**Purpose**

*Amyotrophic lateral sclerosis* (ALS) is a progressive neuromuscular condition characterized by weakness, muscle wasting, fasciculations and increased reflexes. Depending on the site of onset, individuals with ALS progressively lose control of their skeletal muscles; bulbar or the extremities. As symptoms worsen and spread, muscle atrophy becomes apparent and upper motor neuron symptoms such as spasticity complicate gait (in lower limb involvement) and manual dexterity (in upper limb involvement). The patients progress to a state of profound disability and have great difficulty in communicating; some may even be entirely "locked in" to their bodies. The capacity for simple communication could greatly improve their quality of life.

New technologies are giving people with disabilities alternate communication and control options. One such instrument is the EEG-based Brain-Computer Interface (BCI) which can provide both communication and control functions to those who have lost muscle control. By recording electroencephalographic (EEG) signals or brain waves from the scalp and then decoding them, the Wadsworth BCI allows people to make selections on a computer screen. In this study we will be investigating the feasibility of using EEG-based Brain-Computer Interface technology as a communication solution for individuals with ALS. The specific question addressed will be: Can individuals with ALS use the BCI for communication when they present with extreme loss of neuromuscular control and severe communication impairments? The goal of the project is to determine whether this device is a practical and realistic means for individuals with ALS to communicate. The study is intended to evaluate both the complexity of the system and the degree to which each participant will be able to communicate. Trials will consist of asking the subject to follow a series of simple instructions and complete certain tasks while using the BCI.

<table>
<thead>
<tr>
<th>Condition</th>
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<tbody>
<tr>
<td>Amyotrophic Lateral Sclerosis</td>
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<tr>
<td>Cerebrospinal Fluid</td>
</tr>
<tr>
<td>Neurodegenerative Disease</td>
</tr>
<tr>
<td>Motor Neuron Disease</td>
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</table>

**Study Type:** Observational
Study Design: Observational Model: Case Control
Time Perspective: Cross-Sectional

Official Title: EEG-Based Brain-Computer Interface Project for Individuals With ALS

Resource links provided by NLM:

- Genetics Home Reference related topics: amyotrophic lateral sclerosis, familial paroxysmal nonkinesigenic dyskinesia
- MedlinePlus related topics: Amyotrophic Lateral Sclerosis, Degenerative Nerve Diseases
- U.S. FDA Resources

Further study details as provided by Drexel University:

- Estimated Enrollment: 50
- Study Start Date: August 2007
- Estimated Study Completion Date: December 2011
- Estimated Primary Completion Date: December 2010 (Final data collection date for primary outcome measure)

Groups/Cohorts

<table>
<thead>
<tr>
<th>ALS</th>
<th>Subjects having either definite or probable ALS by El Escorial Criteria.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-ALS</td>
<td>Subjects not having either definite or probable ALS by El Escorial Criteria.</td>
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</table>

Eligibility

Ages Eligible for Study: 18 Years to 90 Years
Genders Eligible for Study: Both
Accepts Healthy Volunteers: Yes
Sampling Method: Non-Probability Sample

Study Population

ALS clinic patients at MDA/ALS Center of Hope.

Criteria

Inclusion Criteria:

Medical Subjects:
- Be able to give consent themselves or via a legally authorized representative.
- Diagnosed with a neuromuscular disease and have limited ability to communicate.
- Be able to see visual cues such as targets or letters presented on the screen, and/or ability to hear auditory cues such as tones or words presented through speakers or earphones.
- Be able to understand and remember instructions concerning participation.

Healthy control subjects:
- Be able to consent to give consent themselves or via a legally authorized representative.
Be able to see visual cues such as targets or letters presented on the screen, and/or ability to hear auditory cues such as tones or words presented through speakers or earphones.
Be able to understand and remember instructions concerning participation.

Exclusion Criteria:
Individuals with cognitive impairments that would impact their ability to follow the instructions

Contacts and Locations

Please refer to this study by its ClinicalTrials.gov identifier: NCT00718458

Locations

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MDA/ALS Center of Hope
Philadelphia, Pennsylvania, United States, 19104
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Principal Investigator: Terry Heiman-Patterson, MD

Sponsors and Collaborators
Drexel University
MDA/ALS Center of Hope

Investigators
Principal Investigator: Terry Heiman-Patterson, MD MDA/ALS Center of Hope

More Information

No publications provided

Responsible Party: MDA/ALS Center of Hope (Terry Heiman-Patterson, MD)
ClinicalTrials.gov Identifier: NCT00718458 History of Changes
Other Study ID Numbers: Internal-17016
Study First Received: July 14, 2008
Last Updated: July 16, 2008
Health Authority: United States: Institutional Review Board

Keywords provided by Drexel University:
Amyotrophic Lateral Sclerosis Autonomic Nervous System
Cerebrospinal Fluid Neurodegenerative Diseases
Neurodegenerative Disease Movement Disorders
Motor Neuron Disease

Additional relevant MeSH terms:
Amyotrophic Lateral Sclerosis Central Nervous System Diseases
Sclerosis Nervous System Diseases
Motor Neuron Disease Neuromuscular Diseases
Neurodegenerative Diseases Pathologic Processes
Spinal Cord Diseases

ClinicalTrials.gov processed this record on August 05, 2010