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The Possibilities of Multimodal Sensomotor Correction of Fine Use of the Hand with Digital Interactive Technology and Biofeedback in after-Stroke Patients: A Pilot Study

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Abstract

Background: Digital Interactive Technology (DIT)- based rehabilitation has been reported to have beneficial effects on upper limb function in individuals after Ischemic Stroke (IS), but there is a lack of information about its effects on distal upper extremity function and Health-Related Quality of Life (HRQoL) in the published academic literature. The purpose of this study was to evaluate the efficacy and safety of DIT with artificial intelligence and biofeedback Rehabilitation Glove "SensoRehab" (RGSR) for restoration of in-hand manipulation in patients with IS in the early and late recovery periods.

Methods: Our pilot trial involved 56 IS patients who had undergone Medical Rehabilitation (MR) with the use of SGSR. The primary outcomes were changes in scores on the Fugl-Meyer (FMA-UE) and Action Research Arm Test (ARAT), the secondary outcomes were changes on the Medical Research Council Scale (MRCS), Modified Ashworth Scale (MAS), Montreal Cognitive Assessment (MoCA), Hospital Anxiety and Depression Scale (HADS), the Quality-of-Life scores (HRQoL) and functional independence (Barthel ADL Index). The results were assessed before the therapy, at 14 days and 1 month after the intervention.

Results: After the MR with SGSR, improvements in FMA-UE, ARAT scores and in cognitive and emotional function scores on MoCA and HADS, as well as in independence of daily living and quality of life were noted.

Conclusion: The MR based on DIT with artificial intelligence and biofeedback is effective for patients with impaired fine motor skills of the hand due to the IS in the early and late recovery period.

Keywords: Ischemic stroke; Upper limb; Medical rehabilitation; Digital interactive technology; Artificial intelligence; Biofeedback; Quality of life

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Introduction

The Brain Stroke (BS) is one of the major causes of impaired Upper Limb (UL) function and therefore of limited daily human activity [1]. Impairment of the UL function in the early period of BS occurs in 70% of survivors, and only in 20% of cases a complete functional recovery of the UL is observed [1,2]. Motor, sensory, coordination deficits and impaired praxis lead to the clinical and neurological signs in the form of paresis, spasticity, hyperkinesis, akinetic-rigid syndrome, ataxia, ideomotor and motor apraxia, dysarthria-clumsy hand syndrome, and sensory disorders [2,3]. Impaired fine motor skills of the hand are often combined with cognitive and emotional disorder [3]. Recent studies in patients with BS have shown the effectiveness of dedicated and repetitive interventions relevant to real life and actively performed to stimulate the cortical reorganization and neuroplasticity processes [4-7]. In this context, the classic MR techniques can be combined with such innovative technologies as Digital Interactive Technologies (DIT) based on Biofeedback (BFB), Virtual Reality (VR). At present, rehabilitation techniques based on DIT and BFB are increasingly being used [8-12]. Purpose of the study: to investigate the efficacy and safety of digital interactive technology with artificial intelligence and biofeedback Rehabilitation glove "SensoRehab" (RGSR) for restoration of in-hand manipulation in patients with ischemic stroke in the early and late recovery

periods. The study was a pilot trial. It was conducted on the basis of branch 7 of the Moscow scientific and practical center of medical rehabilitation, restorative and sports medicine of the Department of health of the city of Moscow.

Participants

The study included 56 patients with a primary Ischemic Stroke (IS) in the middle cerebral artery in the right (31) and left (25) cerebral hemispheres. They included: 29 men, 27 women, mean age 57·4 ± 9·23 years, duration of IS from 1 to 12 months (mean: 6.67 ± 3.32 months). Patients with duration of IS 6-12 months prevailed: 45 patients (80.4%). Atherothrombotic stroke according to TOAST criteria [13] was registered in 37 patients (66.1%), cardioembolic - in 11 (19.6%); lacunar - in 3 cases (5.3%), unspecified etiology - in 5 patients (9.0%). The diagnosis in all the patients was verified by MRI of the brain. Patients included in the study had mild to moderate impairment of fine motor skills of the hand and fingers. All patients signed voluntary informed consent to participate in the study. The following trial inclusion criteria were identified for patients:

Men or women aged 18 to 70 years after a first-onset IS, early (1 to 6 months), late recovery (6 to 12 months) periods.

Supratentorial IS according to MRI of the brain.

- The severity of UL paresis ranged from a score of 4 to 3 according to the Medical Research Council Scale (MRCS) [14]. Spasticity of 2 points or less by the Modified Ashworth Scale (MAS) [15].
- Cognitive function more than 20 points on the Montreal Cognitive Assessment (MoCA) [16].
- Affective disorders score less than 11 on the Hospital Anxiety and Depression Scale (HADS) [17].
- The patient's ability and willingness to comply with the requirements of this protocol.
- The trial exclusion criteria for patients were as follows:
- Concomitant neurological diseases causing decreased muscle strength or increased muscle tone in the UL (e.g., cerebral palsy, brain injury).
- Clinically significant limitation of the passive movement amplitude in the joints of the investigated hand, pronounced contracture and deformities of the upper extremity.
- Use of other DIT, BFB techniques to restore impaired UL function within 30 days prior to the patient Inclusion Visit.
- Severe visual impairment decreased visual acuity of less than 0.2 in the worst eye according to the Golovin–Sivtsev Table [18].
- Sensory aphasia, gross motor aphasia.
- Recurrent stroke.
- Unstable angina and/or heart attack in previous month.
- Uncontrolled arterial hypertension.
- Somatic diseases in decompensation stage.
- Alcohol abuse, medical marijuana uses or soft drug abuse within the 12 months prior to the Inclusion Visit.
- Mental disease, epilepsy.
- Pregnancy.
- Lactation.

Procedures

All the patients received the procedure of restoring the fine use of the hand with RGSR. This digital interactive complex includes a set of cognitive interactive computer games controlled by finger and hand movements. By using visual and kinesthetic (proprioceptive) BFB principle the technique is based on neurosensory training and retraining to improve both the fine use of the hand and arm, and the patient's cognitive and emotional state. On the day of the procedure, a patient did not receive any kinesiotherapy, physiotherapeutic sessions or other techniques of BFB and DIT. After a basic assessment of hand motor function and game training, each patient underwent sessions on the RGSR system. The program for IS patients included 10 sessions with the RGSR (15 min to 30 min once a day for the affected hand, 2 weeks) (Figure 1, 2).

Methods

Efficacy and safety were assessed according to a set of scales and methods presented in Table 1. A questionnaire on the side effects and an examination to detect adverse events was carried out at each patient visit.

Primary outcomes

Changes in the FMA-UE and ARAT scales used to assess the dynamics of UL motor activity. Changes in the total ARAT Scale score by 4 points or more and in sections A-D of the FMA-UE Scale by 7 points or more were considered as efficacy.

Secondary outcomes

The following were used to evaluate the efficacy of therapy: percentage of correctly performed tasks; change in the paresis degree according to MRCS; spasticity severity according to MAS; level of impairment or dependence in daily life (Barthel ADL Index), degree of cognitive impairment (MoCA), anxiety and depression degrees (HADS), quality of life scale (EuroQol EQ-5D-5L). Assessment was performed before therapy, after 10 sessions, and 1 month after completion of the course using the scales mentioned above (Figure 3).

Results and Discussion

All 56 patients enrolled in the study completed the 2- and 4-week intervention and assessment programs on the SGSR-complex at visits V2 and V3. All analyzed MR components are summarized in Table 2. By the end of the second week of the study, an improvement in fine use of the hand was demonstrated according to the ARAT and FMA-UE scales. A clinically significant improvement in hand motor function on the ARAT Scale (increase by 4 points or more) was observed in 33.3% of patients, and on the FMA-UE Scale (increase by 7 points or more in sections A-D) in 30.5% of patients. The recovery of hand function (by ARAT and FMA-UE) was independent of the stroke duration and patient's age; restoring the function correlated with initially mild paresis ($r=0.4$, $p<0.05$). The changes in Strength assessed for each UL muscle group were not statistically significant ($p>0.05$). Pain levels did not increase during the treatment period for any joint (all $p>0.05$), indicating good tolerance for physical activity while exercising on the SGSR system. After 2 weeks of systematic training using the SGSR technology, positive dynamics of neurodynamic and regulatory function indices were observed, reaching normal values after 4 weeks at the end of MR ($p=0.61$). The most frequent adverse

Table 1: Methods used in the study.

Studied function	Examination method
Main criteria for efficiency evaluation	
Motor function state of the upper limb	1. Fugl-Meyer Upper Extremity Scale (FMA-UE) dynamics [19] 2. Action Research Arm Test (ARAT) Scale dynamics [20]
Additional criteria for efficiency evaluation	
Accuracy of interface-brain-computer tasks	% of correctly completed tasks, duration of training
State of the locomotor system	1. The 6-point Medical Research Council Scale for assessing muscle strength: MRCS; 2. Modified Ashworth Scale: MAS (0 to 4 points)
Pain assessment in a paretic limb	Visual Analog Pain Scale (VAS) [21]
Cognitive functions	Montreal Cognitive Assessment: MoCA
Presence and severity of depression	The Hospital Anxiety and Depression Scale: HADS
Functional independence	Barthel ADL Index: activities of daily living with analysis of total score and sections: Feeding; Bathing; Grooming; Dressing [22]
Life quality assessment	European Quality of Life Questionnaire EuroQol EQ-5D-5L (version 1.0, 2011 in combination with the visual analogue scale) [23]

Table 2: Primary and Secondary outcomes in the SG Group.

n=56	Visits				
Scales	**V1**	**V2**	**p (V1-V2)**	**V3**	**p (V1-V3)**
Primary outcomes					
FM-UE-total	53.4 ± 18	58.4 ± 1.7	0.047	58.8 ± 1.6	0.03
FM-UE-prox	30.0 ± 1.0	32.5 ± 0.9	0.05	32.7 ± 0.9	<0.05
FM-UE-dist	19.4 ± 0.7	21.2 ± 0.7	0.07	21.3 ± 0.7	0.06
ARAT	32.6 ± 3.2	43.2 ± 4.2	0.048	43.7 ± 4.3	0.047
Secondary outcomes					
MRC-SS	3.8 ± 0.6	4.0 ± 0.47	0.76	4.04 ± 0.47	0.75
mAS	1.2 ± 0.78	1.0 ± 0.7	0.91	0.97 ± 0.7	0.89
VAS (pain)	1.8 ± 0.76	1.6 ± 0.77	0.92	1.62 ± 0.77	0.92
MoCA	24.8 ± 2.8	26.2 ± 2.5	0.37	26.4 ± 2.4	0.61
HADS (Anxiety)	9.9 ± 2.7	7.9 ± 3.5	0.65	7.4 ± 3.3	0.55
HADS (Depression)	9.7± 2.8	8.3 ± 3.4	0.75	7.8 ± 3.5	0.67
Barthel ADL Index	58.2 ± 6.6	75.6 ± 5.6	0.048	77.8 ± 5.6	0.027
EuroQol EQ-5D-5L (VAS)	46.4 ± 6.6	67.8 ± 5.8	0.017	72.3 ± 5.7	0.004
Duration of training (minutes)	10.0 (1.5 to 22.0)	25.0 (4.5 to 35.0)	0.21		
Effective training time (minutes)	16.5 (12.5 to 20.1)	32.1 (23.9 to 37.9)	0.007		
Effective training time - total minutes		290 (246 to 329)			

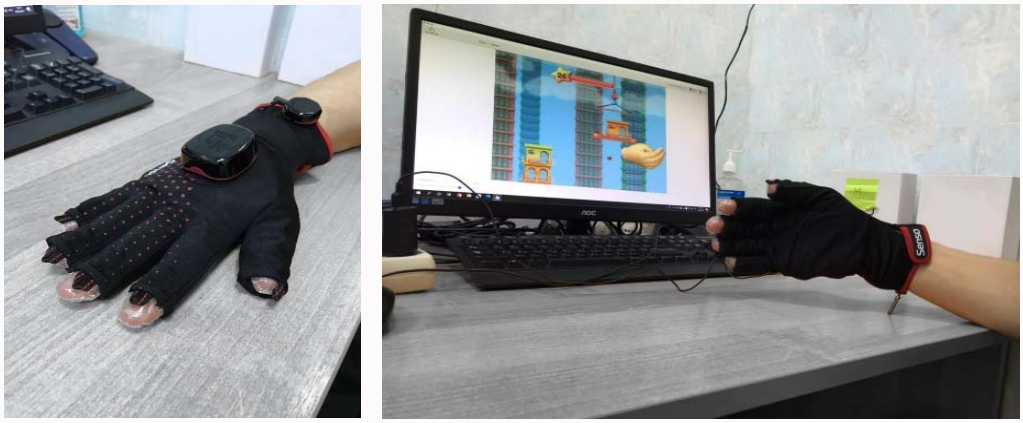

Figure 1, 2: The RGSG system and the task-specific games of this system.

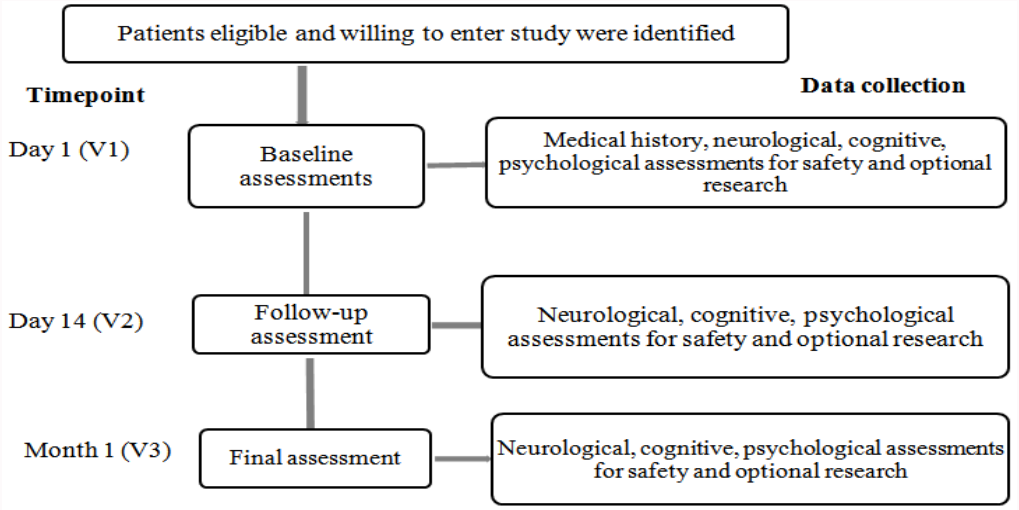

Figure 3: Participant procedures and data collection timepoints (Study design).

event (77.7%) was fatigue by the end of training, but none of the patients withdrew from the study. No serious adverse events have been reported.

Conclusion

This study demonstrated a significant improvement in the upper limb functional status and in targeted, highly coordinated hand movements, neuropsychological and cognitive functions and quality of life of IS patients using the RGSR. This study could be considered as a possibility for a subsequent RCT.

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