Clinical Trial
Currently recruiting participants

What Do We Do?
We are looking for volunteers to undergo a six-week session of intensive rehabilitation therapy. There will be three sessions each week, each session of rehabilitation therapy will last about one hour. The therapy sessions will include traditional rehabilitation exercises, but the patient will receive nerve stimulation while they are performing the exercises.

How Do Patients Qualify for the Study?
If you are 21-80 years old, have had an ischemic stroke (caused by a blood clot) that occurred at least 9 months but no more than 10 years ago, and experience residual arm or hand weakness, then you may qualify for the study.

How Much Does It Cost?
FREE OF CHARGE

Timeline of Study
Visit 1 & 2: Screening Visit and pre-implantation visit
Visit 3: VNS implant
Visit 4: Pre-Therapy Baseline
Visits 5-22: 18 Treatment Sessions
Visits 23-25: Follow Up Assessments

If you receive a placebo or “sham” VNS during the treatment sessions, we will have you wait 3 months and return for another stage of complimentary therapy (18 sessions) with the active VNS.

Eligibility
AGE RANGE: 21-80 years old
INCLUSION CRITERIA:
• Are 21-80 years old.
• Have had an ischemic stroke (caused by a blood clot) that occurred at least 9 months but no more than 10 years ago.
• Experience residual arm or hand weakness.

If you are a stroke survivor, or know someone who has had a stroke, but do not qualify for this study, we ask that you still complete and send us your information. We offer other programs that you or someone you know may be eligible for.

Learn more at burke.weill.cornell.edu/clinical-trials
Burke Neurological Institute | Academic Affiliate of Weill Cornell Medicine
785 Mamaroneck Avenue, White Plains, NY 10605
PATIENT DEMOGRAPHIC INFORMATION

Patient Name: ________________________________________________________________

Address: _____________________________________________________________________

Phone: ____________ DOB/Age: _______________ Medical Record/ID #: ________________

Emergency Contact: ____________________________________________________________________________________________

Please check off the following:

Are you a Veteran?  Yes  No

Handedness:  Right  Left

Body weakness:  Right  Left

Stroke Type:  Ischemic (Blood Clot)  Hemorrhagic

Stroke Date: ______________ Stroke Number: ______

Lesion location (if known):  Cortical  Subcortical  Mixed  Other

Co-Morbid Diseases/Pertinent Medical Conditions: _____________________________________________________________

Pharmacological Treatment/Medication: (Please list or provide a copy)

<table>
<thead>
<tr>
<th>Demographic Data</th>
<th>Yes</th>
<th>No</th>
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<tbody>
<tr>
<td>Smoker</td>
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<td>Ex-Smoker</td>
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<td>Current Alcohol Use</td>
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<td>High Cholesterol</td>
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<td>Diabetes Type I or II</td>
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<td>Previous Stroke or TIA</td>
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<td>Hypertension/High Blood Pressure</td>
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<td>Family History of Stroke</td>
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<td>Atrial Fibrillation (including paroxysmal)</td>
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<td>Implanted Metallic Parts or Implanted Electronic Device (incl. pace maker,</td>
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<td>defibrillators, medication pump, brain stimulator, aneurysm clip)</td>
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<td>Pregnant or Trying to Become Pregnant</td>
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<td>Significant Mental Illness</td>
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<tr>
<td>History of Seizure</td>
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<td>Injection of Botulinium Toxin in Affected Upper Limb in Last 3 months</td>
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<td>Injection of Phenol in Affected Upper Limb in the last 6 months</td>
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<td>Currently Receiving Physical, Speech, and/or Occupational Therapy Services</td>
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Diagnostic Testing (please check one):  CT Scan  MRI  Other
Non-Invasive Stimulation (TMS) Screening Questionnaire

Participant Initials: ___________  Date: __/__/____

Have you ever:

Had TMS before?  Yes  No
Had an adverse reaction to TMS?  Yes  No
Had a seizure?  Yes  No
Does anyone in your family have epilepsy?  Yes  No
Had an unexplained loss of consciousness?  Yes  No
Had a serious head injury?  Yes  No
Had any other brain related, neurological illnesses?  Yes  No
Do you suffer from frequent or severe headaches?  Yes  No
Do you have any metal in your head (outside the mouth)?  Ex: shrapnel, surgical clips, or fragments from welding  Yes  No
Do you have any implanted medical devices?  Ex: cardiac pacemakers or medical pumps  Yes  No

For any “Yes” responses, please provide detailed information below:

________________________________________________________________________

Date: __/__/____

Subject Signature

________________________________________________________________________

Date: __/__/____

Investigator Signature

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