Stroke affected lower limbs rehabilitation combining virtual reality with tactile feedback

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Submitted to Journal:
Frontiers in Robotics and AI

Specialty Section:
Virtual Environments

Article type:
Brief Research Report Article

Manuscript ID:
511679

Received on:
12 Nov 2019

Revised on:
18 Feb 2020

Frontiers website link:
www.frontiersin.org

Conflict of interest statement

The authors declare a potential conflict of interest and state it below

AZ, AK, EK are employees of Samara State Medical University, which developed ReviVR simulator used in the study. VB, YB, GI declare the absence of any commercial or financial interests that could affect the results of the study.

Author contribution statement

AK, AZ, GI were responsible for design and conception of the study; AZ, EK, YB was responsible for neurophysiology aspects, organization of patients' enrollment and evaluation, gathering experimental data; AZ and VB contributed to statistical analysis, manuscript writing and revision; all authors read and approved the submitted version.

Keywords

Stroke, Rehabilitation, virtual reality, Tactile Feedback, biofeedback

Abstract

Word count: 204

In our study we tested a combination of virtual reality (VR) with robotics in the original adjuvant method of post-stroke lower limb walk restoration in acute phase using a simulation with a visual and tactile biofeedback based on VR immersion and physical impact to the soles of patients. The duration of adjuvant therapy was 10 daily sessions of 15 minutes each. The study showed the following significant rehabilitation progress in Control (N=27) versus Experimental (N=35) groups respectively: 1.56±0.29 (mean±SD) and 2.51±0.31 points by Rivermead Mobility Index (p=0.0286); 2.15±0.84 and 6.29±1.20 points by Fugl-Meyer Assessment Lower Extremities scale (p=0.0127); 6.19±1.36 and 13.49±2.26 points by Berg Balance scale (p=0.0163). P-values obtained by the Mann-Whitney U test.

The simple and intuitive mechanism of rehabilitation, including through the use of sensory and semantic components, allows the therapy of a patient with diaschisis, afferent and motor aphasia. Safety of use allows to apply proposed method of therapy at the earliest stage of a stroke.

We consider the main findings of this study that the application of rehabilitation with implicit interaction with VR environment produced by the robotics action has measurable significant influence on the restoration of the affected motor function of the lower limbs compared with standard rehabilitation therapy.

Contribution to the field

Every one in six people worldwide are affected by stroke. Most of survivors suffer from limbs paralysis and its severe forms like hemiplegia etc. The emerging technologies such as virtual reality (VR) and robotics and their combination enhance limits of conventional stroke rehabilitation and allow to begin the motor restoration earlier, improving chances for success. We endeavor to explore complex robotics and VR impact on neuroplasticity of motor and pre-motor cortex in order to find best combination to enhance performance on rehabilitation of early stroke followed by limbs paralysis. Using new equipment prototype we undertook a study dedicated to testing a novel adjuvant therapy method for lower extremities. We consider the main finding of this study that combined life-like VR agency with realistic tactile impact provided by simple robotics has measurable influence on the restoration of limbs motor function, compared to effect of more complicated systems performing the assisted whole lower body motions.

Funding statement

The study was implemented with the financial support of the Ministry of Science and Higher Education of the Russian Federation (grant RFMEFI60418X0208).

Ethics statements

Studies involving animal subjects

Generated Statement: No animal studies are presented in this manuscript.

Studies involving human subjects

Generated Statement: The studies involving human participants were reviewed and approved by Local ethics committee of the Samara Regional Clinical Hospital named after VD Seredavin
(protocol #146, 14.03.2018). The patients/participants provided their written informed consent to participate in this study.

Inclusion of identifiable human data

Generated Statement: No potentially identifiable human images or data is presented in this study.

Data availability statement

Generated Statement: All datasets generated for this study are included in the manuscript/supplementary files.

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(Running title: **Post-stroke rehabilitation combining virtual reality with tactile feedback)**

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Keywords: **Stroke, Rehabilitation, Virtual Reality, Tactile feedback, Biofeedback.**

Abstract

In our study we tested a combination of virtual reality (VR) with robotics in the original adjuvant method of post-stroke lower limb walk restoration in acute phase using a simulation with a visual and tactile biofeedback based on VR immersion and physical impact to the soles of patients. The duration of adjuvant therapy was 10 daily sessions of 15 minutes each. The study showed the following significant rehabilitation progress in Control (N=27) versus Experimental (N=35) groups respectively: 1.56±0.29 (mean±SD) and 2.51±0.31 points by Rivermead Mobility Index (p=0.0286); 2.15±0.84 and 6.29±1.20 points by Fugl-Meyer Assessment Lower Extremities scale (p=0.0127); 6.19±1.36 and 13.49±2.26 points by Berg Balance scale (p=0.0163). P-values obtained by the Mann-Whitney U test.

The simple and intuitive mechanism of rehabilitation, including through the use of sensory and semantic components, allows the therapy of a patient with diaschisis, afferent and motor aphasia. Safety of use allows to apply proposed method of therapy at the earliest stage of a stroke.

We consider the main findings of this study that the application of rehabilitation with implicit interaction with VR environment produced by the robotics action has measurable significant influence on the restoration of the affected motor function of the lower limbs compared with standard rehabilitation therapy.

1 Introduction

The problem of rehabilitation of acute and subacute cerebrovascular disorders does not lose its relevance at all stages of the disease. The use of modern understanding of neuroplasticity expands rehabilitation opportunities, making them available at different periods of stroke and other neurological disease [1, 2]. A comprehensive rehabilitation approach requires rehabilitation from the

earliest time of the disease in order to achieve a meaningful recovery of lost functions in the future. From the point of view of motor rehabilitation in early stroke, one of the most important tasks is a patient's verticalization and restoration of overall mobility [3, 4].

The use of virtual reality (VR) in adjuvant methods of rehabilitation has received much attention recently [5, 6]. Using VR as a tool for repeatedly and naturalistic demonstrating scenes of interaction with real-world objects can influence inter-cortical interactions, in the form of their activation or inhibition in both motor and premotor areas [7, 8]. There are quite powerful cortico-cortical connections between the occipital, frontal and parietal lobes, which are used together in the processing of visual, motor and proprioceptive information [9, 10]. There is evidence that a significant number of neurons in the motor, premotor and parietal regions are modulated by visual information [11, 12] and virtual avatar movements reveal common parieto-frontal links [13, 14].

Thus, our study is based on previous findings that visual stimulation (in terms of VR) and physical impact to affected limbs contribute to increasing the efficiency of motor rehabilitation of patients with acute cerebrovascular accident.

The purpose of the study was to test the effect of a new method of supplementary motor rehabilitation including VR+robotics therapy on the restoration of the affected walking function in the acute and early recovery periods of ischemic stroke with supratentorial localization.

2 Materials and methods

Study continued from November 2018 to October 2019 and included rehabilitation of stroke patients using ReviVR walk simulator (Figure 1; A, B). ReviVR walk simulator is a proprietary product developed in Samara State Medical University and is protected by Russian and international patents (priority date 29.12.2016; RU2655200C1, WO2018124940A1). The simulator provides immersion in life-like virtual reality environment and walking imitation with a visual and tactile biofeedback based on physical impact – alternate pressing to the soles, synchronized with the "steps" of the avatar in VR environment.

The patient was wearing a VR-headset and two orthoses equipped with 4-chamber pneumatic cuffs each fixed on both feet. The chambers in the cuffs were inflated sequentially when a virtual avatar was making a "step". Such sequential inflation of the four chambers imitated the contact of the sole with the surface during a real walk. The operation of the pressure valves in the chambers (pumping and venting) was synchronized to provide pace of the "walking" to 26 taps per minute on each sole (equivalent to 0.43 "steps" per second or one "step" every 2.3 seconds). The maximal pressure of the chambers on the soles was 0.5 kg/cm^2 of the plantar surface of the foot. Stimulation of the soles with pneumatic cuffs occurred for both a paralyzed and a healthy limb. The patients saw virtual environment and their avatar from the "first-person view" in a walking position. By turning a head, the patient could observe the movement of the limbs of the virtual avatar (Figure 1; C, D).

Criteria for inclusion patient in the study (in the presence of all of the following):

1. Age 18 to 80 years with the first-occurred acute ischemic cerebral circulation disorder in the carotid pool.

2. An acute period of cerebrovascular accident: no more than 5 days from the date of stroke.

3. One confirmed focus of ischemic stroke of supratentorial localization according to computerized tomography (CT).

4. Motor disorders in the lower extremities in the form of a central paresis 3 or less points of a six-point Medical Research Council scale for Muscle Strength (MRC, 1981).

5. Ability and willingness of the patient to comply with the protocol of study requirements.

6. Signed written informed consent.

Exclusion criteria (in the presence of at least one of the following):

1. Explicit cognitive impairment: 10 or less points according to the Montreal Cognitive Assessment scale (MoCA, 1996).

2. Neurological diseases that cause a decrease in muscle strength or an increase in muscle tone in the lower extremities due to any pathology.

3. Clinically significant limitation of the amplitude of passive movements in the lower extremities.

4. Lack of lower limb due to amputation.

5. Any medical condition, including a mental illness or epilepsy, that might affect the interpretation of the results of the study, the conduct of the study, or patient safety.

6. The abuse of alcohol or narcotics within 12 months preceding the moment of inclusion in the study.

7. Treatment with botulinum toxin type A or B in the previous 6 months prior to inclusion in the study.

8. Surgery in the previous 6 months prior to inclusion in the study; for example, abdominal, back, leg or knee surgery.

9. The severity of the patient's condition according to neurological or somatic status, which does not allow full rehabilitation intervention.

10. Blindness in one or both eyes, or explicit visual impairment more than 20/30 according to Snellen Eye Chart.

The study was performed in the neurology department of Samara Regional Clinical Hospital named after VD Seredavin (53 patients) and in the Research Center of Cerebrovascular Pathology and Stroke, Ministry of Health of the Russian Federation, Moscow (9 patients). The study was approved by the local ethics committee of the Samara Regional Clinical Hospital named after VD Seredavin (protocol #146, 14.03.2018).

All patients included in the study underwent standard rehabilitation. According to their functional state, in addition to medication, they could receive physiotherapy and neuromuscular electrical stimulation (NMES). The choice of methods and the scope of standard therapy by attending clinicians was based on the set of rehabilitation tasks and the functional state of the patient.

62 patients (M/F, left or right primary hemisphere ischemic stroke) were randomized to the Control (N=27) and Experimental (N=35) groups. Patients clinical data at the moment of inclusion in the study is presented in Table 1.

The patient in the Experimental group, initially lying in bed, and then after 2-3 days – sitting in a chair, received 10 rehabilitation sessions with ReviVR, 15 minutes each. Thus, total adjuvant therapy duration was 2.5 hours for each patient. Adverse events were monitored throughout the study and were not recorded.

Patients in the Control group were also able to receive rehabilitation with ReviVR simulator after completion of their participation in the study.

The study completion visit was carried out at the day of discharge of the patient from the hospital, usually on the 21st day. This visit included an assessment on the study scales by an independent neurologist, who was blinded for the patient's rehabilitation group. Rehabilitation performance was evaluated using NIHSS, RMI, FMA-LE and BBS scales.

Statistical analysis was performed using STATISTICA data analysis software system version 12, (StatSoft Inc., 2014, www.statsoft.com).

3 Results

It should be noted that patients in both Control and Experimental groups showed positive rehabilitation dynamics that was observed when assessing the motor function of the lower extremities when performing isolated motor tasks by an affected extremity and during synergistic movements of both lower extremities.

To assess the effectiveness of rehabilitation in the compared groups, we evaluated the progress points (the difference in scores after and before rehabilitation). The progress points were checked for normality of the distribution with the Shapiro-Wilk test. All data showed a non-normal distribution ($p<0.02$). Assessment of progress in groups was carried out using the two-tailed Mann-Whitney U test.

The following significant rehabilitation progress points in Control and Experimental groups respectively: -1.26±0.62 and -2.83±0.32 points by NIHSS scale ($p=0.0003$); 1.56±0.29 and 2.51±0.31 points by Rivermead Mobility Index ($p=0.0286$); 2.15±0.84 and 6.29±1.20 points by Fugl-Meyer Assessment Lower Extremities scale ($p=0.0127$); 6.19±1.36 and 13.49±2.26 points by Berg Balance scale ($p=0.0163$). Higher decrease is better for NIHSS scale; higher increase is better for RMI, FMA-LE, and BBS scales. Summary information on rehabilitation is presented in Table 2 and Figure 2.

4 Discussion, Conclusion and Further Work

We compared our research with the most similar studies performed in the last six years for VR- and robotics-based lower limb rehabilitation [15-23]. These studies used the same clinical scales to measure the rehabilitation progress of lower limb function and/or were performed in the acute period of ischemic stroke. Authors also noted an increase in the effectiveness of rehabilitation when using adjuvant therapy.

Evaluating the results of similar studies and our own results, we believe that this influence is due to impact on motor and premotor areas neuroplasticity caused by visual, sensory and cognitive evoked inter-cortical interactions. The patient's involvement in the virtual environment and the use of the

game-like component during the rehabilitation of the lower extremities greatly improve motor function. Our results are consistent with the findings that patients assimilated the virtual lower limbs as if they were their own legs [24] and we assume that in our case there was a similar mechanism of identification (agency) that had a positive effect on neuroplasticity and motor recovery.

The main distinctions of our study are:

A. We used the complex activation of neuroplasticity by immersing patients in synchronous visual and sensory passive interaction with virtual environments;

B. In our study we used a relatively simple device to mimic the proprioception sense during the rehabilitation and achieved the progress comparable to the results of interventions with sophisticated robotic equipment that moves the whole lower limbs or the whole body to imitate independent walk;

C. The concept of rehabilitation and the design of equipment allow rehabilitation of patients:
– in acute stroke (all 35 patients in Experimental group);
– bedridden at the beginning of the study (25 of 35 patients);
– with severe paresis, diaschisis or persisting low muscle tone of lower limb (27 of 35 patients);
– afferent and motor aphasia (17 of 35 patients);
– with restrictions for verticalization due to cardiac arrhythmia, which can cause a cardioembolic stroke and the risk of thromboembolic complications (20 of 35 patients).

Our study shows that an adjuvant post-stroke VR+robotics therapy of the lower extremities in acute phase using interaction via realistic proprioceptive and implicit tactile impacts significantly improves performance of standard rehabilitation.

We suggest that use of explicit interaction within walking synergy may show better clinical effects of rehabilitation. We will clarify this hypothesis in our further work.

5 Conflict of Interest

AZ, AK, EK are employees of Samara State Medical University, which developed ReviVR simulator used in the study. VB, YB, GI declare the absence of any commercial or financial interests that could affect the results of the study.

6 Author Contributions

AK, AZ, GI were responsible for design and conception of the study; AZ, EK, YB was responsible for neurophysiology aspects, organization of patients' enrollment and evaluation, gathering experimental data; AZ and VB contributed to statistical analysis, manuscript writing and revision; all authors read and approved the submitted version.

7 Funding

The study was implemented with the financial support of the Ministry of Science and Higher Education of the Russian Federation (grant RFMEFI60418X0208).

8 Acknowledgments

We thank ***Eugene Tunik*** (Bouvé College of Health Sciences, Northeastern University, Boston), ***Alexei Ossadtchi*** (NRU HSE, Moscow), ***Ilia Borishchev*** (IT Universe Ltd, Toronto), ***Sergey Agapov*** (IT Universe Ltd, Samara) for invaluable advisory; ***Dmitry Krasnorylov*** (Samara Regional Clinical Hospital named after VD Seredavin) for collecting biomedical data.

9 Data Availability Statement

Data analyzed for this study is included in the manuscript/supplementary files (a file "Lower_limb_rehab_ReviVR.csv").

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TABLE 1.
Clinical data of patients included in the study; values presented as mean ±SD

Group	Gender (M / F)	Stroke pool localization (left / right)	Age (years)	Points by scale *			
				NIHSS	RMI	FMA-LE	BBS
Control	14 / 13	20 / 7	65.4 ±1.9	13.0 ±1.1	2.6 ±0.4	8.9 ±1.6	8.9 ±2.9
Experimental	18 / 17	22 / 13	68.1 ±1.6	12.7 ±0.7	1.5 ±0.2	6.4 ±1.0	2.5 ±1.1

* Description of scales:

NIHSS – National Institutes of Health Stroke Scale (0-42 points scale; lower value is better; used to quantify the impairment caused by a stroke; measured from 0 points – no stroke symptoms to 21-42 points – severe stroke; range 5-15 defined as moderate stroke).

RMI – Rivermead Mobility Index (0-15 points scale; higher value is better; assesses functional mobility in gait, balance and transfers after stroke; measured from 0 points – an inability to perform any of the activities to 15 points – full mobility performance).

FMA-LE – Fugl-Meyer Assessment Lower Extremity scale (sections E-F) (0-34 points scale; higher value is better; used as an index to assess the motor impairment after a stroke; measured from 0 points – hemiplegia to 34 points – normal motor performance);

BBS – Berg Balance Scale (0-56 points scale; higher value is better; used to determine ability to safely balance during a series of predetermined tasks; score of < 45 indicates individuals may be at greater risk of falling and score of 56 indicates functional balance).

TABLE 2.
Progress of the rehabilitation; values presented as mean ±SD

Group	Sample size	Progress by scale			
		NIHSS	**RMI**	**FMA-LE**	**BBS**
Control	27	-1.26 ±0.62	+1.56 ±0.29	+2.15 ±0.84	+6.19 ±1.36
Experimental	35	-2.83 ±0.32	+2.51 ±0.31	+6.29 ±1.20	+13.49 ±2.26
Statistics U	max = 945	235	329	319	305
Effect size Cohen's d	–	0.609	0.567	0.681	0.659
P-value *	–	0.0003	0.0286	0.0127	0.0163

* Significance of progress scores between the Control and Experimental groups performed by two-tailed Mann-Whitney U test.

FIGURE 1. ReviVR rehabilitation walk simulator: (A) – equipment overview; (B) – patient in a chair with pneumatic orthoses on the feet; (C) – patient's avatar and virtual environment overview, third-person view; (D) – view for a patient in VR-headset, first-person view.

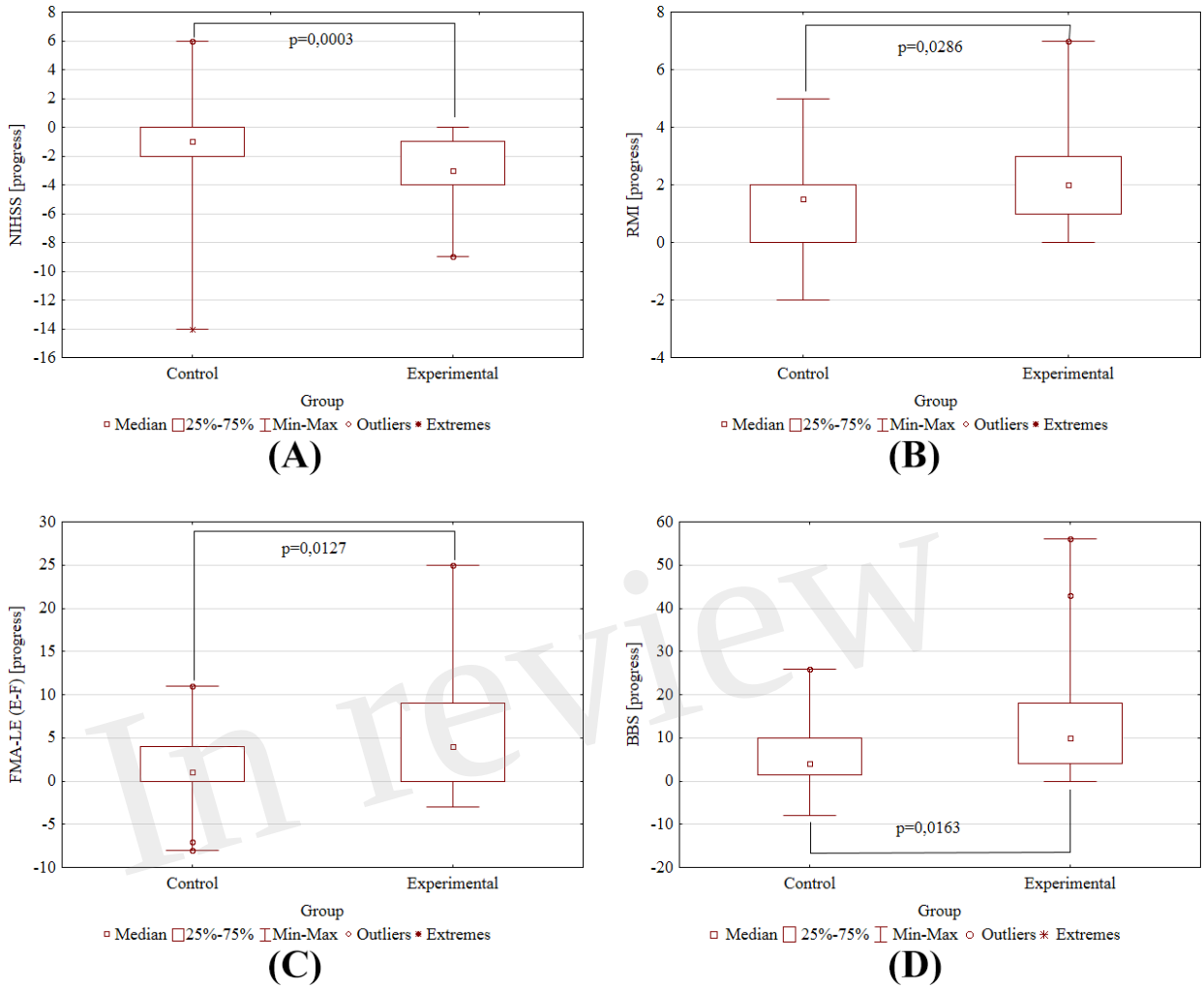


FIGURE 2. The rehabilitation progresses. Comparison of the Control (N=27) and Experimental (N=35) groups by the study scales. The difference in scores after and before rehabilitation. P-value obtained by two-tailed Mann-Whitney U test. (A) – NIHSS progress; (B) – RMI progress; (C) – FMA-LE progress; (D) – BBS progress.

Figure 1.TIF

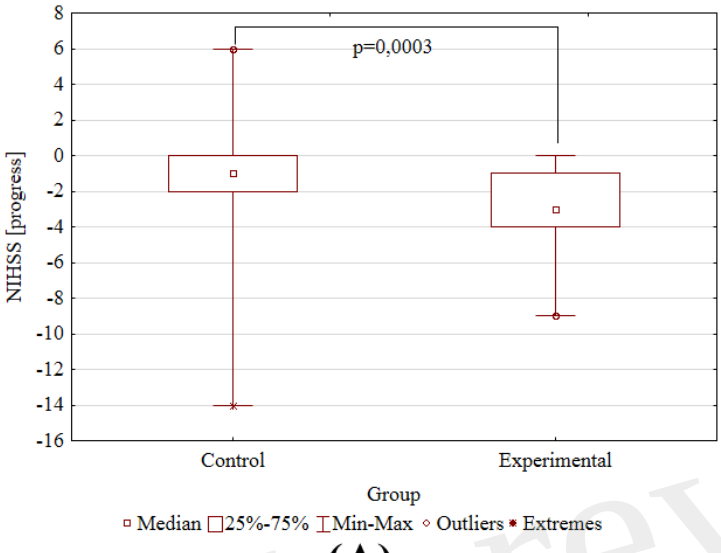
(A)

(B)

(C)

(D)

Figure 2.TIF



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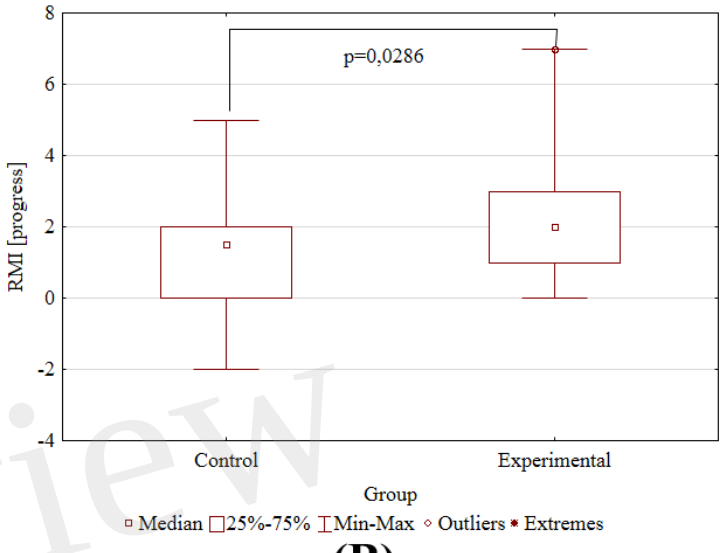

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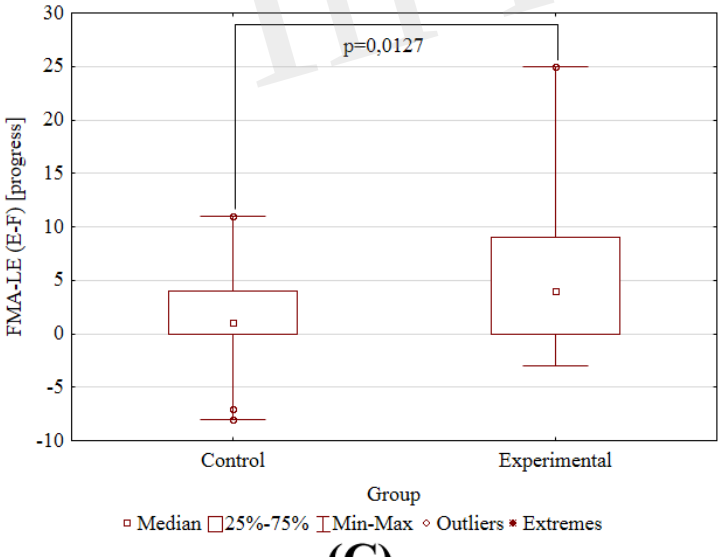

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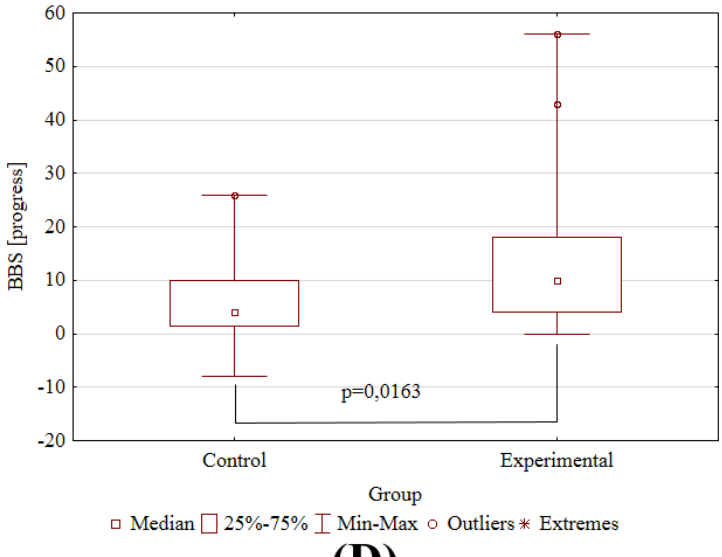

(D)