Evaluation of the safety and potential effectiveness of a digital therapeutic device for neuromotor rehabilitation in children

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Background and objectives:
The last years have seen the technological evolution of interactive games, beneficial for the rehabilitation field: the introduction of inertial systems and the diffusion of virtual reality has given the push to the experimentation of digital rehabilitation protocols [11]. The gamification approach involves the performance of integrated functions in a target context, rather than a single functional movement, thus digital rehabilitation tools have shown how rehabilitation including virtual reality is more effective than standard rehabilitation thanks to the greater involvement of the subjects [7].
This study focuses on pediatric patients with neuromotors disorders who face frequent outpatient rehabilitation sessions characterized by repetitive and standardized exercises: the technicians try to provide captivating activities, not always based on consolidated methods. To overcome this, a digital therapeutic device is used in this study, aiming at the evaluation of its safety and effectiveness with respect to current rehabilitation practices.

Materials and Methods:
The digital therapeutic device under investigation exploits five inertial sensors inserted in shirt pockets, and a software of several game levels characterized by different required movements; a feedforward system allows to customize the targets and each individual session according to the user's capabilities.
The study has been completed in two child neuropsychiatry operative units by 18 outpatients undergoing an initial cycle of eight standard rehabilitation sessions followed by eight rehabilitation sessions carried out using the device: the aim has been to identify any possible patient discomfort in terms of pain, fatigue and level of satisfaction, and to detect the potential therapeutic benefits deriving from the device. Its effectiveness compared to current rehabilitation methods has been assessed through kinematic parameters.
A statistical analysis has been applied for each identified outcome to support the results.

Results:
Referring to the safety of the device, no particular adverse events have been recorded during the study.
Concerning the level of satisfaction all patients have shown interest in continuing the rehabilitation experience with it.
About the effectiveness, important statistically significant differences have been found with regard to the jerk parameter: the use of the device improves the fluidity of the gestures.

Conclusions:
The digital therapeutic device has proven to be a safe device that improves patient engagement: the results suggest a potential better adherence to the rehabilitation treatments, with a consequent potential improvement in motor skills. Indeed, it also improves the fluidity of the gesture. The device is designed to become a useful tool to support a therapist, offering the possibility of planning patient-related rehabilitation activities and facilitating their daily activities. It is also designed to be exported to domestic environments: patients could benefit in terms of cost savings and logistics from combining outpatient rehabilitation sessions with sessions carried out at home.

Bibliography:

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