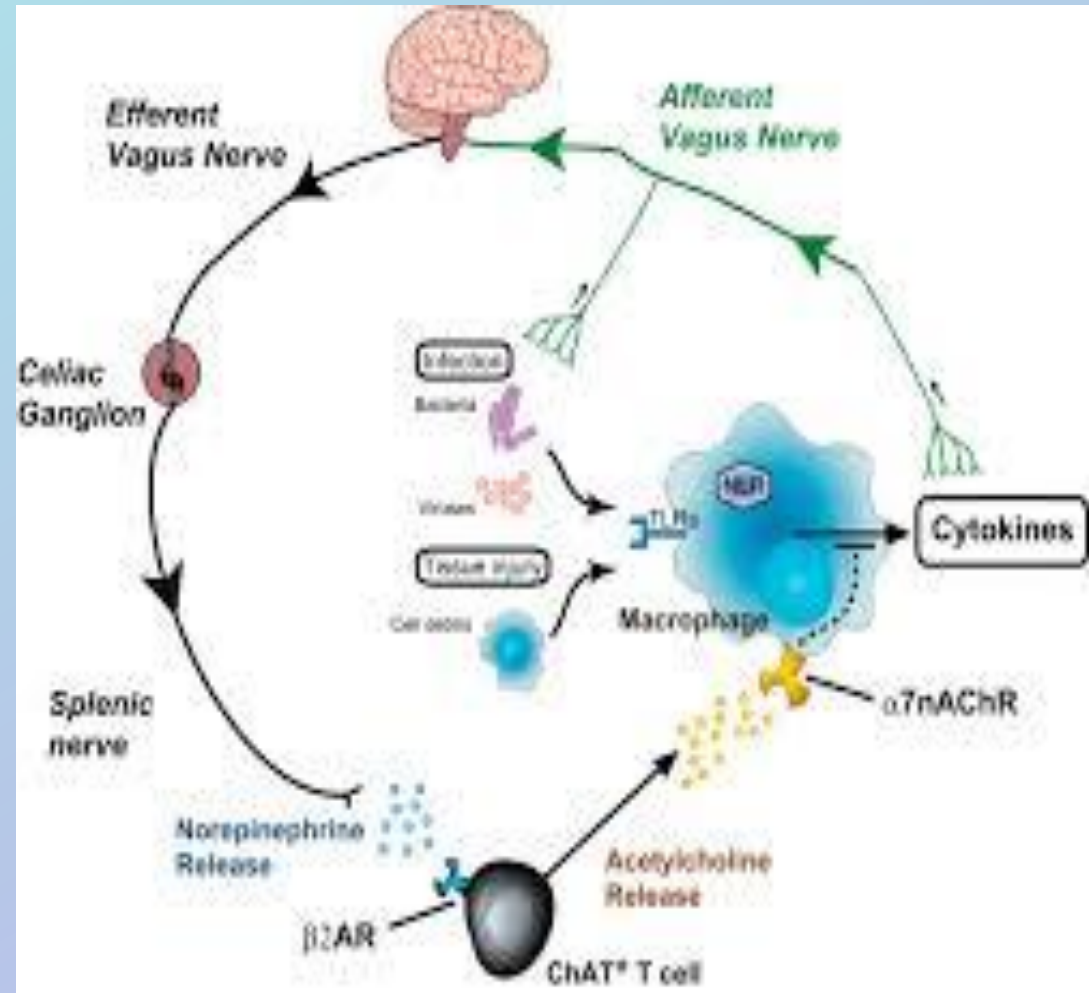


# The Feinstein Institute

- The Feinstein Institutes was established in 1999 as The Institute for Medical Research at North Shore-LIJ
- Board member Leonard Feinstein made a \$25 million gift that led to the institute being renamed as The Feinstein Institutes for Medical Research in 2005.[\[5\]](#)
- That same year, [Kevin J. Tracey](#), MD was appointed President of the Feinstein Institutes and took the place of CEO in January 2006.

# Kevin Tracey, MD

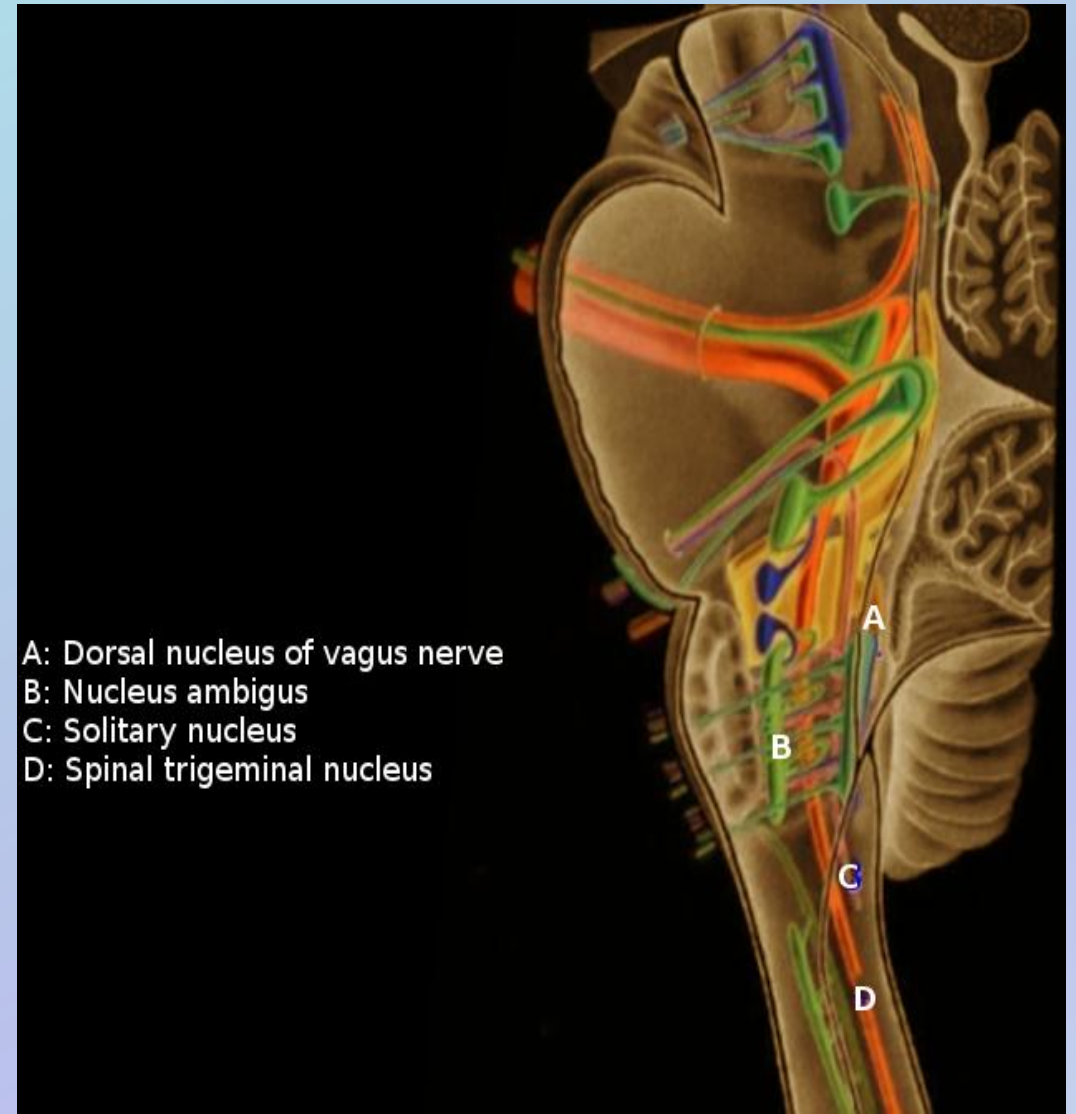
- Kevin Tracey, MD published the groundbreaking research that described the relationship between vagus function and inflammation.
- The Inflammatory Reflex, Nature, 2002
- “Vagus is just one of a number of neuro-immune reflexes that keep inflammation regulated”



The Inflammatory reflex, Nature 420,  
Kevin J Tracey, December 2002, pp 853-859

# FSM Vagal Tone Protocol was Tested

- Quiet Medulla– 4 minutes
- Quiet Midbrain– 4 minutes
- Quiet Sympathetics– 4 minutes
- Trauma to Vagus– 4 minutes
- Increase secretions Vagus– 4 minutes
- Increase Vitality Vagus– 4



Treat the Vagus Directly  
Once you see it, you can't un-see it  
And now there is Data



# Transcutaneous Vagus Nerve Stimulation (tVNS)

## Key Research Findings and Opportunities

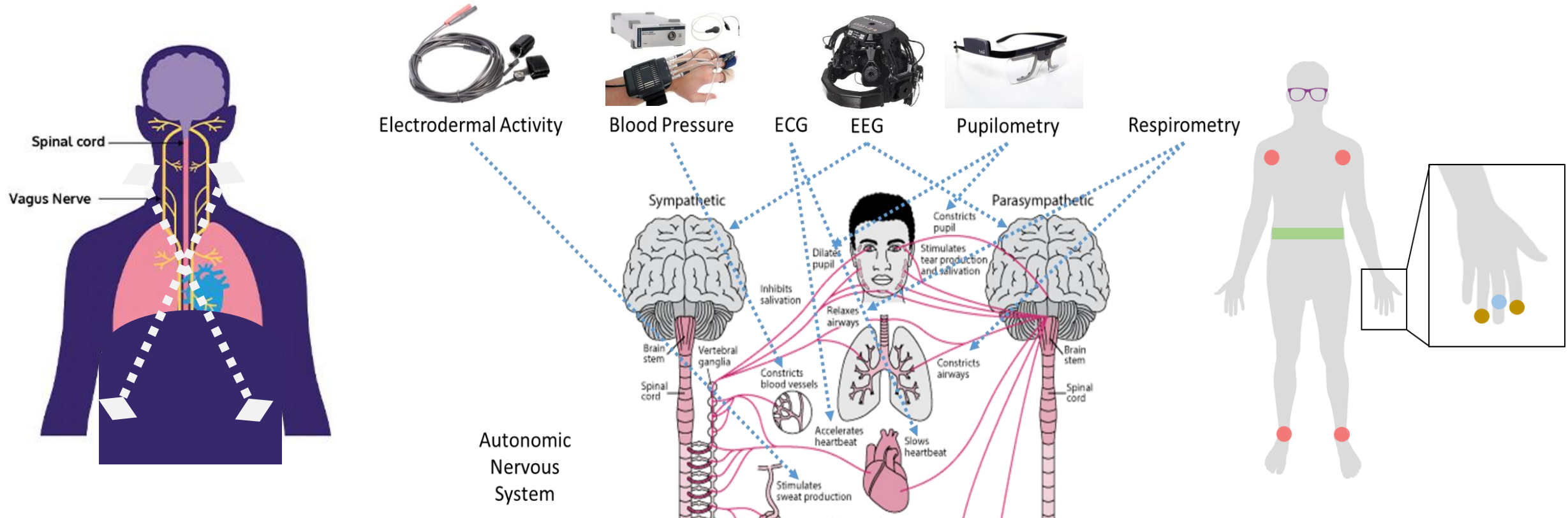
Jennifer Ernst, MBA      CEO    TIVIC

# The Research Question

## Does tVNS Impact Physiologic Function?

### Phase I: Initial Experiments with Feinstein Institute

- Proof-of-Principle Feasibility
- N=20 subjects with multiple outcomes

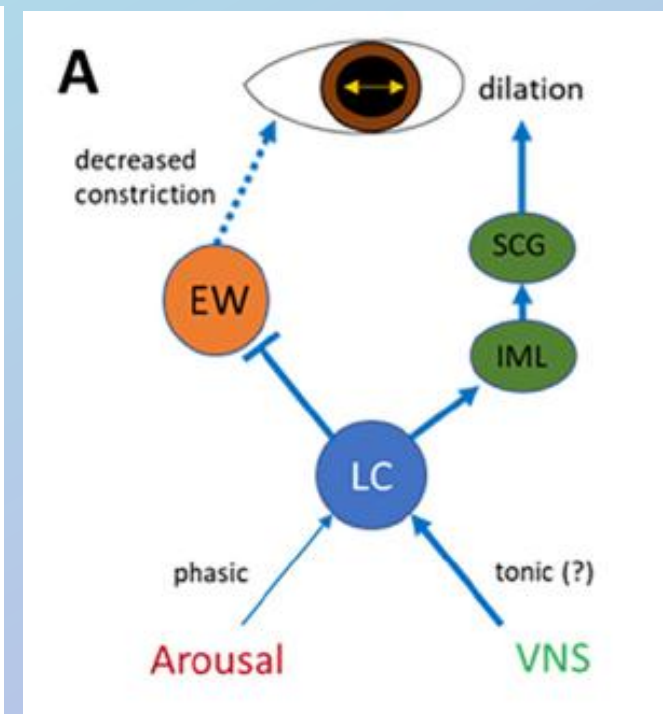
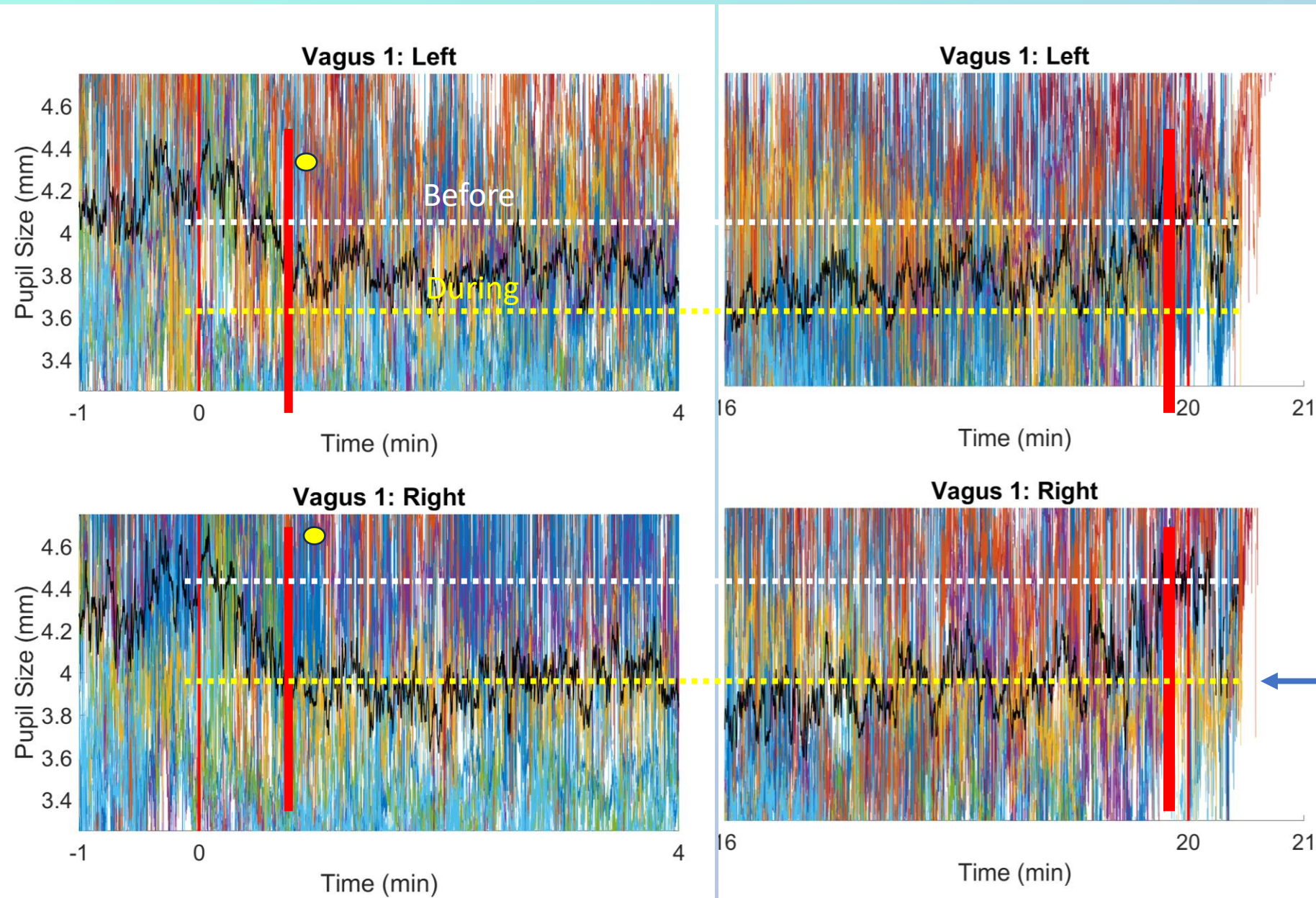


# Does tVNS Impact Physiologic Function?

**Phase I:** Multiple tests completed to examine different physiologic systems

- Pupillary responses - **Positive**
- Cardiovascular responses - **Variable**
- Autonomic tone - **Positive**
- Brain responses via EEG - **Positive**

# FSM Autonomic: Pupil Diameter



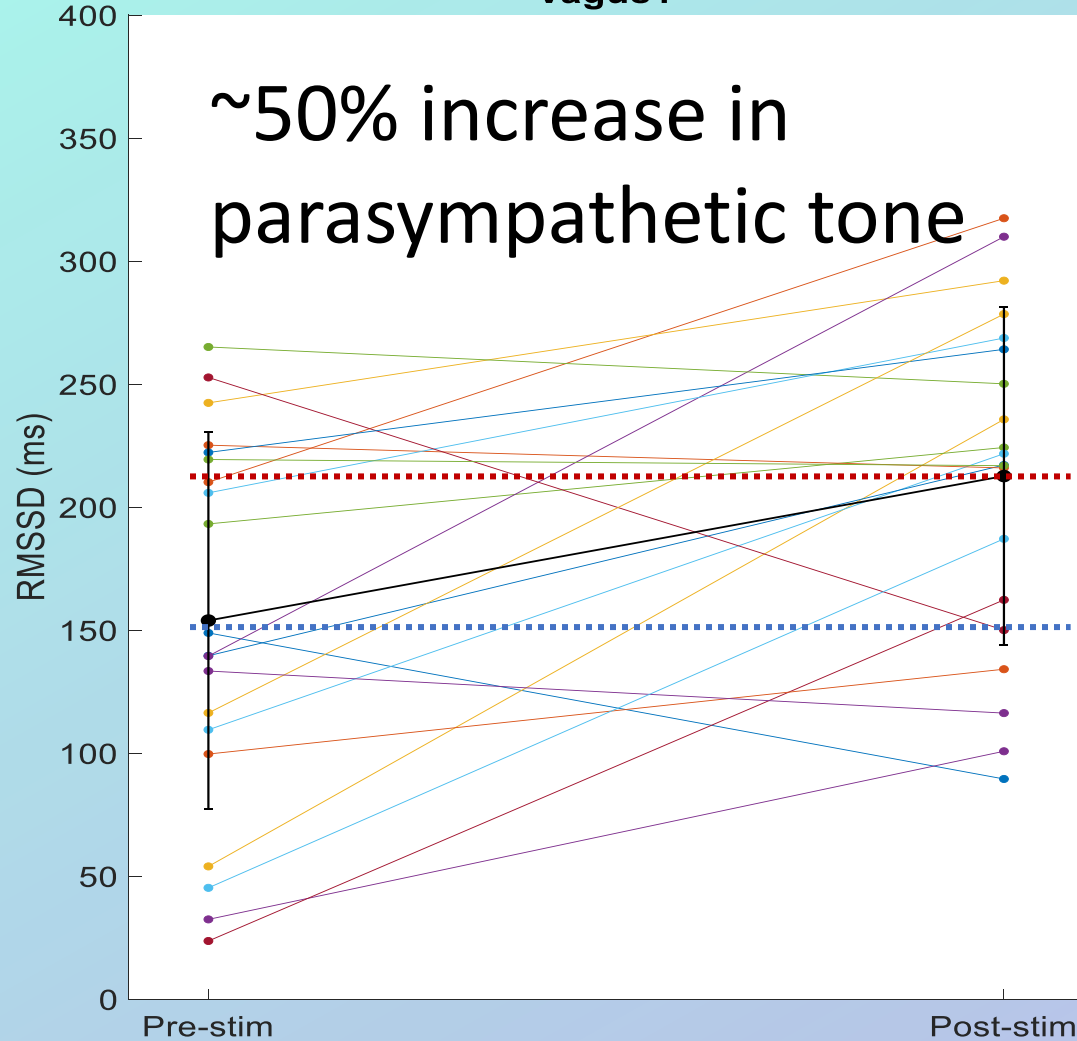
Suggests increased  
parasympathetic  
tone

Lloyd et al Brain Stimul, 2023  
Jul-Aug;16(4):1001-1008.

# FSM: Autonomic/Vagal Tone (Rest and Digest)

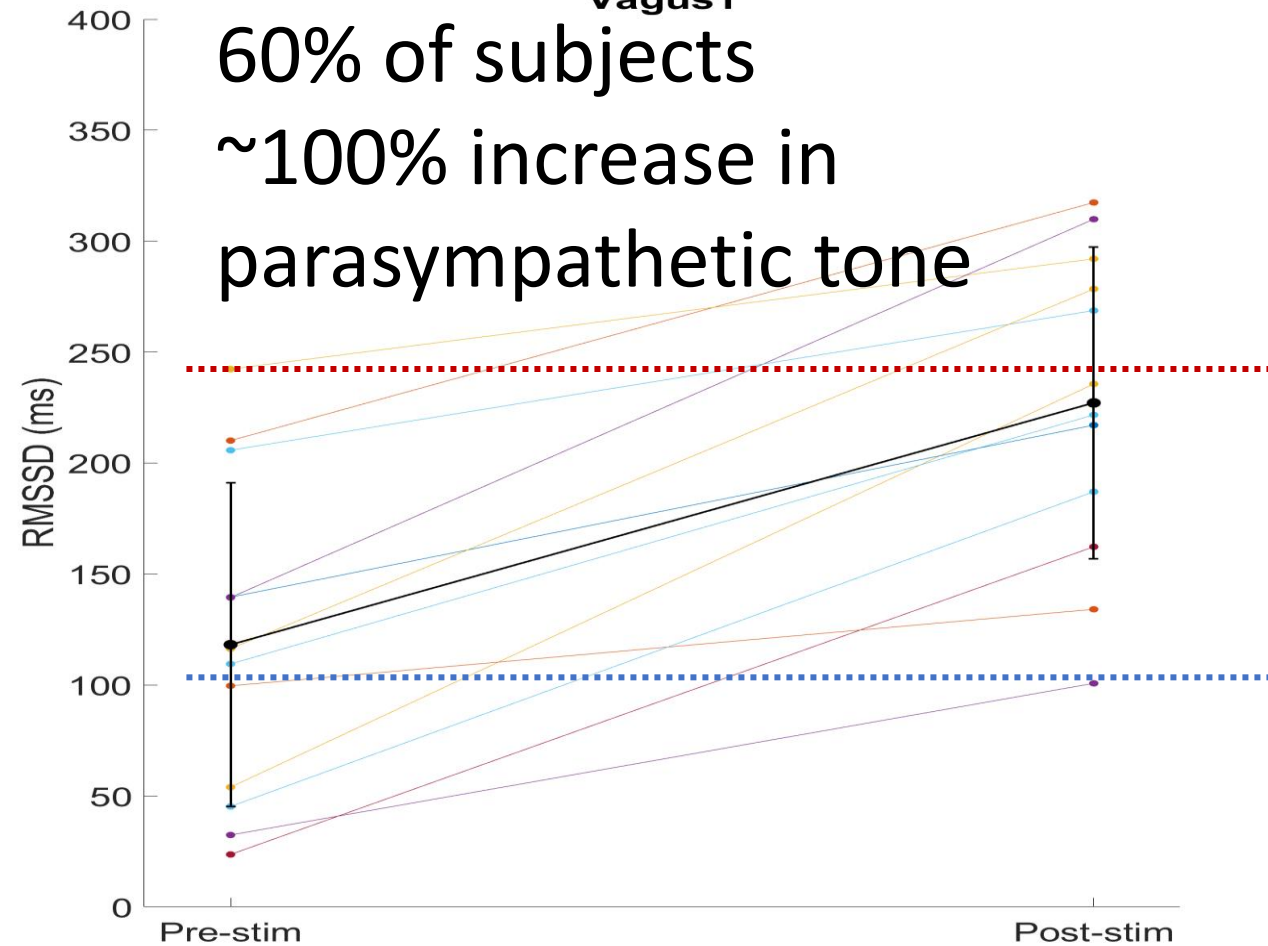
## All Subjects

Vagus1



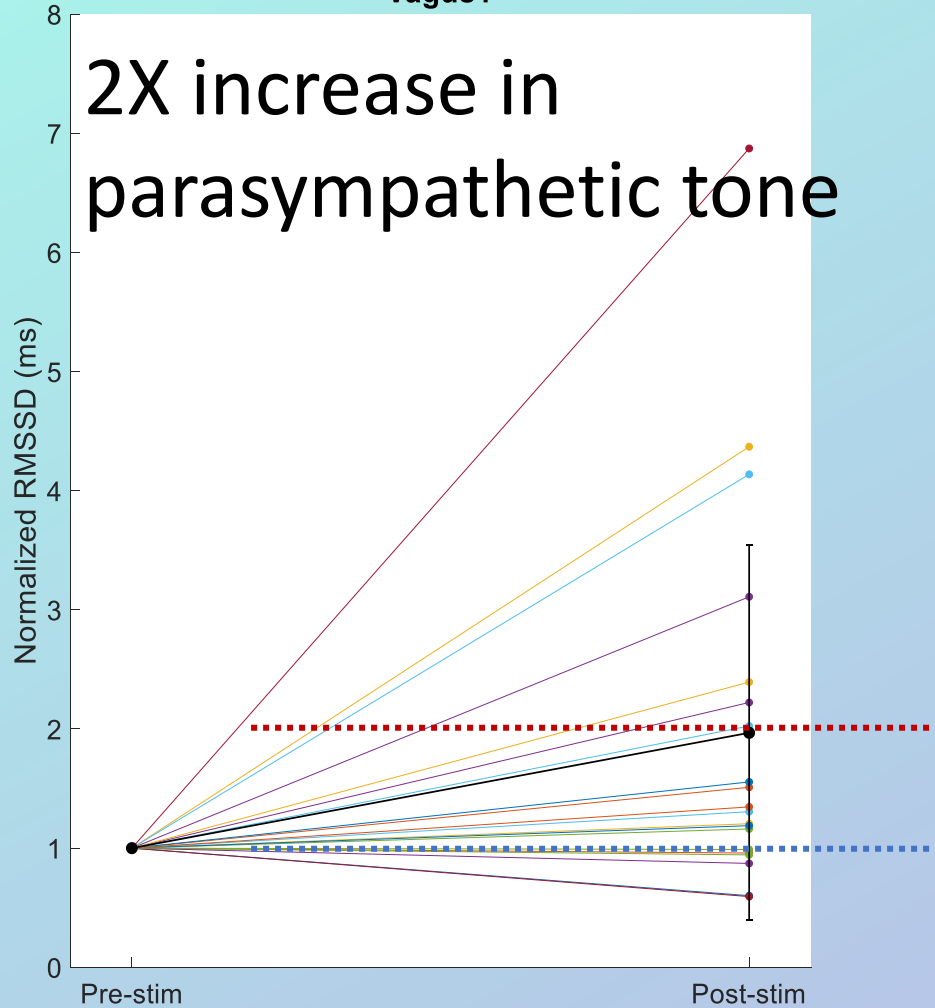
## Responders

Vagus1



## All Subjects

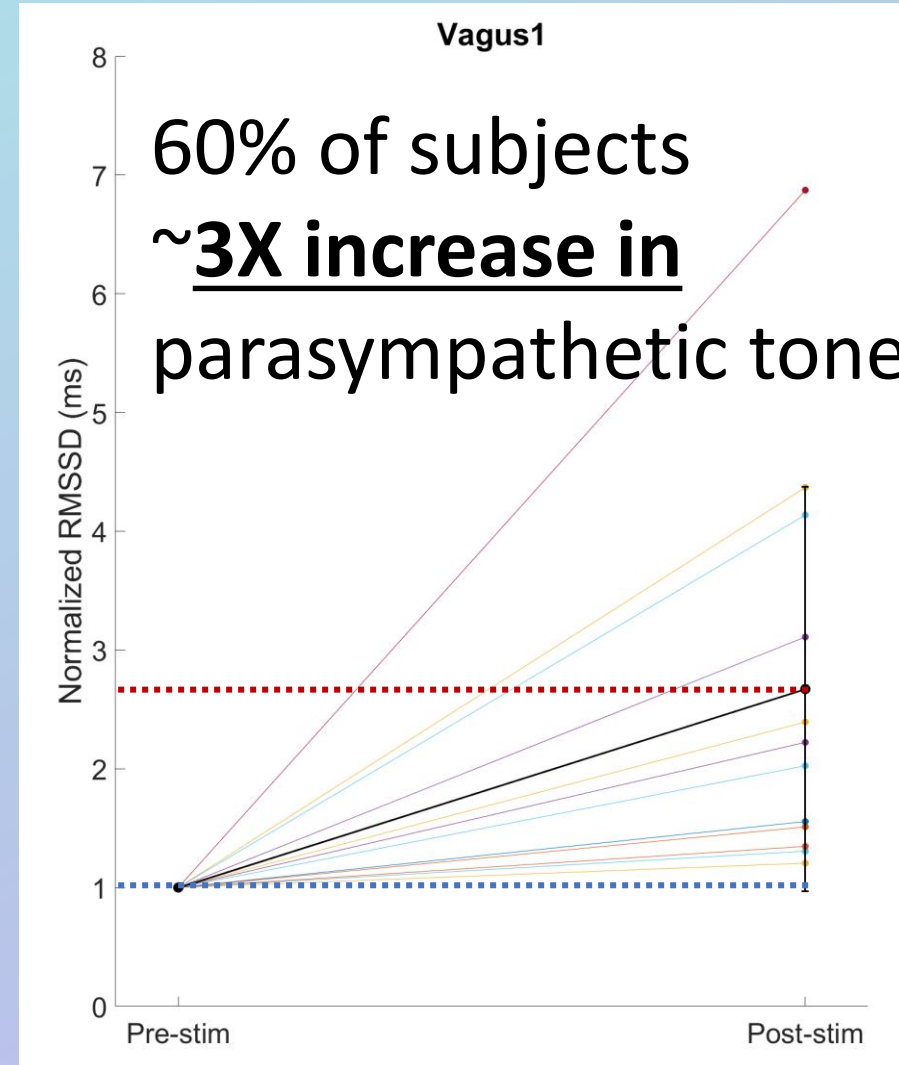
2X increase in  
parasympathetic tone



## Responders

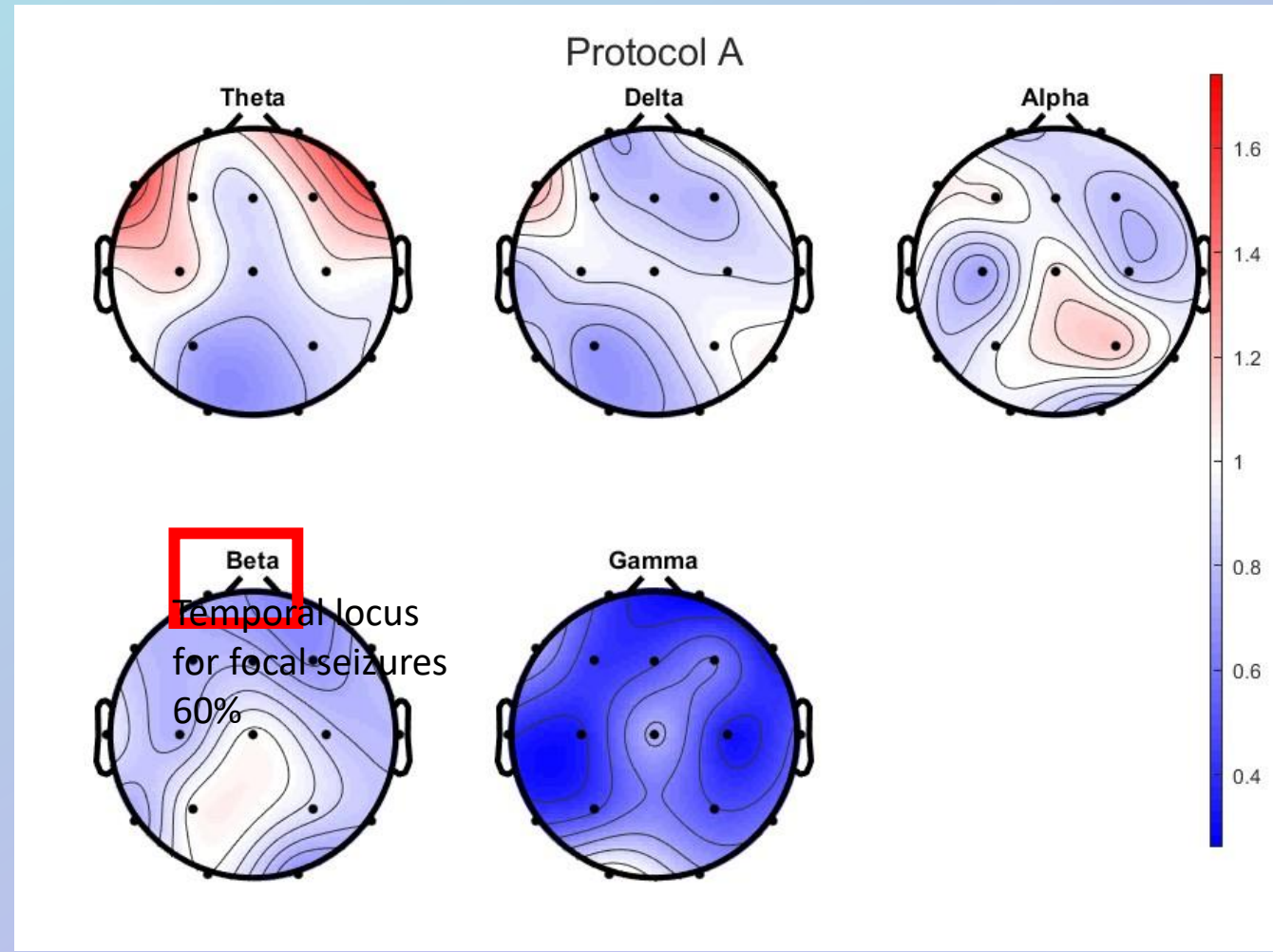
## Vagus1

60% of subjects  
~**3X increase in**  
parasympathetic tone



# FSM Effects on Cerebral Function

- Multiple brain conditions such as epilepsy and mood disorders have demonstrated abnormal brain rhythm frequencies
- tVNS in this study has shown to positively impact these same areas, thus showing brain rhythm correlates of a therapeutic effect

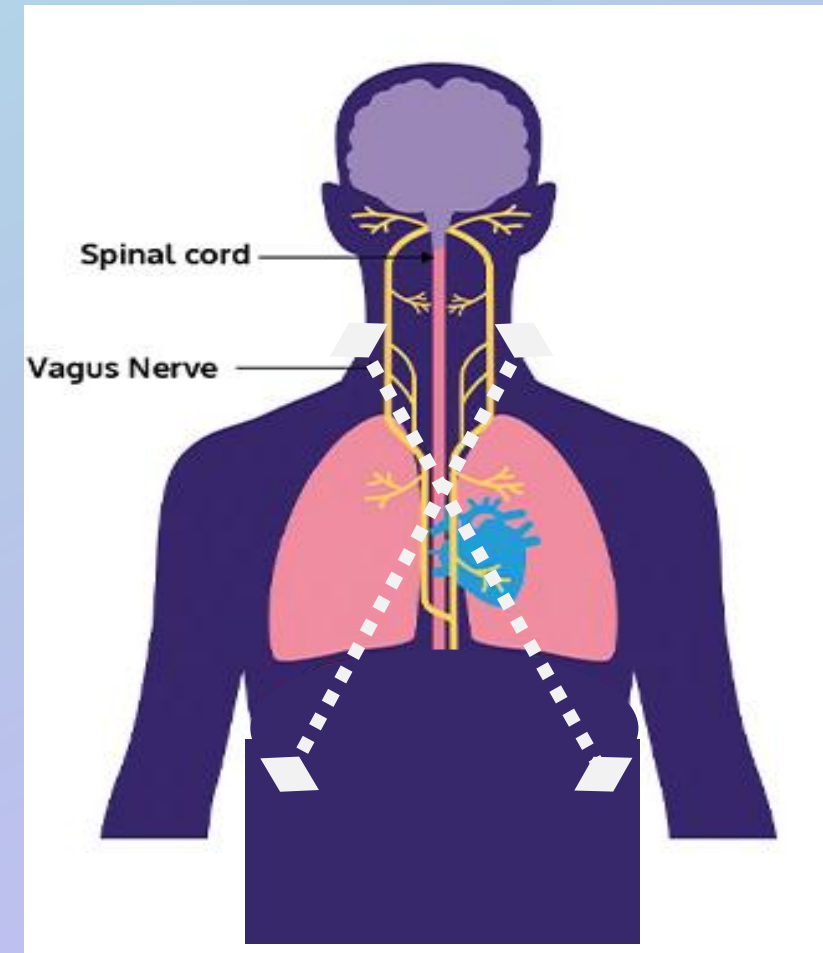


# Intellectual Property

- **Provisional Patent Filed**
- **Nonprovisional patent granted 2025**

## Positioning electrodes at different parts of the body

As part of the report, specific attention was given to patents that regard montaged electrodes at different parts of the body for bilateral stimulation. Within the 801 patents, patents containing “montage”, “arrangement” or “bilateral electrodes” in its title, claims, or abstract were searched for. Of the 23 results, only 1 seems relevant as it shows two surface electrodes on different parts of the body. This (dead) patent can be seen below. Several other patents do regard 2 or more electrodes, for example on the ear, yet these appear to be never more than a few inches apart and are integrated in the same enclosure/device. Therefore, there is seemingly white space for an invention that targets the vagus nerve and uses 2 bilateral electrodes placed far apart from each other.



Treat the Vagus Directly  
Once you see it, you can't un-see it  
And now there is Data

