Evaluation of cognitive state in senior subjects using Neurosteer single-channel EEG with an interactive assessment tool

Clinical Research Center
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Protocol
Version 3.0
05:2021
May 2021

Protocol Summary

OBJECTIVE	To evaluate the ability to differentiate between cognitive states in the senior population using a single-channel EEG with an interactive assessment tool.
STUDY DESIGN	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.
STUDY POPULATION	The study population is comprised of senior patients.
SAMPLE SIZE CONSIDERATIONS	80 subjects
INCLUSION CRITERIA	1. Men and women over the age of 50. 2. MMSE ≥ 24 3. Patient is able to collaborate. 4. No other cognitive comorbidities. 5. No seizure events.
EXCLUSION CRITERIA	1. MMSE < 24 2. Any verbal or non-verbal form of objection from patient or form patient's family member or significant other. 3. Presence of several cognitive comorbidities. 4. Damage to integrity of scalp and/or skull. 5. Skin irritation in the facial and forehead area. 6. Significant hearing impairments. 7. History of drug abuse.
STUDY PROCEDURES	Clinical staff will identify potential subjects and will examine the eligibility of subjects according to inclusion and exclusion criteria. Research staff will inform the patient on study's objective and design. Patients will sign the Informed Consent Form (ICF). Patients will be divided into groups according to their initial MMSE score (mild cognitive impairment MMSE 24-27 and healthy seniors MMSE 28-30). Research staff will set up an initial assessment session using the Neurosteer system. In this session the patient will listen to the auditory assessment battery and perform tasks. The patient will be re-examined in the same experimental setting over the next 7 days and at least 1 day later. Level of cognition will be assessed by Neurosteer technology.

DATA TO CAPTURE	The following data will be collected for the purposes of this study: **Demographics**: age, gender. **Clinical data**: official diagnosis, MMSE score, IADL score, comorbidities, drugs. **Medical history**: number of years with the disease. **Measurements of the research**: electrophysiological data captured by Neurosteer system.
TECHNICAL DESCRIPTION OF THE SYSTEM	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.
STATISTICAL ANALYSIS PLAN	MMSE scores will be taken from previous evaluation performed in the institute. Each patient will be evaluated twice, using the continuous measurement by the Neurosteer system. Statistical analyses will include Pearson correlations between electrophysiological data and MMSE scores, and reaction times in the tasks. Linear mixed models (LMM) will be calculated with group and task level as independent variables.