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RANDOMISED TRIAL

Armeo®Spring therapy improves movement efficiency and contributes to a better quality of life

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ABSTRACT
OBJECTIVES: The main objective was to explore the effect of exoskeleton-assisted rehabilitation on quality of life in the subacute state of ischemic stroke.
BACKGROUND: Central upper extremity hemiparesis affects self-care, social participation, and quality of life. Exoskeleton devices serve as a therapeutic tool and an assessment tool that offers precise tracking of patient progress and evaluation of impairment.
METHODS: The trial was carried out from April 2022 to September 2023. Twenty-seven patients were randomly assigned to the intervention (14 participants; mean age 64.71 years; 5 women, 9 men) and control group (13 participants; mean age 64.69 years; 6 women, 7 men). Both groups received equal total therapy (10 to 12 sessions, 5 times a week). The intervention group received 30 minutes of Armea®Spring training combined with conventional rehabilitation. The control group was subjected to conventional rehabilitation.
RESULTS: In the comparison between groups, the experimental group achieved significant changes in quality of life, movement efficiency, and functional performance of the upper extremities.
CONCLUSIONS: Armeo®Spring therapy combined with usual care led to significantly larger changes in health-related quality of life and upper extremity movement efficiency compared to conventional rehabilitation *(Tab. 4, Fig. 3, Ref. 64.)* Text in PDF www.elis.sk
KEY WORDS: stroke, hemiparesis, health-related quality of life, Armeo®Spring, movement efficiency, activities of daily living.

Introduction

Despite improvements in prevention, diagnosis, and acute treatment, stroke remained the second leading cause of death and the third leading cause of death and disability combined worldwide in 2019 (1). In Europe, the ageing of the population will lead to a dramatic increase in the absolute number of stroke cases during the first half of the 21st century (2). In the Czech Republic, the situation is even more alarming. Although the incidence rate of cerebrovascular accidents remains almost double that of western Europe, mortality is decreasing. The combination of these factors leads to a growing prevalence (3). International projections indicate that the incidence rate of ischemic stroke will increase in both sexes and all age groups between 2020 and 2030 (4).

One of the most serious sequels to stroke is upper extremity impairment such as loss of movement, coordination, sensation, and dexterity. Paresis results in slower, less accurate and less efficient hand movement compared to healthy individuals, while the loss of fractionated movement is apparent in abnormal synergy of the upper extremities (5). This is the origin of functional limitations in the upper extremities after a stroke (6, 7). Therefore, patients cannot perform activities of daily living (ADL) without supervision, direction, or physical assistance, leading to a decrease in participation in social roles and activities (8). This fact represents a decisive factor in their decreased quality of life (9). Optimal restoration of arm and hand function is essential for independent ADL performance. Disruption of the patient's ability to perform activities of daily living negatively affects their health-related quality of life (HRQoL) (10). The general definition of "quality of life" according to WHO is 'an individual's perception of his position in life in the context of the culture and value systems in which he lives and about his goals, expectations, standards, and concerns' (11). HRQoL (health-related quality of life) refers to 'how health affects an individual's ability to function and his or her perceived well-being in the physical, mental and social domains of life' (12). The low quality of life was associated with the number and type of stroke deficits, and its treatment is expected to improve the quality of life in older adults (13).

For a valid assessment of the complex aspects of HRQoL, generic and disease-specific instruments have been developed (14). An interesting study by Polish and Czech authors emphasized the role of kinematic indicators in evaluating functional differences in

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upper limb movement in early and chronic stroke. They serve as an assessment tool and help in planning the therapeutic process (15).

Neurorehabilitation is a medical process aimed at increasing function through plasticity-dependent recovery (16). Neural plasticity or modifiability, and learning are connected processes. The gradual shift from short – to long-term learning follows the development of neural modifiability. Short-term changes associated with synaptic efficiency persist and gradually give way to structural changes, the foundation of long-term learning. This principle also applies to the recovery of function (17). Task-specific, high-intensity exercises in an active, functional, and highly repetitive manner have been shown to enhance motor recovery (18). The application of advanced technologies, for example robotic therapy, in the first months after stroke may lead to large reductions in impairment that are very likely to generalise to functional and ADL scales (19). A systematic review by Mehrholz et al states that people who receive electromechanical and robot-assisted arm training after a stroke might improve their activities of daily living, arm function, and arm muscle strength (20). There is strong evidence for robot-assisted therapy to increase compliance with treatment by introducing incentives to the patient, such as games (21). Another important feature of robots is the possibility of using them also for an objective assessment of upper limb functions (22).

Armeo®Spring (Hocoma AG, Volketswil, Switzerland) is an electromechanical device for upper limb rehabilitation. It is a spring-based weight compensation exoskeleton that allows virtual exercise, gaming, and feedback in a three-dimensional workspace (23). Traditionally, upper limb deficits after stroke are evaluated using established clinical scales. Their limitation is the use of ordinal scales (24), which are not sensitive enough to capture the quality of sensorimotor performance or the effectiveness of therapeutic interventions (25). The relationships between sensorimotor impairments and specific characteristics of movement performance are dynamic during the first few months after stroke, and common clinical measures do not predict large proportions of variance in performance during the subacute phase after stroke (26). Instrumental measurements are a promising way to overcome this disadvantage. The Armeo®Spring device can be used effectively to provide a reliable, objective and quantitative assessment of motor and functional impairments of the upper extremities and to assess therapeutic effects on motor learning in patients after stroke (27). The Armeo®Spring device can also facilitate functional analysis of the upper limb (28). Multiple studies focused on the validation of kinematic parameters as a correlate with established clinical scales in the evaluation of outcomes after stroke. A clear and comprehensive summary of the development in this field of research is presented in the work by Adans-Dester and De los Reyes – Guzmán (29, 30).

Several studies have already been carried out in the Czech Republic investigating the effectiveness of the Armeo®Spring device in recovery of impairment and dysfunction of the upper extremities (31, 32). Recommendations from previous work state that the emphasis should be on measuring both functional outcomes and quality of life in patients (33). For this reason, we decided to conduct a study comparing HRQoL in experimental group training with the Armeo®Spring device and in the control group (conventional rehabilitation). The primary objective of our study is to explore the relationship between the quality of movement of the paretic upper limb and the quality of life that develops in stroke survivors in the subacute stage. The novel approach lies in the use of instrumental evaluation. We also aim to investigate the effect of exoskeleton-assisted rehabilitation on the quality of movement and function of the upper limb. Generic and stroke specific questionnaires were used.

Materials and methods

The prospective monocentric randomised controlled trial was conducted in the inpatient ward of the Department of Rehabilitation and Sports Medicine of the University Hospital in Ostrava from April 2022 until September 2023. The trial was approved by the Ethics Committee of the University Hospital in Ostrava. All patients signed an informed consent.

The trial design is parallel with the treatment and control arm. Subjects are assigned to the intervention arm using Armeo®Spring therapy in combination with conventional rehabilitation or to the control arm using conventional rehabilitation.

The study focused on the population of stroke survivors in the subacute stage of ischaemic stroke (<6 weeks) who suffered impaired upper limb function hospitalised in the inpatient ward of the Department of Rehabilitation and Sports Medicine of the University Hospital in Ostrava between April 2022 and September 2023. The patients were recruited from the Stroke ICU and the inpatient ward of the Department of Neurology of the University Hospital in Ostrava after the standard stroke treatment protocol.

The eligibility criteria for the study included state up to 6 weeks after the onset of cerebrovascular accident, age >18 years, mild or moderate central upper limb impairment with deficient quality and precision of movement, spasticity less than 1 according to the modified Ashworth scale and cardiocirculatory stability. *Exclusion criteria* included patients aged < 18 years old, decompensated state, cardiocirculatory instability, cognitive or sensory impairment (The MoCA Test – Montreal Cognitive Assessment) < 25 points, scored by the occupational therapist) limiting the ability to participate in therapy, severe speech disorder limiting the understanding of instructions (scored by the speech therapist), the following exclusion criteria are based on Armeo®Spring contraindications: severe osteoporosis, bone instability, skin lesions, contraindicated sitting position.

Patients who met the eligibility criteria were randomly assigned to the intervention and control groups immediately after admission to the rehabilitation ward. Participants in both arms underwent two evaluation sessions. The initial examination (T0) was performed on the day of admission and the following day and included the HRQoL survey, the European Quality of Life Questionnaire (EuroQoL EQ-5D-5L index), the Stroke Impact Scale 3.0 (SIS3.0) questionnaire, the Modified Frenchay Scale (MFS) functional upper limb exam performed by the investigator physician. The evaluation of movement quality AGOAL on the

Armeo®Spring device and the Barthel Index (BI) was performed by a trained occupational therapist. The evaluations were conducted consecutively in a calm environment to avoid distractions and fatigue of the participants. Final evaluations (T1), including EQ-5D-5L, SIS 3.0. AGOAL, MFS, and BI were performed before discharge from the rehabilitation ward. Demographic and clinical data were collected from medical records (age, gender, time since the stroke).

Objectives and outcomes

Two primary outcome fields of our study have been established:

1) Change in the quality of life – generic instrument (EQ-5D-5L) and specific instrument (SIS 3.0)
2) Change in the movement quality of the paretic upper limb (AGOAL) and active upper limb function (MFS)

A secondary outcome measure (BI) was established to compare the effect of Armeo®Spring therapy on global performance in ADL tests.

EuroQoL EQ-5D-5L is a generic standard measure of health status developed by the EuroQol Group for clinical and economic appraisal (34) with a certified and accessible Czech version. The questionnaire provides a profile of the health state of the respondent in five dimensions: mobility, self-care, activity, pain, anxiety, and depression. Each dimension includes five levels of severity (1 to 5; no problems to inability). According to EuroQoL recommendations, it is advisable to select an EQ-5D-5L value set for a region with a similar socioeconomic background if a standard value set is not locally available. Therefore, we use the Polish EQ-5D-5L value set with the permission of the author of the Polish valuation study (35).

SIS 3.0 is a patient–centred outcome measure and one of the most comprehensive stroke–specific scales used to measure the health-related well-being of people recovering from stroke (36). The instrument consists of eight domains: (1) Hand function, (2) Activities of Daily Living (ADL)/Instrumental ADL (IADL), (3) Strength, (4) Social Participation, (5) Mobility, (6) Memory/Thinking, (7) Emotion, and (8) Communication (37). The questionnaire examines the activities of the last week. Responses in domains 1–8 are rated on the 5-point Likert scale. Higher scores mean better results and better quality of life. The instrument was tested in the official validation study and is now available in certified Czech version (38).

AGOAL is an assessment exercise included in ArmeoControl software designed to monitor patient progress. The software provides information about coordination and quality of movement. Armeo®Spring testing and therapy are performed by trained occupational therapists. Hand path ratio (HPR) – this variable is a kinematic parameter that characterises the motion of the upper extremity (UE) without considering the forces. This metric is obtained from end-point kinematic data and depicts a specific movement characteristic, in this particular case, the movement efficiency. Tracking the path ratio is performed through sensors on the electromechanical orthosis and computed from spatial positions in the 2D plane. Calculation is carried out by dividing the length of the path by the distance between the base and the target. HPR equals 1 when the movement is perfectly straight. The higher ratio means that the trajectory was longer. The names of this variable in the literature may differ according to the author and device used (30).

The MFS is based on the original Frenchay Arm Test (FAT), which assesses 7 daily tasks. Although representative and feasible, FAT had serious restrictions such as binary pass/fail rating and preference for unimanual tasks (39). The MFS, launched in 2002, differs from the FAT in three points: 1) three bimanual tasks have been added, in an attempt to more realistically reflect the way a hemiparetic patient might function in real life; 2) videotaping of the performance is used to facilitate verification and rater blinding; and 3) the categorical (pass/fail) rating system for each task in the FAT has been transformed into a 10-Interval Visual Analogue Rating Scale. Today, MFS represents objective evaluations of active upper extremity function as part of the Five-step clinical evaluation in spastic paresis (40).

BI was originally developed as an assessment tool in chronic neuromuscular disorders and is one of the most widely used assessment tools to assess functional independence in daily activities and self-sufficiency (41). The strengths of BI are widespread use and ease of application (42). The form of BI includes 10 common activities of daily living (ADL): feeding, bathing, grooming, dressing, bladder and bowel control, toilet use, transfers (bed to chair and back), mobility, and climbing stairs. The items are rated as whether patients can perform activities independently or with assistance and are totally dependent (scored 10, 5, respectively, or from 15 to 0 for transfers and mobility) (43). The test is administered by a trained occupational therapist.

Technical specification of the device used in the study

Armeo®Spring (Hocoma AG, Volketswil, Switzerland) is a system for functional therapy of upper extremity disorders. Technically, it is the 'exoskeleton', the articulated electromechanical orthosis with 5 degrees of freedom without actuation. The complete system consists of a personal computer, arm, and forearm modules with weight compensation and a pressure-sensitive handle embedded in the transportable platform with a lifting column. Regarding the assistance in active movement of the patient, it is the passive device, where the axis of the arm module is parallel to the upper limb of the subject and is attached by a series of cuffs with velcro straps. The length of each segment of the exoskeleton can be adjusted to the patient's proportions. The machine is equipped with sensors to measure joint angles and position, and the hand grip also has a built-in pressure sensor. The device provides antigravitational support of arm weight (23) that is adjustable according to the patient's needs. Patients and therapists interact with the system through Armeo®Control software, which serves both as control software and as an interface for therapists and patients and is equipped with training and evaluation exercises. The duration and difficulty of the exercises can be progressively increased. The software allows for the reinforcement and facilitation of movement using visual feedback in a virtual environment (44). ArmeoControl

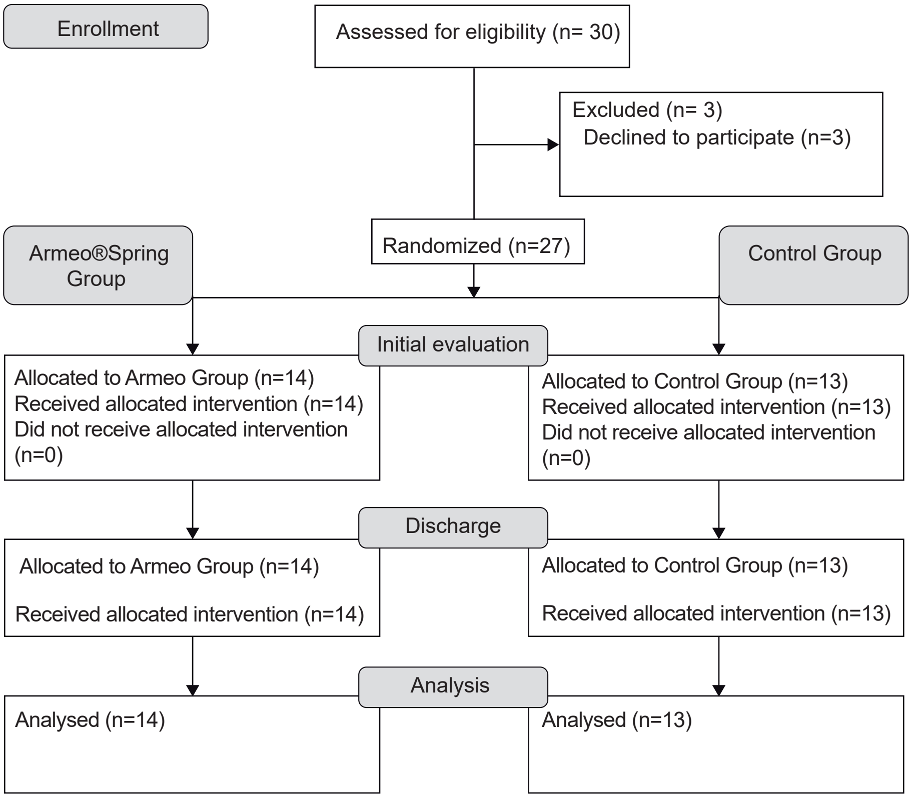

Fig. 1. Flow chart of study participants according to CONSORT.

on the screen. The patient must start movement from the base and stay precisely in the middle of the target for three seconds. When one target disappears, the patient must return to the base, and the new goal is displayed at another location. ArmeoControl software allows one to create a personal training plan according to the patient's needs; it is possible to increase the difficulty level of each exercise. The trajectory of the movement should be as straight as possible.

software also generates exportable patient reports in .xls and .pdf format, allowing for further processing and analysis of the data.

Intervention

Patients in both treatment arms received an equal total dose of therapy. The control group was subjected to conventional physiotherapy and occupational therapy. The intervention group received combined conventional rehabilitation and a session using the Armeo®Spring device. In total, there were a minimum of 10 and a maximum of 12 Armeo therapy sessions of 30 min daily, 5 times a week for 2 to 3 weeks. The initial session was dedicated to setting up and familiarising with the device and completing an initial assessment. The AGOAL assessment exercise evaluates the efficiency of reaching movement because it represents a motion towards a target and symbolises a significant multijoint activity of the upper extremities, very important for independence in daily living activities such as self-feeding, grooming, dressing, and environmental switch operation (45). In this task, the patient must place the indicator precisely on the target. Targets appear consecutively

Statistical analysis

First, a basic descriptive statistics calculation was performed. Subsequently, quantitative data items were tested for normality of distribution using the Shapiro–Wilk test. To compare the experimental and control groups of patients, Chi-square and two sample Mann–Whitney tests were performed. Differences between baseline scores (T0) and postintervention scores (T1) were analysed using the Wilcoxon signed rank test. The test power was verified using differences in the T0 and T1 scores between the groups. The tests were evaluated at a level of significance of 5%. Data from all participants were analysed using Stata version 16 software.

Results

Twenty-seven patients who met the inclusion criteria were recruited and randomised between April 2022 and September 2023. According to the CONSORT requirements, a participant flow chart is presented (Fig. 1). All enroled patients completed the baseline and discharge examination. Three individuals who met the inclusion criteria declined to participate in the research. Therefore, they were not randomised.

The experimental group consisted of 14 participants (mean age 64.71±16.40 years, 5 women, 9 men); the control group consisted of 13 participants (64.69±15.83 years, 6 women, 7 men). The baseline sociodemographic and clinical characteristics of the participants are listed in Table 1 including days after the onset of

Tab. 1. Baseline Characteristics of the Participants.

Group	n	Age, years, mean ± SD	Gender m/f, n	Days after stroke, days, mean, ± SD	Paresis of dominant/ nondominant hand, n	Degree of disability (mRS)	EQ-5D-index, mean, ± SD	HPR, mean, ± SD
Armeo IG	14	64.71±16.40	9 males, 5 females	15.21 ± 6.83	7 dominant, 7 nondominant	3 ± 0.68	0.74±0.15	2.16± 0.65
Armeo CG	13	64.69±15.83	7 males, 6 females	15.69 ± 5.86	2 dominant, 11 nondominant	2.54±0.52	0.83±0.16	1.55± 0.35

IG – intervention group; CG – control group; EQ-5D index – EuroQoL 5 dimensions, 5 levels questionnaire; HPR – hand path ratio stroke, the dominance of the upper extremities, the degree of disability, the quality-of-life questionnaire and the measure of movement efficiency. Both study groups were comparable at the beginning, although there was a disproportion in the baseline value of the HPR parameter that was higher in the Armeo group (Tab. 1). Further explanation is available in the Discussion Section.

Table 2 describes the comparison of the degree of improvement within each study group. The intervention group reached significant and superior differences between T0 and T1 in all variables. The control group did not achieve a significant difference in the SIS 3.0 Communication domain score. Table 3 shows the comparison of the magnitude of improvement between groups. In the Armeo group, statistically significant changes were observed in three main outcomes: the EuroQoL EQ-5D index, the SIS 3.0 physical domain score, HPR and MFS. The difference between T0 and T1 in the Barthel Index was statistically insignificant. Table 4 shows the evolution of SIS 3.0 HRQoL between the groups. Statistically significant results were observed in the scores for Hand function, Emotion and Physical domain in the treatment group.

The scatter plot in Figure 2 illustrates the magnitude of the change in the generic HRQoL measure, the Euro QoL EQ-5D index, and the plot in Figure 3 illustrates the improvement in the Physical domain score of the specific SIS 3.0 instrument. The increase in distance from the diagonal axis indicates an improvement in performance in both parameters. No adverse effects related to Armeo®Spring therapy were reported.

Tab. 2. Intragroup analysis.

Intervention group n=14			**Control group n=13**		
Variable	**Median**	***p***	**Variable**	**Median**	***p***
EQ-5D index	–0.113	<0.001	EQ-5D index	–0.034	0.0039
HPR	0.714958	<0.001	HPR	0.0776348	0.0266
MFS	–16.5	<0.001	MFS	–3	<0.001
BI	–17.5	<0.001	BI	–5	0.0039
Strength	–0.16	<0.001	Strength	–0.07	0.001
Hand function	–0.325	<0.001	Hand function	–0.1	0.0273
Mobility	–0.225	<0.001	Mobility	–0.11	0.0103
ADL/IADL	–0.135	<0.001	ADL/IADL	–0.1	0.001
Emotion	–0.08	<0.001	Emotion	–0.03	0.0283
Memory and thinking	–0.125	0.002	Memory and thinking	–0.03	0.0156
Communication	–0.015	0.0156	Communication	0	0.625
Participation/role function	–0.125	<0.001	Participation/ role function	–0.06	0.002
Emotional score	–0.08	<0.001	Emotional score	–0.05	0.0117
Physical score	–0.215	<0.001	Physical score	–0.09	0.0032
Stroke recovery	–0.275	0.001	Stroke recovery	–0.12	<0.001

EQ-5D index – EuroQoL 5 dimensions, 5 levels questionnaire; SIS 3.0 – Stroke Impact Scale 3.0; HPR– hand path ratio; MFS – Modified Frenchay Scale; BI – Barthel Index; *level of significance 95%

Discussion

Restoration of self-care and participation in social roles after stroke represents the main goal of neurological rehabilitation. The literature suggests that minimising the deficits of stroke survivors is an important factor in their subsequent life satisfaction and that improvements in upper limb function may improve their participation in ADL and also lead to improvements in quality of life (13, 46). The aim of our trial was to clarify whether Armeo®Spring training combined with usual rehabilitation leads to improvement in three crucial areas: a) health-related quality of life (HRQoL), b) movement quality of the impaired upper limb, and c) upper limb and self-care in the subacute state of stroke.

Concerning HRQoL, a generic tool was used to capture the general meaning and a stroke-specific tool to distinguish subtle

Tab. 3. Assessment results.

Group	**IG**		**n=14**	**CG**		**n = 13**	
	T0, mean ±SD	T1, mean±SD	Δ, Δ%	T0, mean SD	T1, mean±SD	Δ, Δ%	*p*-val.
EQ-5D index	0.742±	0.904±	0.162	0.780 ± 0.214	0.828± 0.162	0.0480	<0.001
	0. 151	0.048	21.89%			6.15%	
SIS 3.0 Physical Score	0.592 ± 0.128	0.795 ± 0.969	0.203	0. 676 ± 0.96	0.803 ± 0.125	0.127	0.049
			34.29%			15.82%	
HPR	2.162±	1.354 ±	0.808	1.552± 0.354	1.459 ± 0.376	0.093	<0.001
	0.653	0.337	37.37%			5.99%	
MFS	76.5 ± 11.037	94.286±	17.786	86 ± 14.894	90 ± 13.760	4.0	<0.001
		5.553	23.25%			4.65%	
BI	77.86 ± 16.492	93.571±	15.711	85.385± 13.914	93.462±	8.077	0.068
		10.271	20.17%		8.510	9.47%	

IG – intervention group; CG – control group; EQ-5D index – EuroQoL 5 dimensions, 5 levels questionnaire; SIS 3.0 – Stroke Impact Scale 3.0; HPR– hand path ratio; MFS – Modified Frenchay Scale; BI – Barthel Index; T0 = baseline; T1 = end of treatment; Δ = change between T0 and T1; Δ% = percentage of change between T0 and T1 compared to baseline level T0; Mann–Whitney test; *level of significance 95%

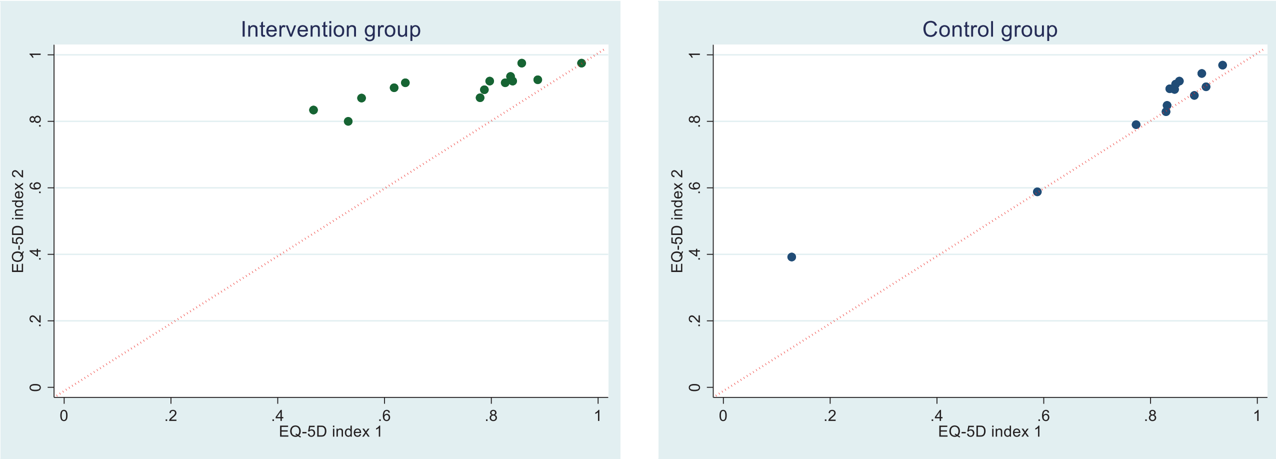

Fig. 2. Scatter plot that illustrates the magnitude of improvement in the HR-QoL variable Euro QoL EQ – 5D index between groups. A higher distance from the diagonal axis indicates a larger difference.

changes in particular domains. In the intragroup comparison, participants from both groups achieved statistically significant results in the generic EQ-5D index, as well as in the specific instrument SIS 3.0. When comparing the magnitude of the change in particular domains, the Armeo group achieved statistically significant results in Hand function, Emotional, and Physical scores. According to Kutner et al, the contribution of robotic assisted rehabilitation is based on enhancing motor recovery in patients who have had a stroke while decreasing labour, which is the most costly aspect of delivering physical therapy interventions (47). Furthermore, Gueye et al showed that patients over 65 years present the same improvements in virtual reality (VR) training as younger individuals (32). In a similar study, Rodriguez-Hernandez et al found that VR as a complement to conventional rehabilitation treatment is associated with a perceived increase in HRQoL in stroke survivors in the first three months after finishing treatment, the effect of the combined intervention is reduced, especially in the dimensions of Pain, Anxiety, and Depression (48).

In the instrumental assessment of the quality of upper limb movement, AGOAL, we observed a statistically significant change between both groups. This parameter describes the ability to maintain the linear path during reaching tasks and therefore represents the movement efficiency and coordination of the UE. Our findings are in line with those of Lang et al (49). This study compared the hemiparetic group of stroke survivors with healthy controls. The UE movement efficiency observed in the hemiparetic group was poor, and the path ratios were also higher in the hemiparetic group than in the control group. This remarkable difference between HPR T0 and T1 in IG can be explained by three facts. First, by the influence of upper limb sensorimotor and coordination impairment, second, by the small sample size. The third possible reason may be the presence of the learning effect (24, 27, 50) despite the fact that we limited the AGOAL evaluation strictly to the evaluation sessions in both groups

Table 4. Differences in SIS 3.0 between baseline and end of treatment

Group	SIS 3.0 domain	n	Median	Mean	Std. dev.	*p*-val.
IG	Strength	14	**–0.16**	–0.19	0.13	0.212
CG	Strength	13	**–0.07**	–0.14	0.15	
IG	Hand function	14	**–0.33**	–0.28	0.20	0.019
CG	Hand function	13	**–0.10**	–0.09	0.13	
IG	Mobility	14	**–0.23**	–0.21	0.13	0.087
CG	Mobility	13	**–0.11**	–0.12	0.15	
IG	ADL/IADL	14	**–0.14**	–0.15	0.10	0.421
CG	ADL/IADL	13	**–0.10**	–0.12	0.08	
IG	Emotion	14	**–0.08**	–0.16	0.14	0.046
CG	Emotion	13	**–0.03**	–0.08	0.12	
IG	Memory and thinking	14	**–0.13**	–0.11	0.10	0.097
CG	Memory and thinking	13	**–0.03**	–0.05	0.08	
IG	Communication	14	**–0.02**	–0.07	0.11	0.130
CG	Communication	13	**0.00**	–0.01	0.06	
IG	Participation/ Role function	14	**–0.13**	–0.15	0.13	0.435
CG	Participation/ Role function	13	**–0.06**	–0.12	0.14	
IG	Stroke recovery	14	**–0.28**	–0.28	0.20	0.204
CG	Stroke recovery	13	**–0.12**	–0.17	0.10	
IG	Emotional Score	14	**–0.08**	–0.15	0.15	0.096
CG	Emotional Score	13	**–0.05**	–0.08	0.12	
IG	Physical Score	14	**–0.22**	–0.20	0.10	0.049
CG	Physical Score	13	**–0.09**	–0.13	0.11	

IG – intervention group; CG – control group; *level of significance 95%

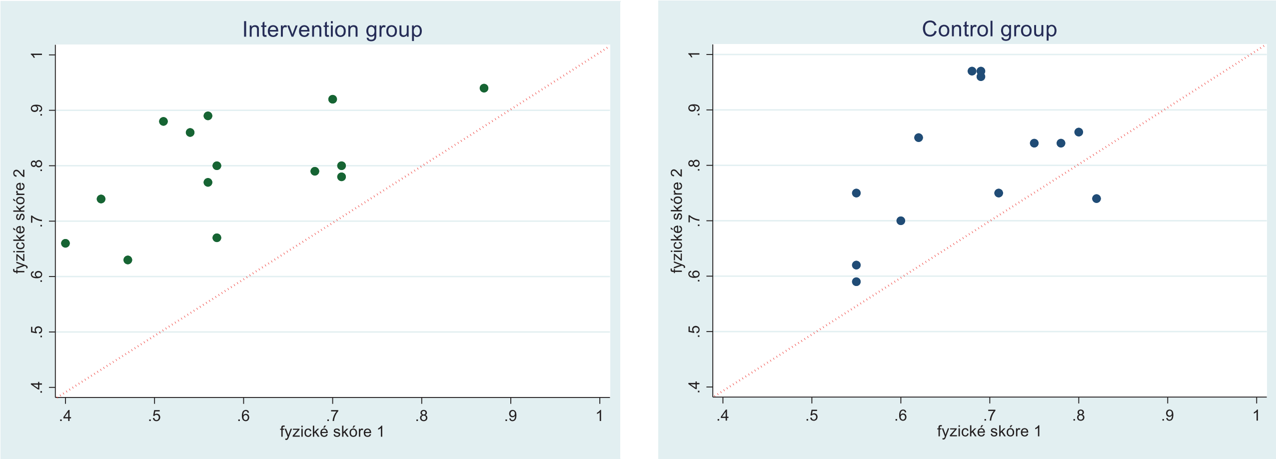

Fig. 3. Scatter plot that illustrates the magnitude of improvement in the HR-QoL variable SIS 3.0 Physical domain score between the groups. A higher distance from the diagonal axis indicates a larger difference.

according to the recommendations from previous evidence (51). Navratilova et al reported similar findings on the temporal evolution of HPR in the experimental group (50). Previous studies focused on improving functional motor skills and smoothness reported a positive effect of arm weight support rehabilitation (52, 53). Furthermore, Bartolo et al found that passive arm orthoses and arm weight support devices lead to more natural active arm control and increase the smoothness of reaching tasks (52). These results indicate a functional improvement obtained with arm weight support therapy. Chan et al specified that arm weight support training is beneficial for patients with subacute stroke, especially to improve vertical control (53). Advanced rehabilitation technologies can reliably measure movement kinematics and/or dynamics throughout recovery, allowing insights into the underlying mechanisms of recovery (19).

Regarding our secondary outcomes, we intended to track the evolution of upper limb functional performance after rehabilitation. For this reason, we selected MFS which constitutes an internally consistent and reliable assessment scale of upper extremity function in hemiparesis through 10 daily tasks (39). The entire study cohort made statistically significant progress in the MFS score within the groups. In the intergroup comparison, the magnitude of the change in the MFS score was significantly larger in the Armeo group. Numerous studies have proved the efficacy of RT or VR combined with usual care in motor and functional recovery not only in the proximal upper extremity, but also in the range of motion of the hand (52). Blazincic et al observed a correlation between training a specific goal in the device and improvement in the ICF Body Function categories (54). Furthermore, this treatment approach was beneficial even for the cognitive abilities of the participants (55).

In the following secondary outcome, the general ADL scale, we selected the well-established Barthel Index. This instrument is still frequently used despite its limitations and, therefore, represents the standardised assessment tool (42). Intragroup evaluations indicate that both trial arms achieved statistically significant improvements. On the other hand, when comparing the magnitude of change, there was no statistically significant difference between groups. We can therefore assume that both the conventional and the exoskeleton combined treatment approaches are equally efficient in the restoration of general ADL capabilities. Our finding corresponds to the assertion that clinical and demographic characteristics do not considerably influence the effects of RT therapy on autonomy in ADL (56). Taking into account the sustainability of ADL performance after rehabilitation, a systematic review by Lo et al stated that robotic training is as effective as conventional training (57). Interestingly, Duret et al emphasised the growing trend of the influence of RT on ADL from no improvement through mild benefits to possible improvement of ADL in the RT group (22).

This study is subject to several limitations. First, the unequal distribution in the IG in the hand path ratio is due to the small sample size, where the extreme values of variables could potentially lead to a confounding effect. However, there were studies of similar scope that worked with small samples (50, 58, 59). Therefore, our findings should be interpreted with caution. To recruit a larger cohort with the possibility of stratifying patients according to the severity of the impairment, we recommend a multicenter trial. Secondly, our trial did not have a follow-up for a longer period. Therefore, it will be useful to establish an outpatient assessment unit for stroke patients. The third limitation concerns the mechanical properties of the Armeo device. Exoskeletons show high interaction forces between the measurement system and the patient due to friction, inertia, and arm weight support. Hence, exoskeleton-based assessment tools require a systematic evaluation to estimate their clinical validity (60). Interestingly, exoskeleton-based motion analysis is used to customise rehabilitation sessions, based on objective quantification of the functional abilities of patients (61). Moreover, according to Merlo et al, the Armeo®Spring may be a promising tool to objectively assess motor skills in UL (62).

Our work differed from previous studies in the Czech Republic by using the Armeo®Spring embedded assessment tool to evaluate the quality of movement performance and simultaneously observe changes in HRQoL. The advantage of our trial is the direct continuity of hospital care from the neurological ward. A study by Park et al comparing the effects and usability of the Armeo®Power active-assissive exoskeleton with the Armeo®Spring passive exoskeleton showed that passive devices encourage active participation that could induce learning and lasting effects (63). Those devices encourage active participation of the patient, his/her attention, effort, and motivation. Hands-on physiotherapy is strenuous, prolonged, and expensive. Robot-assisted technology helps reduce the physical burden of therapists while increasing therapy time and patient cooperation. Robots provide high intensity and a large number of repetitions. Furthermore, robot-aided therapy offers consistency in treatment methods and an objective assessment of patient progress. Most robotic devices provide a means of training in ADL (64).

Learning points

- Kinematic parameters offer a reliable, objective and quantitative assessment of motor and functional impairments of the upper extremities. Numerous studies proved that they can be used as a correlate to clinical scales in the evaluation of outcomes in rehabilitation.
- The combination of Armeo®Spring therapy and usual care contributed to significantly larger changes in the movement efficiency of the paretic upper extremity.
- Perceived health-related quality of life was higher in the group with combined Armeo®Spring and conventional rehabilitation compared to conventional rehabilitation alone.

Conclusion

Armeo®Spring assisted therapy combined with usual care led to significantly larger changes in perceived health-related quality of life and in the movement efficiency of the paretic upper extremity compared to conventional rehabilitation. This finding indicates that the Armeo®Spring device has a beneficial influence on upper extremity motor performance; however, this should be interpreted with caution due to the small sample size. Significant advances in functional upper extremity performance were evident. The changes in the general ADL measure were superior in the Armeo group, although they were not statistically significant.

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