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LETTER TO THE EDITOR

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COMMENTS TO: "CONTRALATERALLY CONTROLLED FUNCTIONAL ELECTRICAL STIMULATION IMPROVES WRIST DORSIFLEXION AND UPPER LIMB FUNCTION IN PATIENTS WITH EARLY-PHASE STROKE: A RANDOMIZED CONTROLLED TRIAL"

The recently published article by Zheng et al. (1) is well documented with interesting findings. It concludes that in patients with early-phase stroke, contralaterally controlled functional electrical stimulation (CCFES) is superior to neuromuscular electrical stimulation (NMES) in both shortening the course of regaining wrist dorsiflexion (WD) and recovery of upper extremity function. However, some points require further clarification from the authors.

First, the study design is described as a randomized controlled trial; however, there is no control group in the study. Perhaps it would be more accurate to describe the study as a 2-group pre-test post-test experimental design (2).

Secondly, the early-phase stroke patients' type is unclear from the inclusion criteria. The authors did not report sensory assessment of the included patients, and thus there is a risk of burn with the reported dosage intensity of NMES (40 mA) in patients with impaired sensations (3).

Thirdly, in the section on outcomes measures (p. 105), the authors performed Manual Muscle Testing (MMT) to measure the strength of the extensor carpi. They recruited patients with Brunnstrom recovery stage 3 or less, but, in these stages, patterns of movements occur in association with spasticity. It is advisable to perform group MMT with an appropriate measurement tool, such as a hand-held dynamometer, rather than performing MMT for a specific muscle (4).

Fourthly, the authors did not specify the parameters (frequency, mode) of CCFES. The parameters of NMES (pp. 104–105) in the study protocol section are also not mentioned clearly.

Fifthly, in the statistical analysis it is not clear why the authors used Student's *t*-test for analysis of demographic data, as it does not fulfil the assumptions for application of this test. Mann–Whitney *U* test should be used to determine the inter-group differences for active range of motion (ROM) for WD, strength of extensor carpi, and Jebsen Hand Function Test (JHFT), rather than the Wilcoxon signed-rank test. The authors mention a sample size for the study of 40 participants; however, in the results section under demographic data they have assigned 50 total participants into 2 groups. Thus, the actual sample size requires clarification.

Lastly, in Table III, the authors have used means and standard deviations to express the central tendency for both data with a normal distribution and for data without a normal distribution. This is inappropriate; they should have used median and interquartile range to express the central tendency for the non-normally distributed data (5).

The work conducted by the authors in this study is, however, commendable for enlightening professionals regarding the authors' innovative ideas and their application.

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RESPONSE TO LETTER TO THE EDITOR FROM ZHENG ET AL.

We appreciate the interest from readers and the comments by Satkarjit Kaur Jhandi and colleagues. Our response to these comments is as follows.

Regarding the study design, there is debate about the definition of "randomized controlled trials (RCT)" and no consensus has yet been reached. In the current study, we considered the group receiving conventional neuromuscular electrical stimulation (NMES) the control group and the group receiving contralaterally controlled functional electrical stimulation (CCFES) the intervention group. We agree that we could also have described the study as having a 2-group pre-test post-test experimental design. The term RCT is, however, usually better understood by the readership and seems justified when participants are randomly assigned to a conventional therapy (control) compared with a new therapy.

The maximum pulse duration, defined as that which produced maximum wrist dorsiflexion (WD) without pain, while the participant remained relaxed, was determined for each electrode. To the best of our knowledge, several studies have applied the same dosage intensity (40 mA NMES) and no adverse event has been reported. Our colleague Shen et al. applied the same device with a dosage of 0–100 mA and found that

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it was safe for patients' skin (6). Knutson et al. applied a pulse amplitude of 40 mA for all patients and 60 mA for one participant (7–9).

Regarding the third point, the target population of the current study was early-phase stroke patients, most of whom were in the flaccid paralysis stage and therefore no patient with high muscular tension was observed. In addition, patients with progressive stroke and in non-stable condition were excluded. In our experience, the muscular strength of patients with early-phase stroke who receive early-phase neurological intervention recovers relatively faster than in those with subacute or chronic stroke, and no abnormally increased muscular tension was observed. After careful consideration, Manual Muscle Testing (MMT) was adopted for evaluating the strength of the extensor carpi. However, group manual muscle testing (i.e. hand-held dynamometer) is also considered reasonable to measure the strength of the muscle groups.

The parameters and protocol of CCFES and NMES were clearly documented in the Methods section as follows:

Parameters of CCFES AND NMES: "stimulators (Weisi Corporation, Nanjing, China) used in this study delivered biphasic rectangular current pulses; the pulse frequency was set at 35 Hz, and the pulse amplitude was set at 40 mA. The electrical stimulation intensity was set at a sustainable level with full balanced WD with tetanic contraction."

Protocol of NMES: "Patients in the NMES group received neuromuscular electrical stimulation (2 20-min sessions each day). Each session consisted of 48 15-s sets, separated by 10 s of rest."

Protocol of CCFES: "Patients in the CCFES group were treated with contralaterally controlled functional electrical stimulation (two 20-min sessions every day). Each session consisted of 48 15-s sets, separated by 10 s of rest. Patients were prompted by sound cues from the stimulator to actively extend both wrists, then the paretic wrist was stimulated to complete WD, assisted by the bioelectrical signal transmitted from the non-paretic side, held still for 15 s when full WD was achieved, then relaxed for 10 s."

We consider the use of independent *t*-tests was justified for statistical analysis of the continuous and normally distributed demographic data. Wilcoxon rank-sum test (also known as Mann–Whitney *U* test or Mann–Whitney–Wilcoxon test) was used for analysis of inter-group difference in active range of motion (ROM) for WD, strength of extensor carpi and JHFT, since those variables were not normally distributed.

As regards the sample size in the current study, 50 eligible patients were enrolled at baseline and 9 dropped out, for a range of reasons, as documented in the Results section.

Lastly, box-whisker plots were used to show the distribution of the variables that were not normally distributed, and these indicate medians and interquartile range. Table III was designed principally to show the statistical results in a uniform format rather than presenting the distribution of the data.

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