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1. Introduction

This is a randomized placebo-controlled study of the efficacy of automated FES-assisted exercise therapy in improving hand function in sub-acute stroke patients. Previously we reported preliminary results in chronic stroke patients (Gritsenko et al., 2001. Soc Neurosci Abs, 210.20).

Study hypotheses:

- Subjects in the treatment group will achieve better hand function than subjects in the control group after FES-assisted exercise therapy.
- The improvements will carry over to unpractised tasks.
- The difference between the treatment and the control groups will be maintained 3 and 6 months later.

2. Methods

An exercise station with instrumented objects was designed and built during the study. It allowed the user to practise tasks similar to activities of daily life and provided kinematic data.



Subjects

11 subjects were recruited in the study. They were randomized into control and treatment groups. Inclusion criteria: 1) stroke occurred only once in the affected hemisphere; 2) stroke occurred between 4-9 weeks prior to the study; 3) normal premorbid hand function; 4) Brunstrom stage for the hand is between 2 and 4. Exclusion criteria: 1) severe cognitive impairment (Mini-Mental Examination score <19); 2) severe sensory impairment (OSOT - severe); 3) FES uncomfortable or ineffective.



Intervention

Treatment group performed one-hour exercise sessions daily for 3-4 weeks (15-20 sessions). The subjects used their affected hand to manipulate three instrumented objects on a workstation for the duration of the session. Hand opening was assisted by triggered electrical stimulation of extensor muscles.

Control group received sham treatment for the same period of time: weak electrical stimulation of arm muscles with the FES device for 15 minutes daily.

Outcome measures:

Kinematic:

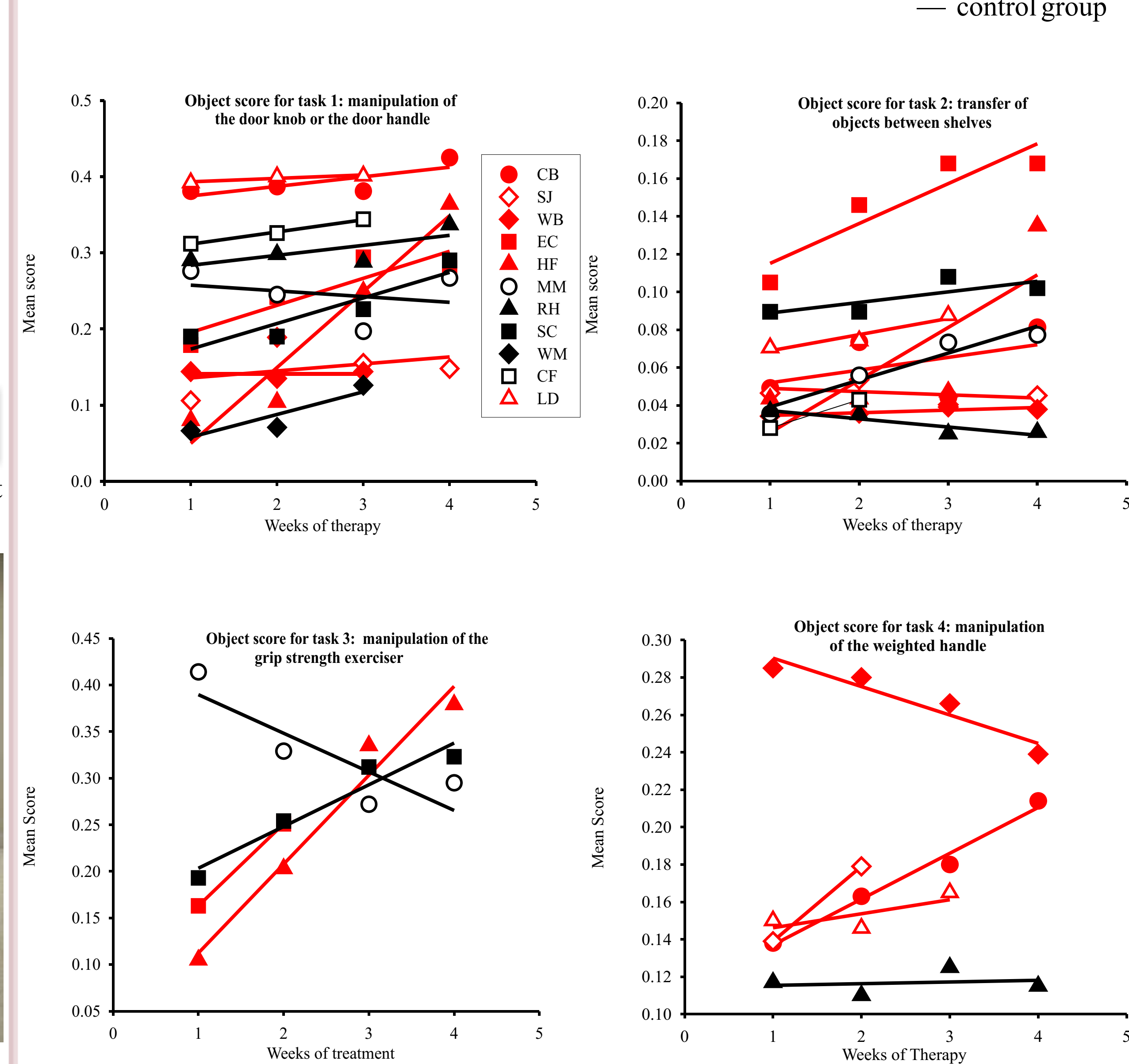
- A performance score S, calculated according to the following formulae:
- $S1 = (mRt1 + mMt1 + mA1) / 3$, where S1 - score for object 1; mRt1 - mean time to reach and grasp object 1; mMt1 - mean time taken to move object 1; mA1 - mean amplitude of movement of object 1. Rt, Mt & A were normalized to values exhibited by an unaffected person.
- $S = (S1 + S2 + S3) / 3$, where S1, S2 & S3 - scores for objects 1, 2 & 3.

Clinical:

- Fugl-Meyer Test (FMT)
- Wolf Motor Function Test (WMFT)
- Functional Independence Measure (FIM)

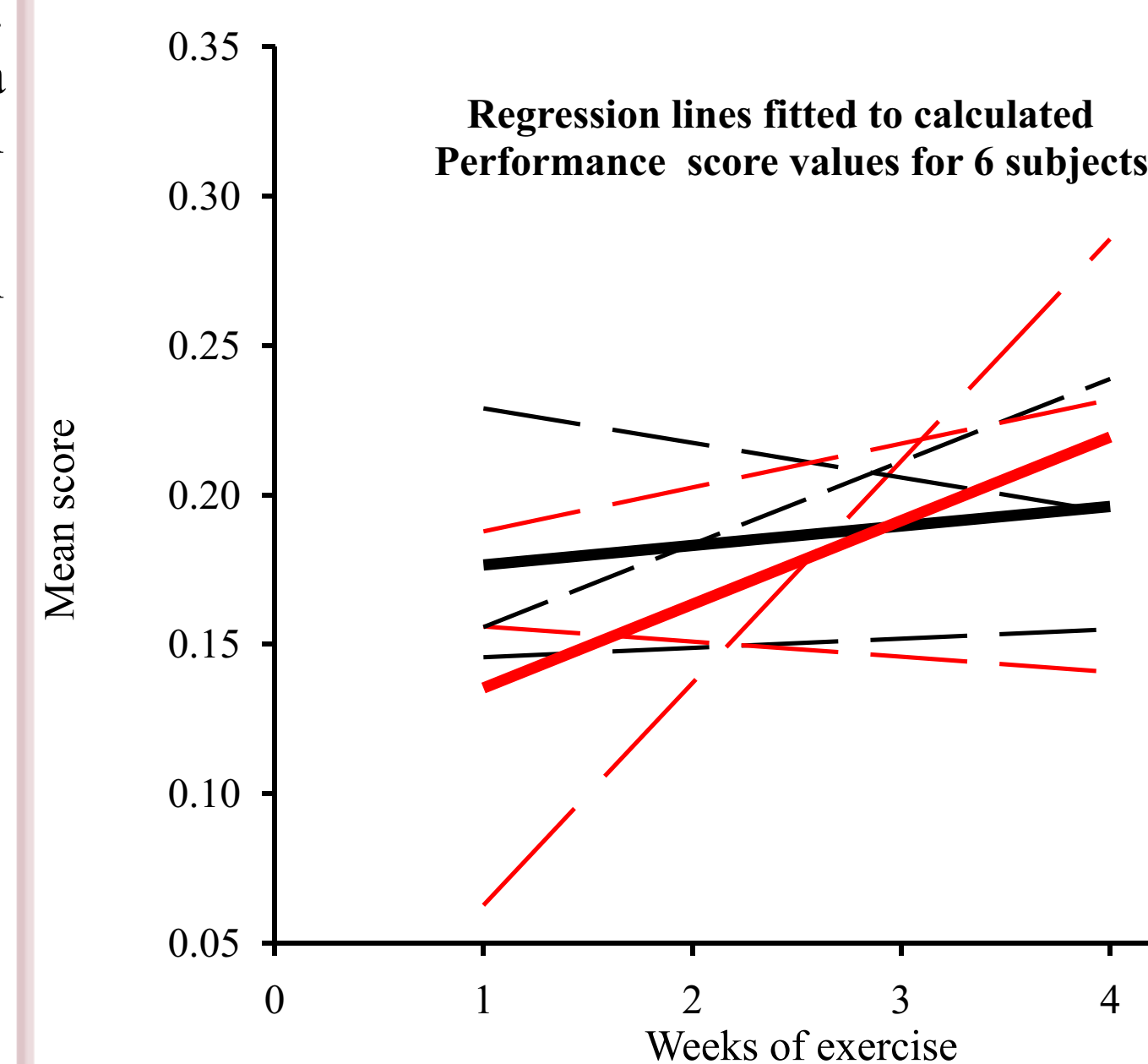
3. Results

Kinematic measures:



Subjects in the treatment group showed larger improvements in the use of objects on the workstation.

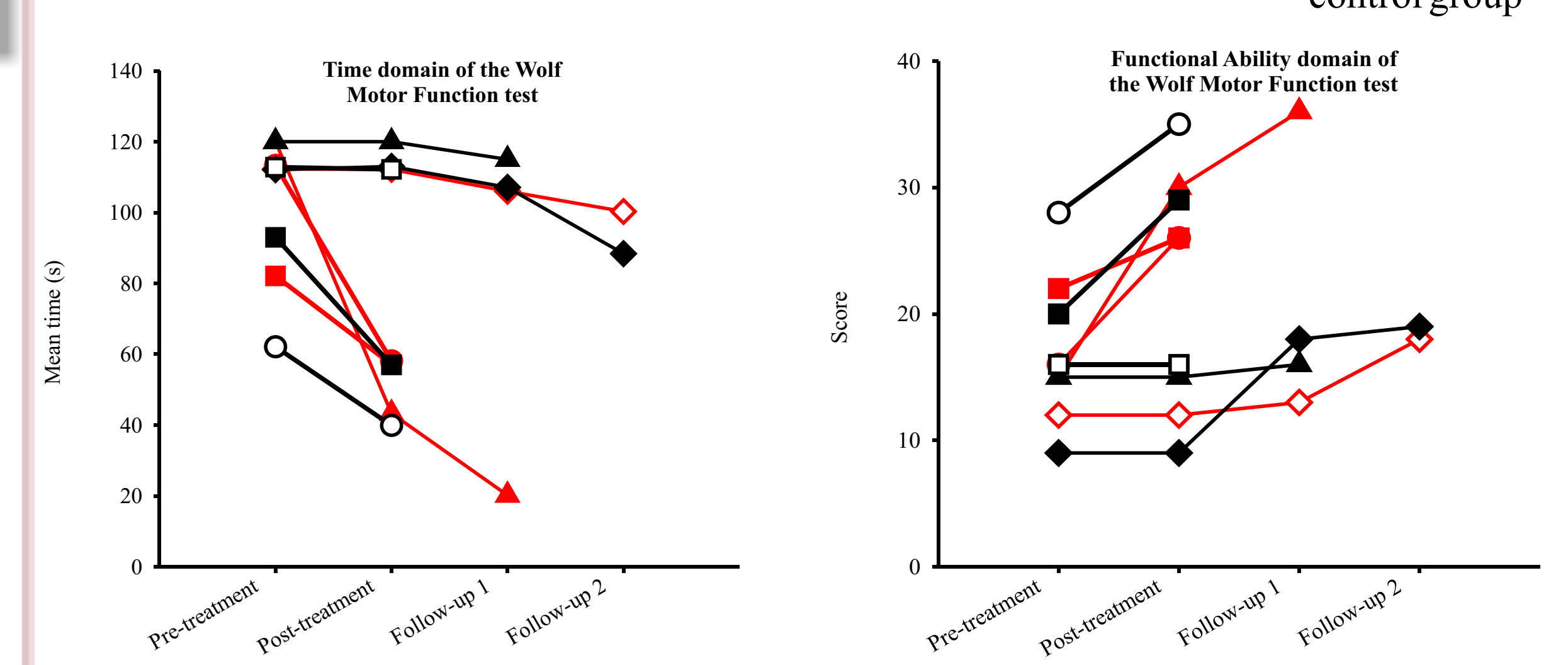
Mean slopes of regression lines for task 1 were 0.009 and 0.008 for the treatment and the control groups respectively. Mean slopes for task 2 were 0.022 and 0.017 for the treatment and the control groups respectively. However, the differences did not reach significance when assessed by a t-test (P=0.25, P=0.33 for task 1 and 2 respectively).



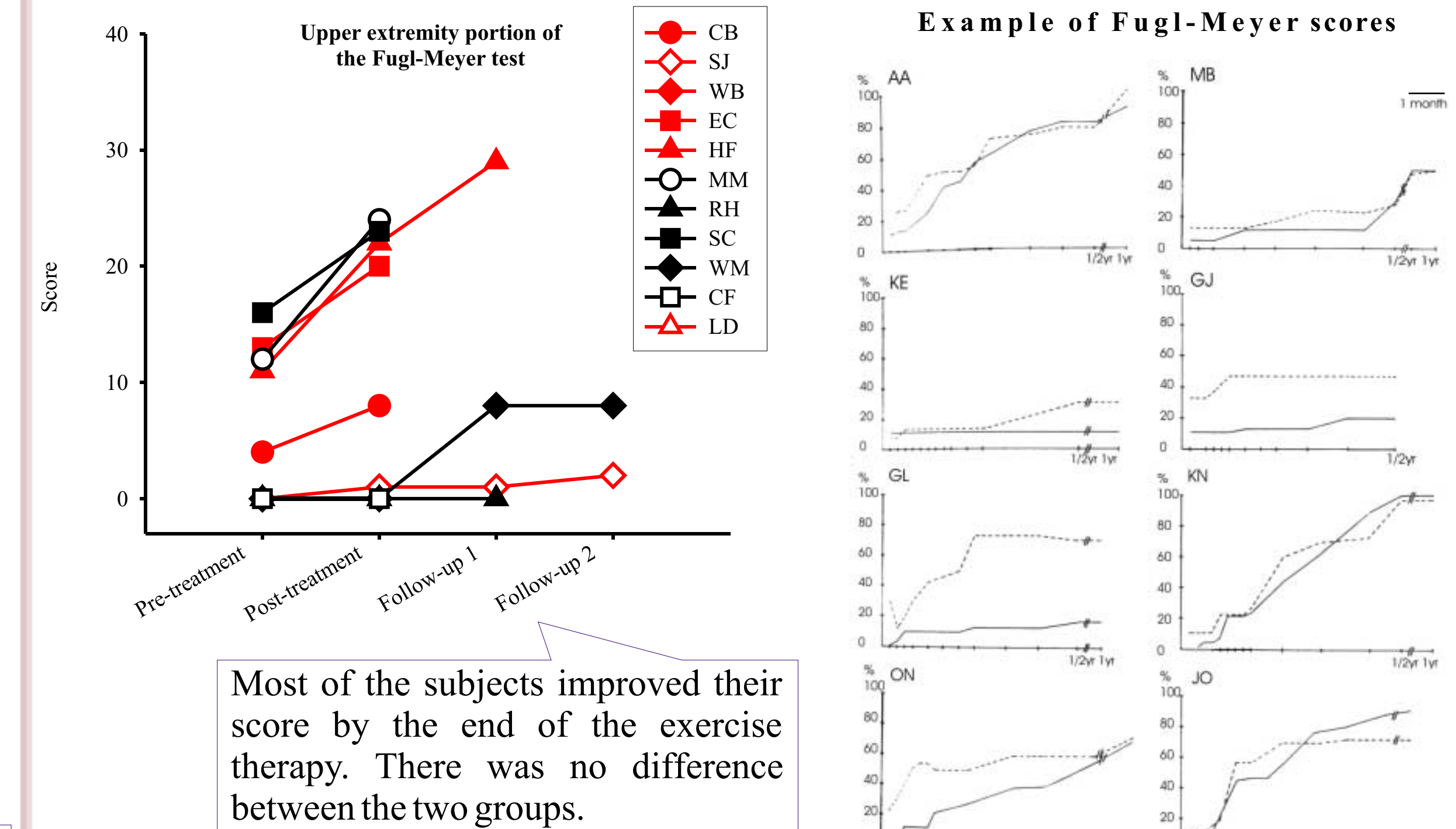
The regression lines (dashed) were fitted to the data from individual subjects, while the solid lines represent the mean values of the performance scores for each group.

Slope of the solid line for the treatment group is higher than the slope for the control group, indicating that the subjects in the treatment group improved more than the subjects in control group.

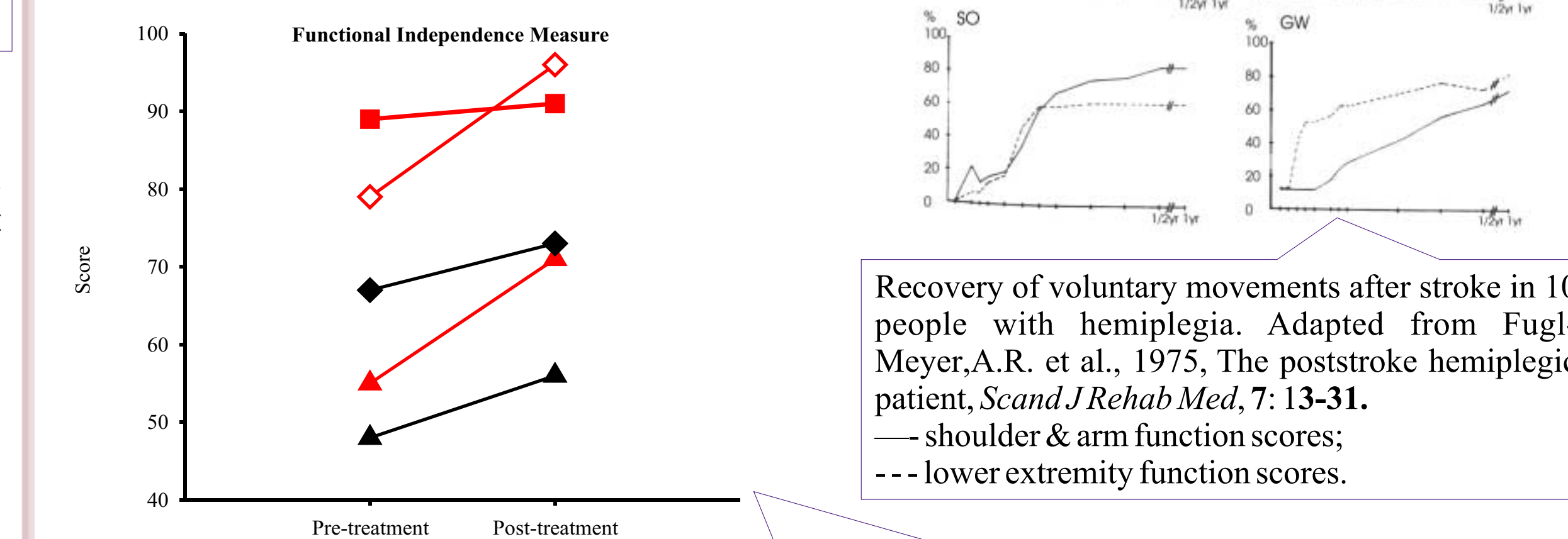
Clinical measures:



Decrease in the mean time plotted on the left and increase in the score plotted on the right indicate improvement in hand and arm function. Subjects from both treatment and control groups improved. 2 out of 4 subjects in the treatment group improved more than the control group.



Most of the subjects improved their score by the end of the exercise therapy. There was no difference between the two groups.



Not all data were available for this graph. All subjects assessed so far improved their score by the end of the exercise therapy. The subjects from the treatment group seem to improve more in their independence.

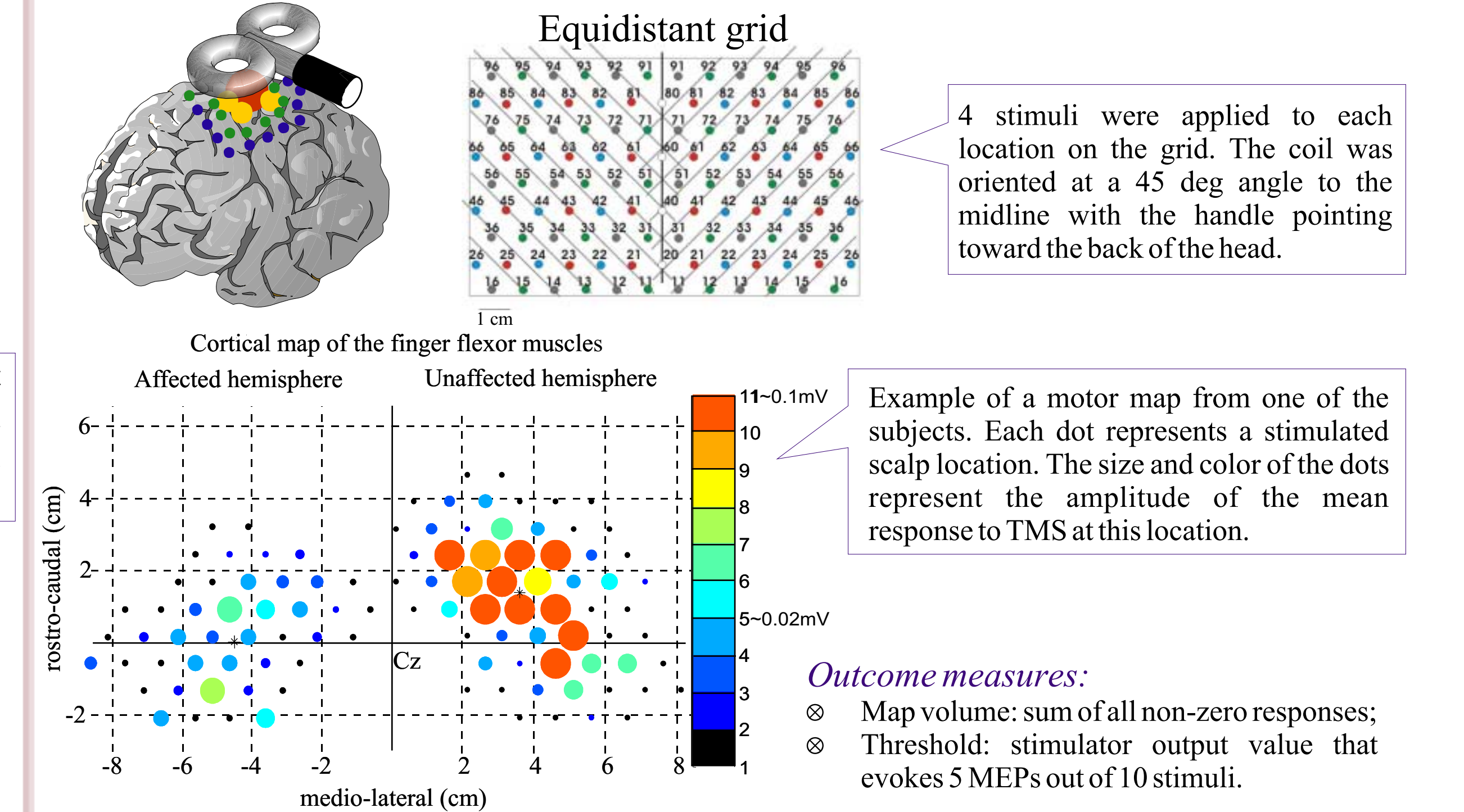
4. Conclusions

- The kinematic data indicate that FES-assisted exercise therapy improves hand function of sub-acute stroke patients.
- The improvements were transferable to unpractised tasks as shown by the Wolf Motor Function test.
- The clinical data suggest that the improvements immediately following the treatment are not large enough to be clinically relevant. However, only when all follow-up assessments are completed, the long-term impact of the therapy will be revealed.

5. Appendix. TMS

Methods

In 8 out of 11 subjects motor cortex of both the affected and unaffected hemispheres was magnetically stimulated before-, after- and following the exercise therapy. A figure-of-eight coil was used to map the cortical representations using an equidistant grid placed over the scalp of the subjects. Representations of the thenar muscles, the finger flexors and the wrist extensors were mapped.

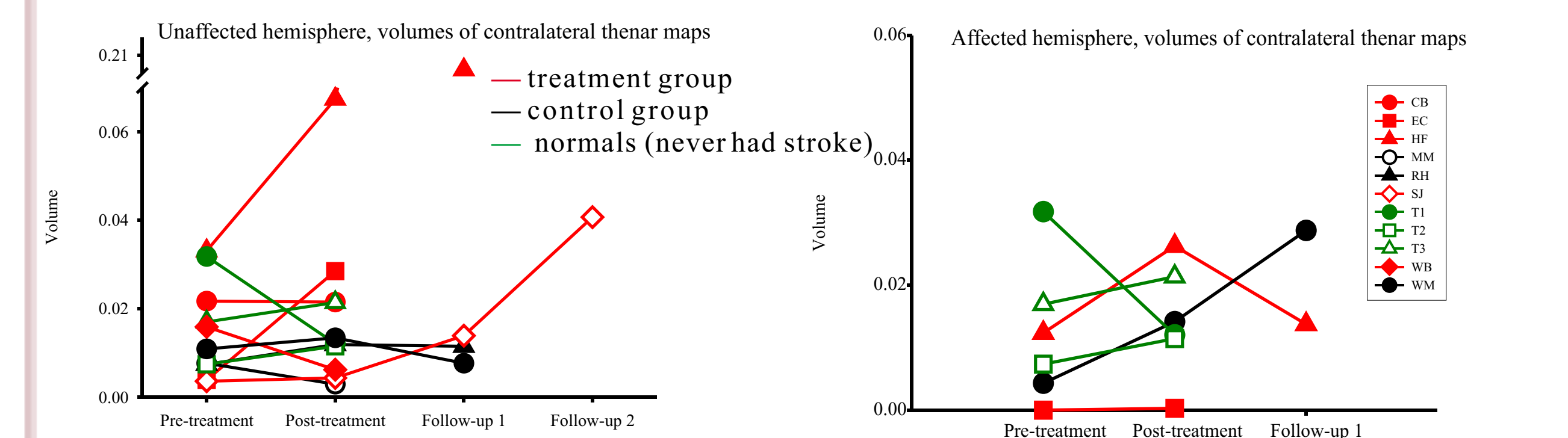


4 stimuli were applied to each location on the grid. The coil was oriented at a 45 degree angle to the midline with the handle pointing toward the back of the head.

Example of a motor map from one of the subjects. Each dot represents a stimulated scalp location. The size and color of the dots represent the amplitude of the mean response to TMS at this location.

Outcome measures:
 ⊗ Map volume: sum of all non-zero responses;
 ⊗ Threshold: stimulator output value that evokes 5 MEPs out of 10 stimuli.

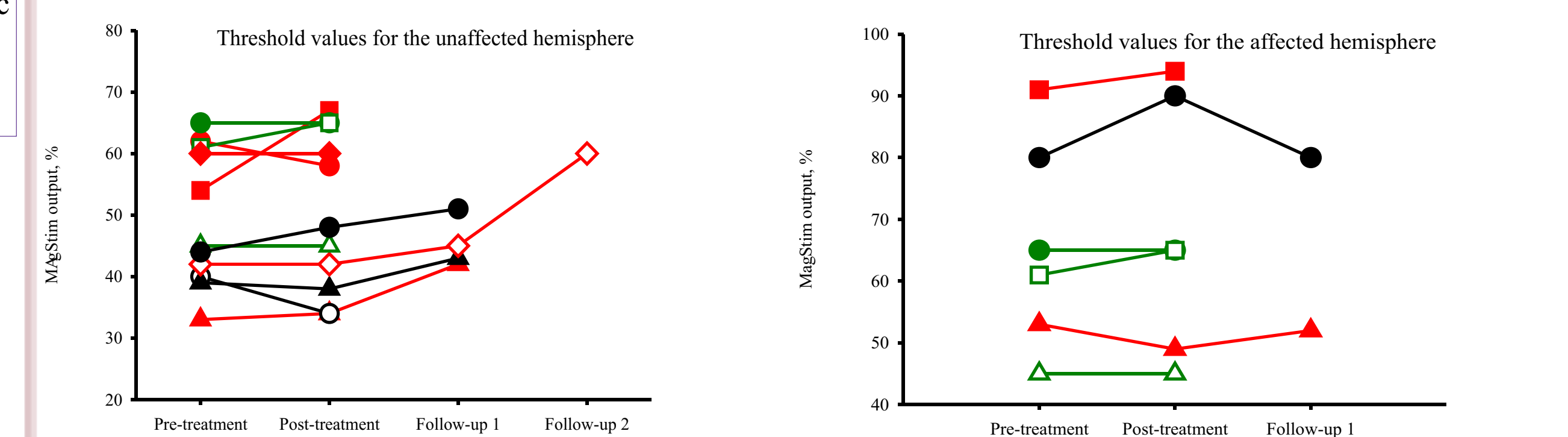
TMS results: map volume



There was no difference in volumes of maps between the control and treatment groups. At the follow-up, there is a tendency for the subjects in the treatment group to show larger increases in map volumes.

There was no difference in volumes of maps between the control and treatment groups.

TMS results: thresholds



MEP thresholds of the unaffected hemisphere increased gradually, while the thresholds of the affected hemisphere did not change. There was no difference between the control and the treatment group.

Conclusions:

While all 8 subjects improved in their hand function, only 3 of them had MEPs contralateral to the affected hemisphere. This shows that absence of MEPs is not well correlated with recovery.

Comparison of motor maps and thresholds proved to be inconclusive.

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