

## **CORNELL UNIVERSITY STUDY**

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### **STUDY DESIGN**

Our study was designed as a randomized, delayed entry trial of the effects of HBOT on children ages 1 to 5 years with moderate to severe CP. Enrollment criteria were 1) age between 1 and 5 years; 2) moderate to severe CP; 3) no evidence of brain malformation; 4) developmental delay of at least 33% in one area; 5) no active seizures for the previous 6 months. The protocol consisted of 40 one-hour sessions HBOT at 1.5 ATA. The sessions were scheduled twice a day, five days a week for four weeks. We did not design a double-blind study, in which some children would receive placebo treatments, for several reasons. First, this was a pilot study to see if there was any evidence of benefit for these children. Second we purposefully enrolled children of various ages and disability levels to evaluate the efficacy of HBOT in a range of affected children. Third, as time in the chamber is very expensive, we wanted as much information about treatment effects as possible. Finally, it seemed unethical to have parents devote so much time and energy to a potentially ineffective treatment.

### **DEMOGRAPHICS**

The study population included 26 children, ages 15 months to 5 years, with cerebral palsy secondary to prenatal insults, premature birth, birth asphyxia, and post-natal hemorrhage. The subjects were enrolled at a rate of 4 per month and matched roughly to age and severity. The average age at enrollment was 30 months. The average motor age was 7.5 months; the average cognitive and language ages were both 12 months. Nine had cortical visual impairments.

### **RANDOMIZATION**

After the initial intake the children were randomly assigned to receive HBOT (immediate group) or in 6 months (delayed group). The delayed group served as an untreated control group.

### **ASSESSMENT**

Intake assessments included a neuro-developmental assessment, Bayley II (cognitive assessment), Preschool Language Scale (language assessment), the Peabody Motor Scales (an assessment of gross and fine motor skills), and Pediatric Evaluation of Disabilities Inventory (PEDI), a parental report of specific skill in mobility, self-care, and social interactions. Assessments were conducted at four time points: T1 - at enrollment; T2 - after the immediate group received treatment; T3 - prior to the delayed group's HBOT, 5 months after enrollment; and T4 - after the delayed group's treatments. Two physical therapists that were blind to group status administered the Peabody and the parents completed the PEDI at all four time points. Child psychologists blinded to group status performed the Bayley II and PLS at T1 and T3.

### **RESULTS**

Eleven of the 12 children in the immediate group completed the 40 HBOT sessions. The twelfth child developed complex febrile seizures and was dropped from the study. Twelve of 14 delayed children received a full course of treatment. Two subjects developed seizures and could not participate. Assessments from each time point were available on 9 subjects from the immediate treatment group and from 11 children in the delayed treatment group.

### **SIDE EFFECTS**

The only side effect of treatment was barotrauma to the middle ear. Nine children and 7 parents required ventilation tube placement or myringotomies.

## **PARENTAL DIARIES**

The parents kept weekly diaries during the treatments. Over the month of treatments, 83% of parents noted a marked improvement in mobility; 43% saw a marked increase in attention and 39% reported a marked increase in language skills. Overall, there was some mobility improvement in 21 of 23 children (91%), in attention in 18 of 23 subjects (78%), in language in 20 out of 23 (87%) and in play in 12 of 23 subjects (52%). One family saw no improvement and six families saw minimal improvement, a total of 30%. Five families (22%) reported major gains in skills and 11 families (48%) claimed modest gains.

## **IMPROVEMENT IN VISION**

Four of the 9 children (44%) with cortical visual impairment, including two infants with no functional vision, had improvement in their vision noted by the families, vision therapists and ophthalmologists.

## **PEDI RESULTS**

There was a significant difference ( $p < 0.05$ ) in the improvement of scores on the mobility sub-domains of the PEDI for the time period T2 minus T1 in favor of the immediately treated group. For the period T4 minus T3, there was a trend favoring the recently treated delayed group ( $p < 0.058$ ). For the social function sub-domain of the PEDI, there was a trend favoring the more recently treated group 2.

## **BLINDED ASSESSMENTS**

The two groups were compared on changes in their Peabody scores for T2 minus T1 and T4 minus T3 and for changes in the Bayley II and PLS scores for T3 minus T1. There was no statistical difference in the change scores on any of the blinded assessments.

## **DISCUSSION**

There are several reasons why our blinded assessments did not show a significant difference while parental reports and observations during therapy saw gains. First, our sample size was quite small and only very dramatic changes would be detected. Second, not all the children were cooperative and happy during their evaluations; we had a student, blind to the group status, review the videotapes of the PT sessions and rate the child's behavior. There was a strong correlation between the child's mood and score; happy kids did better. Third, the instruments we chose as assessment tools are insensitive to the changes that were reported by the parents and observed by the unblinded staff.

The improvements in motor function did not translate into immediate functional gains. Most development tools available required motor dexterity and expressive language skills, areas specifically affected by CP. A better, more sensitive evaluation would involve a skilled professional observing the child at home or in school over a several-hour period.

## **CONCLUSION**

Our conclusion is that, for some children with moderate to severe CP, there is evidence that HBOT improves motor skills, attention, language, and play. For some, an increase in vision was noted. These are not miraculous changes. These children all still have CP, but there are substantial improvements.

In follow-up interviews over 6 months, it was found that the changes in spasticity were most likely to diminish over time, but the improvement in attention, language and play remained. This increase in attention is particularly important for children must be aware of their environment in order to learn. This represents a direct impact on cognitive functioning. The main differences between HBOT and traditional therapies are the rapid gains over time and the impact on cognitive skills which, in general, are not improved by PT, OT and speech therapies. Whether these changes are the direct result of increased levels of oxygen or the intensive contact with the parent or adult in the chamber or another combination of factors should be the focus of further study.