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Hyperbaric Oxygen Therapy for Children with Cerebral Palsy: Jebsen-Taylor test of Hand Function

By

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Abstract

Despite lack of scientific evidence, hyperbaric oxygen therapy (HBO_2) has been used as a treatment for children with cerebral pa'sy (CP). Recently, a multi-centre randomised, double-blind, placebo-controlled trial assessed the efficacy of HBO_2 therapy for children with CP. Using the same cohort, the purpose of this study was to examine the effectiveness of HBO_2 therapy on hand function using the Jebsen-Taylor test. All children received 40 treatments over a 2-month period. HBO_2 treatments were 60 minutes with 100% O_2 at 1.75 atmospheres absolute (ATA). Placebo treatments were also 60 minutes with air (21% O_2) at 1.3 ATA. Seventy-eight children with CP, aged 3-12 years completed pre and post hand function assessments. Hand function was evaluated using one quantitative measure (time) and three qualitative measures. There were no significant changes between baseline and follow-up tests for any of the measures, although both experimental and control groups improved ($p = 0.08$) their total times for the Jebsen test. The HBO_2 group improved by 54.5 seconds (8.8%) while the placebo group improved by 47.8 seconds (7.7%). The results indicate that HBO_2 therapy did not enhance the hand function of children with CP.

Résumé

Malgré l'absence d' évidences scientifiques, l'oxygénothérapie hyperbare (HBO_2) a été utilisée comme traitement chez des enfants atteints de paralysie cérébrale (CP). Les résultats d'une étude pilote réalisée récemment sur un groupe de patients avec CP assignés d'une façon aléatoire au groupe expérimental ou placébo, semblent suggérér un effet positif de ce traitement. Le but de la présente étude était d'examiner sur ce même groupe de sujets l'efficacité de la HBO_2 objectivée par le test de motricité fine de Jebsen-Taylor. Tous les enfants ont subi 40 traitements HBO_2 étalée sur une période de 2 mois. Au cours du traitement HBO_2 d'une durée de 60 minutes, le sujet reposait allongé dans une chambre hyperbare dans laquelle l'atmosphère était maintenue à une pression de 1.75 atmosphère absolue (ATA) et 100% oxygène. Le traitement placebo d'une durée de 60 minutes également était réalisée dans la même chambre hyperbare dont l'air ambiant était constitué de 21% O_2, 79% N_2 à 1.3 ATA. Soixante dix-huit enfants CP de 3 à 12 ans, ont complété l'évaluation de la dextérité manuelle avant et après la période expérimentale. Cette évaluation comportait une mesure quantitative (temps nécessaire à la complétion de l'épreuve) et trois mesures qualitatives de la facilité à accomplir la tâche demandée. Les résultats n'ont pu démontrer aucune modification des mesures quantitatives. Une amélioration ($p = 0.08$) dans le temps nécessaire à la complétion de l'épreuve Jebsen-Taylor a toutefois été observée tant pour le groupe expérimental que pour le groupe témoin. Le groupe ayant subi le traitement HBO_2 a progressé de 54.5 secondes (8.8%) tandis que le groupe témoin ayant subi le traitement placébo a progressé de 47.8 secondes (7.7%). Les résultats suggèrent que le traitement HBO_2 n'a pas d'effect particulier sur la dextérité manuelle des enfants atteints de la paralysie cérébrale.

Effect of Hyperbaric Oxygen Therapy on Hand Function in Children with Cerebral Palsy

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Introduction

Hyperbaric Oxygen (HBO_2) therapy involves the intermittent inhalation of 100% oxygen under greater than 1 atmosphere (atm) of pressure. This form of therapy, once restricted to the treatment of diving accidents, is now recognised officially by the Undersea and Hyperbaric Medical Society (UHMS) (Hampson, 1999) as a primary or adjunct treatment for 13 medical conditions. The benefits of HBO_2 therapy for UHMS approved conditions have resulted in curiosity among the scientific community regarding the potential beneficial effects of HBO_2 for other medical conditions.

HBO_2 treatments for patients with neurological diseases were first publicized in 1979 (Machado, 1989). HBO_2 has been used to treat head injuries and stroke with several studies demonstrating diminished symptoms and improved quality of life (Hart, and Thompson., 1971; Holbach et al., 1976; Anderson et al., 1991). The positive outcomes have been attributed to hyperoxygenation in the plasma and the vasoconstricting effect of HBO_2, which diminishes intracranial pressure and swelling. Furthermore, it has been proposed that these mechanisms may stimulate the "ischemic penumbra", the tissue surrounding the injured area of the brain, rendering it more active and viable (Astrup et al., 1981). It has been postulated that the hypoxic zone surrounding the necrosis may be reactivated metabolically or electrically by hyperoxygenation (Grim et al., 1990). Metabolic changes in brain tissues have been documented in a few traumatic brain-injured and stroke patients (Neubauer and End., 1980; Nighoghossian and Trouillas., 1995). A design limitation in these studies has been the absence of a control group.

CP is defined as a collection of diverse syndromes characterised by disorders of movement and posture caused by a non-progressive injury to the immature brain. This injury to the brain can occur in the prenatal, perinatal or postnatal periods (Molnar, 1985). The combination of immaturity, fragile brain vasculature, and the physical stresses of prematurity

combine to predispose these children to compromised cerebral blood flow (Bozynski et al., 1988). There is no cure for children with CP. Current therapies involve extensive physical therapy, pharmacology and surgery. There is scientific support for physiotherapy in assisting children in the short-term management of their condition, especially spasticity (Mayo, 1991). It is also clear that the long-term benefits of physiotherapy in the treatment of CP remain speculative and somewhat inconsistent (Herndon et al., 1987; Mayo, 1991; Palmer et al., 1988). Medications for spasticity are limited and often have side-effects. Botulim toxin A has been shown to improve spasticity and gait in children with CP (Koman et al., 1993). Surgery, particularly dorsal rhizotomy, is the most effective treatment in reducing spasticity, but many children with CP are not appropriate candidates for this procedure (Park and Owen, 1992; Peacock and Staudt, 1990).

In recent years, organizations such as Hyperbaric Oxygen Trust (HOT4CP) in England have promoted, via the internet, HBO_2 therapy for children with CP. Families, at great financial expense, have sought out HBO_2 facilities for treatments even though there is a lack of scientific evidence to document the therapy. In response to demand for treatments in Quebec, Canada, a pilot study was conducted for 25 children with CP (Montgomery et al.,1999). Following 20 HBO_2 treatments, there were improvements in gross motor function, fine motor function, spasticity, as well as positive feedback from parents. Following this study, a multicenter placebo controlled randomised clinical trial was conducted to assess the efficacy and safety of HBO_2 therapy for children with CP (Collet et al., 2000). One hundred and eleven children with CP were randomly assigned to HBO_2 ($n = 57$) or placebo ($n = 54$). The main outcome measure in this study was gross motor function with secondary outcomes of attention, working memory, speech and functional disability. For all outcomes, both groups improved significantly, however no differences emerged between the HBO_2 and placebo groups. It was concluded that HBO_2 therapy did not improve the condition of children with CP when compared to placebo. The important improvement observed in both groups for all dimensions warrants further investigation.

This study examines the fine motor function of the children who participated in the Quebec study (Collet et al., 2000). The purpose was to evaluate the effect of 40 HBO_2 treatments on hand function as assessed by the Jebsen-Taylor test in children with CP, aged 3-12 years.

Methods

Subjects

This study was a multi-centre, randomised, double-blind, placebo-controlled trial. The subjects were drawn from 17 rehabilitation centres in Quebec. The referrals were from their treating therapists who were aware of the inclusion/exclusion criteria for the study. Inclusion criteria consisted of a diagnosis of cerebral palsy with a history of hypoxic-ischemic event(s) in the peri-natal period, an age range from 3 to 12 years, a motor developmental age between 6 months and 4 years and a psychological developmental age greater than 24 months. Exclusion criteria included: chronic otitis, asthma, thoracic surgery, convulsions, behavioural problems, recent botulinum toxin injections (last 6 months), or orthopedic surgery (last 6 months), dorsal rhizotomy within the last two years and previous exposure to HBO_2 therapy. Drugs affecting concentration and anti-spasticity medication were discontinued 6 weeks prior to this trial. Prior to randomization, the HBO_2 physician performed a medical examination, including a neurological assessment and a systematic review of all inclusion/exclusion criteria.

Informed consent was obtained from the parents or legal guardian of each child before participation in the study. The HBO_2 intervention was administered at five centres in Quebec. Ethical review committees at the five institutions as well as the provincial ethics committee approved the study.

The rehabilitation centres referred 196 children to the study. From this group, 58 children were excluded because they did not meet the inclusion/exclusion criteria and 27 refused to participate. Therefore, 111 children with CP were randomized into two groups (54 placebo and 57 HBO_2). There were 52 males and 59 females. The population included children with spastic

diplegia (n = 48), spastic quadriplegia (n = 38), spastic double hemiplegia (n = 19), spastic hemiplegia (n = 2) and hypotonia (n = 3). Baseline characteristics at inclusion are summarized in Table I.

HBO_2 and Placebo Treatment Protocols

The HBO_2 treatments were administered at five hyperbaric centres. Two centres used monoplace chambers and three centres had multi-place chambers. Subjects underwent forty 60-minute HBO_2 treatments five days a week for 8 weeks. Treatment session for the HBO_2 group included compression and decompression and a 60-minute treatment with 100% oxygen at 1.75 ATA. The placebo group received a compression and decompression time that closely resembled the HBO_2 group with air (21% oxygen) administered for 60 minutes at 1.3 ATA. This level was sufficient for pressure to be felt in the ears. It took approximately 8 minutes to pressurize the chamber to 1.75 ATA and approximately the same time was used for compression to 1.3 ATA in the placebo group since it was important that total treatment times were similar for both groups. Following the 60 min treatment, the chamber was decompressed from 1.75 (or 1.3) to 1.0 ATA in approximately eight minutes. Each centre standardized their procedures so that compression and decompression times were similar. Specific procedures were developed at each centre to keep parents and children blind as to the nature of the intervention.

No children received physical or occupational therapy during the intervention.

Evaluations

In each domain of rehabilitation, the same therapists conducted pre and post treatment evaluations. The post evaluations were conducted in the week following completion of 40 treatments. The tests have been described by Collet et al (2000). The tests measured gross motor function, hand function, speech and language, visuo-spatial and verbal working memory, visual and auditory attention, and pediatric evaluation of disability inventory.

Evaluations of Hand Function

Hand function was evaluated by one quantitative and three qualitative components that were derived from observations of tasks in the Jebsen-Taylor test. The quantitative evaluation was the Jebsen-Taylor test (Jebsen et al., 1969) which is designed to evaluate the hand coordination, finger and palm grasping ability, strength, pinching force, and range of motion of the fingers and hand. In its standard application, the Jebsen-Taylor test is comprised of seven items: 1) turning over 3 X 5-inch cards; 2) picking up small objects and placing them in a container; 3) simulated feeding; 4) stacking checkers; 5) moving empty large cans; 6) moving weighted large cans; and 7) writing a short sentence. Considering the age of this subject population, the writing task was omitted.

The Jebsen-Taylor test is frequently used in evaluating the effectiveness of a specific treatment or intervention or in assessing the degree of disability of an individual. The test is deemed reliable and valid with coefficients for the sub-tests ranging from 0.60 to 0.99 (Jebsen et al., 1969). Test-retest reliability is high with $r = 0.97$ and 0.98 for total time of the dominant and non-dominant hands in children with hand disorders (Taylor et al., 1973). One of the main objectives of the Jebsen-Taylor test is to assess patterns of hand function commonly used in activities of daily living. The test assesses speed and not quality of performance (Spaulding et al., 1988). The timed values can be compared to normative values for the appropriate age group. Among the normal child population, test items are usually completed in 15 seconds or less with no practice effects (Taylor et al., 1973). Although developed for adult populations, the Jebsen-Taylor test can be used to assess the hand functioning of children with neurological impairments and children with CP (Taylor et al., 1973).

Therapists in a hospital setting performed the evaluations. The therapists, children and parents were all blinded to the treatment intervention. The therapist had no contact with the children during the HBO_2 or placebo treatments.

Subjects were seated at a standard height table during the test. The chair was adjusted depending on the height of the child. The sub-tests were presented in the same sequence, administered in the same manner and were always performed first with the non-dominant hand. After the instructions were given, the child was asked if he/she understood the task to be performed. Each task was timed by the therapist and a score in seconds was recorded for each sub-test for both the dominant and non-dominant hand. A video camera was positioned to record the subject's performance. Each child was recorded on a separate tape for the pre and post-tests. Research assistants, blinded to time (pre and post) and type of intervention (HBO_2 and placebo), viewed and scored the tapes for the quantitative and qualitative hand function components. Tapes were only viewed following completion of the study.

The quantitative assessment for each of the six items was comprised of the total time (s) for the non-dominant (ND) and dominant (D) hands. The maximum time for each item was 360 s (180 s for each hand). The sample for this study included only the children who were able to complete three of the six items in less than 360 s. Of the 111 subjects that performed the baseline evaluation, 107 completed the intervention. Only 36 children from the HBO_2 group and 42 children from the placebo group performed both the pre and post-tests within the specified time limits. The 29 children who did not complete at least three of the six sub-tests of the Jebsen-Taylor test were excluded from the data analysis.

Hand movements were also assessed qualitatively by viewing videotapes of the child performing the Jebsen-Taylor test. Three components were examined: 1) the number of correct responses of the six items of the Jebsen-Taylor test, 2) a modification of the Quality of Upper Extremity Skills Test (QUEST) (DeMatteo et al., 1993) and 3) a classification of the child's overall ability on each item. For each sub-test the number of items (i.e. cards) correctly manipulated was recorded. For example, to obtain the maximum score (10) on the first item of the Jebsen-Taylor test, the child must have turned 5 cards in less than 180 s for both non-dominant

and dominant hands. The maximum scores for each item are included with the results in their respective tables.

The QUEST was developed by De Matteo et al (1993) specifically for the pediatric CP population. It is a criterion referenced measure which evaluates the quality of movement in hand function and postural responses. The grasp items are based on normal grasp patterns that develop between birth and 18 months of age (DeMatteo et al., 1993). Scoring is related to the severity of the disability and is independent of age. A child without a disability at 18 months of age should score perfectly in all areas of the QUEST except grasp.

The QUEST includes four categories. For this study, only two of the four domains were used to assess hand function with four elements derived from the dissociated movements category and 11 items from the grasp category. A postural response was included for each item. Two points were assigned for the most advanced movement, and one point for less ideal or absent movements. A normal posture was classified as one where the head was not bent left, right, flexed or extended and the trunk was not bent forward or laterally. The total score was heavily weighted by the grasp category.

Classification of the child's overall ability for each of the Jebsen-Taylor tasks was assessed with a 5-point rating scale. The classification of quality of performance of each task was rated as: ideal (5), adequate (4), guided (3), inadequate (2) or absent (1). Subjects received scores for each task for both their dominant and non-dominant hands with a maximum score of 10. The **ideal** classification corresponded to typical movement patterns and successful completion of the item. The **adequate** classification corresponded to completion of the task but with some difficulty or hesitation. The **guided** classification corresponded to initiating the movement (i.e approaching the target or grasping the object) but unable to complete the item. The **inadequate** classification corresponded to initiating the movement but unable to grasp or hold the object limiting execution of the task. The **absent** classification corresponded to inability to guide movement, which appeared arbitrary, and without trajectory.

Reliability

Two blinded research assistants with no knowledge as to the time of evaluation or group assignment were responsible for video analysis. Inter-rater reliability was determined by comparing scores for 25 tapes. The inter-rater reliability coefficients were 0.99 for total time to complete the Jebsen-Taylor test, 0.98 for total number of correct responses, 0.97 for the qualitative assessment using the modified QUEST, and 0.99 for the overall classification.

Data Analysis

Groups and time (pre and post) were compared using a univariate 2x2 repeated measures analysis of variance (ANOVA). Results are presented as means and standard deviations for HBO_2 and placebo groups at pre and post evaluations. Statistical significance was determined if $p < 0.05$. The analyses were performed with Systat 9.0 for Windows.

Results

Speed of Performance

Table II summarizes the speed of performance of tasks for the Jebsen-Taylor test. Overall, there was no significant improvement from pre to post-test however, a trend *($p=0.08$)* for each group emerged with improvements on the post-test for both groups. The HBO_2 and placebo groups did not differ from each other. Both groups obtained faster scores on the post-test. The HBO_2 group improved by an average of 54.5 s (8.8%) while the placebo group improved by an average of 47.8 s (7.7%).

The sub-tests that took the most time for our sample of children with CP were simulated eating and moving weighted cans. The weighted cans sub-test took on average 19.9 % of the total time for our children with CP. In comparison, children without disabilities took 11% (6-7 years) and 10% (8-9 years) of total time to complete this task (Jebsen et al., 1969).

Correct Responses

Table III summarizes the results based on correct responses for the 6 items of the Jebsen-Taylor test. Both groups did not improve from pre to post-test. In addition, there was no difference between the HBO_2 and placebo groups. At the pre-test, the HBO_2 and placebo groups had overall scores of 51.5 and 51.6, respectively, which represented 86% of the maximum scores. While this percentage may appear to be high, it should be recognized that children who were unable to complete 3 of the 6 tests in the specified time limit were excluded from the sample due to severe limitations of their hand function capabilities. Each of these 29 children had less than 50% correct responses.

Modified QUEST

Table IV summarizes the results of the qualitative analysis using the modified QUEST. There was no change in modified QUEST score from pre to post tests. There were no differences between the groups in the quality of movements. At the pre-test, the HBO_2 group had a slightly higher score compared to the placebo group however at post-test, both groups had identical results. At the post-test, the HBO_2 and placebo groups had overall scores of 195, which represented 73% of the maximum scores.

Overall Classification

Table V summarizes the hand functional evaluation based on overall classification. These results show no difference from pre to post-tests and no difference between HBO and placebo groups. Both groups had an overall classification score of 50, which represented 83% of the maximum score.

Since the purpose of this study was to compare the effect of HBO_2 treatments on hand function, the primary comparison was between HBO_2 and placebo groups. The HBO_2 and placebo groups did not differ from each other in speed of performance, number of correct responses, modified QUEST evaluation, and overall performance for the Jebsen-Taylor test.

Discussion

CP is characterized by impaired motor control. Children with CP have impaired hand function, which includes poor dissociation of finger movements. They usually grasp with the entire hand, using a slow and clumsy power grasp (Brown et al., 1987; Ingram, 1966). These difficulties were apparent in our sample's performance on the Jebsen-Taylor test. Our children with CP (mean age = 7.2 years) averaged 596 ± 72 s to complete the Jebsen-Taylor test. Normative data for children without disabilities (Jebsen et al. 1969) reveal total time scores of 171 s (6-7 years) and 151 s (8-9 years). Children who have mild cerebral palsy often demonstrate decreased control of intrinsic hand muscles and poor active control of metacarpophalangeal flexion, finger abduction, finger adduction and interphalangeal extension (Danella and Vogtle, 1992) as well as movements necessary for efficient hand manipulation of objects (Exner, 1992).

The sub-tests that took the most time for our sample of children with CP were simulated eating and moving weighted cans. Children with Duchenne muscular dystrophy also have difficulty with the weighted can task and the simulated eating task (Hiller and Wade, 1992; Wagner et al, 1993). Lack of proximal muscle strength most likely contributed to their difficulty in lifting the heavy objects (Hiller and Wade, 1992). Like the children with Duchenne muscular dystrophy, our children with CP would also tip and push the can onto the board or grasp the edges of the can. The difficulty with the simulated feeding sub-test has been attributed to immature fine motor control and coordination (Hiller and Wade, 1992).

Improvements following intervention in this study were limited to quantitative measures. Both the HBO_2 and placebo groups improved the speed of execution for completing the Jebsen-Taylor test. The improvements from pre to post tests were 54.5 s (8.8%) and 47.8 (7.7%) for the HBO_2 and placebo groups respectively. Given the similarity of outcomes in both groups, the benefits cannot be attributed to the HBO_2 treatments. The significant improvements in Jebsen-Taylor scores in both groups occurred over a two-month period and are clinically important.

The children with CP in this trial also improved in gross motor functioning, as measured by the Gross Motor Function Measure (GMFM) test (Collet et al., 2000). The GMFM score increased by 2.9 points (5.1%) for the HBO_2 group and 3.0 points (4.5%) for the placebo group. There was no systematic trend of difference in favour of either group with the positive results persisting three months after the intervention. These changes were independent of age at intervention. Collet et al. (2000) attributed these findings to four possibilities: a learning effect, a participation effect, a pressure effect and/or a hyperoxygenation effect. It is unlikely that a learning effect influenced the time scores for the Jebsen-Taylor test since the sub-tasks assess broad aspects of hand function commonly used in activities of daily living and do not improve with practice (Taylor et al., 1973). The participation effect may have occurred as a consequence of the intervention, which was a positive environment for both children and parents. It has previously been shown that positive environments accelerate intellectual development, emotional development, social development, control and self-esteem (Pervin, 1993). The placebo treatments in this trial used 21% oxygen at 1.3 ATA. It was necessary to apply a minimal pressure during the placebo treatment in order for occupants in the chamber to experience pressure on their ears and maintain a "blinded" state regarding group assignment. The placebo treatment increased the arterial partial pressure (P_aO_2) from 100 mm Hg in a normobaric, normoxic environment to 148 mm Hg. It is unlikely that this pressure would "reactivate the penumbra" as is claimed. In comparison, the HBO_2 treatment increased the P_aO_2 from 100 mm Hg to about 1200 mm Hg.

The improvements in gross motor function (Collet et al., 2000) and hand function in this trial are important and occurred over a time frame when physical therapy was absent from their program of treatment. Two studies (Russell et al., 1990; Trahan and Malouin., 1999) have documented increases in GMFM scores of 3.7 and 7.0 % in children with spastic diplegia following intensive physical therapy programs lasting 6 and 8 months, respectively.

In summary, the results of this study show no significant changes from pre to post tests for any of the measures, although both the HBO_2 and placebo groups improved ($p = 0.08$) their

total times for the Jebsen test. The HBO_2 group improved by 54.5 s (8.8%) while the placebo group improved by 47.8 s (7.7%). The qualitative assessments were unchanged from pre to post tests. The results indicate that HBO_2 therapy did not improve the hand function of children with CP.

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Table I

Characteristics of the Children (X ± SD) at entry into the study

	HBO				Placebo			
Statistic	n	%	Mean	SD	n	%	Mean	SD
Age (years)	57		7.2	2.6	54		7.2	56
Developmental age (months)	57		21	18	54		21.9	16
Gender								
Male	30	52.6			22	40.7		
Female	27	47.4			32	59.3		
Type of CP								
Spastic Diplegia	24	43.9			24	44.4		
Spastic Quadriplegia	23	40.4			15	27.8		
Spastic Double Hemiplegia	7	12.3			12	22.3		
Spastic Hemiplegia	1	1.8			1	1.9		
Hypotonia	1	1.8			2	3.7		

Table II

Functional Evaluation of the Hand (X ± SD) – Time (seconds) *

Tasks	Max Score (s)	HBO_2 (n = 36)		Placebo (n = 42)	
		Pre	Post	Pre	Post
Turning cards	360	63.8 ± 11.0	58.2 ± 8.9	63.3 ± 10.2	52.4 ± 8.2
Picking up small objects	360	69.5 ± 10.7	70.4 ± 10.4	76.6 ± 9.9	74.5 ± 9.6
Simulated eating	360	194.6 ± 21.6	172.8 ± 20.8	194.2 ± 20	186.9 ± 19.3
Stacking checkers	360	64.5 ± 15.7	51.6 ± 13.3	82.4 ± 14.5	69.5 ± 12.3
Moving large cans	360	103.9 ± 18.8	93.1 ± 15.0	85.0 ± 14.6	80.4 ± 13.9
Moving weighted cans	360	124.8 ± 19.1	120.3 ± 18.9	120.7 ± 17.6	109.4 ± 17.5
Total	2160	621.3 ± 78.7	566.8 ± 71.3	622.4 ± 72.9	574.6 ± 66.2

* Scores are the sum of the dominant + non-dominant hands.

Table III

Functional Evaluation of the Hand (X ± S.D.) – Correct Responses *

Task	Max Score	HBO_2 (n = 36)		Placebo (n = 42)	
		Pre	Post	Pre	Post
Turning cards	10	9.4 ± 0.2	9.7 ± 0.1	9.7 ± 0.2	9.8 ± 0.1
Picking up small objects	12	11.4 ± 0.2	11.4 ± 0.1	11.3 ± 0.2	11.7 ± 0.1
Simulated eating	10	7.0 ± 0.6	7.4 ± 0.6	6.4 ± 0.5	6.8 ± 0.5
Stacking checkers	8	7.3 ± 0.3	7.6 ± 0.1	6.9 ± 0.2	7.4 ± 0.1
Moving large cans	10	9.2 ± 0.3	9.0 ± 0.4	8.8 ± 0.3	9.0 ± 0.3
Moving weighted cans	10	8.0 ± 0.5	7.5 ± 0.5	7.7 ± 0.4	8.1 ± 0.5
Total	60	51.5 ± 1.8	52.5 ± 1.5	51.6 ± 1.6	53.1 ± 1.4

* Scores are the number of items in each task the child successfully completes.

Table IV

Functional Evaluation of the Hand (X ± S.D.) – Modified QUEST *

Task (s)	Max Score	HBO_2 (n = 36)		Placebo (n = 42)	
		Pre	Post	Pre	Post
Turning cards	44	33.7 ± 1.1	32.0 ± 1.2	33.6 ± 1.0	32.1 ± 1.1
Picking up small objects	52	41.9 ± 1.0	41.3 ± 1.2	40.4 ± 1.0	39.1 ± 1.1
Simulated eating	56	35.6 ± 2.3	36.9 ± 2.3	31.1 ± 2.1	36.6 ± 2.1
Stacking checkers	52	40.9 ± 1.6	40.4 ± 1.5	38.8 ± 1.5	39.7 ± 1.4
Moving large cans	28	23.1 ± 0.9	22.1 ± 1.0	23.0 ± 0.8	23.3 ± 1.0
Moving weighted cans	32	23.8 ± 1.4	23.6 ± 1.4	24.3 ± 1.3	24.5 ± 1.3
Total	264	196.8 ± 7.2	195.4 ± 7.4	191.4± 6.7	195.5 ± 6.9

* Scores are the sum of the dominant and non-dominant hands based on a modification of the QUEST.

Table V

Functional Evaluation of the Hand (X ± S.D.) - Classification *

Task (s)	Max Score	HBO_2 (n = 36)		Placebo (n = 42)	
		Pre	Post	Pre	Post
Turning cards	10	8.8 ± 0.2	9.1 ± 0.1	9.0 ± 0.2	9.0 ± 0.1
Picking up small objects	10	8.9 ± 0.2	9.1 ± 0.1	8.9 ± 0.2	8.9 ± 0.1
Simulated eating	10	7.3 ± 0.4	7.2 ± 0.4	6.9 ± 0.4	6.9 ± 0.4
Stacking checkers	10	8.7 ± 0.3	8.6 ± 0.2	8.6 ± 0.2	8.8 ± 0.2
Moving large cans	10	8.5 ± 0.3	8.5 ± 0.3	8.6 ± 0.2	8.3 ± 0.2
Moving weighted cans	10	8.0 ± 0.3	7.8 ± 0.4	7.6 ± 0.3	8.1 ± 0.3
Total	60	50.4 ± 1.6	50.3 ± 1.4	49.9 ± 1.4	50.2 ± 1.3

Scores are the sum of the dominant and non-dominant hands based on overall ability to perform the item.

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Appendices

Appendix 1

Review of Literature

HBO_2 (hyperbaric oxygen) therapy is the intermittent inhalation of 100% oxygen under greater than 1 atm of pressure. The most significant features of this treatment are the mechanical and physiological effects of increased pressure and the physiological effects of increased oxygen, or hyperoxia (Grim and Gottlieb, 1990). These features have been shown to have beneficial effects in the treatment of many acute conditions such as decompression sickness and air embolism, conditions in which the shrinking of air bubbles in the human body is of critical importance. Moreover, HBO_2 is frequently used in the treatment of carbon monoxide (CO) poisoning, situations in which amounts of oxygen are essential in diminishing the concentration of CO in the tissues. It has also been found that the body's immune system is directly influenced by the concentration of oxygen in the plasma and tissues with higher amounts enhancing wound and tissue healing.

Hunt et. al. (1969) highlighted the critical role that oxygen plays in maintaining wound metabolism, a process which involves the production of energy, collagen synthesis and cell proliferation. HBO_2 seems to provide an unquestionable benefit in such cases where the immune system is seriously compromised. Similarly, it is recognized throughout the HBO_2 literature that the amount of oxygen available to the tissues is crucial for tissue repair and healing. (Hunt, 1988)

Tibbles and Edelsberg (1996) stressed the importance of adequate oxygen tension for the body's immune system and it's critical role in the treatment of CO poisoning. The authors also suggest that a number of other diseases and conditions could be treated with HBO_2 therapy, however only a limited number of such conditions have been officially approved for HBO_2 therapy by the governing medical body in this field, the UHMS (Undersea and Hyperbaric Medical Society). Specifically, the UHMS has approved the administration of HBO_2 treatment

for: air or gas embolism, carbon monoxide poisoning, clostridial myocitis and myonecrosis (gas gangrene), crush injury, compartment syndrome, and other acute traumatic ischemias, decompression sickness, enhancement of healing in selected pr· blem wounds, exceptional blood loss (anemia), intracranial abscess, necrotizing soft tissue infection, osteomyelitis (refractory), delayed radiation injury (soft tissue and bony necrosis), skin grafts and flaps (compromised) and thermal burns.

Cerebral Palsy

Although HBO_2 has only received medical approval for these mentioned conditions, there exist numerous conditions which, based on their etiology and symptoms, merit some degree of scientific investigation in order to ascertain whether HBO_2 treatment would prove beneficial. One such disease which afflicts approximately 1-2 children per thousand, is cerebral palsy (CP). CP is defined as a collection of diverse syndromes characterised by disorders of movement and posture caused by a non-progressive injury to the immature brain. This injury can occur in the prenatal, perinatal or postnatal periods (Molnar, 1985). The condition may also cause learning disabilities, seizures, speech and language defects, visual-motor disorders, hearing loss, behavioural deficits and developmental delays (Kohn, 1990).

Classification of CP is based on the manifestation of the movement disorder as well as the number of limbs affected. Among the manifestations of the condition, a very common movement anomaly that the majority of children suffering from CP exhibit (70-80%) is spasticity (Kohn 1990). Spasticity is said to develop from damage to the cerebral cortex producing contractions of both agonist and antagonist muscles resulting in muscle rigidity. The majority of the children are affected in both the arms and legs, although the functioning of the legs is most compromised; this condition is referred to as diplegia. The most common diagnosis among this affected population is spastic diplegia.

Brain Injuries and HBO_2

Only limited research has focused on the effect of HBO_2 on CP symptoms; however, there has been research examining the effect of HBO_2 on recovery from strokes and closed-head injuries. These conditions, namely CP, stroke and head injuries, parallel each other in such a way that there is an initial edema or swelling usually followed by some neurological damage or tissue death. Although, as mentioned, strokes and head injuries have not been approved for HBO_2 treatment by the UHMS, there is some evidence to suggest that, with respect to these conditions, HBO_2 may be beneficial in improving patient outcome and alleviating associated symptoms.

Neubauer et al. (1994) examined the effect of HBO_2 treatments on a patient who had been in a coma for 28 days due to a head injury. The patient underwent a series of 60 minute treatments at 1.5 ATA twice per day for 14 days, followed by 106 treatments at 1.75 ATA, followed by 54 treatments at 1.5 ATA for a total of 188 treatments. During the course of and following the treatments, the authors noticed a filling of the right defect area and an increase in tracer uptake in the left parietal-occipital cortex. Moreover, the tissue surrounding the damaged area regained metabolic activity, leading the authors to contend that many brain injuries may include a large amount of recoverable tissue.

Neubauer and End (1980) studied the effect of HBO_2 on stroke outcome in 34 patients who had previously had an acute cerebral infarction and 88 patients believed to have had a complete stroke. Based on examinations from neurologists, physiotherapists, nurses and physicians, the degree of improvement in these patients was measured by reported symptoms of cerebral infarction and the signs of neurological dysfunction. Certain patients were treated at 1.5 ATA while others were treated at 2.0 ATA. Patients treated within four hours of their stroke received treatments of 1 hour in duration every 12 hours. If little improvement was measured, prolonged exposure (up to 2 hours) or more frequent treatments during the subsequent 24 hours were administered. Generally, after 10 treatments the number of treatments was reduced

although, there was great variability regarding treatment protocol depending on the onset of the stroke and their response to HBO_2 treatments. The stroke patients treated 4 hours after the onset were given HBO_2 treatments at the rate of 1 treatment per week for approximately 4 weeks and then once a month for maintenance. The patients frequently reported improvements in vision and hearing and a lessening in depression, agitation and dizziness. Furthermore, the subjects who received treatments months and sometimes years after their stroke often reported an improvement in the quality of their lives. This research literature seems to suggest that HBO_2 can be beneficial in improving the outcome of stroke patients.

Nighoghossian et al. (1995) examined the effect of HBO_2 treatments on 27 individuals, ranging in age from 20 to 75 years, who had experienced middle cerebral artery occlusion. All subjects were seen 24 hours after the onset and were randomly assigned to either an oxygen or a placebo group. There were 13 subjects in the placebo group and 14 in the HBO_2 group. The protocol involved 40-minute sessions daily for 10 days given at 1.5 ATA. The results showed a significant improvement for the HBO_2 group on the Orgogozo scale (a 100-point quantitative scale). A one year follow-up however yielded no differences in the scores obtained at the beginning of the study nor were there any differences between the placebo and the HBO_2 group at the one year follow-up. The authors concluded that HBO_2 might be effective in improving outcome in stroke patients, however studies with larger population sizes would be necessary before any firm conclusions could be made.

Holbach et al. (1976) examined the effect of HBO_2 on the outcome of 40 patients with cerebral infarction. Each patient had a series of 10 to 15 HBO_2 treatments performed daily at 1.5 ATA for 40 minutes. The patient's EEG (electroencephalogram) activity was analysed and the change in alpha-wave and beta-wave activity over the affected area was used as the measure of improvement. The authors found that in 27 % of the cases the improvement was considerable, in

53 % of the cases the patients had moderate improvement, while 20 % showed no change in condition.

Elto-ai and Montroy (1991) elaborate on the outcome of a 58 year old incomplete quadriplegic who suffered a concussion which subsequently lead to a coma state. The patient remained in a coma unresponsive to stimuli for approximately 2 months. The authors began HBO_2 treatments at 2 ATA for 90 minutes. There was a rapid improvement in the patient's neurological condition. After 24 treatments the patient was able to talk, eat and was fully responsive to stimuli. Even though the patient was wheelchair bound, he was able to return to the level of independence that he had experienced prior to the accident. While the authors concede that aspects of the recovery were mysterious, they attribute the successful recovery to the abundance of oxygen available to the patient during his intubation.

Rockswold et al. (1992) investigated the effects of HBO_2 treatment of severely brain-injured patients. The results of this study showed that HBO_2 reduced intra-cranial pressure and significantly decreased the mortality rate in severe head-injured patients: there was a 17 % mortality rate for the HBO_2 group, while the mortality rate among the control group was 32 %.

Although the above-mentioned literature appears to offer promising results with respect to HBO_2 and recovery from stroke, Anderson et al. (1991) conducted a double-blind prospective study, examining 39 patients between the ages of 20 and 90 years of age with an ischemic cerebral infarction. The subjects underwent HBO_2 treatments of 1 hour at 1.5 ATA with subsequent treatments every 8 hours until 15 treatments had been completed. Of the 39 patients, 27 terminated their treatments voluntarily. The results favoured the air-treated subjects. The authors stated that numerous articles involving both animal and human experiments have found benefits using HBO_2, however, their study did not yield conclusions demonstrating advantages and benefits of this type of treatment. The authors also emphasised the importance of using large

sample sizes in order to enable the detection of potential benefits while limiting the effect of unforeseen circumstances that may arise.

The results of these studies seem to suggest that in the cases of brain injury, namely stroke where there is ischemic tissue, HBO_2 has a positive effect of decreasing tissue edema, delivering supplemental amounts of oxygen to the damaged area and alleviating some of the symptoms sometimes for years after the original insult to the brain. HBO_2 has also been used experimentally in other diagnoses including multiple sclerosis (MS), spinal injuries and epilepsy, although the conclusions about HBO_2's efficacy in such circumstances remain equivocal.

Multiple Sclerosis and HBO_2

MS is a slowly progressing disease of the central nervous system (CNS) with inflammation of and demyelinization in the brain and spinal cord. Investigations related to the effects of HBO_2 on MS symptoms began in 1983 (Kleijnen and Knipschild, 1991).

Neubauer (1985) investigated the effect of HBO_2 on the improvement of symptoms in individuals with MS. In individuals suffering from MS, there appears to be a blood-brain barrier disturbance. After one hour of HBO_2 therapy, magnetic resonance imaging (MRI) scans were performed on the patients. The results indicated that one or more of the lesions appearing on the scan disappeared in 11 of the 35 patients. The authors hypothesized that the disappearance of the lesion was due to the resolution of focal edema, which is a characteristic of HBO_2. Furthermore, Pallota et al. (1982) reported significantly less relapses in MS patients who received HBO_2 treatments twice a month followed by 2 treatments a year for 5 years. They emphasised that only long-term studies had found benefits from HBO_2 treatments for individuals with MS.

Barnes et al. (1987) examined the effect of HBO_2 on 120 patients with MS. Treatments were randomised with subjects receiving either 100% oxygen at 2 ATA for 90 minutes daily for 20 sessions or a placebo treatment with a similar compression procedure. The authors did not find any significant improvement in bowel/bladder function, in the progression of the disease or

the rate of relapses as measured by the Kurtzke disability status scale. Nonetheless, at the 6 month and one year assessments, less deterioration in cerebellar function in the patients in the HBO_2 group was evident.

Finally, Kleijnen & Knipschild (1991) reviewed 14 controlled trials, which assessed the effects of HBO_2 for MS. For most of the trials, HBO_2 was supplied at pressures of 1.75- 2 ATA during 20 sessions of 90 minutes for 4 weeks. In 8 of the 14 trials, the methodology was deemed to be adequate; however, only 1 of the 8 studies yielded favourable results, with the others showing no beneficial effect for this population. As such, the literature seems to suggest that there are no apparent benefits in administering HBO_2 to patients with MS.

Spinal Injuries and HBO_2

Holbach (1977) examined the effect of HBO_2 on patients who suffered from compressed spinal cord injuries. In this study, the HBO_2 treatment comprised 10-15 sessions lasting 40 minutes each, administered daily at 1.5 ATA. Of the 13 patients, six made marked improvements especially in motor functioning; however, sensory improvements in these same patients were negligible. The improvements were most evident between the 1st and 7th treatments. The author hypothesised that the patients' improvements may have been attributable to an increase in blood flow to the affected region as well as slight cerebral vasoconstriction where cerebral circulation has retained its integrity.

Epilepsy and HBO_2

Epilepsy is another condition that is affected by a disturbance in the nervous system. Epilepsy has received some attention in the research and literature regarding HBO_2 therapy, although no firm conclusions have been established. For example, Qibiao (1995) surveyed 100 cases, all involving children, ranging in age between 4 days and 14 years, with 84% of them between the ages of 1 month and 9 years old. Patients were given 80 minute HBO_2 treatments daily, at 1.7 to 2.0 ATA for 15 to 30 days. Some patients were treated 35-45 times. The treatment

was effective in 84% of the patients, in that the frequency of seizures diminished and the EEG recordings improved. Moreover, intelligence, personalities and mentalities were improved in 82% of the children and 43% had stopped taking anti-convulsant medication. A follow-up study was carried out on 76 of the original population, and after 3 years, 40 of the patients were free of anticonvulsant medication.

Cerebral Palsy and HBO_2

Although in many of the disorders for which HBO_2 therapy is used or is being researched it is unknown precisely which mechanisms are involved in alleviating symptoms or improving prognosis, it appears evident that further attention is needed to ascertain quantitatively and qualitatively the benefits that HBO_2 could offer for diseases not yet recognised for HBO_2 treatment by the UHMS: namely CP (cerebral palsy).

Firstly, given the paucity of literature examining the effect of HBO_2 on children with CP, a clear understanding of the effects of HBO_2 for conditions that bear significant similarities to cerebral palsy is critical in reasonably inferring the potential benefits that this treatment could offer for CP. For example, stroke is a condition that resembles cerebral palsy in that it is a condition featuring cerebral tissue damage or death as a result of initial edema or swelling; however, unlike cerebral palsy, strokes have more frequently been the topic of scientific investigation when assessing the benefits of HBO_2. Given the weight of the documentation of the positive effects of HBO_2 on stroke and head-injured patients and given the significant similarities between these conditions and CP, it seems worthwhile and reasonable to investigate its effects for children with CP.

As described previously, explanations for the beneficial effects of HBO_2 on stroke outcome have been consistent and frequently focus on the term ischemic penumbra which, as explained by Hakim (1987), is the intermediate zone between the most ischemic tissue and the more normally perfused brain. This penumbral area has reduced blood flow, thereby interrupting

neuronal functioning and rendering the neurons dormant or "idling"; however, it seems that neuronal death is not unavoidable. Astrup et al. (1981) suggest that idling neurons are metabolically lethargic and electrically non-functional; though remain viable in the ischemic penumbra because of low oxygen availability. It is widely hypothesized that increasing oxygen availability by administering HBO_2 treatments, metabolically stimulates idling neurons and restores electrical function. The important characteristic of this zone of "idling" neurons is the interrupted state of electrical and clinical function, which is hypothesized to be reversible yet time-limited. It is the regeneration of this viable but inactive tissue that has been the explanation for the improvement, and sometimes the recovery of many stroke patients. Moreover, it is this explanation that is the foundation upon which rests the rationale for scientifically investigating the effect of HBO_2 on children with CP. Since this condition originates from a trauma to the brain and subsequent neuronal death, the possible presence of fibres and neurons in the ischemic penumbra having the potential to become active and contribute to motor and/or psychological improvement when exposed to high levels of oxygen motivates this investigation and supports its argument.

At present, the most common intervention for children with CP involves physiotherapy, which attempts to diminish spasticity and encourage proper movements and posture. Mayo (1991) examined the effectiveness of weekly intensive and monthly (basic) neurodevelopmental therapy on the motor development of 29 young children with suspected CP over a six month period. The subjects were under 2 years of age and had delayed or abnormal acquisition of motor behaviour. Seven particular aspects of the motor development of the subjects were assessed: primitive reflexes, postural reactions, gross motor ability, fine motor skills, Bayley Scale of Infant Development, The Abnormal Movement Scale, and Activities of Daily Living. Subjects were evaluated on each scale before and after their physiotherapy sessions. Overall, children that

received the more intensive program had higher scores on the scales, compared to the group undergoing the basic regimen.

Palmer et al. (1988) examined the mental quotient and motor ability of 48 infants with spastic diplegia. One group received 12 months of physical therapy and the second group received 6 months of infant stimulation followed by 6 months of physical therapy. The infant stimulation program consisted of motor, sensory, language and cognitive activities of increasing complexity. Masked outcome was performed at 6 months and 12 months of therapy to evaluate motor ability and mental quotient. After 6 months, the infants in the stimulation program demonstrated a higher mean motor quotient than the infants in the physical therapy program and this difference persisted after 12 months of therapy. The authors concluded that the use of physical therapy offered no short-term advantages over the infant stimulation program. Although physical therapy remains the most common intervention for children with CP, HBO_2 could, based on the theory that there exists an ischemic penumbra capable of becoming metabolically active, offer benefits to these children.

For example, Montgomery et al. (1999) specifically examined the effect of HBO_2 on 25 children with spastic diplegic CP. The children underwent 20 treatments at 95% oxygen at 1.75 ATA for 60 minutes. The subjects were evaluated before and after treatments on the basis of the following: the gross motor function measure (GMFM), fine motor function (Jebsen-Taylor test for hand function), spasticity (modified Ashworth scale), video analysis and a parental questionnaire. The results of the treatments demonstrated an improved gross motor function score on 3 of the 5 items in the GMFM, improved fine motor function in 3 of the 6 hand tests, reduced spasticity in 3 of the 4 muscle groups and improvements in 4 of the 9 questions posed to parents. Based on the results of this study, the authors recommended that a subsequent investigation was warranted using the same measures, incorporating a placebo group, and using a larger sample of children with spastic CP.

Jebsen-Taylor Test of Hand Function

The changes in metabolic and circulatory pathways in the brain can be assessed either directly using the SPECT and MRI scans or indirectly with motor functioning tests and scales. For the purpose of this study, assessment will be done indirectly by employing the Jebsen Taylor Test of Hand Function (Jebsen et. al. 1969). The test is devised to assess a patient's functional capabilities by measuring gross functional dexterity. The test assesses speed and not quality of performance of tasks simulating everyday activities (Spaulding, 1988). The test is comprised of seven items representative of various hand activities and should be thought of as providing a standardised and objective evaluation of several major aspects of hand function. The seven test items include (1) hand-writing a short sentence, (2) turning over 3 inch by 5 inch cards, (3) picking up small objects and placing them in a container 4) stacking checker game pieces, (5) simulated eating (6) moving empty large cans, and (7) moving weighted large cans. In normal subjects, both hands can be tested in approximately 15 minutes. Norms have been established for the adult (20 years and older) male and female populations. In assessing the reliability of these norms, 26 patients with stable hand disabilities were tested on two occasions. The coefficients ranged from 0.60 to 0.99 and an absence of a practice effect was noted (Jebsen et al. 1969). This test has been suggested as providing an objective evaluation of several aspects of hand activities commonly encountered in daily living (i.e feeding oneself and turning pages) and as providing evidence for the possible value of various treatments or interventions.

Taylor et al. (1973) outlined the methods to standardise the Jebsen Taylor Hand Function Test for children six years and older. Norms were obtained for normal male and female children. The authors made the appropriate equipment adjustments (for example, seat adjustments) and omitted the writing item for the children in the 6-7 year age group. In general, the females were faster than the males (except for the "heavy objects" task). Also, the authors demonstrated the test's reliability and lack of a significant practice effect using children with various stable hand disabilities. Among the population of children without disabilities, test items were typically

completed in 15 seconds or less. As the children age from 6 years to 19 years, there was an overall decrease in the amount of time required to complete the sub-tests.

Spaulding et al. (1988) used the Jebsen-Taylor test of hand function to evaluate 49 hemiplegic patients (mean age = 66 years; standard deviation = 15 years). The test was administered three weeks after admission to a rehabilitation centre following a cerebrovascular accident. Overall, there was a significantly slower performance on all items of the test for both the nonparetic and paretic hands when compared to previously published norms. The 27 left hemiplegic patients performed all sub-test items more slowly than the 22 right hemiplegic subjects with their weak hand. Performance with the nonparetic hand was significantly different between left and right hemiplegic subjects on the writing test. The authors emphasised that hand function among this population was dependant on age, side of brain involvement, and the degree to which their perceptual abilities remained intact. The authors emphasised that the purpose of the test, is to measure gross functional dexterity, speed and not quality of movement, and to have the tasks correspond to activities of daily living. The Jebsen-Taylor test does not, however, provide for expectations regarding performance among the hemiplegic group, and therefore the results are, according to the authors, somewhat difficult to interpret. In this particular study, there were no significant differences between the dominant and non-dominant hands of these children, therefore the test may not be as sensitive to hand differences for this population as it is for the normal population.

Wagner and Vignos (1993) examined the performance of 18 males over 15 years of age with Duchenne Muscular Dystrophy (DMD) using the Jebsen-Taylor test. The author identified the tasks that were problematic for the subjects, namely, simulated feeding and picking up small objects. The tasks of hand writing and card turning, however, were performed by 85% of all subjects. Essentially, the test was able to discriminate between the muscles that are least affected compared to those which are less functional. Based on these results, the authors were able to infer, to some degree of confidence, the daily functional ability of the subjects.

Hiller and Wade (1992) compared the Brooke Upper Extremity Functional Rating Scale and the Jebsen-Taylor test of hand function in the evaluation of 23 subjects with Duchenne Muscular Dystrophy (DMD). The purpose of the study was to assess whether or not the Jebsen-Taylor test of hand function was a more discriminative measure of upper extremity function in patients with DMD. There was a positive relationship between the two scales; however, the Jebsen-Taylor test of hand function was found to be a more sensitive measure of hand function among this population. The large range of scores was attributed to the significant discriminative ability of the test. The Jebsen-Taylor test proved to be a useful tool to evaluate this population since it can be completed in a short time frame, is inexpensive and relatively easy to administer. There are, however, some limitations to the test when assessing this population. Firstly, the boys were not able to complete the feeding task since they possessed immature fine motor control and coordination. In addition, the tasks that required lifting demanded muscular strength of the proximal muscles, a fitness component that was low in many of these children. The article highlighted the need for additional standardised tests that are reliable and valid for populations with varied disabilities. Nonetheless, the Jebsen-Taylor test remains an informative tool since it provides parametric data, unlike the Brooke Scale, which simply provides ordinal data.

The Jebsen-Taylor test has been used for a variety of populations from healthy adults and children, to the evaluation of treatments and interventions for individuals with various disabilities. Norms however, for these different populations are lacking and are needed for a more precise interpretation.

Appendix 2

Conclusion

In summary, the results of this study show no significant changes from pre to post tests for any of the measures, although both the HBO_2 and placebo groups improved ($p = 0.08$) their total times for the Jebsen test. The HBO_2 group improved by 54.5 s (8.8%) while the placebo group improved by 47.8 s (7.7%). The qualitative assessments did not detect changes from pre to post tests. The results indicate that HBO_2 therapy did not improve the hand function of children with CP.

Appendix 3

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Appendix 4

Additional Tables

Table

Table VI

Children with CP from this study compared to Norms for the Jebsen-Taylor Test(s*)

Task (s)	6-7 yrs	8-9 yrs	10-11 yrs	CP subjects **
Turning cards	17.0 ± 2.9	13.3 ± 2.2	10.4 ± 1.1	59.4 ± 9.5
Picking up small objects	15.3 ± 1.4	13.9 ± 1.6	12.0 ± 0.8	72.8 ± 10.1
Simulated eating	25.1 ± 3.4	24.5 ± 4.7	16.9 ± 1.6	187.1 ± 20.4
Stacking checkers	9.5 ± 0.9	8.0 ± 0.7	7.1 ± 0.5	67.0 ± 13.9
Moving large cans	9.1 ± 0.6	7.7 ± 0.9	6.5 ± 0.5	90.6 ± 15.5
Moving weighted cans	9.6 ± 0.6	7.9 ± 0.8	6.6 ± 0.5	118.8 ± 18.2
Total	85.6 ± 6.1	75.3 ± 8.4	59.5 ± 3.6	595.7 ± 72.2

Task (% of total time)	%	%	%	%
Turning cards	19.8	17.6	17.4	10.0
Picking up small objects	17.8	18.4	20.1	12.2
Simulated eating	29.3	32.5	28.4	31.4
Stacking checkers	11.0	10.6	11.9	11.2
Moving large cans	10.6	10.2	10.9	15.2
Moving weighted cans	11.2	10.4	11.0	19.9
Total	100	100	100	100

* Norms from Jebsen et al. (1969). Scores represent an average of the dominant and non-dominant hands.

** Scores represent the sum of the dominant and non-dominant hands and the average score for the HBO_2 and placebo groups.

Table VII

HBO_2 Subjects- Functional Evaluation of the Hand- Total Time (s)

Subject #	Pre Test	Post Test	Excluded from Sample
102	2160	2160	*
104	2160	2160	*
105	556	397	
108	2160	2160	*
110	1602	1639	*
112	287	No post	*
113	1034	880	
117	550	581	
118	523	280	
120	966	970	
121	1360	1255	
122	1182	1063	
125	1611	1395	*
126	130	No post	*
128	78	88	
202	384	214	
205	541	524	
206	572	663	
301	2160	1916	*
304	122	79	
v306	932	971	
308	212	260	
401	1577	1700	*
402	1856	1679	*
502	1586	1393	
504	278	208	
505	292	167	
507	713	900	
510	1625	1992	*
512	78	112	
515	426	492	
516	272	176	
519	204	200	
521	2160	2160	*
523	1873	1862	*
528	332	529	
529	159	189	
530	605	517	
532	1513	504	
535	1822	1685	*
537	1184	1008	
538	952	867	
541	254	219	
542	1469	1241	
543	1952	1954	*
549	80	95	
551	224	249	
553	189	388	
555	111	136	
559	2160	2160	*
560	1899	1968	*
561	1226	1205	
564	1209	1385	
567	1763	No post	*
n = 54			n = 18

Table VIII

Placebo Subjects- Functional Evaluation of the Hand- Total Time (s)

Subject #	Pre Test	Post Test	Excluded from Sample
101	438	590	
103	159	166	
106	584	215	
107	745	473	
109	1315	1680	
111	798	470	
114	768	620	
115	522	293	
116	2160	2160	•
119	837	700	
123	2160	2160	•
124	2160	2160	•
127	1513	1307	
201	1412	1385	
203	238	95	
204	261	288	
302	1068	573	
303	855	644	
305	1069	905	
307	764	502	
403	622	465	
404	2160	2120	•
501	2160	2160	•
503	149	211	
506	222	364	
508	334	322	
509	910	1098	
513	666	908	
514	95	108	
517	1538	1539	•
518	1380	1242	
520	133	162	
522	181	167	
524	1162	1456	
525	629	392	
526	450	597	
533	97	158	
534	551	678	
536	1123	1280	
540	149	173	
544	466	408	
545	1593	1676	•
546	1938	No post	•
547	1474	1958	•
548	238	555	
550	114	135	
552	92	106	
554	123	134	
556	687	1217	
557	168	187	
558	2055	652	
562	499	No post	•
563	1568	1873	•
565	143	No post	•
569	122	No post	•
n = 55			n = 13

Table IX

HBO_2 Subjects- Functional Evaluation of the Hand- Number of Correct Responses

Subject #	Pre Test	Post Test	Excluded from Sample
102	0	0	*
104	0	3	*
105	55	60	
108	0	0	*
110	27	34	*
112	26	No post	*
113	39	43	
117	58	56	
118	59	60	
120	52	45	
121	28	30	
122	47	43	
125	19	26	*
126	60	No post	*
128	60	60	
202	60	62	
205	54	59	
206	47	53	
301	2	11	*
304	60	60	
306	34	44	
308	60	60	
401	18	14	*
402	8	17	*
502	32	35	
504	60	60	
505	60	60	
507	48	55	
510	30	12	*
512	60	60	
515	58	55	
516	60	60	
519	60	60	
521	0	0	*
523	6	12	*
528	54	51	
529	60	60	
530	54	51	
532	22	50	
535	21	25	*
537	36	49	
538	50	49	
541	50	60	
542	60	40	
543	21	12	*
549	60	60	
551	60	60	
553	60	55	
555	60	59	
559	0	0	*
560	18	14	*
561	45	27	
564	42	50	
567	23	No post	*
n = 54			n = 18

Table X

Placebo Subjects- Functional Evaluation of the Hand- Number of Correct Responses

Subject #	Pre Test	Post Test	Excluded from Sample
101	57	59	
103	60	60	
106	57	60	
107	46	60	
109	21	28	
111	48	54	
114	44	55	
115	50	60	
116	0	0	•
119	46	51	
123	0	0	•
124	0	0	•
127	42	46	
201	33	36	
203	60	60	
204	60	60	
302	46	55	
303	50	55	
305	44	48	
307	55	57	
403	58	60	
404	4	4	•
501	0	2	•
503	60	60	
506	60	60	
508	60	60	
509	45	36	
513	50	43	
514	60	60	
517	25	22	•
518	27	39	
520	60	60	
522	60	60	
524	46	25	
525	52	55	
526	62	59	
533	60	60	
534	59	50	
536	41	38	
540	60	60	
544	57	54	
545	21	19	•
546	12	No post	•
547	30	18	•
548	60	52	
550	60	60	
552	60	60	
554	60	58	
556	38	50	
557	60	60	
558	50	45	
562	55	No post	•
563	40	35	•
565	60	No post	•
569	60	No post	•
n = 55			n = 13

Table XI

HBO_2 Subjects- Functional Evaluation of the Hand- Modified QUEST

Subject #	Pre Test	Post Test	Excluded from Sample
102	30	24	•
104	42	30	•
105	227	240	
108	2	8	•
110	126	130	•
112	111	No post	•
113	164	163	
117	203	218	
118	212	240	
120	153	132	
121	53	114	
122	142	114	
125	81	117	•
126	242	No post	•
128	232	214	
202	238	235	
205	226	234	
206	166	207	
301	20	50	•
304	252	214	
306	135	151	
308	232	228	
401	110	66	•
402	50	72	•
502	120	120	
504	204	226	
505	211	210	
507	203	199	
510	52	90	•
512	236	252	
515	226	232	
516	222	218	
519	250	244	
521	30	10	•
523	46	36	•
528	176	191	
529	212	219	
530	182	192	
532	202	76	
535	102	82	•
537	110	130	
538	208	168	
541	242	216	
542	157	172	
543	64	72	•
549	226	244	
551	234	240	
553	248	240	
555	248	224	
559	2	16	•
560	67	96	•
561	140	142	
564	193	178	
567	118	No post	•
n = 54			n = 18

Table XII

Placebo Subjects- Functional Evaluation of the Hand- Modified Quest

Subject #	Pre Test	Post Test	Excluded from Sample
101	191	188	
103	236	230	
106	234	248	
107	191	206	
109	94	78	
111	185	211	
114	160	195	
115	176	231	
116	8	4	•
119	177	163	
123	4	4	•
124	2	2	•
127	112	120	
201	133	160	
203	220	232	
204	220	215	
302	138	163	
303	174	191	
305	180	189	
307	189	196	
403	228	229	
404	32	24	•
501	52	16	•
503	194	208	
506	223	234	
508	234	244	
509	135	144	
513	184	212	
514	232	219	
517	96	94	•
518	143	103	
520	186	204	
522	242	237	
524	122	148	
525	206	189	
526	237	237	
533	222	230	
534	179	195	
536	136	140	
540	207	226	
544	171	200	
545	66	70	•
546	78	No post	•
547	98	130	•
548	232	238	
550	144	228	
552	248	225	
554	230	206	
556	155	173	
557	246	245	
558	194	84	
562	231	No post	•
563	70	92	•
565	248	No post	•
569	230	No post	•
n = 55			n = 13

Table XIII

HBO_2 Subjects- Functional Evaluation of the Hand- Classification

Subject #	Pre Test	Post Test	Excluded from Sample
102	12	13	•
104	15	16	•
105	54	58	
108	5	12	•
110	35	32	•
112	32	No post	•
113	45	41	
117	52	52	
118	50	59	
120	44	36	
121	33	34	
122	42	39	
125	24	32	•
126	59	No post	•
128	60	59	
202	59	55	
205	55	57	
206	44	51	
301	14	23	•
304	60	59	
306	29	43	
308	57	57	
401	25	22	•
402	18	22	•
502	34	36	
504	59	55	
505	58	55	
507	50	48	
510	31	20	•
512	60	59	
515	54	55	
516	57	56	
519	60	60	
521	12	14	•
523	18	18	•
528	52	49	
529	59	59	
530	49	48	
532	27	51	
535	21	25	•
537	45	33	
538	43	46	
541	59	60	
542	39	28	
543	27	17	•
549	60	60	
551	60	59	
553	59	55	
555	60	59	
559	12	12	•
560	25	20	•
561	44	38	
564	43	44	
567	25	No post	•
n = 54			n = 18

Table XIV-

Placebo Subjects- Functional Evaluation of the Hand- Classification

Subject #	Pre Test	Post Test	Excluded from Sample
101	56	47	
103	60	58	
106	52	60	
107	48	51	
109	32	29	
111	51	49	
114	40	50	
115	50	57	
116	12	12	•
119	45	46	
123	12	12	•
124	12	12	•
127	33	38	
201	35	38	
203	58	60	
204	60	55	
302	43	48	
303	47	50	
305	43	45	
307	51	49	
403	51	48	
404	16	16	•
501	12	16	•
503	58	55	
506	60	57	
508	60	59	
509	43	37	
513	48	48	
514	60	60	
517	29	29	•
518	30	40	
520	56	57	
522	60	60	
524	42	31	
525	46	53	
526	52	54	
533	60	59	
534	51	45	
536	39	36	
540	59	56	
544	50	47	
545	25	29	•
546	19	No post	•
547	29	20	•
548	59	53	
550	60	60	
552	60	60	
554	59	59	
556	47	39	
557	58	60	
558	23	49	
562	54	No post	•
563	36	30	•
565	60	No post	•
569	59	No post	•
n = 55			n = 13

Table XV

Intra-Rater Reliability Correlation

Subject	Total time (s)		Correct Responses (#)		Modified QUEST (total score)		Classification (total score)	
	1	2	1	2	1	2	1	2
1	529	534	51	51	176	183	49	49
2	364	360	60	60	235	239	60	59
3	713	710	47	47	203	213	46	46
4	490	485	55	55	226	230	55	54
5	908	913	43	43	174	176	48	43
6	334	325	60	60	234	232	60	59
7	108	106	60	60	232	235	60	60
8	586	582	60	59	237	240	52	54
9	211	204	60	60	200	217	58	58
10	181	176	60	60	242	246	60	58
11	112	108	60	60	236	242	60	60
12	1157	1146	37	38	133	139	37	38
13	278	275	60	60	204	218	59	59
14	1730	1722	25	26	108	112	25	28
15	674	673	50	50	175	183	45	47
16	867	865	49	47	208	194	43	43
17	158	158	60	60	222	231	60	58
18	272	268	60	60	222	221	57	57
19	1184	1182	36	36	222	222	57	57
20	292	294	60	60	211	210	58	58
21	1280	1278	41	40	132	140	39	37
22	392	389	52	50	208	222	54	54
23	2160	2160	0	0	24	24	14	12
24	189	189	60	60	218	225	59	59
25	1501	1501	30	30	108	104	34	31
	$r = 0.999$		$r = 0.999$		$r = 0.993$		$r = 0.991$	

Table XVI

Inter-Rater Reliability Correlation

Subject	Total time (s)		Correct Responses (#)		Modified QUEST (total score)		Classification (total score)	
	1	2	1	2	1	2	1	2
1	529	533	51	59	176	195	49	48
2	364	360	60	60	235	222	60	58
3	713	705	47	47	203	195	46	46
4	490	486	55	55	226	211	55	52
5	908	910	43	42	174	185	48	45
6	334	330	60	60	234	220	60	58
7	108	106	60	60	232	211	60	59
8	586	570	60	55	237	205	52	21
9	211	203	60	60	200	181	58	58
10	181	179	60	60	242	235	60	57
11	112	107	60	60	236	224	60	58
12	1157	1130	37	36	133	140	37	40
13	278	270	60	60	204	209	59	55
14	1730	1700	25	27	108	100	25	25
15	674	676	50	50	175	194	45	45
16	867	860	49	51	208	184	43	45
17	158	165	60	60	222	208	60	58
18	272	267	60	60	222	205	57	57
19	1184	1130	36	36	222	200	57	57
20	292	292	60	60	211	194	58	56
21	1280	1269	41	38	132	148	39	39
22	392	387	52	55	208	205	54	55
23	2160	2160	0	0	24	24	14	12
24	189	180	60	60	218	213	59	56
25	1501	1485	30	32	108	106	34	33
	r = 0.099		r = 0.989		r = 0.970		r = 0.991	

Appendix 5

Faculty of Education - Ethics Approval

MCGILL UNIVERSITY
FACULTY OF EDUCATION

STATEMENT OF ETHICS OF PROPOSED RESEARCH

1. Informed Consent of Subjects

Explain how you propose to seek informed consent from each of your subjects (or should they be minors, from their parents or guardian). Informed consent includes comprehension of the nature, procedures, purposes, risks, and benefits of the research in which subjects are participating. Please append to this statement a copy of the consent form that you intend to use.

All subjects receive medical clearance for hyperbaric oxygen treatments. This involves a medical examination by a physician knowledgeable of the risks associated with hyperbaric oxygen treatments. Following medical clearance, the child and parent(s) (or legal guardian) observe a hyperbaric oxygen treatment. Informed consent will be obtained from the parent (or legal guardian) of the subject. The consent form contains an explanation of the purpose, procedures, risks and benefits of the research. The Hyperbaric Oxygen Research Assistant (Ms. Jacqueline Lecomte) will read the consent forms with each parent (or legal guardian) and inform him/her of their right to withdraw their child from treatment at any time. Treatment will only begin after the consent form has been completed and signed by the parent or guardian.

2. Subject Recruitment

2.1 Are the subjects a captive population (e.g., residents of a rehabilitation centre, students in a class, inmates in a penal establishment)?

No. The subjects that receive treatments at McGill University will be 6 children diagnosed with cerebral palsy. They will be randomly selected from a population of Quebec children with spastic diplegic cerebral palsy. The children and their parents (guardians) will be volunteer participants in this study. The total sample will include 135 children with cerebral palsy, which will be grouped as follows:

Location	Group			
	Treatment	Placebo	Control	Total
McGill University	2	2	2	6
CIMH – Longueuil	24	24	24	72
Hotel Dieu – Lévis	4	4	4	12
Rimouski	15	15	15	45
Total Group	45	45	45	135

2.2 Explain how institutional or social pressures will not be applied to encourage participation.

After an explanation of procedures and potential benefits, the parent(s) or legal guardian will be asked if they wish their child to participate in the study. The parent(s) or legal guardian will be informed of their right to withdraw their child from the study at any time.

2.3 What is the nature of the inducement you intend to present to prospective subjects to persuade them to participate in your study?

A pilot project conducted in the fall of 1998 concluded that hyperbaric oxygen (HBO) is a promising modality for individuals with cerebral palsy. In this study there were improvements in gross motor function, fine motor function, a reduction in muscle spasticity when assessed by a physician specializing in cerebral palsy, and positive changes as viewed by parents of the children in 4 of 9 areas. Free hyperbaric treatments will be given to all children in the treatment, placebo and control groups. Each child would receive a total of 40 free hyperbaric oxygen treatments for participation in the study.

Presently, the Undersea and Hyperbaric Medical Society approves HBO therapy for 13 conditions. Cerebral palsy is not an approved condition and is therefore considered experimental. Participation in this study would enable the subjects with cerebral palsy a chance at gaining access to an experimental treatment that may provide benefits relating to motor function.

2.4 How will you help prospective participants understand that they may freely withdraw from the study at their own discretion and for any reason?

Withdrawl from treatment at any time and for any reason will be clearly stated in the consent form. Additionally, during the explanation of treatment procedures, the parent(s) or legal guardian will be reminded of their right to withdraw their child from the study at their own discretion at any time.

3. Subject Risk and Wellbeing

What assurance can you provide this committee (as well as the subjects) that the risks, physical and/or psychological, that are inherent to this study are either minimal or fully justifiable given the benefits that these same subjects can reasonably expect to receive?

The research assistant (Jacqueline Lecomte) will inform individuals of the benefits of hyperbaric oxygen (HBO) therapy only after they have been given medical clearance by one of the research physicians. At this point, the subject and parent (or legal guardian) can volunteer their child for participation in this study. The HBO treatment will consist of a 7-10 minute decompression period, a 60-minute treatment at 1.75 Atmospheres of pressure and 95% oxygen concentration, and end with a 7-10 minute decompression period. The placebo treatment will consist of a 7-10 minute

decompression, a 60-minute treatment at 1.3 Atmospheres of pressure and 21% oxygen concentration, and end with a 7-10 minute decompression. The physical risks involved in hyperbaric oxygen procedures are: A) ear discomfort due to increased pressure which can be equalized by swallowing or yawning; B) oxygen toxicity which has signs such as tingling in the fingers, nausea, dry cough, seizures and chest pain (This is a rare condition which affects 1 in 10, 000 persons); C) pneumothorax, which is a rupture to the lung caused by a buildup of pressurized air in the chest cavity (usually due to a person holding their breath while inside the chamber); D) myopia (nearsightedness/change in vision) which may occur after a large number of treatments. This condition is reversible once hyperbaric oxygen treatments are no longer administered. All these conditions are addressed in the consent form under the section "possible side effects". Each side effect is defined and instructions on how to minimize them are explained to the subject prior to receiving treatment. If a subject were uncomfortable for any reason while inside the chamber they would be removed from the chamber.

For children with cerebral palsy, hyperbaric oxygen may provide the following benefits: increased oxygen delivered to injured tissue, greater blood vessel formation, and improved motor function.

4. Deception of Subjects

4.1 Will the research design necessitate any deception to the subjects?

Yes. There will be a treatment group and a placebo group.

4.2 If so, what assurance can you provide this committee that no alternative methodology is adequate?

In order to eliminate the "placebo" effect associated with treatments, we have selected the most stringent research design – a double blind protocol where the subjects do not know if they received HBO or placebo treatment and the evaluators do not know if the subjects received HBO, placebo or in the control group. The scientific community will expect this design before accepting HBO treatments as an effective modality for cerebral palsy.

4.3 If deception is used, how do you intend to nullify any negative consequences of the deception?

At the conclusion of the study, subjects will be informed whether they received the placebo or HBO treatment. Subjects in both the control and placebo groups will be given 40 free hyperbaric treatments upon completion of the study. The typical cost for 40 hyperbaric treatments is $10,000 per subject.

A randomized double-blind, multi-centre study of hyperbaric oxygen treatments for children with motor deficits of cerebral origin or post-traumatic encephalopathy.

The purpose of this study is to determine the effectiveness of hyperbaric oxygen treatments for children with motor deficits of cerebral origin or post-traumatic encephalopathy. Subjects will be 135 Quebec children between the ages of 3 and 10 years with motor deficits of cerebral origin or post-traumatic encephalopathy. Informed consent will be obtained from a parent or legal guardian of each subject prior to participation in the study. Subjects will be randomly assigned to three groups at four locations.

Location	Group			
	HBO	Placebo	Control	Total
McGill University	2	2	2	6
CIMH – Longueuil	24	24	24	72
Hotel Dieu – Lévis	4	4	4	12
Rimouski	15	15	15	45
Total Group	45	45	45	135

Subjects will be evaluated at the beginning of the study, after 20 treatments, and after 40 treatments. These evaluations will consist of tests to measure the following:

Gross motor function (Gross Motor Function Measurement test)
Fine motor function (Jebsen test)
Muscle spasticity (Ashwoth scale)
Attention (Test of Variables of Attention)
Speech and language

The evaluations will be conducted by individuals accustomed to assessing children with motor deficits of cerebral origin and post-traumatic encephalopathy. None of these evaluations will be conducted at McGill University.

At McGill University, six children will be treated in the Cleghorn hyperbaric oxygen laboratory. During the study, 2 children will receive 40 HBO treatments, 2 children will receive 40 placebo treatments, and 2 children will be control subjects who do not receive either HBO or placebo treatments. The HBO and placebo treatments will be approximately 80 minutes in duration and consist of a compression period of 7-10 minutes, 60-minute treatment, and decompression period of 7-10 minutes. The HBO treatment will be at 1.75 Atmospheres with 95% oxygen in the chamber. The placebo treatment will be at 1.3 Atmospheres with 21% oxygen in the chamber. The children will be accompanied in the chamber by an adult (usually the parent or guardian). During treatments, children watch videos. At the conclusion of the study, all groups will be informed of the nature of their treatment. Children in the placebo and control groups will then be offered 40 free HBO treatments.

Appendix 6

Faculty of Medicine - Ethics Approval

DATE OF I.R.B. APPROVAL

SEP 29 1998

SEP 29 1998

Faculty of Medicine
McGill University

A randomized, double blind, multi-centre study of hyperbaric oxygen (HBO) therapy for children with cerebral palsy or post-traumatic encephalopathy.

Cleghorn Hyperbaric Oxygen Lab, McGill University

Principal Investigator: Dr. Jean Paul Collet
McGill Co-Investigators: Drs. Vincent Lacroix & David Montgomery

1. *Introduction*

This study will investigate children (3-12 years old) with cerebral palsy (diplegic, quadriplegic or double hemiplegic) or a traumatic injury (occurring more than 2 years ago). Your child has been selected to participate in this study because they have cerebral palsy and he/she meets all of the inclusion/exclusion criteria.

Cerebral palsy is typically treated with physical and occupational therapy. Sometimes a selective posterior rhizotomy (surgical procedure where the nerves are cut to reduce spasticity) may be performed or botulin injections may be given to reduce spasticity in the lower limbs and permit greater mobility. This study is being conducted to determine the effectiveness of hyperbaric oxygen (HBO) therapy in children with cerebral palsy.

A pilot study was conducted in the fall of 1998 with 25 children receiving 20 HBO treatments. The children were evaluated pre and post HBO therapy. Each evaluation consisted of the following: 1) video analysis of gross motor movements; 2) a test to measure gross motor function (GMFM); 3) a test to measure hand function (Jebsen Test); 4) spasticity level; and 5) a questionnaire given to the parents. Results showed improved gross motor function in 3 of the 5 items in the GMFM test, improved fine motor function in 3 of the 6 hand tests, reduced spasticity in 3 of 4 muscle groups when assessed by a physician specializing in cerebral palsy, and improvements for 4 of 9 questions posed to parents. It should be noted that this pilot study was not a randomized trial with a control group or placebo group. The results are preliminary and require further investigation.

The purpose of this study is to evaluate the effectiveness of 40 hyperbaric oxygen (HBO) treatments in children with cerebral palsy compared to a placebo group.

2. *Study Procedures*

Hyperbaric oxygen treatments (40) will be the therapeutic experimental procedure in this study. Non-therapeutic procedures will be clinical evaluations to assess changes from the pre to post HBO evaluations. A total of 140 children will participate in this study. The children will be randomly assigned to receive either HBO treatments (n=70) or placebo treatments (n=70). Under the supervision of Dr. Jean-Paul Collet, principal investigator for this study, six children

McGill

Department of Physical Education
McGill University

475 Pine Avenue West
Montreal, PQ, Canada H2W 1S4

Tel.: (514) 398-4184
Fax: (514) 398-4185

Étude multicentrique, randomisée et à double insu de l'oxygénothérapie hyperbare pour le traitement d'enfants présentant un déficit moteur d'origine cérébrale.

Equipe de Recherche:

Maxime Amar, M.D., spécialiste de médecine hyperbare, Centre hospitalier régional de Rimouski et Institut maritime du Québec à Rimouski.

Jean-Paul Collet, MD, PhD, (chercheur principal) pédiatre, Directeur de l'Unité d'essais cliniques, Hôpital Général Juif (SMBD), Département d'Epidémiologie, Université McGill.

Mario Côté, M.D., spécialiste en médecine hyperbare, Hôtel-Dieu de Lévis.

Josée Fortin, Ph.D., orthophoniste, Hôpital Sainte-Justine.

Joanne Goldberg, M.Sc., P.T., physiothérapeute et assistante de recherche, Hôpital Marie Enfant.

Jacques Lacroix, MD, FRCP(C), intensiviste, Hôpital Sainte-Justine.

Vincent Lacroix, M.D., spécialiste de médecine hyperbare, Centre Seagram des sciences du sport, Université McGill.

Jean Lambert, Ph.D., biostatisticien, Département de médecine sociale et préventive, Faculté de médecine, Université de Montréal.

Maryse Lassonde, Ph.D., neuropsychologue, Département de psychologie, Université de Montréal.

Pierre Marois, M.D., FRCP(C), physiatre, Hôpital Sainte-Justine et Hôpital Marie Enfant.

David L. Montgomery, Ph.D., spécialiste en physiologie de l'exercise, Centre Seagram des sciences du sport, Université McGill.

Ann Robinson, RN, infirmière de recherche, unité d'essais cliniques, Hôpital Général Juif.

Bernard Rosenblat, MD, FRSP(C), neurologue, Hôpital pour Enfant

Michel Sylvain M.D., FRCP(C), neuropédiatre, CHUL, Québec

Stéphane D. Tremblay, M.D., Ph.D., biologiste, urgentologue, Hôtel-Dieu de Lévis.

Michel Vanasse, M.D., FRCP(C), neurologue, Hôpital Sainte-Justine.

Montréal, 24 août 1999

Amendment (September 28, 1999) to the Proposal (A00-M36-99) titled

A randomized, double blind, multi-centre study of hyperbaric oxygen (HBO) therapy for children with cerebral palsy or post-traumatic encephalopathy.

The original proposal did not indicate that the children would be filmed on videocassette during the evaluations conducted at Marie-Enfant Hospital. The following clinical evaluations will be used to assess changes in the children resulting from the intervention:

- GMFM test
- Jebsen test
- Spasticity
- Visual and auditory attention tests (TOVA)
- Visual and auditory working memory tests
- Speech and language tests

Selected items from each of these tests will be filmed on a videocassette. The purpose of filming will be to verify that the tests are administered correctly and evaluated appropriately. An independent researcher will view the videocassettes to determine the objectivity of the evaluations. Confidentiality will be maintained since the identity of the children will remain anonymous. The videocassettes will be coded with numbers. No names will be used. The researcher viewing these films will not know if the child has received the HBO or the placebo intervention. The films will be stored in a locked cabinet and then will be destroyed after the study is completed.

Since the filming and storage of the videocassettes will occur at Marie-Enfant Hospital, their researchers have prepared a separate consent form for permission to film each child. We have attached their consent form titled:

Formulaire de Consentement pour Film Video de l'Evaluation.

DATE OF I.R.B. APPROVAL

SEP 29 1999

Faculty of Medicine
McGill University

Appendix 7

Consent Forms

INFORMED CONSENT - Child

Title of Study : **A randomized, double blind, multi-centre study of hyperbaric oxygen (HBO) therapy for children with cerebral palsy or post-traumatic encephalopathy.**

Investigators : **Dr. Vincent Lacroix, McGill University Tel. : 514 398-7007.**
Dr. David Montgomery, McGill University Tel: 514 398-4184 ext. 05588

Funded by: **Fonds de la recherche en santé du Québec (FRSQ), 550, Sherbrooke St. west, suite 1950, Montréal (Québec) H3A 1B9.**

The purpose of the study, the procedures to be used, the benefits and risks associated with my participation in this study, as well as the confidentiality of the data that will be collected during the study have been explained to me.

I have had the opportunity to ask questions concerning different aspects of the study and my questions have been answered to my satisfaction.

I, the undersigned, voluntarily accept that my child participate in this study. I am aware that we are free to withdraw from the study at any time and for any reason without penalty.

I acknowledge that I have received a signed copy of this consent form.

_____
Name of child

Name of parent/guardian	Signature	Date
Name of witness	Signature	Date
Name of researcher	Signature	Date

SEP 2 9 1999

DATE OF I.R.B. APPROVAL

SEP 2 9 1999

Faculty of Medicine
McGill University

CONSENTEMENT - Enfant

TITRE DE L'ÉTUDE : **Étude multicentique, randomisée et à double insu de l'oxygénothérapie hyperbare pour le traitement d'enfants présentant un déficit moteur d'origine cérébrale.**

INVESTIGATEUR : **Docteur Vincent Lacroix, l'Université McGill Tél. : 514 398-7007.**
Docteur David Montgomery, l'Université McGill Tel: 514 398-4184 ext. 05688

COMMANDITAIRE : **Fonds de la recherche en santé du Québec (FRSQ), 550, rue Sherbrooke ouest, Bureau 1950, Montréal (Québec) H3A 1B9.**

La nature de l'étude, les procédés utilisés, les risques et bénéfices que comportent ma participation à cette étude ainsi que le caractère confidentiel des informations qui seront recueillies au cours de l'étude m'ont été expliqués.

J'ai eu l'occasion de poser toutes les questions concernant les différents aspects de l'étude et de recevoir des réponses qui m'ont satisfait(e).

Je, soussigné(e), accepte volontairement que mon enfant participe à cette étude. Je peux me retirer en tout temps sans que cela ne nuise aux relations avec mon médecin et les autres intervenants et ce sans préjudice d'aucune sorte.

Je reconnais avoir reçu une copie signée de ce formulaire d'information et de consentement.

_____

Nom de l'enfant

Nom du sujet ou parent/tuteur légal	Signature	Date
Nom du témoin	Signature	Date
Nom du chercheur	Signature	Date

SEP 29 1999

DATE OF I.R.B. APPROVAL

SEP 29 1999

McGill University

INFORMED CONSENT – Accompanying Adult

Title of Study : **A randomized, double blind, multi-centre study of hyperbaric oxygen (HBO) therapy for children with cerebral palsy or post-traumatic encephalopathy.**

Investigator : **Dr. Vincent Lacroix, McGill University Tel. : 514 398-7007.**
Dr. David Montgomery, McGill University Tel: 514 398-4184 ext. 05684

Funded by: **Fonds de la recherche en santé du Québec (FRSQ), 550, Sherbrooke St. west, suite 1950, Montréal (Québec) H3A 1B9.**

The purpose of the study, the procedures to be used, the benefits and risks associated with my participation in this study, as well as the confidentiality of the data that will be collected during the study have been explained to me.

I have had the opportunity to ask questions concerning different aspects of the study and my questions have been answered to my satisfaction.

I, the undersigned, voluntarily accept to participate in this study. I am aware that I am free to withdraw from the study at any time and for any reason without penalty.

I acknowledge that I have received a signed copy of this consent form.

_____
Name of child

Name of parent/guardian	Signature	Date
Name of witness	Signature	Date
Name of researcher	Signature	Date

SEP 29 1999

CONSENTEMENT - Adulte

TITRE DE L'ÉTUDE : **Étude multicentique, randomisée et à double [illegible] hyperbare pour le traitement d'enfants présentant un déficit moteur d'origine cérébrale.**

INVESTIGATEUR : **Docteur Vincent Lacroix, l'Université McGill Tél. : 514 398-7007.**
Docteur David Montgomery, l'Université McGill Tel: 514 398-4184 ext. 00588

COMMANDITAIRE : **Fonds de la recherche en santé du Québec (FRSQ), 550, rue Sherbrooke ouest, Bureau 1950, Montréal (Québec) H3A 1B9.**

La nature de l'étude, les procédés utilisés, les risques et bénéfices que comportent ma participation à cette étude ainsi que le caractère confidentiel des informations qui seront recueillies au cours de l'étude m'ont été expliqués.

J'ai eu l'occasion de poser toutes les questions concernant les différents aspects de l'étude et de recevoir des réponses qui m'ont satisfait(e).

Je, soussigné(e), accepte volontairement que je participe à cette étude. Je peux me retirer en tout temps sans que cela ne nuise aux relations avec mon médecin et les autres intervenants et ce sans préjudice d'aucune sorte.

Je reconnais avoir reçu une copie signée de ce formulaire d'information et de consentement.

_____
Nom de l'enfant

Nom du sujet ou parent/tuteur légal	Signature	Date
Nom du témoin	Signature	Date
Nom du chercheur	Signature	Date

SEP 29 1999

CONSENT FORM FOR FILMING THE EVALUATIONS

A randomized, double-blind, multi-centre study of hyperbaric oxygen (HBO) therapy for children with cerebral palsy or post-traumatic encephalopathy

Name of child _____

Date of birth _____

Address _____

Telephone _____

DATE OF I.R.B. APPROVAL
SEP 29 1999
Faculty of Medicine
McGill University

I have fully explained to _____ the objectives of the procedures in the above mentioned study, also the possible risks and benefits of this study. I have answered the questions of the participants to the best of my knowledge. I will communicate to the participants any changes to the procedures, or risks and benefits that may occur during the course of the study.

_____ _____

Principal Researcher of the Institution Date

CONSENT TO PARTICPATE IN THE RESEARCH STUDY

A randomized, double-blind, multi-centre study of hyperbaric oxygen (HBO) therapy for children with cerebral palsy or post-traumatic encephalopathy

I have been informed of the purpose of this study. I agree to my child's participation in this study and that the procedures will be filmed on videocassette. The researchers have responded to my questions. I am aware that I am free to withdraw my child from the study at any time even after the signing of this form. My withdrawal from the study will have no effect on the benefits that my child will receive. I understand that there will be no material benefit for my child's participation in the study and that the videocassettes will not be used for any other purpose except for this study, unless I authorize and the videocassettes are destroyed by December 2002 at the latest. The videocassettes will be stored in a locked cabinet that the researchers will be responsible for. I have read this document and acknowledge receiving a copy.

_____

Signature or Parent or Guardian

_____

Signature of Child (If able to understand the project.

_____

Signature of the Witness

Date _____

SEP 2 9 1999

FORMULAIRE DE CONSENTEMENT POUR FILM VIDEO DE L'ÉVALUATION

DATE OF I.R.B. APPROVAL
SEP 2 9 1999
Faculty of Medicine
McGill University

PROJET DE RECERCHE

Étude multicentrique, randomisée et à double insu de l'oxygénothérapie hyperbare pour le traitement d'enfants présentant un déficit moteur d'origine cérébrale

Nom de l'enfant: _____

Date de naissance: _____

Adresse: _____

_____

_____

No de téléphone: _____

J'ai pleinement expliqué à _____ la nature et les buts des procédures prévues dans le projet de recherche sus-mentionné, de même que les risques possibles les bénéfices escomptés. J'ai répondu et répondrai aux questions des participants au meilleur de mes connaissances. Je donnerai l'information de tout changement dans les procédures ou des risques et bénéfices qui pourraient subvenir au cours de cette étude.

_____ _____

Chercheur(e) principal(e) de l'établissement Date

Consentement à participer au project de recherche
Étude multicentrique, randomisée et à double insu de l'oxygénothérapie hyperbare pour le traitement d'enfants présentant un déficit moteur d'origine cérébrale

J'ai été bien informé(e) de la nature de cette recherche. Je permets que mon enfant participe à cette étude et que les rencontres soient enregistrées sur bandes magnétoscopiques. Je sais que les chercheurs répondront aux questions que je pourrais formuler. Je suis libre de retirer mon autorisation à la participation de mon enfant en tout temps, même après la signature de ce

For parent or guardian providing consent for child

Cleghorn Hyperbaric Treatment and Research
Seagram's Sports Science Center, McGill Unive

INFORMED CONSENT FOR HYPERBARIC OXYC

This is to certify that _____ has received instructions in **Hyperbaric Oxygen Therapy** including the following:

1. Hyperbaric Oxygen Therapy_____
2. What is treatment like?_____
3. Ear clearing_____
4. Possible side effects?_____
5. Pregnancy_____
6. Smoking_____
7. Alcohol_____
8. Safety_____
9. Cold/Flu symptoms_____
10. Medication_____

In addition, the nature and purpose of hyperbaric oxygen therapy has been explained to me by Dr. (s)_____ and I hereby acknowledge that I know and understand the nature and the purpose of the treatments. Additionally, these physicians have explained to me the consequences, risks (listed below) and alternatives to receiving hyperbaric oxygen treatment and have given me the opportunity to ask any questions I might have concerning this matter. Further, the physicians have answered my questions.

I hereby consent to the performance of hyperbaric oxygen therapy for my son/daughter, _____ and am aware that I am free to discontinue participation at any time:

_____

Signature of Parent or Guardian Date

_____

Signature of Witness Date

Risks of Hyperbaric Oxygen Therapy:

1. Oxygen toxicity – central nervous system/lung (seizure)
2. Ear drum discomfort/rupture, sinus pain
3. Myopia (reversible after HBO) – nearsightedness/change in vision
4. Increased cataract growth rate (thickening of lens/change in vision)
5. Increased risk of fire
6. Lung over pressure-embolism, pneumothorax, emphysema (collapsed lung/bubbles in bloodstream)

{PRIVATE} **Unité Cleghorn de recherche et d'oxygénothérapie hyperbare**
Centre Seagram des sciences du sport, Université McGill

CONSENTEMENT ÉCLAIRÉ - OXYGÉNOTHÉRAPIE HYPERBARE

Je, _____ certifie avoir reçu des renseignements sur **l'oxygénothérapie hyperbare**, notamment en ce qui a trait aux points suivants :

1. L'oxygénothérapie hyperbare ____
2. En quoi le traitement consiste-t-il? ____
3. Désobstruction de l'oreille ____
4. Effets secondaires possibles ____
5. Grossesse ____
6. Tabagisme ____
7. Alcool ____
8. Sécurité ____
9. Symptômes grippaux ____
10. Médicaments ____

Je connais et comprend la nature et le but de l'oxygénothérapie hyperbare que le(s) docteur(s) _____ m'a(m'ont) décrits et expliqués. Les médecins m'ont également décrit les conséquences et les risques (voir liste ci-dessous) de l'oxygénothérapie hyperbare, en me précisant quels sont les autres options possibles. J'ai eu l'occasion de poser toutes les questions voulues et les médecins y ont répondu.

Je consens à ce que l'oxygénothérapie hyperbare soit administrée à mon fils/ma fille _____et je sais que je peux mettre fin au traitement à tout moment.

_____

Signature du parent ou tuteur Date

_____

Signature du témoin Date

Risques associés à l'oxygénothérapie hyperbare

1. Toxicité de l'oxygène - système nerveux central(épilepsie)/poumon
2. Douleur dans l'oreille/perforation du tympan, sinusalgie
3. Myopie (réversible à la fin du traitement) - myopie/modification de la vision
4. Augmentation du taux de croissance des cataractes (épaississement du cristallin/modification de la vision)
5. Exposition à un risque d'incendie accru
6. Surpression pulmonaire - embolie, pneumothorax, emphysème (affaissement des alvéoles pulmonaires/bulles de gaz dans le sang)

For each adult that may possibly accompany child in chamber

Cleghorn Hyperbaric Treatment and Researcl
Seagram's Sports Science Center, McGill Univ

INFORMED CONSENT FOR HYPERBARIC OXYGEN THERAPY

This is to certify that _____ has received instructions in **Hyperbaric Oxygen Therapy** including the following:

1. Hyperbaric Oxygen Therapy_____
2. What is treatment like?_____
3. Ear clearing_____
4. Possible side effects?_____
5. Pregnancy_____
6. Smoking_____
7. Alcohol_____
8. Safety_____
9. Cold/Flu symptoms_____
10. Medication_____

In addition, the nature and purpose of hyperbaric oxygen therapy has been explained to me by Dr. (s)_____ and I hereby acknowledge that I know and understand the nature and the purpose of the treatments. Additionally, these physicians have explained to me the consequences, risks (listed below) and alternatives to receiving hyperbaric oxygen treatment and have given me the opportunity to ask any questions I might have concerning this matter. Further, the physicians have answered my questions.

I hereby consent to the performance of hyperbaric oxygen therapy and am aware that I am free to discontinue participation at any time:

_____

Patient Date

_____

Witness Date

Risks of Hyperbaric Oxygen Therapy:

1. Oxygen toxicity – central nervous system/lung (seizure/fits)
2. Ear drum discomfort/rupture, sinus pain
3. Myopia (reversible after HBO) – nearsightedness/change in vision
4. Increased cataract growth rate (thickening of lens/change in vision)
5. Increased risk of fire
6. Lung over pressure-embolism, pneumothorax, emphysema (collapsed lung/bubbles in bloodstream

{PRIVATE} **Unité Cleghorn de recherche et d'oxygénothérapie hyperbare**
Centre Seagram des sciences du sport, Université McGill

CONSENTEMENT ÉCLAIRÉ - OXYGÉNOTHÉRAPIE HYPERBARE

Je, _____ certifie avoir reçu des renseignements sur l'oxygénothérapie hyperbare, notamment en ce qui a trait aux points suivants :

1. L'oxygénothérapie hyperbare ____
2. En quoi le traitement consiste-t-il? ____
3. Désobstruction de l'oreille ____
4. Effets secondaires possibles ____
5. Grossesse ____
6. Tabagisme ____
7. Alcool ____
8. Sécurité ____
9. Symptômes grippaux ____
10. Médicaments ____

Je connais et comprend la nature et le but de l'oxygénothérapie hyperbare que le(s) docteur(s) _____ m'a(m'ont) décrits et expliqués. Les médecins m'ont également décrit les conséquences et les risques (voir liste ci-dessous) de l'oxygénothérapie hyperbare, en me précisant quels sont les autres options possibles. J'ai eu l'occasion de poser toutes les questions voulues et les médecins y ont répondu.

Je consens à ce que l'oxygénothérapie hyperbare soit administrée et je sais que je peux mettre fin au traitement à tout moment.

_____

Signature Date

_____

Signature du témoin Date

Risques associés à l'oxygénothérapie hyperbare

1. Toxicité de l'oxygène - système nerveux central(épilepsie)/poumon
2. Douleur dans l'oreille/perforation du tympan, sinusalgie
3. Myopie (réversible à la fin du traitement) - myopie/modification de la vision
4. Augmentation du taux de croissance des cataractes (épaississement du cristallin/modification de la vision)
5. Exposition à un risque d'incendie accru
6. Surpression pulmonaire - embolie, pneumothorax, emphysème (affaissement des alvéoles pulmonaires/bulles de gaz dans le sang)

Cleghorn Hyperbaric Treatment and Research Unit
Seagram's Sports Science Center, McGill University

Instructions on Hyperbaric Oxygen Therapy

1. *HYPERBARIC OXYGEN THERAPY*

Definition: Hyperbaric oxygen (HBO) therapy is a procedure where a person sits inside a chamber and breathes 95% oxygen while their body is subjected to pressure greater than 1 atmosphere (i.e.normal barometric pressure at sea level). Increased pressure surrounds the person inside the hyperbaric chamber, which is similar to the increased pressure surrounding a scuba diver.

Purpose: To increase oxygen levels in tissue so that the normal healing mechanisms can be enhanced.

2. *WHAT IS TREATMENT LIKE?*

Preparation:
- Medical exam and clearance by hyperbaric physician
- Special clothing - 100% cotton T-shirt and shorts (provided)
- Pre-treatment checklist

Pressurization:
- Pressure inside the chamber increases gradually until treatment level is achieved and remains constant until the end.
- Ears may need to be cleared to adjust to the rising pressure (see below)
- The temperature inside the chamber may increase for a few minutes at the beginning of treatment.

3. *EAR CLEARING*

The pressure changes within the chamber are normally felt in the ears. The sensation is similar to landing in a plane. The following techniques can be done to clear the ears:

1. Swallowing
2. Yawning
3. Chewing motion
4. Blowing out through your nose while holding it

***If you are unable to fill your middle ear with air, notify the technician immediately so that the pain can be alleviated as soon as possible.

WHAT ARE THE POSSIBLE SIDE EFFECTS?

A. Barotrauma: This refers to injury or discomfort caused by increased pressure. If the ears are not properly cleared, the eardrum could become bruised. Reducing the chamber pressure or removing the patient from the chamber usually alleviates this. If severe enough, it can interrupt the patient's daily treatment schedule. Usually after a few days rest the patient can return for treatment.

B. Pneumothorax: It is important *NOT* to hold your breath during the time the pressure is being decreased in the chamber (this is at the end of each treatment). Air is expanded during this time and if a person holds their breath, it is possible to rupture a lung and subsequently let air into the chest cavity. This is very rare and is easily avoided by breathing normally throughout the time the chamber is being decompressed.

C. Sinus Trauma: Congested sinuses (sinusitis) can cause pain in the sinus area during the time the chamber is either being compressed or decompressed. Reversing the pressure in the chamber usually relieves the pain. To prevent problems one can use a decongestant provided the hyperbaric physician approves it. On occasion, the sinusitis can be severe enough to prevent the patient from going into the chamber. Treatment will be resumed only until the patient is free of sinusitis-type symptoms. It is important that the patient inform the physician of any symptoms of congested sinuses so that trauma can be avoided.

D. Airway Irritation: Although this is rare and not normally seen in healthy patients, high dose oxygen can cause airway irritation,. It starts with a dry hacking cough. Should this occur the HBO physician would evaluate the patient and make a decision as to how the problem would be alleviated.

E. Stomach Distension: Should a patient swallow a large amount of air while in the chamber, this air will expand when the pressure is being removed from the chamber. This can cause the patient to vomit or have pains in the stomach and abdominal areas. The best way to avoid this is to relax and breathe normally through the nose. Avoiding carbonated beverages before a treatment may be helpful. The operator should be told immediately if one feels this problem is occurring.

F. Oxygen Toxicity: Oxygen is a medication. Like all other medications dosage is important. According to scientific studies, you will receive the safest dose possible at the depth at which you are being treated. Sometimes, there are those patients which are more sensitive to oxygen than others. If this is the case, the patient can experience different symptoms such as the following:

Visual	- tunnel vision, loss of acuity (i.e. clarity)
Ears	- knocking, ringing, music, distortion of normal sounds
Nausea	- very common symptom
Twitching	- especially about the eyes and lips
Irritability	- apprehension, fidgeting, disorientation, clumsiness
Dizziness	- vertigo (i.e. sensation of room revolving)
Dyspnea	- shortness of breath, ~~hiccups~~

*****If you experience any one of these symptoms please don't hesitate. Notify the technician immediately.*

G. Visual Changes: During the course of multiple hyperbaric oxygen treatments (20 treatments or more) some patients may develop myopia (nearsightedness) which is characterized by a blurred distant vision or a sudden ability to read without glasses. It is presumed to be due to changes in the lens. In most cases, if a change in vision does occur it is temporary and eyesight will return to normal refraction 3-4 months after hyperbaric oxygen treatments stop. Do not throw old lenses out since it is likely that eyesight will return to the pre-treatment level.

It has been suggested in the scientific literature that hyperbaric oxygen may mature pre-existing cataracts, although it does not cause them. The literature also suggests that short-term treatments, which you will be receiving, produce no changes in cataract formation.

In any case, if you notice any visual changes, please inform one of the hyperbaric staff members. If the hyperbaric physicians feel you are in a high-risk group as far as visual changes are concerned, they will have you see your ophthalmologist or refer you to one.

5. *PREGNANCY AND HBO*

Are you pregnant? Yes_____ No X

Current scientific data shows that the effects of some hyperbaric oxygen on pregnancy are uncertain. Some animal studies reveal that in very early pregnancy, the fetus may be affected. Yet, some studies show that there is no apparent harm in later pregnancy.

If you are of childbearing age, it is felt that you should be informed that there could be risks involved if treated during pregnancy. If you are pregnant or should you think you have become pregnant during your treatment series, please tell a physician immediately.

6. *SMOKING AND HBO*

Are you a smoker? Yes_____ No_____

Smoking is not recommended during the time period that you are receiving hyperbaric oxygen (HBO) therapy for the following reasons:

- Blood supply to the tissues is significantly decreased because the nicotine in cigarettes causes small blood vessels to constrict.
- Smoke and tar decrease lung function, so less oxygen is absorbed by the lungs and transferred into the blood.
- If you do smoke, it is strongly recommended that you refrain from smoking 2 hours before and 1 hour after the hyperbaric oxygen therapy so that maximum benefits are achieved.

7. *ALCOHOL AND HBO*

The ingestion of alcohol, particularly in large amounts, is inadvisable before treatment since it may lower the threshold for oxygen toxicity.

8. *SAFETY*

Many precautionary measures have been implemented to ensure the highest safety standards for the laboratory, hyperbaric chamber and ultimately for the staff and patients using the HBO facilities.

1. Fire safety is assured with flame resistant materials.

2. The following are materials that are not allowed in the chamber:
   - Synthetic materials
   - Vaseline based products
   - Oil based products
   - Glycerine based products
   - Colognes or perfumes
   - Hair spray or hair gel
   - Wigs or hair pieces
   - All oil or alcohol based make-up
   - Skin lotions
   - Smoking materials
   - Watches and jewellery (To prevent scratches on the acrylic cylinder)
   - Gum or candy
   - Moustache wax
   - Paper products including books, magazines and newspapers
   - Electronic devices (e.g. walkmans, discmans, etc.)
   - Contact lenses

3. The following materials are allowed in the chamber.
   - Eyeglasses

9. *REPORT COLD OR FLU-LIKE SYMPTOMS*

Symptoms which one suspects as being caused by a virus should be reported to the hyperbaric staff prior to treatment. In laboratory studies, viruses may become stronger when exposed to HBO therapy.

You will be asked if you have any of the following symptoms prior to each treatment:

1. Stuffy or runny nose
2. Stuffy ears
3. Nausea and/or vomiting.
4. Diarrhea
5. Generalised weakness.

The physician will decide whether the patient should be treated or not. Sometimes it is best to sit out for a day or two so that viral symptoms are not worsened.

10. *MEDICATION*

Are you presently taking any medications? Yes_____ No_____

Appendix 7

Contribution of Co-Authors in the Research Article

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