Evaluation of cognitive state in seniors using Neurosteer single-channel EEG with an auditory assessment tool

Clinical Research Center
Neurosteer Ltd.

Protocol
Version 1.0
04:2022
March 2022

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 auditory instructions and performing cognitive and functional tasks. EEG recordings will be analyzed using proprietary computational analyses.
STUDY POPULATION	The study population is comprised of senior patients.
SAMPLE SIZE CONSIDERATIONS	90 subjects
INCLUSION CRITERIA	1. Men and women over the age of 50. 2. MMSE $\geq$ 10. 3. Patient is able to collaborate. 4. No seizure events.
EXCLUSION CRITERIA	1. Advanced stage of cognitive decline (MMSE < 10). 2. Any verbal or non-verbal form of objection from patient or form patient's family member or significant other. 3. Significant hearing impairments. 4. Significant vision impairments. 5. Damage to integrity of scalp and/or skull. 6. Skin irritation in the facial and forehead area. 7. Epilepsy or seasure activity. 8. 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 or legal guardian/ family/ accompanying individuals on study's objective and design. Patients will sign the Informed Consent Form (ICF). 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 cognitive tasks. Over the next 7 days, clinical staff will set up another session using the Neurosteer system. In this session the patient will listen to auditory instructions and perform two PASS sub-tasks: a drug sorting task and a phone use task. Level of cognition will be assessed by validated screening tools (MMSE and MoCA) and the Neurosteer technology.
DATA TO CAPTURE	<u>The following data will be collected for the purposes of this study:</u> **Demographics**: age, gender, year of education. **Clinical data**: official diagnosis, comorbidities, drugs, MMSE score, MoCA score, GDS score, CLOX score, PASS drug sorting and phone use sub-scores. **Medical history**: number of years with the disease, date of surgery. **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 and MoCA scores will be taken from previous evaluations performed in the institute. Each patient will be evaluated using the continuous measurement by the Neurosteer system. Statistical analyses will include Pearson correlations between electrophysiological data and MMSE and MoCA scores, and reaction times in the tasks. Linear mixed models (LMM) will be calculated with group and task level as independent variables.