TITOLO DEL PROGETTO:

Effetti di un trattamento intensivo robot assistito sul recupero funzionale della mano e sull'autonomia nelle ADL in persone con Sclerosi Multipla: studio randomizzato controllato in singolo cieco

DATA DI INZIO: Marzo 2014

DURATA: 2 anni

DIPARTIMENTI CHE PARTECIPANO
DIPARTIMENTO UNIVR: Dipartimento di Scienze Neurologiche e del Movimento dell'Università degli studi di Verona

RESPONSABILE SCIENTIFICO: Prof. Nicola Smania

ENTE FINANZIATORE: FISM (Fondazione Italiana Sclerosi Multipla)
IMPORTO TOTALE: 75.000 euro

OBIETTIVI:
Conventional rehabilitation of the upper limb in patients with neurological disorders has been enriched by the development of robots as they can provide high-intensity, repetitive, interactive and task-specific exercises. These devices can provide various feedbacks that can guide patients during the sensorimotor training and allow quantitative measurement of motor performance during training. One of these devices is the Amadeo, a modern, mechatronic end-effector robotic device designed to improve sensorimotor functions in patients with restricted movement in individual fingers or in the entire hand. Another important issue concerns cortical plasticity, which plays a fundamental role in motor learning and neurorehabilitation. To date, the specific mechanisms leading to UL recovery after neurological rehabilitation are still unclear. The development of new EEG instruments allows brain activity to be tested under specific rehabilitation tasks contributes to give new insight in the dynamics of cortical networks reorganization promoted by rehabilitation. *The main aim* of the study is to perform a single blind RCT on 60 outpatients with MS (age:18-65 years; EDSS<8) in order to compare the efficacy of high-intensity robot-assisted training with conventional treatment on sensorimotor hand recovery, disability in ADLs and QoL.
The secondary aim is to explore the underlying neuronal mechanisms of UL recovery by using EEG investigations and innovative robotic equipment. 10 controls (age 18-65 yrs) will undergo one session of the same Video-EEG acquisition to collect normative data to compare with data collected on patients. Each participant will receive 40-minute sessions over an 8 week period (3 days/week). Each session will consist of 30 minutes of hand training and 10 minutes of passive upper limbs mobilization. The experimental group will receive robot-assisted therapy by Amadeo. The control group will receive conventional rehabilitation. Before treatment, immediately after treatment, 1 month after treatment patients will be evaluated with a comprehensive protocol of all ICF domains as well as acquisition by Video-EEG acquisition combined with Amadeo robotic training device. Primary outcome measures: Fugl-Meyer Assessment Motor Scale. Secondary measures: UL electromyographic analysis, Tremor Severity Scale, Nine Hole Peg Test, Amadeo hand muscle strength (Newton), Motricity Index, VAS for tiredness and fatigue; TEMPA, Motor Activity Log, Action Research Arm test, Multiple Sclerosis Quality of Life-54 and the assessment of Life Habits. Parametric tests and nonparametric tests will be performed according to variable distribution (p<.05)

AREE DI RICERCA DEL PROGETTO:
Fisiatria