Melodic-Intonation-Therapy and Speech-Repetition-Therapy for Patients With Non-fluent Aphasia

**Purpose**

We are doing this clinical trial in order to evaluate two different treatments for non-fluent aphasia: Melodic Intonation Therapy (MIT) and Speech Repetition Therapy (SRT). MIT uses a simple form of singing, while SRT uses intensive repetition of a set of words and phrases. We want to see which intensive form of treatment is more effective in leading to an improvement in speech output compared to a no-therapy control period, and whether either treatment can cause changes in brain activity during speaking and changes in brain structure. We will use a technique known as functional Magnetic Resonance Imaging (fMRI) to measure blood flow changes in the brain and structural MRI that assess brain anatomy and connections between brain regions. We will use fMRI to assess brain activity while a patient speaks, sings, and hums. We will assess changes in brain activity and in brain structure by comparing scans done prior to treatment to scans obtained after treatment and we will also examine changes between treatment groups. We will correlate changes in brain activity and brain structure with changes in language test scores.

**Condition**

- **Aphasia**
- Stroke
- Cerebrovascular Accident
- Apoplexy
- Cerebral Infarction

**Intervention**

- Behavioral: Melodic Intonation Therapy
- Behavioral: Speech-Repetition-Therapy

**Phase**

Phase 3

**Study Type:** Interventional

**Study Design:**
- Allocation: Randomized
- Endpoint Classification: Efficacy Study
- Intervention Model: Parallel Assignment
- Masking: Single Blind (Outcomes Assessor)
- Primary Purpose: Treatment

**Official Title:** Behavioral and Neural Correlates of Melodic-Intonation-Therapy (MIT) and Speech-Repetition-Therapy (SRT) for Patients With Non-fluent Aphasia

**Resource links provided by NLM:**

- MedlinePlus related topics: Aphasia
- U.S. FDA Resources

**Further study details as provided by Beth Israel Deaconess Medical Center:**

Primary Outcome Measures:
Correct Information Units (CIU)/min and CIUs/phrase elicited during spontaneous speech [ Time Frame: Baseline (x2), midpoint of therapy, end of therapy, 4 weeks after end of therapy ] [ Designated as safety issue: No ]

Secondary Outcome Measures:
1) Items named on a standard picture naming test; 2) timed automatic speech; 3) linguistically-based measures of phrase and sentence analysis; 4) functional and structural imaging measures [ Time Frame: baseline (x2), midpoint of therapy, end of therapy, 4 weeks after end of therapy ] [ Designated as safety issue: No ]

Estimated Enrollment: 30
Study Start Date: February 2008
Estimated Study Completion Date: December 2016
Estimated Primary Completion Date: December 2016 (Final data collection date for primary outcome measure)

<table>
<thead>
<tr>
<th>Arms</th>
<th>Assigned Interventions</th>
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</thead>
<tbody>
<tr>
<td>Experimental: MIT Melodic Intonation Therapy</td>
<td>Behavioral: Melodic Intonation Therapy</td>
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<td></td>
<td>MIT emphasizes the prosody of speech through the use of slow, pitched vocalization (singing).</td>
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<td>Active Comparator: SRT Speech-Repetition-Therapy</td>
<td>Behavioral: Speech-Repetition-Therapy</td>
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<tr>
<td></td>
<td>Speech-Reception-Therapy is an equally intensive, alternative verbal treatment method developed for this study.</td>
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No Intervention: NTC
No-Therapy Control; Patients in this arm will be re-randomized to the two active arms at the end of the NTC period.

Detailed Description:
One of the few accepted treatments for severe non-fluent aphasia is Melodic Intonation Therapy (MIT). Inspired by the common clinical observation that patients can actually sing the lyrics of a song better than they can speak the same words, MIT emphasizes the prosody of speech through the use of slow, pitched vocalization (singing), and has been shown to lead to significant improvements in propositional speech beyond the actual treatment period. It has been hypothesized that this effect is due to the gradual recruitment of right-hemispheric language regions for normal speech production, and this is further supported by our functional magnetic resonance imaging (fMRI) pilot data. Although the MIT-induced treatment effect has been shown in several small case series, it is not clear whether the effect is due to the intensity of the treatment or to the unique, components of MIT that are not found in other, non-intonation-based interventions. Thus, our overall aim is to test our hypothesis that MIT’s rehabilitative effect is achieved by using its melodic and rhythmic elements to engage and/or unmask the predominantly right-hemispheric brain regions capable of supporting expressive language function. In order to test this hypothesis, we have developed an experimental design that includes the randomization of chronic stroke patients with persistent, moderate to severe non-fluent aphasia into three parallel groups receiving 1) 75 sessions of Melodic Intonation Therapy (approximately 15 weeks), 2) 75 sessions of an equally intensive, alternative verbal treatment method developed for this study (Speech Repetition Therapy), or 3) an equal period of No Therapy. All patients will undergo two pre-therapy and two post-therapy behavioral assessments in addition to the pre- and post-therapy fMRI studies and structural MRI studies examining the neural correlates of overtly spoken and sung words and phrases. This design allows us to 1) examine the efficacy of MIT over No Therapy, 2) examine the effects of elements specific to MIT (e.g., melodic intonation and rhythmic tapping) by comparing it to a control intervention (SRT) that is similar in structure and intensity of treatment, 3) compare post-therapy effects with pre-therapy baseline variations, and 4) examine post-treatment maintenance effects. Our primary speech outcome measure will be the number of Correct Information Units (CIU)/min produced during spontaneous speech. Secondary outcome measures include correctly named items on standard picture naming tests, timed automatic speech, and linguistically-based measures of phrase and sentence analysis.

Eligibility
Ages Eligible for Study: 21 Years to 80 Years
Genders Eligible for Study: Both
Accepts Healthy Volunteers: No

Criteria
Inclusion Criteria:
1. 21-80 years of age
2. first-time ischemic left-hemispheric stroke or cerebrovascular accident
3. at least 12 months out from first ischemic stroke
4. right-handed (prior to stroke)
5. diagnosis of non-fluent or dysfluent aphasia

Exclusion Criteria:
1. older than 80 years of age
2. more than 1 stroke
3. presence of metal or metallic or electronic devices that cannot be exposed to the MRI environment
4. a terminal medical condition; history of major neurological or psychiatric diseases (e.g. epilepsy; meningitis, encephalitis)
5. use of psychoactive drugs/medications such as antidepressants, antipsychotic, stimulants
6. active participation in other stroke recovery trials testing experimental interventions

News
Looking for more information about this study? Visit https://clinicaltrials.gov/ct2/show/NCT00903266?term=aphasia&recr=O...

Contacts and Locations
Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the Contacts provided below. For general information, see Learn About Clinical Studies.

Please refer to this study by its ClinicalTrials.gov identifier: NCT00903266

Contacts
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National Institute on Deafness and Other Communication Disorders (NIDCD)

Investigators
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Study Director: Andrea Norton, BM  Beth Israel Deaconess Medical Center

More Information
Additional Information:
Under "projects" we provide details of our aphasia studies and other studies currently going on in our laboratory.

Publications:


Responsible Party: Gottfried Schlaug, Associate Professor of Neurology; Staff Neurologist, Beth Israel Deaconess Medical Center
ClinicalTrials.gov Identifier: NCT00903266  History of Changes
Other Study ID Numbers: DC008796, 3R01DC008796-02S1, RO1 DC008796
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Last Updated: January 29, 2015
Health Authority: United States: Federal Government
Keywords provided by Beth Israel Deaconess Medical Center:

**Aphasia**
- Speech Impairment
- Stroke
- Cerebrovascular Accident

Additional relevant MeSH terms:

**Aphasia**
- Cerebral Infarction
- Brain Ischemia
- Brain Infarction
- Cerebrovascular Disorder

ClinicalTrials.gov processed this record on March 23, 2015