

**Evaluation of cognitive state using Neurosteer system  
in patients suffering from cognitive decline**

Clinical Research Center  
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Protocol  
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## Protocol Summary

<b>OBJECTIVE</b>	To evaluate the tolerability of the Neurosteer system in elderly population and to demonstrate the ability of the system to differentiate between cognitive states in patients with cognitive decline.
<b>STUDY DESIGN</b>	This is an observational study. Patients who fulfill all inclusion criteria and none of the exclusion criteria will be enrolled in the study, be neurologically evaluated and will go through EEG recordings while listening to an auditory cognitive assessment tool and performing tasks. EEG recordings will be analyzed using proprietary computational analyses.
<b>STUDY POPULATION</b>	The study population is comprised of patients with cognitive decline.
<b>SAMPLE SIZE CONSIDERATIONS</b>	60 subjects, a pilot study
<b>INCLUSION CRITERIA</b>	<ol style="list-style-type: none"> <li>1. Men and women over the age of 45.</li> <li>2. <math>MMSE \geq 10</math>.</li> <li>3. <math>MMSE \leq 30</math>.</li> <li>4. Patient is able to collaborate.</li> <li>5. No other cognitive comorbidities.</li> <li>6. No seizure events.</li> </ol>
<b>EXCLUSION CRITERIA</b>	<ol style="list-style-type: none"> <li>1. Advanced stage of cognitive decline (<math>MMSE &lt; 10</math>).</li> <li>2. Any verbal or non-verbal form of objection from patient or from patient's family member or significant other.</li> <li>3. Presence of several cognitive comorbidities.</li> <li>4. Damage to integrity of scalp and/or skull.</li> <li>5. Skin irritation in the facial and forehead area.</li> <li>6. Significant hearing impairments.</li> <li>7. History of drug abuse.</li> </ol>
<b>STUDY PROCEDURES</b>	Clinical staff will identify potential subjects and will examine the eligibility of subject according to inclusion and exclusion criteria. Patients or legal guardian will sign the Informed Consent Form (ICF). Research staff will inform the patient or legal guardian/ family/ accompanying individuals on study's objective and design. Patients will be divided into groups according to their initial MMSE score (mild cognitive impairment 24-27, mild dementia 19-23, and moderate dementia 10-18). Research staff will set up an initial assessment session using Neurosteer system. In this session the patient will listen to the auditory assessment battery and perform tasks. According to initial assessment and patient compliance, the patient will be re-examined in the same experimental setting over the following weeks. Level of cognition will be assessed by Neurosteer technology.

<b>DATA TO CAPTURE</b>	<p>The following data will be collected for the purposes of this study:</p> <p><b>Demographics:</b> age, gender.</p> <p><b>Clinical data:</b> official diagnosis, MMSE score, comorbidities, drugs.</p> <p><b>Medical history:</b> number of years with the disease.</p> <p><b>Measurements of the research:</b> electrophysiological data captured by Neurosteer system.</p>
<b>TECHNICAL DESCRIPTION OF THE SYSTEM</b>	<p>The system is composed of hardware and software modules that facilitate the capture and interpretation of electrophysiological data as well as enable viewing the processed data in real time and offline. An electrode patch is attached on the subject's forehead to capture the electrophysiological signal. The signal is sent via low energy Bluetooth to an EEG Monitor. The signal is then sent via Wi-Fi to the cloud where the data is stored on a HIPAA compliant server. Data analysis performed in the cloud transforms the electrophysiological signal into easily readable data of brain activity, which is accessible via any web interface. The brain activity features (BAFs), which comprise the main novelty of the method, are created using a variant of the wavelet packet analysis and the best basis algorithm. Statistical analysis will be performed on the data.</p>
<b>STATISTICAL ANALYSIS PLAN</b>	<p>MMSE scores will be taken from previous evaluation performed in the institute. Each patient will be evaluated using the continuous measurement by the Neurosteer system.</p> <p>Statistical analyses will include Pearson correlations between electrophysiological data and MMSE scores, and reaction times in the tasks.</p> <p>Linear mixed models (LMM) will be calculated with group and task level as independent variables.</p>