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Stroke

Rehabilitation of Patients with Post-Stroke Cognitive Impairments Using a P300-Based Brain–Computer Interface: Results of a Randomized Controlled Trial

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Objective. To study the effects of 10 days of cognitive training using brain–computer interface (BCI) technology based on the P300 wave on the recovery of cognitive functions in patients with stroke. **Materials and methods**. The study included 30 patients aged 22–82 years with ischemic stroke occurring less than three months previously and moderate cognitive impairment (<26 points on the Montreal Cognitive Assessment Scale, MoCA). All patients underwent neuropsychological testing, assessment of the presence of depression, and assessment of the activities of daily living. Patients were randomized into two groups: patients of group 1 received 10-day courses of cognitive rehabilitation in the form of daily exercises in a BCI environment based on the P300 wave, with a headset for recording the electroencephalogram (EEG). Patients of group 2 received a standard set of rehabilitation measures. **Results**. The study group experienced an increase in the mean score on the "Attention" domain of the MoCA scale as compared with the control group: from 2.3 ± 1.24 to 5.2 ± 1.16 points in the study group compared with a decrease from 5.9 ± 1.00 to 4.2 ± 0.94 points in the reference group ($p < 0.05$). Analysis of covariance with repeated measures taking into account the factors "Visit" and "Group" and the covariates "Depression" and "Training session number" revealed statistically significant effects for the MoCA domains "Naming" ($p < 0.05$), "Attention" ($p < 0$ .05), and "Abstraction" ($p < 0.05$). By the end of 10-day cognitive BCI training courses, patients in group 1 displayed a statistically significant increase in the number of letters entered (from 20.8 ± 2.01 to 25.9 ± 1.7 characters ($p = 0.02$)) compared with an increase from 21.9 ± 1.9 to 23.1 ± 1.8 in group 2 ($p = 0.06$). Comparison of the number of words entered by patients after 10 days demonstrated a statistically significant between-group difference ($p < 0.05$). **Conclusions**. Rehabilitation of patients with post-stroke cognitive impairment using a BCI based on the P300 wave had significant positive effects on restoration of cognitive functions, primarily attention.

Keywords: neurorehabilitation, cognitive training, stroke, brain–computer interface.

Stroke is a medical and social problem of continuing relevance [1]. The high incidence of stroke – 500,000 new cases per year [2] – contributes to increased population mortality and an increased proportion of patients with disabilities [3]. Only 15% of stroke patients are able to return to previous work activity [4]. Most patients require constant medical monitoring [5].

The leading factors limiting daily functioning and significantly reducing quality of life in stroke patients are motor deficits and post-stroke cognitive impairment (PSCI) [6]. Vascular cognitive impairment (CI) is among the most common forms of CI, along with Alzheimer's disease dementia and mixed dementia. Since 2019, the occurrence of CI has been associated with COVID-19 [7].

Among high-tech methods for decreasing damage in cerebral catastrophes [8], there is demand for the medical re-

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habilitation of patients after acute cerebrovascular accidents, including rehabilitation programs based on contemporary innovatory technologies [9]. A group of methods promoting neuronal plasticity – rehabilitation training using brain–computer interface (BCI) technology, which can be used to improve cognitive functions in patients with PSCI – has now been described. BCI is regarded as a promising biofeedback (BF)-based cognitive training method [10–13]. The results of many studies have shown that the use of a BCI in addition to a personalized approach to learning can influence θ and α rhythms, the α/θ ratio, the β and γ rhythms, sensorimotor rhythms, and other types of brain electrical activity recorded on the electroencephalogram (EEG) [14–17].

Biofeedback training is a set of measures with the objective of teaching a person to carry out conscious control of one or more physiological parameters. Signals indicating physiological parameters are recorded by specific sensors and are amplified and presented to the test subject/patient in the form of an accessible "metaphor" (for example, in the form of a sound indicating the success or failure of self-regulation). During biofeedback training, subjects take part in multiply repeated exercises seeking to achieve the desired result in the form of self-regulation of brain patterns. Training with biofeedback is, consequently, monotonous and tiring for patients.

The "training transfer" hypothesis [18, 19] proposes that the positive effect of biofeedback training propagates to adjacent cognitive areas, i.e., they apply not only to the paradigm of trained tasks, but also to untrained tasks. Successful transfer effects are based on similar functional processes and activation of similar neural circuits (functional and neural overlap). In accordance with this, the weak point of cognitive training implemented using biofeedback is its dubious functional overlap.

In the context of modern views of functional and neural overlap during transfer of learning, it may seem more rational to use BCI methods involving the patient in more naturalistic tasks and work on the basis of processing the activity of neural circuits associated with the implementation of a number of cognitive functions, such as different types of attention, working memory, etc.

Evidence of the effectiveness of training in the three-dimensional gaming environment of a BCI for the purpose of correcting manifestations of attention deficit hyperactivity disorder (ADHD) has been reported: during training, children learned to apply the acquired skills to solve academic problems (mathematical and language tasks immediately after each training session). Results from a randomized controlled trial (RCT) showed that the training improved the attention span of children with ADHD [11]. A method of using a BCI for the treatment of CI in the elderly has been described. A pilot study showed that use of BCI improved memory and attention in older adults [10].

During BCI training, the need to focus on a task results in recruitment of intact cognitive, motor, and other neural connections, which can strengthen neural connections affected by stroke and lead to clinically significant improvements.

BCI of this type include, in particular, BCI-spellers based on the P300 wave. The P300 cognitive evoked potential reflects the functioning of a distributed neural network and is directly related to the implementation of executive functions [20]. As the P300 is easily and naturally generated in response to target stimuli, the patient can interact efficiently with the proposed learning tool in a BCI environment.

Data on the use of P300-based BCI environments in patients with post-stroke impairment are limited, though there is sufficient to demonstrate the ability of such patients to operate this type of interface with varying degrees of success [19, 21]. There is insufficient information regarding the neuromodulatory effect of BCI based on the P300 wave on the recovery of PSCI.

The aim of the present work was to investigate the effect of 10 days of cognitive training using BCI technology based on the P300 wave on the recovery of cognitive functions in poststroke patients.

Materials and Methods. An open, parallel-group RCT was conducted from May 2020 to June 2022 in the Russian Federation, based at the Department of Rehabilitation, Federal Scientific and Clinical Center for Reanimatology and Rehabilitation, in compliance with state standard GOST R 52379–2005 "Good Clinical Practice," the rules of good clinical practice as approved by Order No. 200n of the Russian Ministry of Health, April 1, 2016, and the Declaration of Helsinki of the World Medical Association. The study was approved by the local Ethics Committee, decision No. 1/20/2 of March 2020.

Inclusion criteria: inpatients of both sexes aged 22–82 years; ischemic stroke less than three months previously and confirmed by computed tomography (CT)/magnetic resonance imaging (MRI) of the brain; moderate CI (<26 points on the Montreal Cognitive Assessment Scale, MoCA); a marked decrease in the activities of daily living (21–60 points on the Barthel scale), due to factors including motor disorders; signed informed consent form to take part in the study.

Non-inclusion criteria: severe visual impairment preventing task performance, dementia, epilepsy, head injuries, and inflammatory brain lesions with persistent neurological deficit.

At the screening stage, CI were assessed using the MoCA scale. The absence of severe depression was confirmed by Hamilton Depression Rating Scale (HDRS) scores (<14 points on the HDRS scale).

At Visit 1 (week 1 ± 3 days), after completion of screening and inclusion of patients in the study, patients were randomized into two groups at a ratio of 1:1 using a random number generator. Patients of group 1 (the study group) took part in a 10-day course of cognitive rehabilitation in which they performed specified exercises in a P300 wave-based BCI environment using a neurocommunication system equipped with a headset for EEG recording. Patients of group 2 (the reference group) received a standard set of rehabilitation measures, including physical therapy, massage, mechanical therapy, cardiorespiratory training, and sessions with a speech therapist and a neuropsychologist.

Daily training exercises using the stimulus environment and the algorithms of the system software lasted no more than 1 h. Patients carried out the exercises sitting at a table bearing the monitor used for presentation of visual stimuli. The Russian alphabet, with a fixed arrangement of letters, was shown on the monitor screen.

Each training exercise consisted of two stages. The first stage consisted of calibration and was performed to adapt the BCI to the EEG patterns characteristic of individual patients, i.e., the BCI system was individually configured for each specific patient. The results of this adjustment/calibration were used to determine the individual characteristics of the patient's EEG patterns, such that the text could be entered letter by letter at the next stage.

On completion of the calibration stage, success was assessed using an index calculated by the BCI software. Successful completion of the first stage was followed by the patient being invited to proceed to the second stage, which consisted of entering text as specified in the task set. If calibration accuracy was insufficient (below a specified threshold), calibration was repeated, depending on the patient's performance.

The second stage included intentional entering of letters. A card with a three-letter word in large print was placed next to the screen in front of the patient, the word being a noun in the nominative singular case. Frequent Russian words were used. As skills in working in the BCI environment improved, the patient was offered words with larger numbers of letters. To enter a letter, the patient was required to fix attention on the highlights of the desired letters in sequence, until the desired letter appeared in the entry line. As soon as a cell with a letter recognized by the classifier was highlighted, the corresponding letter appeared in the top line of the set.

After 5 sec, the patient moved on to entering the next letter of the word. When errors occurred, incorrectly entered letters did not disappear. Patients were asked to enter at least three different words in a single training session. The number of alphabetic characters entered was assessed. At the patient's request, a 1-min pause for rest was included between sets of words. The researcher ended the session if the patient became too tired.

Monopolar EEG recordings were made in eight leads. The electrode on the right earlobe was used as reference, and electrode Fp1 was used as the midpoint of the amplifier.

At Visit 1 (week 1 ± 3 days) and Visit 2 (day 10 ± 3 days), patients of both groups underwent neuropsychological testing: the severity of CI was assessed on the MoCA scale with the additional use of different forms to prevent answers from being memorized on retesting after 10 days; speed of attention-switching was assessed using the Schulte test and the state of auditory-verbal memory was evaluated using the A. R. Luria 10-word memorization test.

During the study, patients received basal therapy for treatment of the underlying disease and prevention of secondary stroke, along with a standard set of rehabilitation measures.

The primary outcome measures were changes in mean MoCA and domain scores after 10 days between the study group and the reference group. Additional criteria for assessment of effectiveness were used: the change in the mean time (sec) of completing the Schulte test after 10 days in the main group and the reference group; the change in the number of correctly reproduced words in the 10-word memorization test after 10 days in the main group and the reference group; the change in the number of correctly entered letters after 10 days in the main group and the reference group.

The study included 32 patients and 30 were randomized. Data from two patients were excluded because of noncompliance with the inclusion/non-inclusion criteria. During the study, data from one patient were excluded from group 2 due to inability to comply with protocol requirements.

Effectiveness was analyzed using the study results obtained in a cohort ($n = 29$) including 14 patients from the main group and 15 from the reference group.

Statistical analysis. Student's t-test was used to assess differences between visits when the initial data had normal distributions. If this condition was not met, the paired Wilcoxon test and the Kruskal–Wallace method were used to compare sample means. Covariance analysis of variance with repeated measures (ANCOVA RM) was carried out taking account of the within-individual variability factor "Visit" (2 levels: Visit 1, Visit 2) and the between-individual variability factor "Group" (2 levels: study group, control group), along with covariates, i.e., "Depression" and "Number of training sessions." The relationship between the number of correctly entered letters using the BCI and test parameters was assessed using Pearson correlation analysis, because of the normal distribution of the values obtained and the fact that they belonged to the category of values assessed on an interval scale. The level of statistical significance was taken as $p < 0.05$. Statistical analysis was run in the statistical package IBM SPSS Statistics 23.

Results. The mean age of the patients who were included in the study and randomized and who provided data included in the analysis was 57.4 ± 6.9 years in group 1 and 57.0 ± 6.5 years in group 2. Men accounted for 78.6% and 53.3% in groups 1 and 2 respectively and women for 21.4% and 46.7%. Patients in the two groups showed no differences in age ($p = 0.19$) or gender ($p = 0.91$).

A total of 50.0% of patients had higher education, of whom two (13.3%) had academic degrees; the remaining patients had secondary education.

Ischemic strokes were located in the territory of the left middle cerebral artery (MCA) in 15 patients (50.0%),

TABLE 1. Dynamics of the Mean MoCA Scale Scores after 10 Days, Points, $M \pm SD$

MoCA scale domain	Group 1 (n = 14)		Group 2 (n = 15)	
	baseline	10 days	baseline	10 days
Visual-constructive/executive skills	3.7 ± 0.94	3.8 ± 0.89	3.8 ± 0.9	3.4 ± 0.93
Naming	2.0 ± 0.02	2.9 ± 0.01**	3.0 ± 0.0	2.8 ± 0.02
Memory	4.5 ± 0.18	4.4 ± 0.19	4.3 ± 0.23	4.5 ± 0.19
Attention	2.3 ± 1.24	5.2 ± 1.2*,**	5.9 ± 1.00	4.2 ± 0.94
Speech	1.9 ± 0.05	2.1 ± 0.03	1.5 ± 0.03	1.7 ± 0.02
Abstraction	1 ± 0.13	1.7 ± 0.1**	1 ± 0.14	1.3 ± 0.12
Delayed reproduction	1.8 ± 0.06	2 ± 0.04	1.9 ± 0.05	2.1 ± 0.06
Orientation	4.9 ± 0.19	5.9 ± 0.15**	5.4 ± 0.15	5.8 ± 0.13
Total score	20.7 ± 0.35	22.7 ± 0.40**	20.9 ± 0.38	22.3 ± 0.45**

*$p < 0.05$ compared with group 2; **$p < 0.05$ compared with baseline. Wilcoxon test.

in the territory of the right MCA in 11 (36.7%), in the vertebrobasilar system in three (10.0%), and in the basin of the posterior MCA in one (3.3%).

Patients entered a mean of 4.3 words per session (21.4 ± 2.3 characters).

Patients in both groups had moderately severe PSCI. The initial mean MoCA score in group 1 was 20.7 ± 0.4 points, compared with 20.9 ± 0.38 points in group 2. Four patients (28.6%) in the study group had higher education, among whom one (25.0%) had an academic degree and the remaining patients had secondary education. In the reference group, 11 patients (68.8%) had higher education, of whom one (9.1%) had an academic degree and the remaining patients had secondary education.

Concomitant diseases – at least one per patient – were present in 99.0% of patients in group 1 and 97.9% of those in group 2, $p = 0.44$. Vascular diseases were recorded in 96.6% of patients in group 1 and 93.8% in group 2. Heart diseases occurred at frequencies of 46.6% and 48.2% in groups 1 and 2 respectively, diseases of the nervous system were present in 47.5% and 45.1%, metabolic and nutritional disorders in 33.3% and 36.7%, diseases of muscular, skeletal, and connective tissues in 25.0% and 26.7%, diseases of the visual organs in 21.4% and 22.6%, and diseases of the gastrointestinal tract in 20.1% and 19.9% respectively. Other diseases occurred at lower frequencies.

Totals of 96.6% of patients in group 1 and 96.9% in group 2 received concomitant therapy ($p = 1.0$), including drugs acting on the renin-angiotensin system (88.9% and 85.5% respectively), antithrombotic drugs (83.9% and 85.2%), β-blockers (72.6% and 75.0%), lipid-lowering drugs (72.4% and 73.3%), diuretics (49.1% and 45.7%), and calcium channel blockers (25.7% and 23.8%). Patients took medications from other pharmacological groups at lower frequencies.

There were no significant between-group differences in the numbers of concomitant diseases ($p = 0.44$) or the use of concomitant drugs ($p = 1.00$).

By the end of 10 days, statistically significant increases in mean MoCA scores were observed in both groups: in group 1 from 20.7% ± 0.35 to 22.7% ± 0.40 ($p = 0.013$) and in group 2 from 20.9% ± 0.38 to 22.3% ± 0.45 ($p = 0.041$). Table 1 shows the dynamics of neuropsychological test indicators on the MoCA scale and its domains at 10 days in both groups.

Detailed analysis of neuropsychological test results on the MoCA scale in patients of the study group demonstrated significant increases in mean scores as compared with baseline values for the Naming, Attention, Abstraction, and Orientation domains ($p < 0.05$). Scores on the MoCA Attention domain at 10 days were significantly different between the two groups ($p < 0.05$). There were no statistically significant changes in mean scores on MoCA scale domains in the control group (see Table 1).

ANCOVA RM analysis results revealed statistically significant effects for the Naming, Attention, and Abstraction domains of the MoCA scale. The patients' neuropsychological test scores given below are adjusted for covariate values: Depression = 4.54, Number of training sessions = 4.38.

For the Naming domain, the interactions between the Visit factor and the Depression and Number of training sessions covariates were found to be statistically significant: $F1,21 = 7.61$, $p = 0.01$, $\eta_p^2 = 0.26$ for the former and $F1,21 = 6.77$, $p = 0.02$, $\eta_p^2 = 0.24$ for the latter.

In the case of the Attention domain, the influence of the Visit factor was found to be statistically significant ($F1,21 = 7.38$, $p = 0.01$, $\eta_p^2 = 0.26$) in the form of an increase in the mean score from Visit 1 (4.1 ± 0.4) to Visit 2 (4.7 ± 0.37), as was its interaction with the Group factor ($F1,21 = 6.3$, $p = 0.02$, $\eta_p^2 = 0.23$): the study group showed an increase in the mean score from Visit 1 (2.29 ± 1.24) to Visit 2 (5.19 ± ± 1.16), while the reference group showed changes in the opposite direction, in the form of a decrease in the mean score (5.92 ± 1 points at Visit 1 and 4.21 ± 0.94 points at Visit 2). An interaction was found between the Visit factor and the Number of training sessions covariate (F1,21 = 6.9, $p = 0.02$, $\eta_p^2 = 0.25$).

In the case of the Abstraction domain, the interaction between the Visit factor and the Depression covariate was found to be significant (F1,21 = 5.51, $p = 0.03$, $\eta_p^2 = 0.21$).

Analysis of variance results in the study group showed that changes in mean scores for the Naming and Abstraction domains of the MoCA scale were significantly influenced by the interaction of the Visit × Depression factors (χ^2 = = 7.61; $p = 0.01$ and $\chi^2 = 5.51$; $p = 0.03$). Changes in the Attention domain indicator were significantly influenced by the Visit factor ($\chi^2 = 7.4$; $p = 0.011$) and the interaction of the Visit × Group factors ($\chi^2 = 6.3$; $p = 0.02$).

By the end of 10 days, assessment of the dynamics of memory indicators on the Schulte test and the A. R. Luria 10-word memorization test did not identify significant differences between the main and control groups.

Patients of the main group working with the BCI system for an hour every day showed significant increases in indicators by training day 10: the total number of letters entered per session increased from 20.8 ± 2.01 to 25.9 ± 1.7 ($p = 0.02$). In the reference group, the increase in the number of letters entered did not reach statistical significance over 10 days: from 21.9 ± 1.9 to 23.1 ± 1.8. Comparison of the number of characters entered by patients after 10 days demonstrated a statistically significant between-group difference ($p < 0.05$).

Additional correlation analysis established that the BCI operating parameters were significantly associated with the Attention domain of the MoCA scale in patients of the study group ($r = 0.8$; $p = 0.01$).

Discussion. The results of this RCT showed that rehabilitation of patients with PSCI using a BCI based on the P300 wave had positive effects on the restoration of cognitive functions, apparent as statistically significant improvements in indicators of attention on neuropsychological testing and an increase in the number of letters entered during daily work in the neurocommunication system.

The issues of cognitive training of patients with focal brain lesions using BCI technology represent a relatively new direction in neurorehabilitation.

The process of cognitive rehabilitation of patients with PSCI using BCI technology triggers the activation mechanisms of adaptive brain systems, the long-term effect of which is based on the phenomenon of neuroplasticity. The effects of training in a BCI environment lead to effective changes in the neural networks of the brain, as our study demonstrated [22], with optimization of functional cerebellothalamocortical connections.

The functional connectivity results (resting functional MRI data) obtained in a similar study demonstrated increased functional connectivity in the right thalamic region and cerebellum (T = 10.74, $p < 0.05$), as well as the right superior frontal gyrus (T = 8, 75, $p < 0.051$), in patients after 10 days of training in a BCI environment. The same study demonstrated a decrease in functional connectivity between the thalamus and cerebellum in the reference group after 10 days of standard medical rehabilitation in a hospital setting [22].

The rehabilitation potential of the BCI is revealed through the gradual modulation of the patient's cerebral activity in terms of the signals produced in response to short-term highlighting of individual Russian-language letters on the computer screen and the rapid (1–2 sec) detection in these reactions of the indication of the patient's selection of specific letters. The key feature is the positive component of evoked potentials, i.e., P300, which is generated 300 msec after the start of illumination of the corresponding letter. P300 generation reflects the functioning of a neural network and is associated with implementation of the brain's executive functions [20].

Conclusions. We present here preliminary results from a study addressing the important challenge of providing effective restoration of cognitive functions in poststroke patients using communication BCI technology.

Some limitations of the study should be noted. This RCT was restricted to a 10-day period; further studies are needed to examine the long-term effects of BCI on cognitive function in patients with PSCI. Of note is the disproportionate distribution of patients with higher education across the groups, which was corrected by supplementing with an additional point in the analysis of the results of neuropsychological testing on the MoCA scale for ≤12 years of education.

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The authors declare no conflict of interest.

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