Research Article

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Impact of Repetitive Peripheral Magnetic Stimulation on Post-Stroke Patients with Upper Limb Spasticity - A Randomized Controlled Trial

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ABSTRACT

Background: *Spasticity is a common consequence of stroke and in many cases leads to the patient's full dependence on the caregiver. Early treatment can significantly reduce the impairments and health limitations and thus enable the patient to manage daily activities. Botulinum toxin injections only eliminate undesirable manifestations of spasticity without leading to an improvement in the mobility of the limbs while conventional physiotherapy did not prove a direct effect in spasticity reduction. Repetitive peripheral magnetic stimulation represents a promising method for post-stroke spasticity reduction and the simultaneous enhancement of the patient's movement limitations.*

Aim: *The aim of this randomized controlled trial was to evaluate the impact of peripheral magnetic stimulation in patients with spasticity of the upper limb after a cerebral stroke in the early recovery period.*

Methods: *Patients suffering from post-stroke spasticity were randomly assigned to experimental and control groups. Both groups underwent 10 sessions of a conventional physiotherapy program including gymnastics, massage, low-intensity magnets, whirlpool baths, limb development using the Amadeo stimulator, and biofeedback. The participants in the experimental group also underwent repetitive peripheral magnetic stimulation within each session. Before the first and after the last treatment session, the Modified Ashworth scale, angles of spasticity defined by the Modified Tardieu scale, and the Arm Activity Measure questionnaire were obtained.*

Results: *Non-parametric Wilcoxon sign rank test confirmed a significant improvement in the Modified Ashworth scale, Arm Activity Measure, and angles of spasticity for both groups. The experimental group reported improvements of 36%, 15%, 24%, 6.6%, and 6.8% higher than the control group in terms of Modified Ashworth scale, Arm Activity Measure - section A, Arm Activity Measure - section B, angles of spasticity R1 and R2, respectively.*

Conclusion: *Repetitive peripheral magnetic stimulation proved to be effective in upper limb spasticity reduction, enhancement in functionality during daily activities, and increase in range of motion in post-stroke patients in the early recovery phase.*

Keywords
Post-stroke spasticity, Peripheral magnetic stimulation, Modified Ashworth scale, Angle of spasticity, Modified Tardieu scale, Arm Activity Measure.

Introduction
Seventeen million people experience a stroke worldwide every year, i.e. approximately every two seconds a stroke occurs somewhere in the world. Globally, it represents the second most common cause of death and disability and remains a major cause of depression and dementia [1]. Of the 800,000 strokes that occur in the US each year, about 75% are first-time strokes. The risk of stroke increases significantly with age - after reaching the age of 55, the incidence doubles with each decade. The occurrence of stroke is about 30 to 120 out of 100 000 per year for adults aged 35 to 44 while it is 670 to 970 out of 100 000 for those aged 65 to 74 [2].

Most stroke survivors suffer from serious health limitations affecting their daily activities such as eating and self-care and thus remain dependent on the help of a caregiver.

These impairments are associated with developed post-stroke sequelae including impaired motor function and post-stroke spasticity [3]. Post-stroke spasticity, defined as velocity-dependent muscle over activity [1], occurs in 20-30% of all stroke patients, it is more prevalent in the upper than the lower limb and seems to affect younger than older adults [4]. Spasticity can cause a wide range of constraints in the upper limb from limited grip control to a clenched fist and inability to gasp. If spasticity is not treated, the consequences are more serious resulting in pain, deformity, severe contractures, and involuntary movement [5]. For this reason, it is critical to provide patients with effective spasticity treatment in an early post-stroke phase.

Current treatment methods are primarily based on botulinum toxin injections, the administration of antispastic drugs, and the application of various physiotherapeutic procedures [4].

The first choice treatment for post-stroke spasticity management represents botulinum toxin injection. Although this spasticity treatment is verified by more than thirty years of clinical evidence, it certainly has limitations that give space for the emergence of new treatment procedures. The principle is based on the inhibition of acetylcholine release and thus preventing the initiation of muscle contraction. Once botulinum toxin injection is precisely injected into the muscle, local spasticity is reduced due to a developed neuromuscular block followed by spastic muscle paresis. Such a mechanism of action leads to the elimination of spasticity at the cost of weakening the already weak spastic muscles resulting in the worsening of their motor performance. Furthermore, the botulinum toxin effect is not immediate (clinical results do not manifest until several days following the procedure) and has a limited duration requiring repeated injections every 3-4 months [6].

Although physiotherapy is recommended for spasticity treatment by English National Guidelines for Stroke, clinical evidence is slightly contradictory [4]. Katalinic et al. conducted a systematic review and found no significant changes in spasticity after regular stretching in patients with neurologic conditions [7]. Ward et al. focused on impairment and activity of the upper limb after intensive neurorehabilitation in chronic stroke patients. Significant improvement was reported both immediately post-6-month program and at the 6-month follow-up [8]. It is believed that physiotherapy of post-stroke spastic pareses is not primarily beneficial in spasticity reduction but rather in the enhancement of impairment and activity limitation [4].

Most antispastic drugs are of limited tolerance and efficiency due to their accompanying depressing effect on the central nervous system [9].

Despite many years of experience and extensive clinical evidence in the treatment of post-stroke patients, there is still plenty of room for new methods enabling the treatment of spasticity while simultaneously improving motor performance. This study aims to evaluate the effect of peripheral magnetic stimulation on the spastic upper limbs of post-stroke patients.

Materials and Methods
This randomized controlled trial was conducted in a government clinic in Russia between October 2021 and March 2022.

The male and female post-stroke adult patients willing to participate suffering from upper limb spasticity were enrolled. Pregnant participants and those with a current or history of cancer, electronic or metal implant, and blood coagulation history were excluded.

To ensure the possibility of evaluating the impact of the treatment technology, the patients were randomly assigned into equally distributed experimental and control groups. Randomization with blocks of size 10 was performed by computer program in order to generate the allocation sequence. A chief physiotherapist provided enrollment and assignment into the respective group. Chief physiotherapist was also responsible for providing the repetitive peripheral magnetic stimulation. Another clinician who was not informed about patient allocation provided a physiotherapy program and collected reported outcome measures. Researcher who was not aware of group distribution was responsible for data processing and evaluation. For the allocation blinding purposes, participants in the control group were given sham stimulation at an intensity of 1% instead of repetitive peripheral magnetic stimulation.

Based on published data showing the baseline MAS of post-stroke patients with upper limb spasticity and desired intergroup difference [10] it was estimated that at least 18 patients in each group would give 80% power to detect a significant ($p < 0.05$) difference between the groups.

Before the start of the clinical trial, information about the treatment program was provided to participants and they were asked to sign informed consent containing an agreement with study participation and publication. The study design was compatible with the 1975 Declaration of Helsinki ethical guidelines adopted by the General Assembly of the World Medical Association (1997-2000) and by the Convention on Human Rights and Biomedicine of the Council of Europe (1997) [11].

The treatment protocol consisted of a conventional physiotherapy program including gymnastics, massage, low-intensity magnets, whirlpool baths, limb development using the Amadeo simulator and biofeedback, and currently evaluated peripheral magnetic stimulation (BTL Industries Ltd.). A physiotherapy program was provided to both patient groups while peripheral magnetic stimulation was only performed on the experimental group. In total, participants underwent 10 treatment sessions.

Before the magnetic stimulation, the patient was positioned so that the impaired upper limb was in the most relaxed position. The therapist placed the center of the applicator above the spastic muscle motor point, started the therapy, and set the patient's motor threshold intensity. Intensive magnetic pulses affected the spinal level of muscle tone control and caused an antispastic effect on the agonist muscle. After this section, the therapist moved the applicator above the muscle motor point of the antagonist muscle to induce a facilitatory effect. The following sections ensured higher blood perfusion resulting in circulation and trophic improvement. The therapy was painless. Patients felt intense muscle contractions, tingling, or gentle pulsation.

Several spasticity measurement tools were used to monitor changes during the study. As the primary outcome measure, Modified Ashworth scale (MAS) was reported. Secondary outcome measures included angles of spasticity (AoS) defined by the Modified Tardieu scale, and Arm Activity Measure (ArmA). All collected outcomes were reported at the baseline and after the last treatment session. The Modified Ashworth scale remains, despite some criticism, one of the most commonly used scales for the assessment of spasticity. The scale represents a six-point assessment of the degree of muscle tone (0, 1, 1+, 2, 3, 4) where 0 means 'No tonus increase' and 4 'Affected parts are rigid in flexion and extension. The limitations include the dependence of the result on the evaluator and the applied stretching speed and the inability to distinguish spasticity from other tonus disorders [12]. For statistical analysis purposes, the scale was adjusted in the current trial (0, 1, 2, 3, 4, 5).

Angles of spasticity are resulting joint angles measured by a goniometer as defined by the Modified Tardieu scale. After a fast velocity stretch, the R1 angle and after a slow velocity stretch, the R2 angle is reported [13]. The difference between the two angles (R1-R2) is defined as the dynamic component of spasticity [14]. The size of this value determines the potential for improvement - a large dynamic component predetermines a greater possibility of change while a small value means predominantly fixed muscle contracture and a weaker chance of improvement [15].

Arm Activity Measure is a self-report questionnaire assessing upper extremity function in daily activities following spasticity treatment. In total, it contains 20 items divided into two sections. The first 7 items belong to section A (ArmA-A) and focus on passive functions while the remaining 13 items sorted under section B (ArmA-B) cover active functions. Each item is scored using a five-point Likert system, assigning 0 to 'no difficulty' and 4 to 'unable to do the task' [5].

A Matlab script (MatLab software processes, MatLab R2010b, Mathworks, Inc., Natick, MA, USA) was written for the purpose of data processing and evaluation. MAS, AoS, and ArmA data were evaluated for the control and experimental group by non-parametric Wilcoxon signed rank test as the Shapiro-Wilk test showed a significant departure from the normality (p=0.05).

Results

A total of 40 patients (24 males, 16 females) with spasticity of the upper limb after a cerebral stroke in the early recovery period; aged 57.33±10.31; were randomized into two groups. All participants were able to finish the full study course with no reported adverse events and good tolerability of the procedure.

Modified Ashworth scale

Significant spasticity improvement ($p<0.05$) was reported using the Modified Ashworth scale for both patients' groups. The basic statistics of the MAS data are summarized in Table 1. Patients within the experimental group experienced a 36% greater improvement than those treated in the control group.

Table 1: Summary of MAS score for control and experimental groups obtained before and after the last treatment session.

		Modified Ashworth scale	
		BEFORE	AFTER
Control	AVG	3.60	2.35
	STDEV	0.50	0.75
	Difference	-1.25	
	Difference (%)	-34.72	
	Wilcoxon P (0.05)	<0.001	
Experimental	AVG	3.10	0.90
	STDEV	0.31	0.55
	Difference	-2.20	
	Difference (%)	-70.97	
	Wilcoxon P (0.05)	<0.001	

For the purposes of a better visual comparison, MAS data distribution is presented using a box plot graph (Figure 1). Although a significant decrease in after score is visible for both groups, this decrease is more pronounced for the experimental group.

Arm Activity Measure

Significant improvement ($p<0.05$) in passive and active upper limb function was reported using Arm Activity Measure for both control and experimental group. The basic statistics of the ArmA-A and ArmA-B data is summarized in Table 2. Patients within the experimental group experienced a 15% and a 24% greater improvement than those treated in the control group in the

ArmA-A and ArmA-B sections respectively.

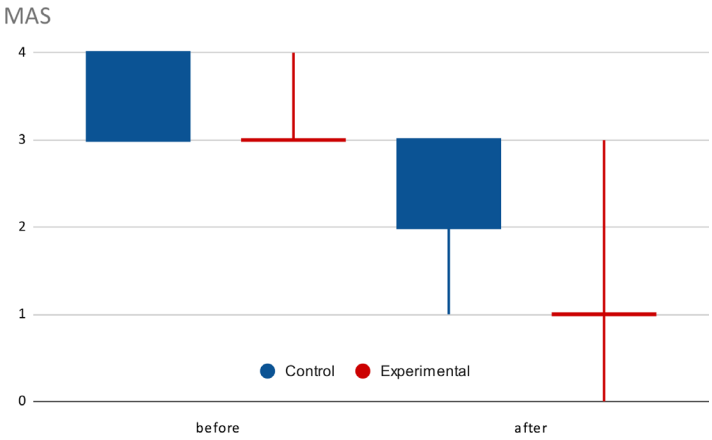

Figure 1: MAS before and after data visualization for control and experimental group.

Table 2: Summary of ArmA score for control and experimental groups obtained before and after the last treatment session.

		Arm Activity Measure			
		Section A (passive functions)		Section B (active functions)	
		BEFORE	AFTER	BEFORE	AFTER
Control	AVG	24.10	17.45	50.40	45.60
	STDEV	2.38	3.30	2.39	4.59
	Difference	-6.65		-4.80	
	Difference (%)	-27.59		-9.52	
	Wilcoxon P(0.05)	<0.001		<0.001	
Experimental	AVG	19.15	10.95	42.05	27.90
	STDEV	3.47	2.87	8.20	8.72
	Difference	-8.20		-14.15	
	Difference (%)	-42.82		-33.65	
	Wilcoxon P(0.05)	<0.001		<0.001	

Box plot graph (Figure 2) shows significant drop of ArmA-A and ArmA-B values for both groups. More pronounced change was reported within the experimental group.

It is obvious from scatter plots in Figure 3 that all participants experienced some degree of improvement in their upper limb functionality as reported by ArmA questionnaire.

Angles of Spasticity

Significant improvement ($p<0.05$) in R1 and R2 angles was measured for both control and experimental groups while the dynamic component of spasticity (R1-R2) remained without significant difference for both groups. The basic statistics of angles of spasticity data is summarized in Table 3. Patients within the experimental group experienced a 6.6% and a 6.8% greater improvement than those treated in the control group of the R1 and R2 angles respectively.

Box plot graph (Figure 5) shows significant increase of R1 and R2 angles for both groups. Larger post treatment program range of motion was measured in patients from the experimental group.

Scatter plots in Figure 6 display that all participants experienced enhancement in their upper limb range of motion in terms of both R1 and R2 angle increase.

Discussion

Peripheral magnetic stimulation proved to be beneficial in the treatment of upper limb spasticity in post-stroke patients in the early recovery stage in terms of Modified Ashworth scale, Arm Activity Measure and Angles of Spasticity R1 and R2 as defined by Modified Tardieu scale. The only parameter, which did not report significant change, was the dynamic component of spasticity (R1-R2). This fact can be logically explained - if both parameters (R1, R2) improve to a similar extent, then their difference will remain unchanged. The control group of patients experienced significant improvement in the same parameters. However, in a mutual intergroup comparison of the results, a higher improvement is evident in patients who, in addition to conventional rehabilitation, also underwent peripheral magnetic stimulation. The experimental group reported improvements of 36%, 15%, 24%, 6.6% and 6.8% higher than the control group in terms of MAS, ArmA-A, ArmA-B, R1 and R2, respectively. The highest difference in MAS is in accordance with Sommerfeld's finding that classical physiotherapy contributes to the improvement of post-stroke patients more by improving functional parameters than by directly reducing spasticity.

Despite extensive clinical evidence of the electrical stimulation effects [16], the impact of peripheral magnetic stimulation, which is considered more suitable, have been investigated in this area on a significantly smaller scale. The repetitive peripheral magnetic stimulation unlike neuromuscular electrical stimulation enables painless treatment through clothes, penetration into deep structures, generation of high muscle torque and applicability to children [17,18]. The mechanism of action is similar to a neuromuscular electrical stimulation with the difference that it uses an intensive magnetic field.

As the changing magnetic field is capable of inducing electrons flow, a repetitive magnetic stimulation is able to induce electric currents within the neuromuscular tissue [19]. Subsequent nerve depolarization results in concentric muscle contraction yielding an antispastic effect via post-facilitatory inhibition affecting the spinal level of muscle tone control. Muscle balance ensured by relaxation of spastic and stimulation of weakend muscles contributes to improvement of spasticity within the impaired segment [10].

Jiang et al. [19] conducted a randomized controlled trial with the primary aim to assess the Fugl-Meyer upper extremity motor section after repetitive peripheral magnetic stimulation in post-stroke patients with severe upper limb impairment. Study further investigated impact on Barthel Index and root mean square of surface electromyography for muscle strength and stretch-induced spasticity. In conclusion, a significant effect of repetitive peripheral

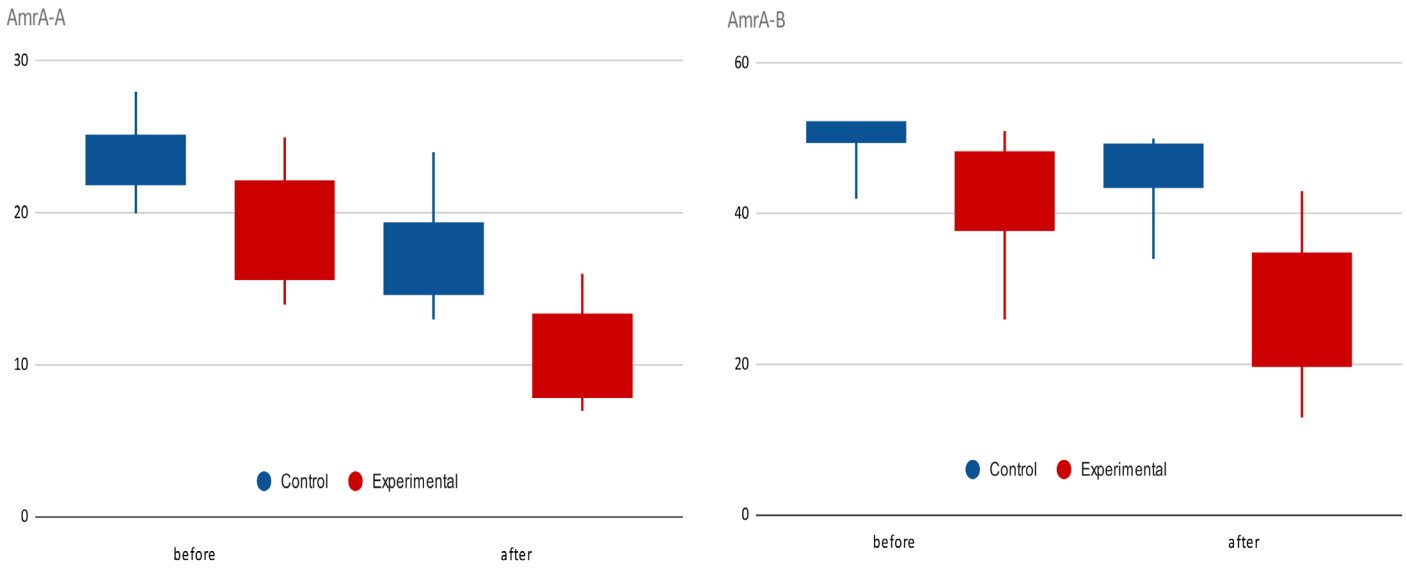

Figure 2: ArmA-A and ArmA-B before and after data visualization for control and experimental group.

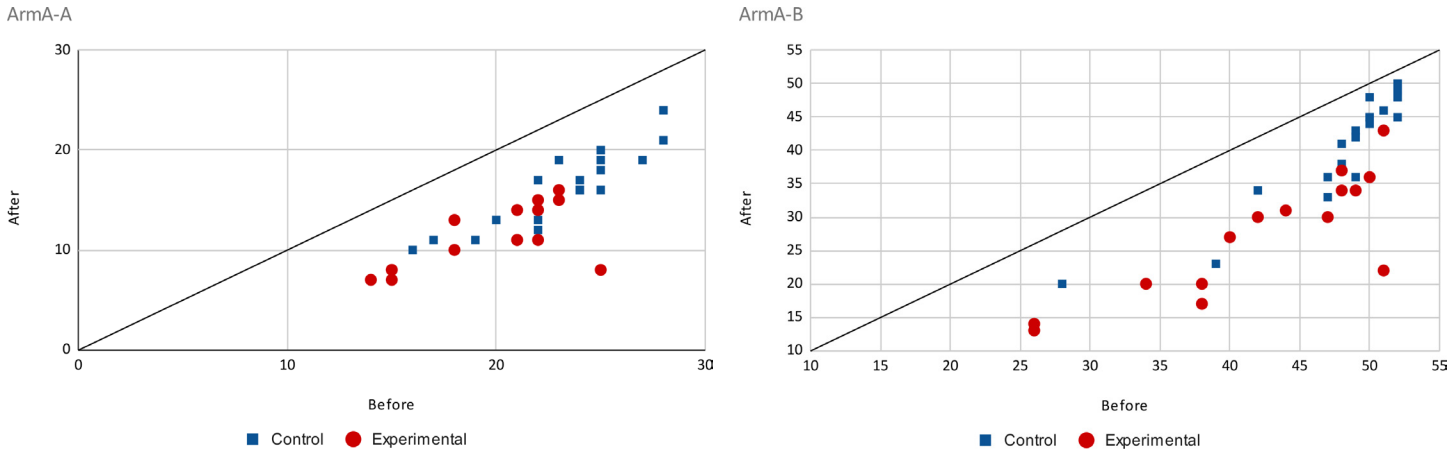

Figure 3: Baseline (Before) data plotted against final post-treatment program scores (After). The linear middle line represents patients with 'no change'. Patients below this line have improved while those above the line were left with worse condition as reported by ArmA questionnaire.

Table 3: Summary of Angles of Spasticity score for control and experimental groups obtained before and after the last treatment session.

		Angles of Spasticity (Modified Tardieu scale)					
		R1		**R2**		**R1-R2**	
		BEFORE	AFTER	BEFORE	AFTER	BEFORE	AFTER
Control	AVG	129.50	140.00	95.65	107.25	33.85	32.55
	STDEV	8.90	9.14	7.42	10.98	5.66	10.21
	Difference	10.50		11.60		-1.30	
	Difference (%)	8.11		12.13		-3.84	
	Wilcoxon P(0.05)	<0.001		<0.001		0.396	
Experimental	AVG	137.75	158.00	103.00	122.50	34.75	35.50
	STDEV	9.72	8.34	7.55	7.34	10.41	7.60
	Difference	20.25		19.50		0.75	
	Difference (%)	14.70		18.93		2.16	
	Wilcoxon P(0.05)	<0.001		<0.001		0.635	

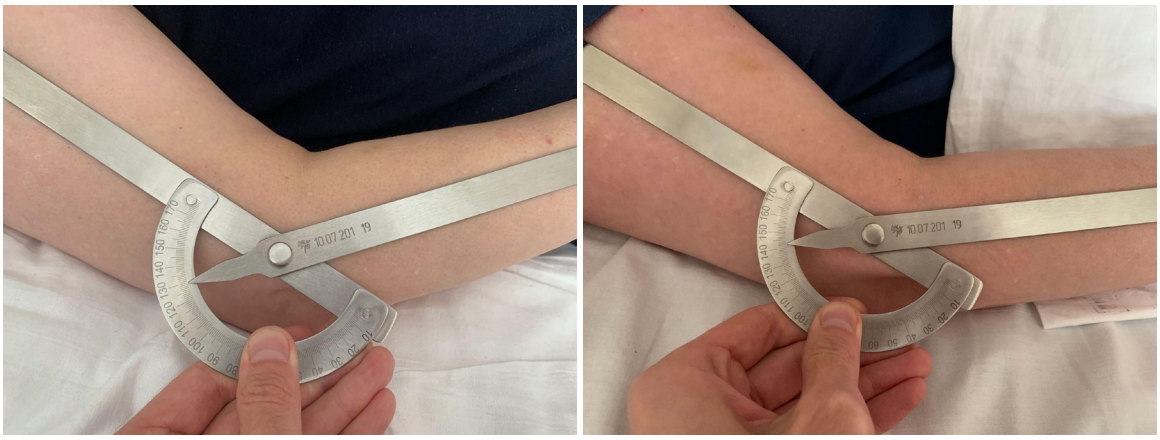

Figure 4: Example of before (left) and after (right) measurement of R1 angle.

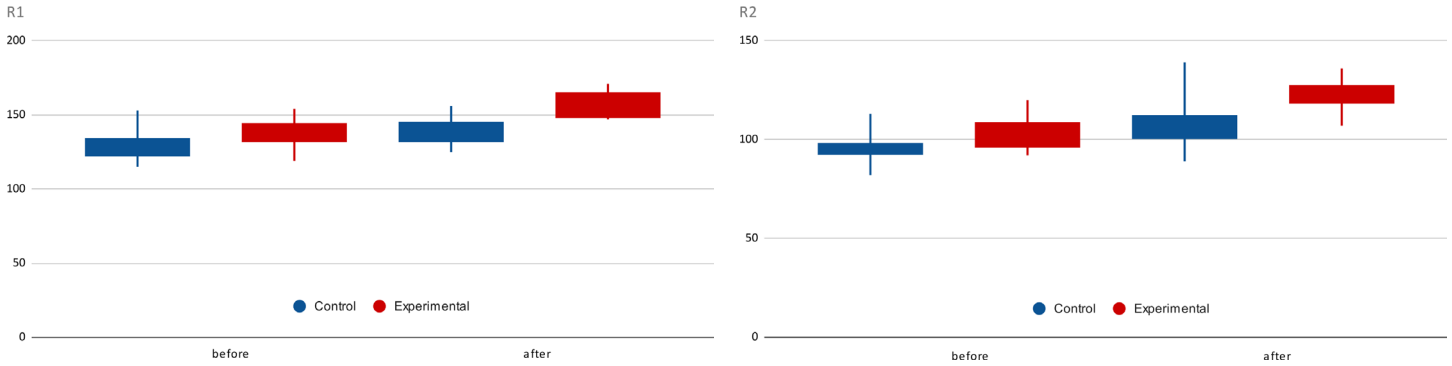

Figure 5: R1 and R2 angles before and after data visualization for control and experimental group.

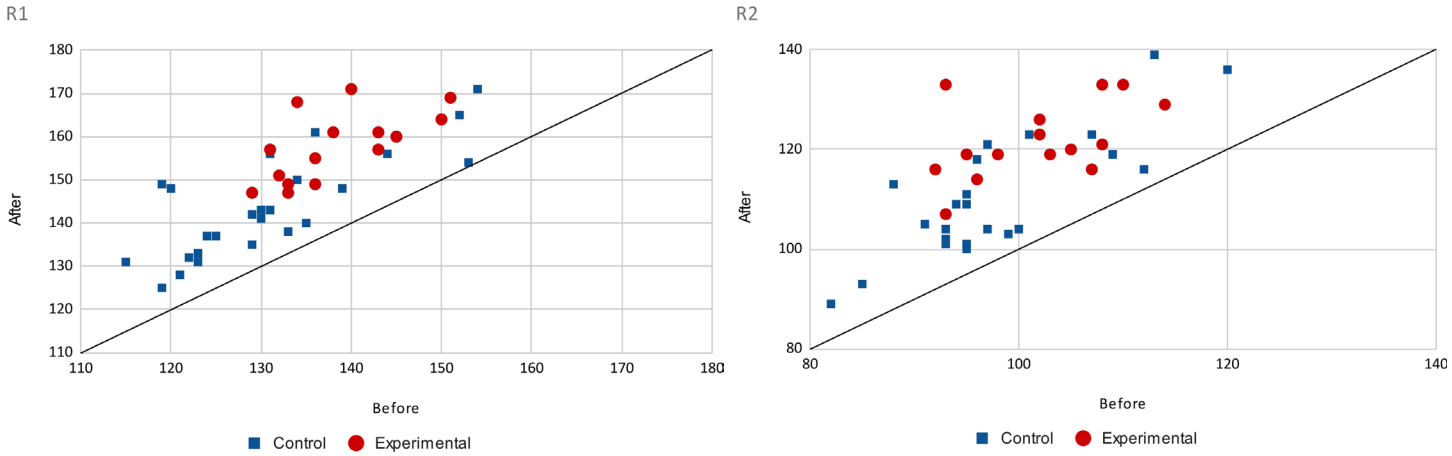

Figure 6: Baseline (Before) R1 and R2 data plotted against final post-treatment program scores (After). The linear middle line represents patients with 'no change'. Patients above this line have increased the range of motion while condition of those below the line has worsened based on measured angles of spasticity.

magnetic stimulation on upper extremity function and daily living was found. Similar results were achieved by Prouza et al.[10]. Significant spasticity improvement in terms of MAS, significant enhancement in quality of life evaluated by Barthel index were reported. Patients within a treatment group experienced 35% and 9% better results in MAS and Barthel index, respectively, than patients from the control group. Conclusions of both studies are well aligned with findings of the current trial confirming the significant impact of peripheral magnetic stimulation on upper limb functionality in post-stroke patients in early recovery phase.

We acknowledge that the present study has certain limitations and leaves room for further research. In future studies it is recommended to increase the number of participants in order to reduce the probability of their unequal distribution into control and experimental groups. Despite all the efforts and randomization, patients from the control group show a worse baseline condition, especially in terms of ArmA and angles of spasticity. Also, the

use of other evaluation methods is to be considered - even though the MAS, ArmA and angles of spasticity are among commonly used tools for post-stroke patients evaluations [5,10,14,19], the range of spasticity evaluation tools is so wide and the existing clinical evidence in the field of peripheral magnetic stimulation is so limited that a direct comparison is impossible. As a limitation, we also admit the absence of follow-up, which is necessary to determine the lasting of the achieved effect.

Despite all the limitations, this study fulfilled the purpose and prepared the basis for further research. The peripheral magnetic stimulation impact on patients in the late recovery phase with chronic spasticity appears to be a next direction of future trials.

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