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Efficacy Assessment of Upper Limb Home-Based Exercises Using a Prototype Exercise Robot for Continuous Passive Movement Among Individuals with Paresis in the Long-Term Follow-Up: Preliminary Report

Ocena skuteczności domowych ćwiczeń kończyny górnej z wykorzystaniem prototypu robota do ćwiczeń ciągłego ruchu biernego u osób z niedowładem w obserwacji długoterminowej – doniesienie wstępne

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Key words
home exercises, continuous passive movement, paresis

Abstract
Introduction: Home exercises are a promising alternative to outpatient care or in-hospital exercise programmes. The forms of exercises with the use of robotic devices is constantly developing, and their positive effects have been well-documented.
Research objective: The aim of this study was to evaluate the effectiveness of upper limb home-based exercises with the use of the "Best Arm" robot following the onset of diseases causing spastic paresis in long-term observation.
Materials and methods: The study comprised 40 participants at an average age of 58.73 ±16.80. For a period of 8 months, training of the limb with paresis using the "Best Arm" device was carried out to test joint mobility, hand grip strength, and to measure the circumference of the forearm and upper arm.
Results: Statistical analysis shows a significant change in active and passive range of motion, as well as muscle strength after an 8-month intervention period in the group under study.
Conclusions: Home-based exercises using a prototype of the "Best Arm" device for exercising the upper limb with paresis have had a moderate effect on improving range of motion and muscle strength. However, these exercises did not significantly improve muscle tone or the functional capabilities of the upper limb.

Słowa kluczowe
ćwiczenia domowe, ciągły ruch bierny, niedowład

Streszczenie
Wprowadzenie: Ćwiczenia domowe są obiecującą alternatywą dla opieki ambulatoryjnej lub programu ćwiczeń realizowanych w szpitalu. Forma ćwiczeń z wykorzystaniem zrobotyzowanych urządzeń jest stale rozwijana a jej efekty są dobrze udokumentowane.
Cel pracy: Celem badań była ocena skuteczności domowych ćwiczeń kończyny górnej z wykorzystaniem robota – „Best Arm" w schorzeniach powodujących niedowład spastyczny w obserwacji długoterminowej.

The individual division of this paper was as follows: A – research work project; B – data collection; C – statistical analysis; D – data interpretation; E – manuscript compilation; F – publication search

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Materiał i metody: Do badania zakwalifikowano 40 osób ze średnią wieku 58.73 ±16.80. Przez okres 8 miesięcy zastosowano trening niedowładnej kończyny przy pomocy urządzenia „Best Arm". Na początku i na końcu tego okresu interwencji zastosowano następujące testy: zmodyfikowana skala Ashwortha, skala Brunnstorma, czynny i bierny zakres ruchomości stawów, test oceny siły uścisku dłoni, pomiar obwodu przedramienia i ramienia.
Wyniki: Analiza statystyczna wskazuje na istotną zmianę w badanej grupie czynnego i biernego zakresu ruchu oraz siły mięśniowej po okresie 8 miesięcznej interwencji.
Wnioski: Ćwiczenia domowe z wykorzystaniem prototypu urządzenia „Best Arm" do ćwiczeń kończyny górnej z niedowładem mają umiarkowany wpływ na poprawę zakresu ruchomości oraz siły mięśniowej. Ćwiczenia te nie mają wpływu jednak na istotną poprawę napięcia mięśniowego i możliwości funkcjonalnej kończyny górnej.

INTRODUCTION

Restoring the functions of the upper limb requires intensive and systematic treatment. The need for constant training has contributed to the development of rehabilitation robots. The results of this study allow to indicate that passive and active therapy supported by rehabilitation devices is safe and well-tolerated. Determining the appropriate treatment strategy at home, through the adoption of innovative technologies, can support the treatment of upper limb motor disorders[1,2].

Home-based physical therapy (PT) is a promising alternative to outpatient care or hospital-based physiotherapy programmes due to its favourable family atmosphere. There is a lack of literature in which the impact would be described of home rehabilitation programmes, specifically designed for people with various types of physical disabilities[3]. Automated rehabilitation is a new method of intervention. In a current review of publications, it has been suggested that this form of exercise, along with the use of robotic devices, may improve functioning of the upper limbs and increase patients' level of physical activity[4].

RESEARCH OBJECTIVE

The aim of this study was to assess the effectiveness of home-based exercises of the upper limbs with the use of the "Best Arm" robot following the onset of diseases causing spastic paresis in long-term observation and, above all, to answer the following questions:

1. What is the impact of upper limb home-based exercises with the use of the "Best Arm" robot on improvement regarding range of motion and muscle strength in long-term observation?
2. What is the impact of upper limb home-based exercises with the use of the "Best Arm" robot on improvement regarding muscle tone and the functional capabilities of the hand?

Based on such research questions, the following research hypotheses have been formulated:

1. Home-based exercises, performed with the use of automatic exercise rehabilitation devices, improve muscle strength.
2. Home-based exercises, performed with the use of automatic exercise rehabilitation devices, improve the functional capabilities of the upper limbs.

MATERIALS AND METHODS

Materials

All the results of this research have been presented in the format: measurement value ± standard deviation. The study received funding for the development and manufacture of the "Rehabilitation Robot – Best Arm" medical device from the National Centre for Research and Development – NCBiR. The conducted clinical trial was carried out in accordance with the guidelines proposed by the institution supervising the trial, which approved the clinical trial protocol, and the institution intermediating in the trial of the National Centre for Research and Development. The sponsor of the study had the financial means to test only 40 people on the device.

This study has been approved by the Bioethics Committee of the Medical University of Silesia in Katowice – Research Number: MIDMED/BA/2017, and each participant signed a consent form to participate in the study. The study comprised 40 individuals from a group of 123 men and women who met the inclusion criteria for the study . The selection of the study group was deliberate. Members of the group were recruited via correspondence in response to a written invitation. The average age of groups participants was 58.73 ±16.80, the mean body mass was 75.30 ±12.78, and the body mass index (BMI)[5] averaged 26.16 ±16.

The group of patients under study was characterised by the following diagnosed diseases: 77.50% (n = 31) stroke, not defined as haemorrhagic or infarct – I 64; 17.50% (n = 7) post-cervical spinal cord injury causing total or partial inertia – G82, 5.00% (n = 2) multiple sclerosis – G35.

The inclusion criteria were: patients after a stroke that occurred no later than 4 weeks prior to enrolment in the study or stroke after which at least 6 months had passed; patients with cervical spinal cord injuries causing total or partial paralysis; and patients with other medical conditions and neurological disorders that impair active movement within the upper limb.

The exclusion criteria were: fixed contracture in the area of the hand, wrist and/or elbow joints preventing the device from being put on; unusual dimensions regarding individual sections of the upper limb; pregnancy and/or breastfeeding; skin diseases; unhealed wounds; allergies to the material from which the device is made; rheumatoid diseases causing changes to the joints of the upper limb that prevent proper movement; fresh thrombotic processes within the arterial and venous vessels of the upper limb; mental illness, including lack of co-operation with the specialist; selected connective tissue diseases such as scleroderma that prevent freedom of movement in the upper limb joints; and other diseases that make the use of the "Best Arm" impossible.

Parameter measurements

The total duration of the observation was 8 months, during which the following parameters were assessed at the beginning and end of this period: spastic tension scales – the modified Ashworth scale[6] and the Brunnstorm scale[7,8]; the range of motion (ROM)[9]; elbow, radiocarpal, metacarpophalangeal and metacarpophalangeal joints of the thumb and finger joints; muscle strength tests - the Lovett test and[10] hand grip strength test[11]; and the measurement of forearm and upper arm circumference using a measuring tape[12].

Intervention

The "Best Arm" rehabilitation robot has been designed to improve paresis of the upper limb-hand due to properly designed movement simulating opening and clenching of the hand, as well as the movement of the radiocarpal joint and elbow. During the operation of this device, movement is forced in the joints of the hand through the appropriate operation of motors imitating its natural movement.

During the first visit, the patient was informed on how to use the device, while the range of motion and speed of movement were adjusted to the patient's current functional abilities. Within 8 months, a physical therapist carried out a monthly control visit in which the range of motion and speed of movement were regulated during the operation of the device depending on the current condition of the patient's upper limb.

Patients had the opportunity to comment on the operation of the device. The "Best Arm" rehabilitation robot is capable of performing passive exercises in the elbow joint during flexion and extension movements, the radiocarpal joint in flexion and extension movements, the metacarpophalangeal and the interphalangeal joints during flexion and extension movements. Exercises using the "Best Arm" device were carried out daily for a period of forty-five minutes. The patient used the device at home, in a sitting position, and the lengths of the individual components of the exercisers were individually adjusted to the patient's individual values. The programmed number of repetitions of a given exercise (100 for each exercise) was a constant value for each patient. The angle of movement and the speed of the exercise were selected individually to the patient's abilities. After four weeks of exercising, during the next visit, the device was reprogrammed according to the patient's suggestions and his current state. This process was repeated until the 32nd week of exercises.

During the eight-month period of physical therapy at home, patients also had the opportunity for telephone consultation with the physical therapist supervising this form of treatment.

Statistical analysis

The collected results were analysed and processed in the Microsoft Office program, whereas the statistical calculations were made using the Statistica 10 program by the Stat-Soft company. In order to test the relationship for nominal variables χ^2, Pearson's test was used, while the calculated value of the *p* coefficient was lower than the assumed level of statistical significance $\alpha=0.05$, and the relationship between the variables (statistical significance) was obtained. Additionally, the strength of the relationship between the variables was calculated using Cramer's V-correlation coefficient, which is interpreted only for statistically significant variables. In addition, the hypothesis concerning normal distribution of the studied variables was verified using the Shapiro-Wilk test. When the calculated value of the *p* coefficient is greater than the assumed significance level $\alpha=0.05$, we obtain the normality of the distribution. In order to verify the hypothesis concerning the difference between the variables, analysis of variance (ANOVA) was used for variables with normal distribution and the Wilcoxon test (non-parametric test) in the case of non-normally distributed variables.

RESULTS

Body mass index did not vary between the sexes among the subjects (Table 1). The most common comorbidities (n = 40) mentioned by the patients were: (n = 23): hypertension (n = 23; 57.50%); diabetes (n = 10; 25.00%); and epilepsy and coronary heart disease (n = 4; 10.00%). It is noteworthy that 70.97% (n = 22) of the respondents from group I64 suffered from hypertension, while 29.03% (n = 9) had been diagnosed with diabetes. Moreover, no comorbidities were diagnosed in the G82 group (n = 7). What is more, the diagnosis of comorbid disease had no effect on the sex of the examined people ($p = 0.1725$) (Table 2).

In the functional assessment, respondents were able to perform active movements in the elbow and radiocarpal joints. According to the modified Ashworth scale, the average spastic tension was less than 2 points. This movement improved significantly after 8 months of exercise. In the metacarpophalangeal and interphalangeal joints, passive movement was possible to evaluate, which increased significantly in the 2nd, final examination. There was a significant increase in muscle strength as measured by the subjective Lovett test and the standardised hand grip strength test. Forearm and upper arm circumferences are the other parameters in which a significant change in value was noted.

In the assessment of increased muscle tone, according to the Ashworth scale, the analysed values indicated slight improvement in the group of respondents, while maintaining statistical significance. Using another scale related to the assessment of upper limb functional capabilities no significant changes were demonstrated in the value (Table 3).

Table 1

Characteristics of included patients

Variables	x̄ ± *SD*	median	min	max
	Study Group			
Age [years]	58.73±16.80	63	86	26
Body mass [kg]	75.30±12.78	75	126	50
Body height [m]	169.40±8.78	170	190	147
BMI/Females [kg/m²]	25.40±3.20	25.39	29.90	18.82
BMI/Males [kg/m²]	26.45±3.19	26.06	34.90	20.02
BMI* [kg/m²]	26.16±16	26.01	34.90	18.82

*Whole group

Table 2

Gender of respondents compared to diagnosis of comorbid disease

Diagnosed diseases	Gender of the respondents				Statistical analysis		
	Female		Male		x^2	*p*	V
	n	%	n	%			
I64 – Stroke, not specified as haemorrhage or infarction	10	90.91	21	72.41	3.52	0.1725	0.30
G82 – Paralysis of the limbs	0	0.00	7	24.14			
G35 – Multiple sclerosis	1	9.09	1	3.45			

x^2 – Pearson's test

Table 3

Values of study variables

	Study Group									
	pre- intervention				post- intervention					
Parameters	**x̄ ±*SD***	**M**	**max**	**min**	**x̄ ±*SD***	**M**	**max**	**min**	**Z**	***p***
AROM° Radiocarpal joint – extension	30.56±14.16	35	45	0	37.22±12.35	40	55	5	3.52	0.0004
AROM° Radiocarpal joint – flexion	31.30±13.84	35	45	0	37.22±14.10	40	60	0	3.29	0.0010
AROM° Cubital joint – flexion	86.88±29.28	90	120	10	90.80±26.94	90	120	12	3.30	0.0010
Grip strength [kg]	2.25±3.22	1	10	0	3.08±4.13	1	14	0	2.93	0.0033
PROM° Interphalangeal joints – flexion	57.28±29.26	50	101	0	62.40±24.38	55	101	40	2.82	0.0049
Lovett scale score	2.65±1.48	3	5	0	3.03±1.42	3	5	0	2.80	0.0051
PROM° Metacarpophalangeal joints – flexion	54.85±26.85	40	101	10	57.25±24.74	47.5	101	10	2.42	0.0157
Arm circumference [cm]	26.05±3.06	25.5	38	22	26.28±3.17	26	38	22	2.37	0.0180
Forearm circumference [cm]	25±2.87	25	33	20	25.20±2.83	25	33	21	2.20	0.0277
Ashworth scale score	1.90±0.90	2	3	1	1.78±0.83	2	3	1	2.02	0.0431
Brunstorm scale [score]	2.08±1.47	1.5	5	0	2.15±1.5	1.5	6	0	1.21	0.2249

PROM – passive range of motion; AROM – active range of motion; M – median

DISCUSSION

Analysis of the obtained results has allowed to indicate that in long-term observation, improvement was noted for parameters which are important motor features, such as strength and flexibility. Significant improvement in the range of joint mobility in the examined upper limb during active and passive movement has demonstrated a positive effect on the amplitude of movement. Subsequent tests, with an increase in muscle strength, have demonstrated a positive effect on the extended mobility of the upper limb subjected to supervised home-based exercises using the "Best Arm" robot. A significant increase in upper arm and forearm circumference of the examined upper limb may be clinical confirmation of the increase in muscle strength. Other important motor qualities are coordination and dexterity.

Evaluation of the variable using the Brunnstorm Scale indicates a low level of motor skills that did not improve 8 eight months of exercise. A slight but significant increase in the score on the modified Ashworth scale is not conducive to the improvement of coordination and motor dexterity, which has impact on the fine motor skills[13,14]. One explanation is that the "Best Arm" robot performs a continuous passive movement within the range of motion determined by the physiotherapist and at an appropriate speed, comfortable for a given patient.

The biological benefits of continuous passive motion in preventing joint stiffness, increasing joint metabolism and improving blood and lymph circulation have all been well-documented. These effects can improve the range of active and passive mobility in patients with paresis of the upper limbs caused by various neurological diseases. However, improvement in coordination and dexterity requires the involvement of the patient's attention through various forms of training, based on biofeedback[15,16].

Based on a review of publications by other authors, it can be seen that exercise protocols vary in intensity, duration and training amount. The parameters for assessing the effects of the exercises used were also different[17]. The basis for the effectiveness of physical therapy in patients with paresis of the upper limb is its regularity. A caregiver-mediated exercise programme can improve outcomes for body function, activity, and participation in stroke survivors. Moreover, caregivers were more actively involved in the rehabilitation process, which may have increased the patients' sense of independence[18].

In a systematic review of tele-rehabilitation interventions in post-stroke care, promising results have been shown, although the quality of evidence on tele-rehabilitation in post-stroke care is low[19].

Stroke, as damage to the upper motor neuron, causes an increase in pathological muscle tension - spasticity. As its result, spastic paresis of the upper limb depends on the size and course of the stroke. These patients significantly increase their hand function, control, movement and grip capabilities under the influence of physiotherapy. Paralysis, as damage to the lower motor neuron as a result of a spinal cord injury, causes reduction in muscle tension - flaccidity. People with paralysis are less likely to recover, and physical therapy can inhibit the process of reducing hand functionality. Devices using 3D technology aid restoration of this the connection, possibly creating new connections responsible for the flow of the impulse controlling the work of the upper limb, or improving the control and accuracy of the upper limb. The cost of physiotherapy with this method is much higher, but its purpose is also different. Many new devices with the use of feedback have been developed, however, it is difficult to indicate the greater usefulness of one over the other[20-23].

The innovation of the Best Arm device is its availability and ease of use at home. The intention of the authors was that anyone in need could use this device at home and exercise even several times a day. The objective of the designers was to create a device available to everyone. The Best Arm device should not be compared to highly technologically-advanced robots. It should be treated as a supplement to daily physiotherapy.

In the conducted research, the regularity of training was supervised by monthly visits and telephone consultations by physical therapists. This supervision ensured control of training and gave the opportunity to submit comments on the prototype of the device during its operation.

Nonetheless, there are some limitations such as the lack of a control group, small group size and no statistical analysis of differences between sexes and disease entity. The adopted inclusion criteria have allowed, however, to create a group in which people with upper limb paresis due to stroke, traumatic paralysis of the upper limbs or multiple sclerosis have the same percentage of comorbidities, confirming a similar level of health. The device itself is easy to use and enables the performance of home exercises according to the patient's physical therapist's recommendations. This method of physical therapy, based on technological solutions, can increase the availability of physiotherapy and reduce its costs.

This article should be treated as a pilot study. It is compliant with the protocol approved by NCBiR. The lack of a control group in this study is also due to the fact that there was no intention to compare the 2 groups, but to confirm the overall suitability of the designed device. Further research, which will include division into a control and test group, is planned.

CONCLUSIONS

The obtained results authorise the formulation of the following conclusions:

1. Home exercises with the use of a prototype of the "Best Arm" device for exercising the upper limb with paresis have had a moderate effect on improving the range of motion and muscle strength in long-term observation.
2. These exercises do not significantly improve muscle tone and functional capabilities of the upper limb.
3. Further research must be focused on expanding the technological capabilities of the device, which will allow the patient to fully engage in exercises based on biofeedback.

Conflict of Interest
None declared

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