Hyperbaric Oxygen and Focused Rehabilitation Program: A Feasibility Study in Improving Upper Limb Motor Function After Stroke

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Background and Purpose- Neuroplasticity and recovery after stroke can be enhanced by both exercise and mental imagery (EMI) rehabilitation program and hyperbaric oxygen (HBO) therapy, but there are no studies investigating their combined effects. The current study aimed to assess the feasibility and safety of the combined approach of HBO therapy and EMI program, and derive preliminary estimates of its efficacy versus EMI program alone in patients recovering from stroke.

Methods- Twenty-seven patients with arm hemiparesis/hemiplegia were randomized 1:1 to receive either combined EMI rehabilitation program with HBO therapy (intervention group), or EMI program alone (control group). Feasibility and safety were assessed as total session attendance, duration of sessions, attrition rates, missing data, and intervention-related adverse events. Secondary clinical outcomes were assessed with both objective tools (Box and Block Test, Wolf Motor Function Test (WMFT), Chedoke-McMaster Stroke Assessment Scale (CMSA)) and self-reported measures (Stroke Impact Scale (SIS), Numeric Pain Rating Scale, Visual Analog Fatigue Scale) at: baseline, end of the treatment sessions at 8 weeks, and at 12-weeks follow up.

Results-118 patients were approached; 47 were excluded, 44 declined participation. Following randomization, 3 patients withdrew.

Feasibility- Session attendance and duration did not differ between the intervention group and the control group (EMI duration per session (min) 59.8 ± 1.1 vs 59.8 ± 0.8; EMI duration per complete study (min) 2229 ± 479 vs 2303 ± 269). Adherence and attendance at follow-up did not differ either at 8 weeks (85% vs 91%) or at 20 weeks (77% vs 73). Missing data were similar (at baseline 3.5% vs 2.4, at 8 weeks-F/U 2.4% vs 2.6%, at 20 weeks-F/U 3.3 vs 2.5).

Safety- No serious adverse events were reported. Five mild non-serious adverse events attributed to HBOT included four mild ear-barotrauma and one chest pain (cardiac tests negative, attributed to anxiety). In each case, after appropriate treatment, patients continued study participation.

Efficacy & Patients Outcomes- As reflected in the Table, when compared to baseline, there was significant improvement with respect to CMSA, SIS, WMFT-FA and WMFT-14 pounds in the intervention group, sustained at 12-weeks F/U. The control group registered a single un-sustained improvement in WMFT-14 pounds.

Conclusions- The current study demonstrated that the combined approach of HBO therapy with EMI program administered to patients recovering from stroke was a safe and feasible practice. There were also trends for improved functional recovery in the affected limbs after the treatments. Clinical Trial Registration-URL:https://www.clinicaltrials.gov. Unique identifier: NCT02666469.

Table 2. The Study Feasibility, Adherence to follow-up, and missing data.

	Intervention Group	Control Group
Randomized Patients, n	14	13
Patients withdrew before baseline assessments, n	1	2
Baseline assessments, n (%)	13 (100)	11 (100)
Attendance for follow-up assessments		
At 8 weeks, n (%)	11 (85)	10 (91)
At 20 weeks, n (%)	10 (77)	8 (73)
Duration of EMI per session, min	59.8 ± 1.1	59.8 ± 0.8
Duration of EMI per complete study, min	2228.8 ± 478.6	2302.9 ± 269.4
Missing data		
Baseline assessments, n (%)	7 (3.5)	4 (2.4)
Follow-up assessments		
At 8 weeks, n (%)	4 (2.4)	4 (2.6)
At 20 weeks, n (%)	5 (3.3)	3 (2.5)

Intervention Group (Hyperbaric Oxygen therapy combined with exercise and mental imagery program (EMI)); Control Group (EMI alone). A total of 15 EMI tests/tasks were required for each patient per session. Missing data was recorded as a number of tests that were not performed, and is expressed as a number (%) per group.

Table 3. Within-group and between-group comparison of patient outcomes, for interventional and control groups.

Measures	**Within-group Comparison**						**Between-Group Comparison**	
	Intervention Group (n=13)			Control Group (n=11)				
	Baseline	Post-Intervention	Follow-up	Baseline	Post-Intervention	Follow-up	Baseline to Post-intervention *ΔMean (CI)*	Baseline to follow-up *ΔMean (CI)*
Box & Block Test (dominant hand), n	35 ± 6	39 ± 6	41 ± 6**	15 ± 6	17 ± 6	18 ± 6	*0.2 (-9, 9)*	*0.06 (-9, 9)*
Box & Block Test (non-dominant hand), n	27 ± 6	34 ± 6	31 ± 6	42 ± 6	44 ± 6	46 ± 6	*0.17(-9, 18)*	*-0.4 (-10, 9)*
Wolf Motor Function Test, sec	14 ± 8	14 ± 9	14 ± 9	30 ± 9	18 ± 10	15 ± 11	*-4 (-30, 23)*	*-11 (-39, 17)*
Wolf Motor Function Test, Functional Assessment	40 ± 3	47 ± 3*	49 ± 4*	39 ± 4	46 ± 4	42 ± 4	*1.7 (-9, 13)*	*7 (-4, 18)*
Wolf Motor Function Test, 7 pounds	7 ± 1	7 ± 1	8 ± 1	6 ± 1.5	8 ± 1.5	8 ± 1.7	*-0.5 (-5, 4)*	*0.6 (-4, 5)*
Wolf Motor Function Test, 14 pounds	18 ± 3	24 ± 3 **	23 ± 3*	11 ± 4	21 ± 4**	17 ± 4	*3 (-8, 14)*	*6 (-5, 17)*
Chedoke-McMaster Stroke Assessment, n	30 ± 3	26 ± 3	24 ± 3	28 ± 3	28 ± 3	21 ± 3	*-1 (-10, 8)*	*3.5 (-5, 12)*
Stroke Impact Scale (emotion)	57 ± 5	62 ± 5	62 ± 6	51 ± 6	56 ± 6	54 ± 7	*6. (-10, 22)*	*8 (-9, 25)*
Stroke Impact Scale (communication)	84 ± 4	97 ± 4	84 ± 5	84 ± 4	91 ± 5	90 ± 5	*-1.2 (-14, 12)*	*-6 (-19, 7)*
Stroke Impact Scale (memory)	68 ± 4	62 ± 4	71 ± 4	60 ± 4	72 ± 4	64 ± 5	*-9 (-21, 3)*	*6 (-7, 20)*
Stroke Impact Scale (social participation)	80 ± 6	88 ± 6	90 ± 6*	82 ± 7	88 ± 7	88 ± 7	*0.6 (-18, 20)*	*1.9 (-17, 21)*
Stroke Impact Scale physical domain	230 ± 18	265 ± 19	276 ± 20*	218 ± 20	245 ± 21	250 ± 22	*19 (-37, 77)*	*26 (-33, 85)*
Stroke Impact Scale perceived recovery (0 to 100)	58 ± 4	60 ± 5	64 ± 5	55 ± 5	59 ± 5	64 ± 6	*0.5 (-14, 15)*	*0.2 (-16, 16)*
Numeric Pain Rating Scale, n	0.6 ± 0.4	0.6 ± 0.4	0.5 ± 0.5	0.6 ± 0.4	0.9 ± 0.5	0.9 ± 0.5	*- 0.4 (-1.7, 0.9)*	*-0.4 (-1.9, 0.9)*
Visual Analog Fatigue Scale, n	9 ± 0.3	9 ± 0.3	9 ± 0.4	9 ± 0.4	9 ± 1	9 ± 0.4	*-0.4 (-1.5, 0.7)*	*-0.01 (-1, 1.2)*

Data are presented as mean ± standard error for within-group analysis, and point estimate confidence interval (CI) for between-groups. *p<0.05, **p<0.01

Fig. 2. CONSORT diagram.