NEUROPSYCHOLOGICAL REHABILITATION IN CHILDREN WITH MODERATE OR SEVERE TBI. RANDOMIZED TRIAL: INTERVENTION AIMED AT PARENTS, CHILDREN THROUGH ROBOTICS AND CONTROL GROUP

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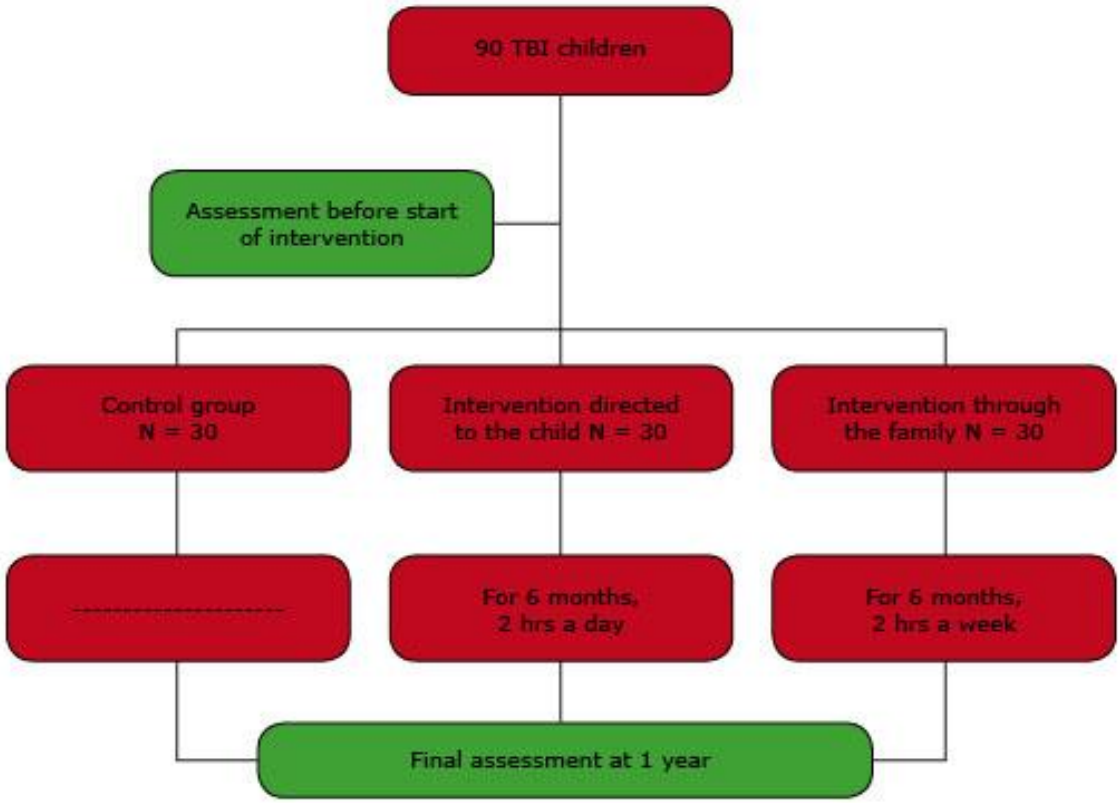
1. Randomized comparative clinical trial with blind evaluator

The study sample was to be 90 patients aged between 6 and 18 years with a history of moderate or severe TBI, acquired at least 6 months prior to inclusion in the study. Those patients with previous diagnoses of serious psychiatric disorder, those presenting an intelligence quotient below 70 points and those who had severe sensory and motor deficits that could interfere with the administration of assessment tests were excluded from the study.

Prior to the inclusion of the participants into 3 study groups, a neuropsychological, psychopathological and functional assessment was conducted. The sample was randomly distributed between the robot stimulation group and the parental intervention group. Those participants who for reasons of location could not attend the working sessions were assigned to the control group.

Initial design of the sample:



Rehabilitation sessions for children

The cognitive rehabilitation treatment through robotics lasted for 6 months, at a rate of 2 hours a day 5 days a week.

It was decided to work through a robot to encourage adherence to treatment. The robot was programmed by the La Salle team and activities were designed by our team. From meetings between the two collaborating centers in the project (Hospital San Juan de Dios and La Salle), clinical intervention program needs and the technological solutions were defined. The meetings were held weekly for 3 months. The main objective of this program was to achieve ecological exercises, i.e. exercises which were very applicable to the child's daily life. This ecological line led to the proposal for the program's intervention, which is divided into 3 modules:

1) **Virtual pet module.** This module was designed to provide feedback to patients on their implementation during rehabilitation with the ultimate goal of enhancing their motivation and adherence to treatment. The virtual pet is sensitive to the patient's performance and execution in the various proposed activities during the intervention program, so that the robot/virtual pet would be sad or happy depending on how these activities were undertaken (activities within the schedule marked by therapists, taking care of the robot's battery, or remembering to turn the robot off in the evening to save battery life). There are other functions, like feeding it, dressing it, taking it to the doctor, telling it how the day has gone (journal or diary) that help us work on motivation and responsibility in children.

2) **Personal school diary module.** This specific module was designed with the objective that the patient should organize his or her time by using an application with calendar, alarm and clock.

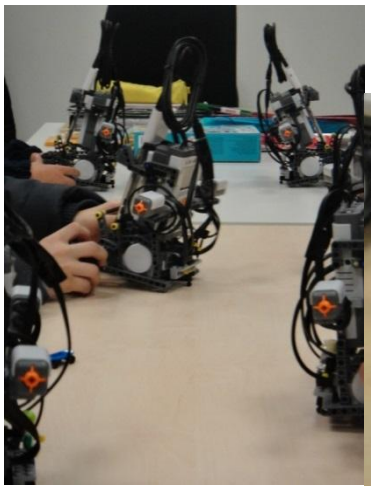
3) **Cognitive stimulation module.** This module includes specific activities for working on attention functions, memory, language, reading and writing and executive functions, and represents the central axis of the neuropsychological rehabilitation program. The difficulty of the exercises is determined by the age of the child and their grade. The academic content of their school year indicated the type of expertise that they should gain. The objective of these activities is not to work directly on the school content, but to incorporate them to work on the cognitive functions already described.

Before each exercise, guidelines are provided to give the children some self-instructions in order to focus attention during the performance of the task, to plan to optimize the execution or give mnemonic rules to improve memory.

During the hospital sessions, the following areas were also targeted:

1. Group cohesion: the main objective consisted of cooperative group work. When the children worked on computers, they had an increase in self-esteem, responsibility, recognition, respect and self-confidence.
2. Emotional work with children (self-esteem). Among others, we targeted the development of sense of identity, self-reflection, personal awareness and awareness of uniqueness, and learning to respect others.
3. Behavior strategies through self-instructions. These were used mainly for working on planning and attention difficulties.
4. Strategies for establishing routines and habits in everyday life. These were worked on with the aim of improving the daily planning and facilitating the accomplishment of everyday tasks.
5 Exercises for cognitive stimulation through dynamic exercises. Mainly to boost processing speed, since it is a very common sequela to brain damage.

Robot photos:



Parental intervention also lasted 6 months (22 sessions) at a rate of 2 hours per week per group and 5 individual sessions with a therapist over 6 months of intervention. Finally there were three groups of parents.

Content of the 22 sessions:
-1st: Introductory: presentation, explanation of the treatment and development families' own goals.
-2nd: The brain: basic explanation about the neuroanatomy of the brain and the functioning of a healthy brain in order to understand the possible deficits that brain damage causes.
-3rd to 5th: Blog dedicated to behavior at home, how to establish habits, schedules, give orders or make rules, increase positive behaviors and decrease negative behaviors.
-6th to 11th: Blog dedicated to school, mainly dedicated to how to organize academic work, time for homework, studying strategies, how to treat TBI problems in literacy or mathematics etc.
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-12th session: Dedicated to memory problems, understanding the differences between what is a memory problem or an attention problem.
-13th session Dedicated to resolving conflicts mainly with teenagers, families were given strategies and techniques for resolving disputes.
-14th to 19th block mood: 6 sessions were devoted to talking about emotional problems that can lead the child with a TBI to experience sadness, emotional lability or anxiety. Tools were given to the parents to be able to detect and act. The restructuring of thought and social problems that these children may experience was discussed. A session was devoted to discussing self-control and anger control in children.
-20th session: Dedicated to talking about parents, the impact caused by the TBI to the family, how it had impacted on personal, work and other aspects of their lives. Emotional ventilation session.
-21st meeting: Social work session given by the hospital's Head of Social Work, David Christmas. This session provided information to parents in relation to the degree of decline, guardianships, and current legal support appropriate to the disorder of their children.

-22nd session: Last working session with families. It did not provide new information, instead, we reviewed the contents worked on during 6 months of treatment and each family individually drafted a roadmap for their child taking into account from that moment on what needed to be worked on and how. The objective was that parents should end the session feeling that they knew what they would have to do at each moment, and that if they did not they would know where to find the information.

At the same time, contact was made with all the homeroom teachers of the children participating in the parent group. Parent-teacher conferences were held for each child. Meetings were held with tutors and other teachers at different schools.

As part of the study design, a re-evaluation, neuropsychological, psychopathological and functional monitoring was performed 3 months after starting the intervention phase, at end of treatment, and a year later

Patients

Despite all the media publicity that the project received, 76 families participated. After the briefing, more than half refused to be part of the treatment group and stayed in the control group. To optimize the statistical analysis, a match was made by sex and age between the control group and treatment group. In the end there were groups of 13 patients.

2. Results

As expected, the treatment group achieved better results in some of the measured parameters.

In the intervention group children, there were improvements in all the attentional, executive and behavior variables with a medium effect size. Moreover, this improvement is statistically significant in the Tower of London score and with a tendency to significance in reverse digits and in the externalizing index of the Child Behavior Checklist. Clinically, it means an improvement in cognitive flexibility, goal setting and behavior. In contrast, the control group maintained a stable profile between the two assessments.

In the parent intervention group, significant improvements with a tendency to significance in the variables were observed: thought and externalizing problems of the Achenbach Child Behavior Checklist, the Vineland social scale, the family pressure index and BRIEF (behavior scale for executive functions).

Analyzing the goals, we want to stress that not only was an improvement in externalizing problems found, but improvements in symptoms that make up the scale of thinking problems were found, symptoms that initially we did not think would be modified.

Given the sample size, further analysis is included to study the intragroup changes before and after the intervention (intragroup effect size).

Regardless of the time since the TBI, behavioral and cognitive improvements can be obtained through a specific intervention.

3. Relevance and possible implications

Despite the complications that we have had carrying out the study, the results have been positive.

The results indicate that designed tools (robot and the sessions for parents) can be applied to children who have suffered a moderate/severe TBI with a guarantee of success.

Every day there is more evidence of the effectiveness of the overall approach to the patient with acquired brain injury within the pediatric population. According to our knowledge, it is not currently standard practice in Catalonia to offer cognitive rehabilitation after a moderate/severe TBI as part of the therapeutic approach. Our results demonstrate the potential future of the cognitive rehabilitation in this group of patients.
Consequently, our results indicate that in a hospital setting, intervention in three scenarios should be contemplated:

-Family: offer psycho-education and strategies
-School: offer psycho-education and strategies
-Children: cognitive rehabilitation from a very practical approach (eco-friendly).

As already reported, the sooner the cognitive consequences of the TBI are treated, the better the prognosis. And this is not only important for the actual patient, but we must also take into account public resources to help people with sequelae of a TBI. A comprehensive approach at the time of injury would reduce these cognitive sequelae and therefore long-term public spending.

4. Generated literature

Marta Sanz-Palau, MD, Anna López-Sala, PhD, Marc Turón, MD, Laura Callejón-Póo, MD, Andrea Palacio-Navarro, MD, Cristina Boix, MD, Maria del Pilar Póo, MD, Roser Colomé, PhD (2016) *Executive Functions and Behavioral Outcome of Children with Moderate to Severe TBI in Spanish Pediatric Sample IN REVISION IN PEDIATRICS*

Neuropsychological rehabilitation after moderate and severe childhood TBI, a controlled study with robotics. IN FINAL WRITING

Efficacy of a new parent and school supported intervention after moderate and severe childhood TBI. IN FINAL WRITING