

# Advances in Devices for Stroke Rehabilitation

UT Southwestern Cerebrovascular and Stroke Symposium

Kim Barker, MD

December 13, 2025

# Disclosures

- None

# Objectives



REVIEW OF PERTINENT REHAB  
ASSESSMENTS FOR STROKE  
PATIENTS



DEVICES UTILIZED TO IMPROVE  
UPPER EXTREMITY MOTOR  
SCORES AND FUNCTION



DEVICES UTILIZED FOR  
PHARYNGEAL DYSPHAGIA

**FUGL-MEYER ASSESSMENT**  
**UPPER EXTREMITY (FMA-UE)**  
**Assessment of sensorimotor function**

**ID:**  
**Date:**  
**Examiner:**

*Fugl-Meyer AR, Jassko L, Leyman I, Olsson S, Steglind S: The post-stroke hemiplegic patient. A method for evaluation of physical performance. Scand J Rehabil Med 1975, 7:13-31.*

A. UPPER EXTREMITY, sitting position					
<b>I. Reflex activity</b>		<b>none</b>	<b>can be elicited</b>		
Flexors: biceps and finger flexors (at least one)		0	2		
Extensors: triceps		0	2		
Subtotal I (max 4)					
<b>II. Volitional movement within synergies, without gravitational help</b>		<b>none</b>	<b>partial</b>	<b>full</b>	
<b>Flexor synergy:</b> Hand from contralateral knee to ipsilateral ear. From extensor synergy (shoulder adduction/ internal rotation, elbow extension, forearm pronation) to flexor synergy (shoulder abduction/ external rotation, elbow flexion, forearm supination). <b>Extensor synergy:</b> Hand from ipsilateral ear to the contralateral knee	Shoulder	retraction	0	1	2
		elevation	0	1	2
		abduction (90°)	0	1	2
		external rotation	0	1	2
	Elbow	flexion	0	1	2
	Forearm	supination	0	1	2
	Shoulder	adduction/internal rotation	0	1	2
	Elbow	extension	0	1	2
Forearm	pronation	0	1	2	
Subtotal II (max 18)					
<b>III. Volitional movement mixing synergies, without compensation</b>		<b>none</b>	<b>partial</b>	<b>full</b>	
<b>Hand to lumbar spine</b> hand on lap	cannot perform or hand in front of anti-sup iliac spine hand behind anti-sup iliac spine (without compensation) hand to lumbar spine (without compensation)	0	1	2	
<b>Shoulder flexion 0°- 90°</b> elbow at 0° pronation-supination 0°	immediate abduction or elbow flexion abduction or elbow flexion during movement flexion 90°, no shoulder abduction or elbow flexion	0	1	2	
<b>Pronation-supination</b> elbow at 90° shoulder at 0°	no pronation/supination, starting position impossible limited pronation/supination, maintains starting position full pronation/supination, maintains starting position	0	1	2	
Subtotal III (max 6)					
<b>IV. Volitional movement with little or no synergy</b>		<b>none</b>	<b>partial</b>	<b>full</b>	
<b>Shoulder abduction 0 - 90°</b> elbow at 0° forearm pronated	immediate supination or elbow flexion supination or elbow flexion during movement abduction 90°, maintains extension and pronation	0	1	2	
<b>Shoulder flexion 90° - 180°</b> elbow at 0° pronation-supination 0°	immediate abduction or elbow flexion abduction or elbow flexion during movement flexion 180°, no shoulder abduction or elbow flexion	0	1	2	
<b>Pronation/supination</b> elbow at 0° shoulder at 30°- 90° flexion	no pronation/supination, starting position impossible limited pronation/supination, maintains start position full pronation/supination, maintains starting position	0	1	2	
Subtotal IV (max 6)					
<b>V. Normal reflex activity</b> assessed only if full score of 6 points is achieved in part IV; compare with the unaffected side		<b>0 (fl. hyper)</b>	<b>lively</b>	<b>normal</b>	
biceps, triceps, finger flexors	2 of 3 reflexes markedly hyperactive or 0 points in part IV 1 reflex markedly hyperactive or at least 2 reflexes lively maximum of 1 reflex lively, none hyperactive	0	1	2	
Subtotal V (max 2)					
<b>Total A (max 36)</b>					

# Fugl-Meyer Assessment Upper Extremity

<30 severe  
impairment

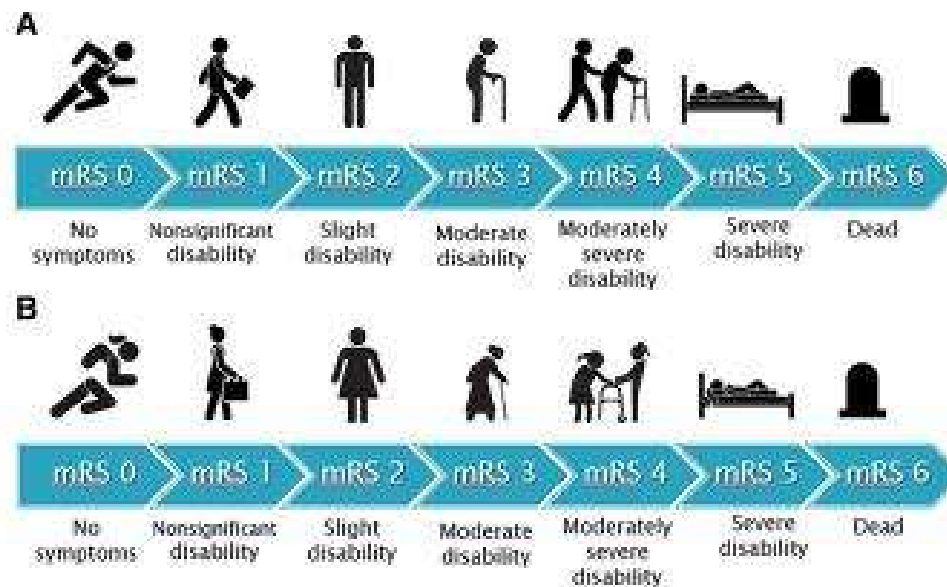
31-45  
moderate  
impairment

>45 mild  
impairment

# Wolf Motor Function Test

Task	Time	Functional Ability	Comment
1. Forearm to table (side)		0 1 2 3 4 5	
2. Forearm to box (side)		0 1 2 3 4 5	
3. Extend elbow (side)		0 1 2 3 4 5	
4. Extend elbow (weight)		0 1 2 3 4 5	
5. Hand to table (front)		0 1 2 3 4 5	
6. Hand to box (front)		0 1 2 3 4 5	
7. Weight to box	_____lbs.		
8. Reach and retrieve		0 1 2 3 4 5	
9. Lift can		0 1 2 3 4 5	
10. Lift pencil		0 1 2 3 4 5	
11. Lift paper clip		0 1 2 3 4 5	
12. Stack checkers		0 1 2 3 4 5	
13. Flip cards		0 1 2 3 4 5	
14. Grip strength	_____kgs.		
15. Turn key in lock		0 1 2 3 4 5	
16. Fold towel		0 1 2 3 4 5	
17. Lift basket		0 1 2 3 4 5	

# Modified Rankin Scale

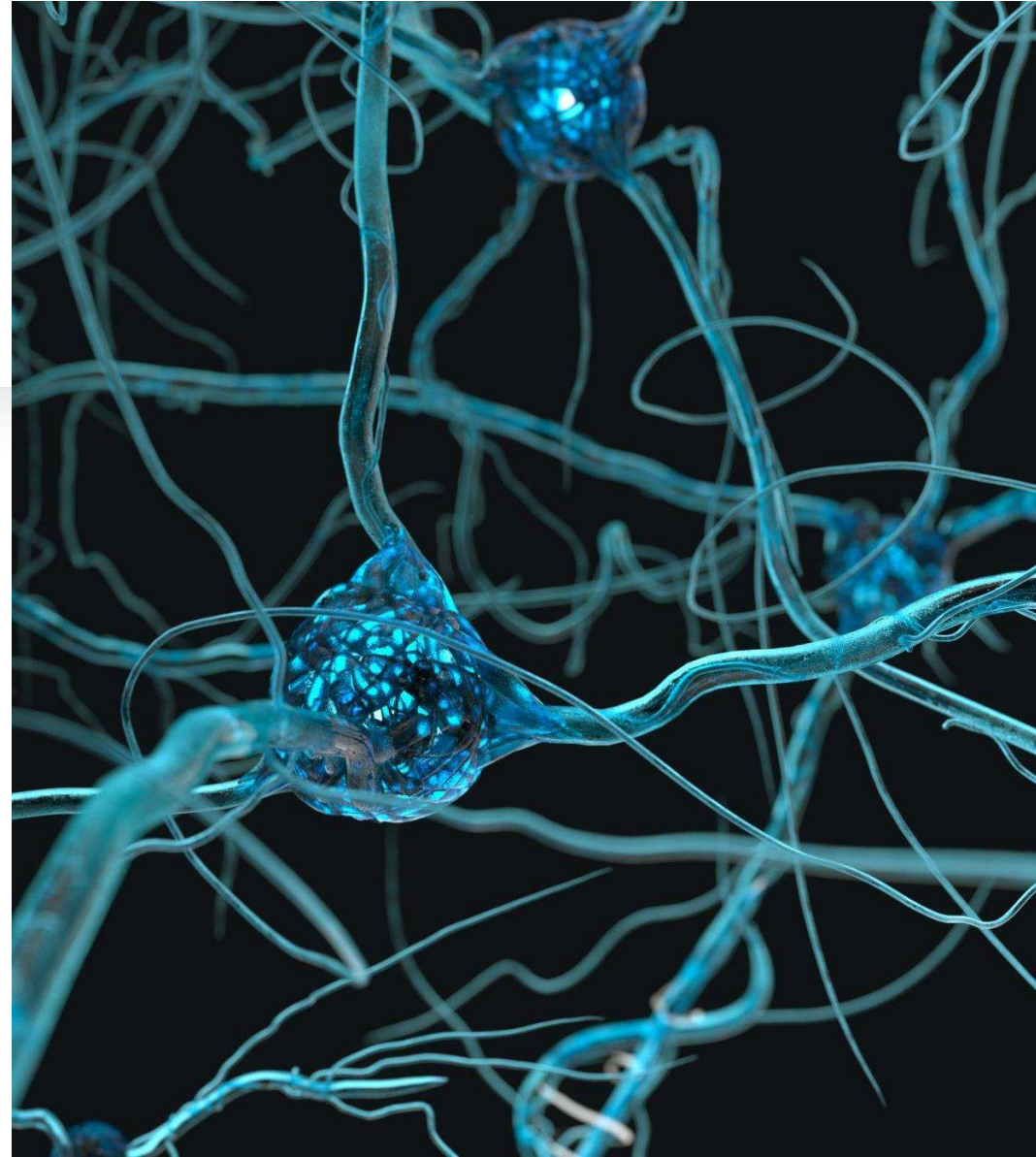


Jeffrey L. Saver. Stroke: Standardized Nomenclature for Modified Rankin Scale Global Disability Outcomes: Consensus Recommendations From Stroke Therapy Academic Industry Roundtable XI, Volume 52, Issue 9, Pages 3054-3062, DOI: (10.1161/STROKEAHA.121.034480)

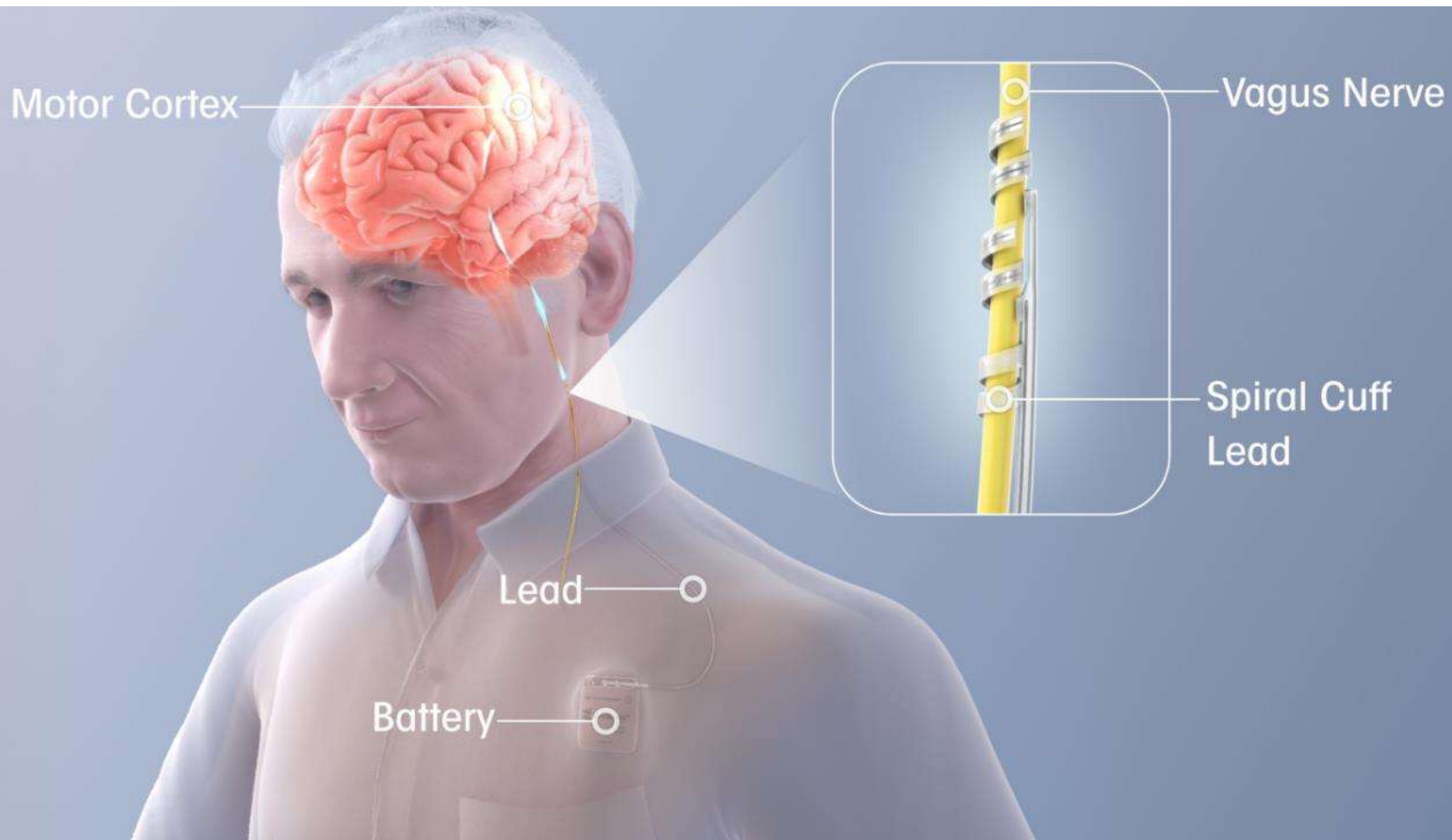
© 2021 American Heart Association, Inc.

# Vagus nerve stimulation

- Enhance the reorganizational potential and neuroplasticity of the brain by modulating cholinergic and monoaminergic motor cortex neurons
- Done by stimulating the vagus nerve while pairing with sensory or motor training



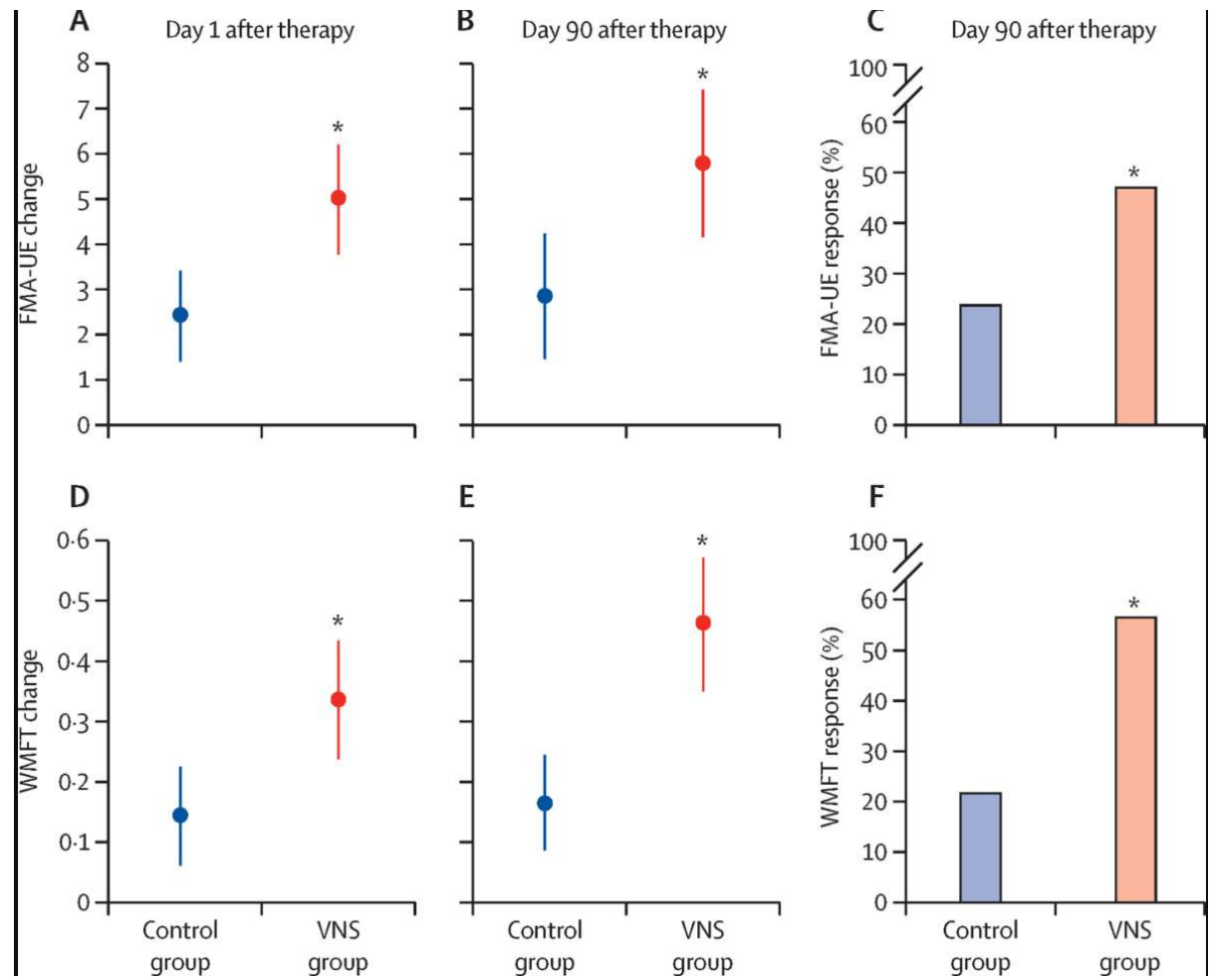




# Vagus nerve stimulation & Upper Extremity

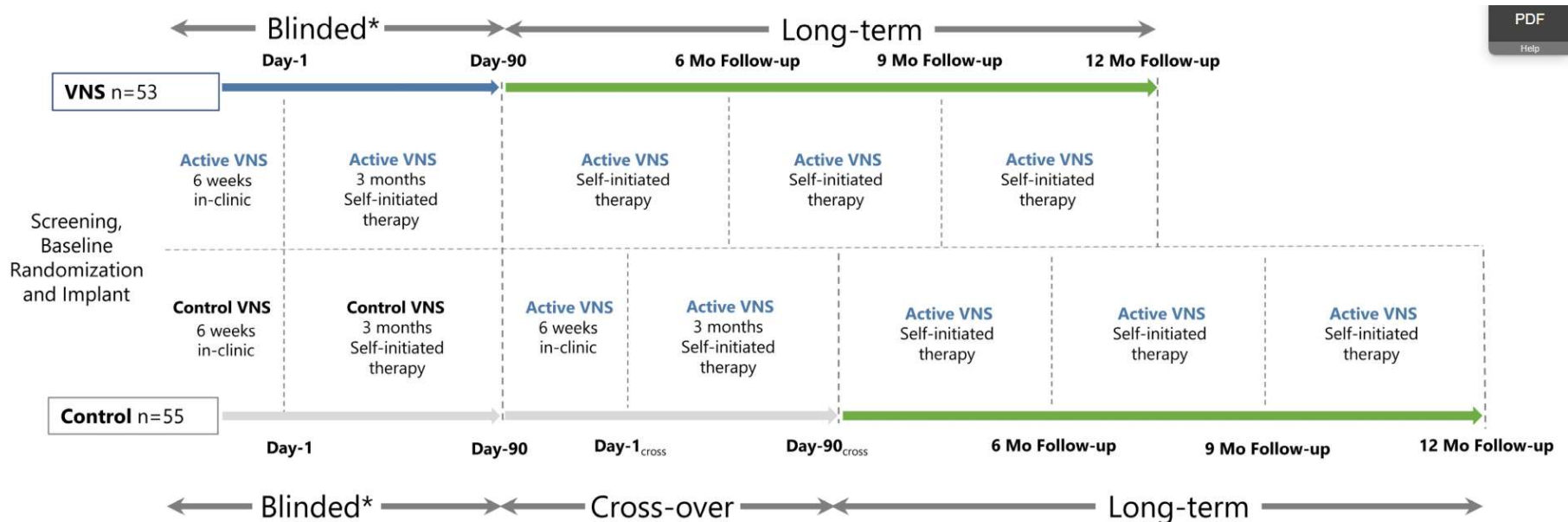
- 
- VNS-REHAB study
    - Triple blind, sham-controlled trial at 19 locations in the US and UK, 108 participants
    - Moderate to severe arm weakness  $\geq$  9 months s/p ischemic stroke
    - Everyone had a device implanted
      - 0.8mA, 100 microseconds, 30 Hz stim pulses lasting 0.5s
      - 0mA pulses
    - 6 weeks of in-clinic therapy (3x/wk, 18 total sessions), then home program
    - Fugl-Meyer was assessed at 90 days
    - Dawson et al.

## Response and change to FMA-UE and WMFT



Dawson et al.

# Long-term outcomes of VNS with UE Rehabilitation



Kimberley et al.

## Long-term Outcomes of Vagus Nerve Stimulation (VNS) Paired with Upper Extremity Rehabilitation After Stroke

- Participants with chronic ischemic stroke and moderate to severe arm impairment
- Participants from the VNS-REHAB pivotal trial completed one year outcomes

### VNS Implant

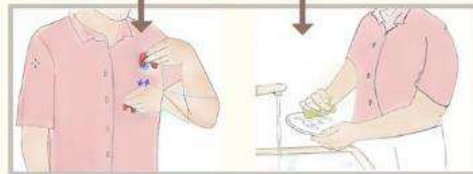


### In-clinic Therapy



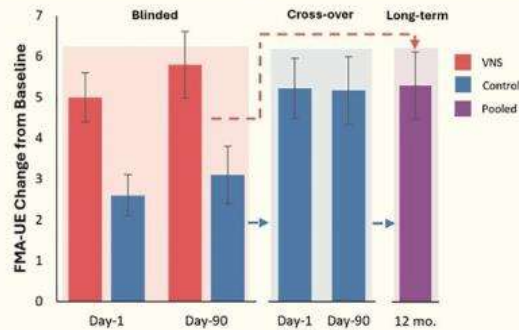
In-clinic, intensive, task-based therapy paired with VNS

### Self-initiated VNS with Home Therapy



Long-term phase: home therapy with magnet swipe

### Results



- Controls achieved additional improvement after cross-over to Active VNS
- Improvements in upper extremity impairment (FMA-UE, primary outcome) were maintained after Paired VNS

### Conclusions

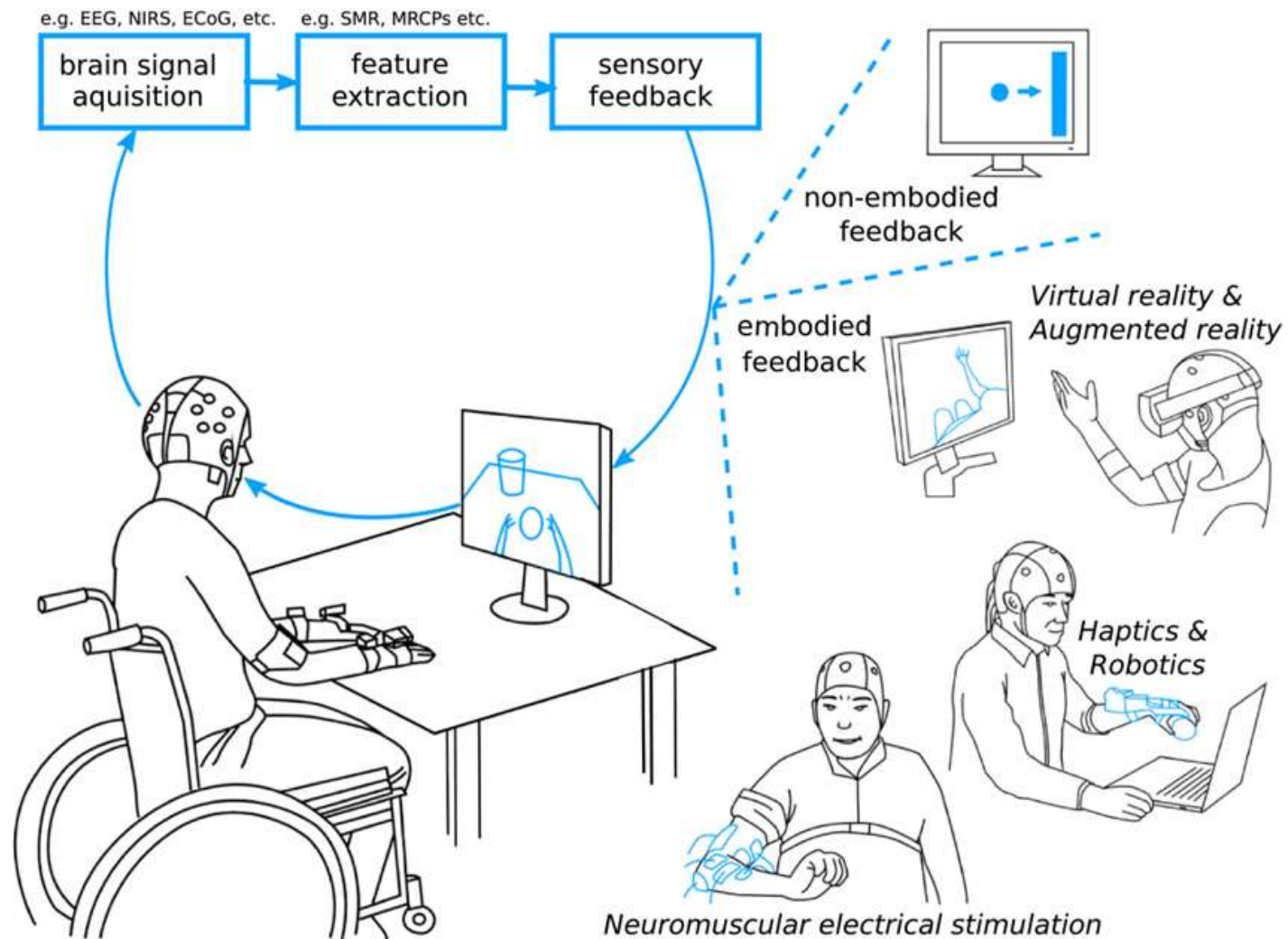
- People treated with Paired VNS **maintained long-term improvements in impairment, activity, participation, and quality-of-life at one year**
- Paired VNS is an FDA-approved, useful treatment option for long-term benefit in individuals with chronic upper extremity limitations after ischemic stroke

# Brain Computer Interface (BCI)

Direct communication between the brain's electrical activity and an external device, such as a robotic limb

For stroke patients, it can provide sensory feedback to modulate purposeful sensorimotor activities

- Potentially repeated use can trigger neurological recovery and improvement in motor function



# BCI and post-stroke motor recovery

- Meta-analysis (Cervera et al.)
- 6 smaller studies demonstrated improvement in the FMA-UE exceeding the minimally clinically important difference
  - N varied from 14 to 47
- Overall, standardized mean improvement of 0.79 in FMA-UE
- Studies with larger sample sizes are needed though

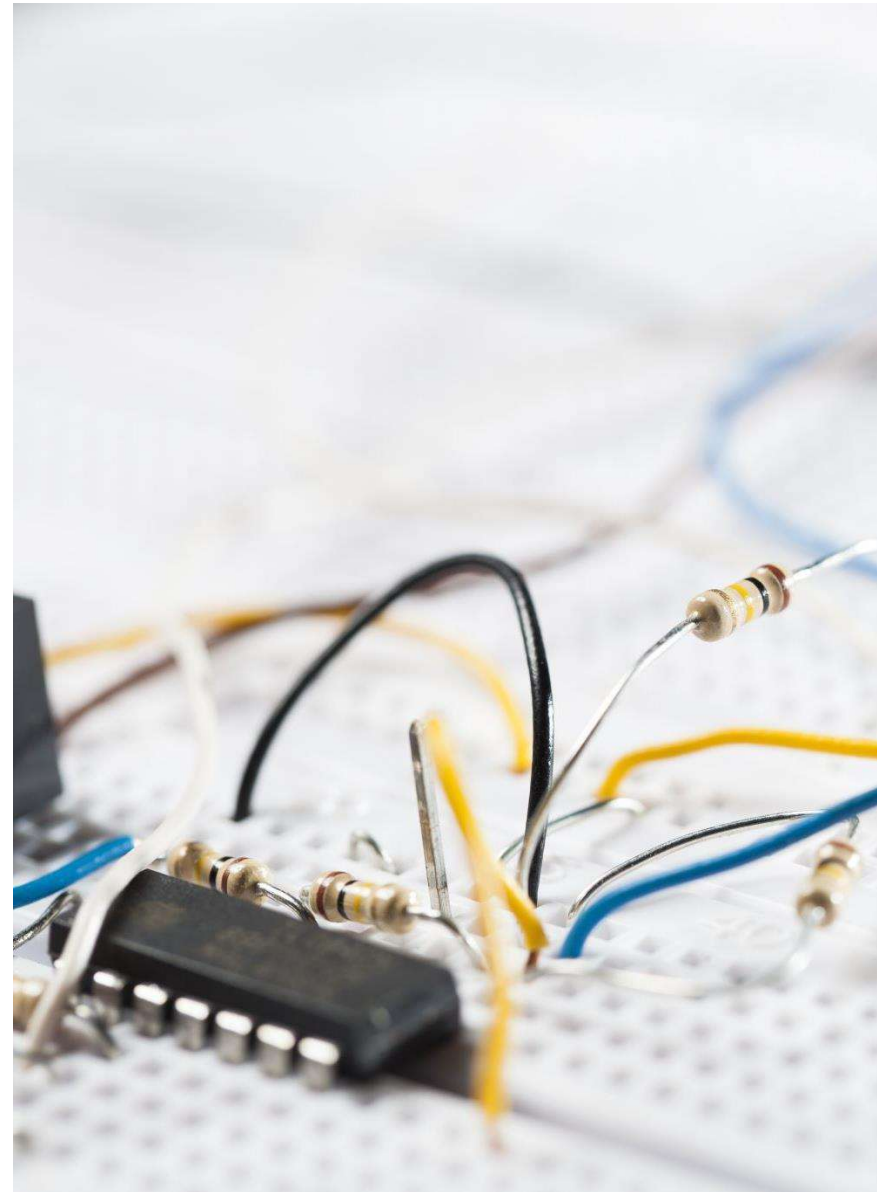


# BCI and post-stroke motor recovery

- Another meta-analysis suggests slight efficacy in improving upper limb functioning
- Possibly slight improvement
  - Subgroup analysis demonstrated better effects if <12h of training rather than >12h of training
  - No difference in ADLs
- Follow-up times in the studies was quite variable, from 2 weeks to 18 weeks
- Zhang et al

# Electromagnetic Network Targeting Field (ENTF) Therapy

- Non-invasive electromagnetic field treatment
  - Low frequency 1-100h
  - Low intensity electromagnetic field ( $<1$  Gauss)
- Exposing impaired neuronal networks to oscillating fields similar to a healthy CNS produces neuroprotective mechanisms AND promotes functional network reorganization
- Encouraging pilot study ...



# Frequency tuned electromagnetic field treatment

- EMAGINE-Study
- Moderate to moderately-severe global disability stroke patients with upper extremity impairment
- More acute than other studies (4-21 days after the stroke)
- 45 treatment sessions

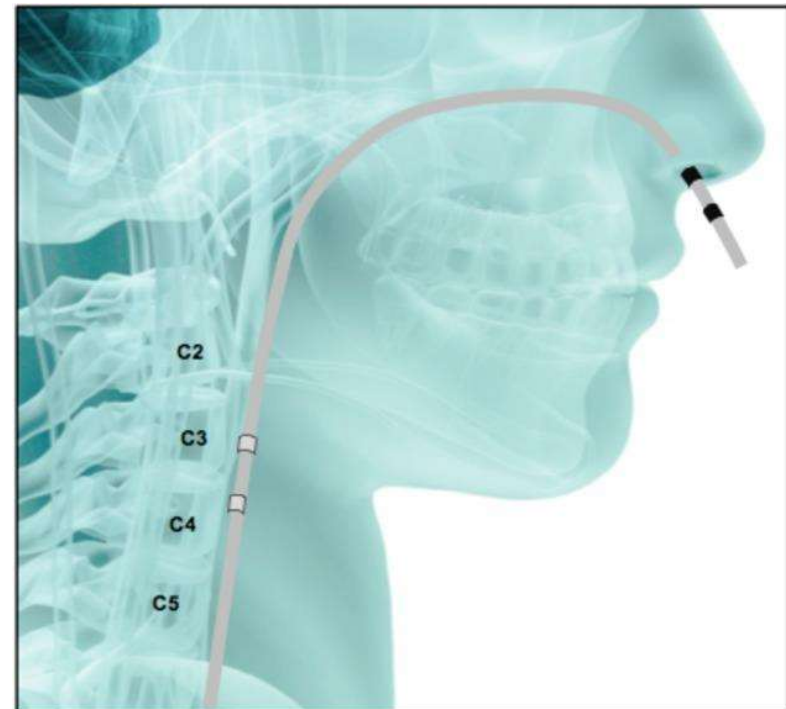


# EMAGINE

- Trial was stopped after 100 participants were enrolled
- Interim analysis did not show that results would meet statistical significance
- Difficulties:
  - Imbalance in randomization treatment group tended to have more R hemisphere strokes, larger strokes, and greater disability at baseline

# Pharyngeal E-stimulation

- An internal device inserted similar to an NG tube with built-in stimulation electrodes
- Maximal corticobulbar excitability occurs at 5Hz, 10 minutes, 75% maximum tolerated intensity (Hamdy, Fraser)
  - Demonstrated faster initiation of each swallow and a reduction in the frequency of aspiration for at least 1h after stimulation.



# Pharyngeal E-stimulation

- Bath et al.'s RCT 162 patients with recent ischemic or hemorrhagic stroke and dysphagia with Penetration Aspiration Score  $\geq 3$  on VFSS
  - Within 42 days of stroke
  - 3 on the scale = entry of material into the larynx without clearing
  - Threshold and tolerance levels were determined for both groups, but sham did not receive stimulation afterwards.
  - Researchers were not blinded

# Pharyngeal E-stimulation

- Primary outcome: swallowing safety at 2 wks
- Secondary outcome: dysphagia severity, function, QOL, and serious adverse events at 6 and 12 weeks
- Results:
  - Study demonstrated swallowing safety at 2 weeks
  - No serious adverse events at 6 and 12 weeks
  - But when compared to sham stimulation, no significant superiority regarding aspiration

# Pharyngeal E-stimulation

- Another study with participants with wider variety of causes of neurogenic related dysphagia (Bath et al.)
- Safe, but no evidence of statistically significant improvement in swallow



# References

- Bath PM, Scutt P, Love J, et al. Swallowing Treatment Using Pharyngeal Electrical Stimulation (STEPS) Trial Investigators. Pharyngeal electrical stimulation for treatment of dysphagia in subacute stroke. A Randomized Controlled Trial. *Stroke*. 2016; 46;1562-1570. doi:10.1161/STROKEAHA.115.012455
- Bath P, et al. Pharyngeal electrical stimulation for neurogenic dysphagia following stroke, traumatic brain injury or other causes: Main Results from the PHADER cohort study. *eClinicalMedicine*. 2020;28.100608.
- Cervera MA, Soekadar SR, Ushiba J, et al. Brain-computer interfaces for post-stroke motor rehabilitation: a meta-analysis. *Annals of Clin and Transl Neurol*. 2018;5(5): 651-663. doi: 10.1002/acn3.544
- Dawson J, Liu CY, Francisco GE, et al. Vagus nerve stimulation paired with rehabilitation for upper limb motor function after ischaemic stroke (VNS-REHAB): a randomised, blinded, pivotal device trial. *Lancet*. 2021;397(10284):1545-1553. doi: 10.1016/S0140-6736(21)00475-X
- Fraser C, Power M, Hamdy S, et al. Driving plasticity in human adult motor cortex is associated with improved motor function after brain injury. *Neuron*. 2002;34:831-840. doi: 10.1016/s0896-6273(02)00705-5
- Hamdy S, Rothwell JC, Aziz Q, Singh KD, Thompson DG. Long-term reorganization of human motor cortex driven by short-term sensory stimulation. *Nat Neurosci*. 1998;1:64-68. doi: 10.1093/264.
- Kimberley TJ, Cramer SC, Wolf SL, et al. Long-Term Outcomes of Vagus Nerve Stimulation Paired with Upper Extremity Rehabilitation After Stroke. *Stroke*. 2025. 56(8):2255-2265. doi: 10.1161/STROKEAHA.124.050479
- Saver JL, Dunca PW, Stein J, et al. Electromagnetic Stimulation to Reduce Disability After Ischemic Stroke: The EMAGINE Randomized Clinical Trial. 2025;8(10);e2537880. doi:10.1001/jamanetworkopen.2025.37880
- Zhang M, Zhu F, Jia F, et al. Efficacy of brain-computer interfaces on upper extremity motor function rehabilitation after stroke: A systematic review and meta-analysis. *NeuroRehabilitation*. 2024;54(20):199-212. doi: 10.3233/NRE-230215