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STATIONARY REHABILITATION ROBOT AND FUNCTIONAL ELECTROSTIMULATION FOR THE TREATMENT OF PATIENTS IN THE INITIAL SIX MONTHS AFTER STROKE: A RANDOMIZED CONTROLLED TRIAL

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A – study design, **B** – data collection, **C** – statistical analysis, **D** – interpretation of data, **E** – manuscript preparation, **F** – literature review, **G** – sourcing of funding

ABSTRACT

Background: Results from studies investigating the effects of rehabilitation robots, including those using robots combined with functional electrostimulation (FES), on gait quality and postural control post-stroke are conflicting. Therefore, the evidence supporting the use of this approach to rehabilitation remains inconclusive and further research is required into how robotic therapy and FES can improve gait function and postural control at different times after stroke.

Aim of the study: To gain knowledge on the effectiveness of stationary robotic exercises, and robotic exercises combined with FES of the lower extremity muscles, on activities of daily living, gait quality, postural control, and quality of life, in people who were between one and six months post-stroke.

Material and methods: A randomized controlled clinical pilot study was conducted. Forty-three post-stroke patients hospitalized at a rehabilitation center were randomly assigned to the following three groups: the GEO Group, for whom stationary robotic exercises were provided, the GEO+FES Group, for whom stationary robotic exercises were provided in combination with FES, and the Control Group, for whom conventional overground gait training was provided. Exercises were undertaken by all groups for 20 minutes a day, six days a week, for three weeks. In addition, all patients were provided with basic post-stroke therapy based on the principles of best clinical practice. All patients were assessed for stroke symptoms before and after therapy using the National Institutes of Health Stroke Scale (NIHSS), for independence in activities of daily living using the Barthel Index, and for quality of life using the Stroke Impact Scale Questionnaire. Static and dynamic postural control and gait performance were assessed using the Berg Balance Scale, the Timed Up and Go Test, the Functional Reach Test, and the 10 Meter Walk Test. Static postural control and gait quality were also assessed using a treadmill with a stabilometric platform.

Results: Exercising on a stationary robot, both with and without FES of the lower extremity muscles, contributed to a statistically significant reduction in stroke symptoms (NIHSS, $p<0.05$). Additionally, exercising on a stationary robot without FES application significantly improved patient quality of life ($p<0.05$). However, these effects were not significantly different between the experimental and control groups.

Conclusions: Stationary robotic exercise, either with or without FES, can be used as a substitute for traditional overground gait training to reduce stroke symptoms and improve quality of life in the first six months post-stroke. They can also be used as exercises to augment standard post-stroke therapy.

KEYWORDS: robotic rehabilitation, functional electrical stimulation, gait, postural control, stroke

Background

Stroke is a serious medical and social problem and, according to the World Health Organization, it is the second most common cause of death and the third most common cause of disability worldwide [1]. Post-stroke rehabilitation is multidirectional and long-lasting and is conducted in line with the principles of best clinical practice. Different types of therapies are implemented in stroke patients to enable neuromuscular re-education and restore functions that were lost or impaired as a result of stroke [2, 3].

New therapeutic methods are still being sought for post-stroke rehabilitation that aim to expand on the methods available and to be motivating and attractive to patients. Modern devices such as rehabilitation robots, which are used for gait re-education and postural control, are currently being introduced. Attempts are also being made to combine robotic exercises with functional electrical stimulation (FES) of the lower limb muscles. From this, it is thought that robots could provide a complete and reproducible gait pattern, which is difficult to achieve using conventional overground gait training [4].

Both stationary and mobile robots are used in post-stroke rehabilitation. Stationary robots are mainly used to exercise patients with severe functional impairments of the lower limbs and spine. In contrast, people with paresis of the lower limbs can exercise on mobile robots, but they require the ability to at least partially stabilize their spine. Although robots have been used in rehabilitation for several years, there is still insufficient science-based knowledge regarding their effectiveness and application in post-stroke rehabilitation.

Stationary robots have been evaluated in eleven randomized clinical trials [5-15] for their suitability to re-educate and improve postural control [6-8, 10] and gait [5-15] in stroke patients. The majority of these studies involved people who were between one and three months post-stroke [5, 7, 9-14], with only three studies focusing on the chronic (>6 months) post-stroke period [6, 8, 15].

In all of the cited studies, conventional therapy was used in both the experimental and control groups. Stationary robotic exercises were used in the experimental groups, and results were compared to those obtained for the control groups. The studies employed several different strategies for their control groups, including standard rehabilitation therapy that was not specifically directed at improving gait and postural control [8, 9, 13], traditional overground gait training [6, 7, 10-12, 14], and exercises on a treadmill [5, 15].

In three of the trials, additional experimental groups were formed in which exercise on a stationary robot was combined with FES of the lower limb muscles. Results from therapy in these groups were compared with the results of robotic therapy without FES and with the results of overground gait training [6, 7, 10]. Two of these studies were conducted in people who were up to three months post-stroke [7, 10], and one study involved individuals in the chronic post-stroke period [6].

In all studies that followed patients for up to three months after stroke, stationary robot therapy significantly improved functional gait quality, which was assessed using the Functional Ambulation Categories (FAC) scale [5, 7, 9-14]. Four studies also reported significant improvements in walking during the 6-minute Walk Test (6MWT) [6, 11], and in the 10-Metre Walk Test (10MWT) [7, 10, 11], after exercise on a stationary robot. However, these effects were not found in two separate studies [5, 14]. Different results were also found when the effects of stationary robot exercise on static and dynamic body balance in patients three months post-stroke were assessed using the Berg Balance Scale (BBS) [7, 10]. Tong et al. [7] reported an improvement in body balance after exercise on the stationary robot, whereas Ng et al. [10] did not show this effect.

For chronic post-stroke patients, only one study has reported an improvement in gait parameters, including speed, cadence, and stride length, assessed on a treadmill [15], and in body balance assessed by the BBS [15], after stationary robot therapy. In the other two studies, exercise on a stationary robot did not have a significant effect on gait quality [6, 8] or body balance [6, 8] in chronic post-stroke patients.

In those who were within six weeks of their stroke, significantly better gait quality was reported after stationary robotic exercises combined with FES of the lower limb muscles when compared to traditional overground gait training [7,8]. In addition, improvements in body balance were found when robotic exercise was combined with FES [7], though such an effect was not shown in other research [14]. In the only study to be conducted in chronic post-stroke patients, FES combined with stationary robotic exercise did not affect gait quality or body balance [6].

Due to conflicting results from studies carried out to date, evidence of the effect of rehabilitation robots, including robots combined with FES, on gait quality and postural control after stroke remains inconclusive. Therefore, further research is required to clarify how robotic therapy and FES can be applied to improve gait function and postural control in different post-stroke periods.

Aim of the study

The goal was to gain knowledge on the effectiveness of stationary robotic exercise and stationary robotic exercise combined with FES of the lower limb muscles on activities of daily living, gait quality, postural control, and quality of life, in patients who were between one and six months post-stroke.

Material and methods

Study design

A randomized controlled clinical trial was designed to compare the effectiveness of three weeks of post-stroke rehabilitation treatment between three parallel groups of patients. Participants in the study undertook either, exercises on a stationary rehabilitation robot, exercises on a stationary rehabilitation robot plus FES, or overground gait training. The study was approved by the Bioethics Committee for Scientific Research at The Jerzy Kukuczka Academy of Physical Education in Katowice (No. 5/2020 of 09 July 2020).

Inclusion and exclusion criteria

The following inclusion criteria were adopted: men and women over 18 years of age who had a first ischemic or hemorrhagic stroke between one and six months prior to entering the study, who had attended a 3-week rehabilitation course as an inpatient, had given consent to participate in the study, who understood and could follow the physiotherapists' instructions, and who were able to walk a distance of 10 meters independently. Those with subarachnoid hemorrhage were excluded from the study, as were individuals with conditions other than stroke that impaired body balance or gait quality. Individuals who had contraindications to FES and the exercises used in the study, in particular, body weight above 95 kg, body height below 150 cm or above 199 cm, >1.5 cm length difference between lower limbs, spasticity above grade 3 on the Ashworth scale, or wounds at the body attachment points on the robot, were also excluded from participating.

Information on patient demographics and health status was obtained from medical history, medical records, and from medical and physiotherapeutic examinations.

Location and funding of the study

The study was conducted at the Solanki Inowrocław Health Resort and was co-financed by the European Development Fund for the Kujawsko-Pomorskie Voivodeship (No. RPKK.01.02.01-04-0016/18; Solanki Inowroclaw Sp. z o.o., 77 Solankowa Street, 88-100 Inowroclaw).

Patient information and randomization

Patients were referred to the study by their physicians. Before entering the study, all patients were informed in writing about the purpose and conduct of the study. They were also informed of the possibility of resigning from the study, at any stage, without giving a reason. Withdrawal from the study did not affect the future treatment of the patient.

After consenting to participate in the study, patients were randomly assigned to one of three groups. The first experimental group underwent stationary robotic exercise therapy (GEO Group), the second experimental group underwent stationary robotic exercises with FES of the lower limb muscles (GEO+FES Group), and the third group (Control Group) had conventional overground gait training.

Patients, the physicians qualifying patients for the examination, and the medical personnel involved in the therapy and diagnostics of patients, were not aware of which group participants would be assigned to as a result of randomization. Randomization was carried out by the main study investigator, who had no direct contact with the patients included in the study prior to randomization.

Prior to the start of the study, the study leader prepared 45 opaque envelopes and 45 cards with the letters A (15 cards), B (15 cards), or C (15 cards) on them. Letter A represented the Control group, letter B the GEO Group, and letter C represented the GEO+FES Group. The envelopes and cards were given to a person not involved in the study, who placed one card into each envelope, sealed the envelopes, and then numbered them randomly from 1 to 45 and returned them to the main study investigator. Once a patient was qualified to participate in the study, the main study investigator opened an envelope, in sequential order, and the patient was directed to a group based on the symbol on the card inside the envelope.

Blinding

The person who assessed the clinical progress of the therapy and the person who performed the statistical analysis of results were blinded to the study groups.

Therapeutic interventions

In both experimental groups, exercise on the stationary robot G-EOSYSTEM™ (RehaTechnology, Germany) was undertaken once a day for 20 minutes, six days a week (Monday to Saturday), for three weeks. If the patient could not withstand the entire training routine at once, a break of 5 minutes was taken in the middle of the exercise or the session was stopped completely. The actual exercise duration was recorded for each session. The only form of therapy provided to the GEO Group was the stationary robot (Figure 1). Meanwhile, training on the robot was combined with simultaneous FES of the lower limb muscles (extensors and flexors of the hip, knee, and ankle) in the GEO+FES Group (Figure 2). Electrodes were attached along the course of the muscle fibers, at the beginning and end of the muscle bellies. An example of electrode placement during FES is shown in Figure 3.

Electrostimulation was carried out using several electrical circuits, which allowed simultaneous stimulation of the thigh and calf muscles of both lower limbs. The flow of current in the individual electrical circuits was activated automatically, depending on the phase of gait, to allow sequential and alternating work of the extensors and flexors of the lower limbs. An alternating rectangular current with a pulse duration of 400 μs and a frequency of 40 Hz was used. The current intensity was dosed individually for each patient to obtain non-painful but visible muscle contractions. Amplitude was modulated to allow con-

Figure 1. GEO stationary robot

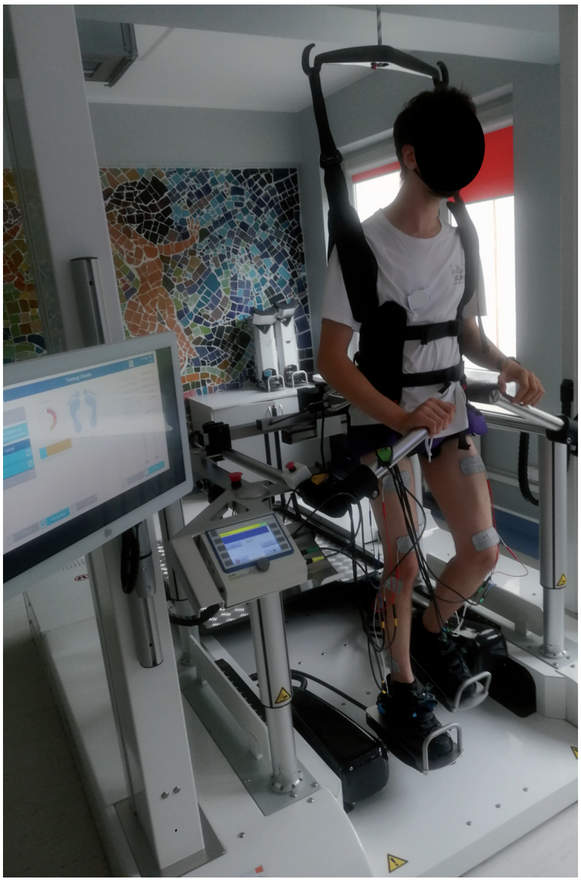

Figure 2. GEO training with FES

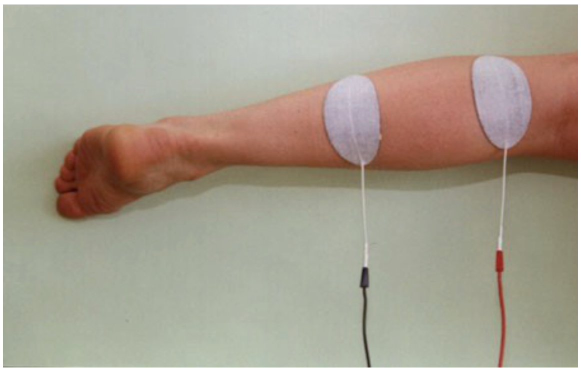

Figure 3. FES electrode placement

traction and relaxation of individual muscle groups depending on the gait phase.

If necessary, partial support of patient body weight was provided for both groups during the robotic exercises, the value of which was individually adjusted so that the patient's knee joints were straightened. Walking speed (0.7-2.5 km/h) and stride length (34-48 cm) were individually selected for each patient. The gait cycle ratio phases were 60% and 40% between the stance and swing phases, respectively.

In the Control group, overground gait training was undertaken once a day for 20 minutes, six days a week (Monday to Saturday), for three weeks. All exercises were carried out under the direct supervision of a physiotherapist. When additional patient assistance was required, the exercises were supported by two physiotherapists.

In addition to the experimental rehabilitation, basic post-stroke therapy based on the principles of best clinical practice was provided to all three groups, six days a week, for three weeks. Therapy included exercises focused on re-education and improvement of movement patterns.

Measures

Immediately before and after therapy, all patients were assessed for stroke symptoms using the National Institutes of Health Stroke Scale (NIHSS). Assessments were also carried out for activities of daily living with the 100-degree Barthel Index (BI), of motor function using the Brunnström Scale, of muscle spasticity using the Ashworth Scale, and quality of life using the Stroke Impact Scale Questionnaire (SIS 59). Postural control and gait quality were also assessed in all patients before and after therapy using functional clinical tests, including the BBS, Timed Up and Go Test (TUG), and 10MWT.

Static body balance and gait quality were assessed on a treadmill equipped with a stabilometric platform (Zebris FDM-T; Rehawalk, MaxxusDaum h/p Cosmos Force, Germany). Static balance was tested with eyes open for 60 seconds. During the test, the patient stood still on the platform in a relaxed upright posture (with arms lowered alongside the body and feet comfortably apart). The gait quality test lasted for 30 seconds, with treadmill speed selected individually for each patient to allow them to walk freely forward at their maximum comfortable pace.

Outcomes

Treatment effects in individual groups were used as primary study outcomes. In all three groups, the results after treatment were compared to baseline results, taking into account the severity of stroke symptoms (NIHSS), activities of daily living (BI), quality of life (SIS – 59), functional quality of gait and dynamic balance (TUG), static and dynamic body balance (BBS), walking speed (10MWT), static body balance assessed on a stabilometric platform, and gait quality assessed on a treadmill.

Secondary study outcomes compared the effects of therapy between the groups concerning the severity of stroke symptoms (NIHSS), activities of daily living, (BI), quality of life (SIS – 59), functional quality of gait, and dynamic balance (TUG), static and dynamic body balance (BBS), walking speed (110MWT), static body balance assessed on a stabilometric platform, and gait quality assessed on a treadmill.

To compare treatment effects between groups, percentage change rates in diagnostic variables obtained in each group were calculated and compared. Percentage change rates were calculated using the following formula: $\%WZ=[(Z1 - Z0) / Z0] \times 100\%$; where %WZ=percentage change rate, Z0=value of the variable before therapy, and Z1=value of the variable after therapy.

Statistical analysis

Statistica 12 software (StatSoft, Poland) was used for all statistical analyses, with statistical significance set at $p \leq 0.05$ for all tests. The distribution of variables characterizing the patients was examined using the Shapiro-Wilk test, whilst homogeneity of variance was examined using Levene's test. Due to the non-normality of distribution and the lack of homogeneity of variance between groups, non-parametric tests were then used for statistical analysis. Also, as the skewness and kurtosis were <2.5 and the distributions of variables were unimodal, in addition to median and quartiles, means and standard deviations were given as measures of location and dispersion, respectively.

Variables characterizing patients in both groups before treatment were compared using the Chi-square test of highest reliability, the Kruskal-Wallis rank-sum analysis of variance (ANOVA) test, and the Kruskal-Wallis post hoc test. Pre-therapy and post-therapy scores between groups were compared using the Wilcoxon signed-rank test. Percentage changes in post-therapy versus pre-treatment scores were compared between groups using the Kruskal-Wallis rank-sum ANOVA test and the Kruskal-Wallis post hoc test.

Results

Between 10th October 2021 and 30th June 2022, 48 people were enrolled in the study. Three subjects did not meet the inclusion criteria, and the remaining 45 were included and randomized into three groups of 15, including the GEO, GEO+FES, and Control Groups. Two subjects (4.44%) did not complete the study due to health deterioration unrelated to study procedures (one subject in the GEO Group and one subject in the GEO+FES Group). Therefore, statistical analysis was performed on the treatment results obtained for 43 subjects, including 14 in the GEO Group, 14 in the GEO+FES Group, and 15 in the Control Group. The course of the study is shown in Figure 4.

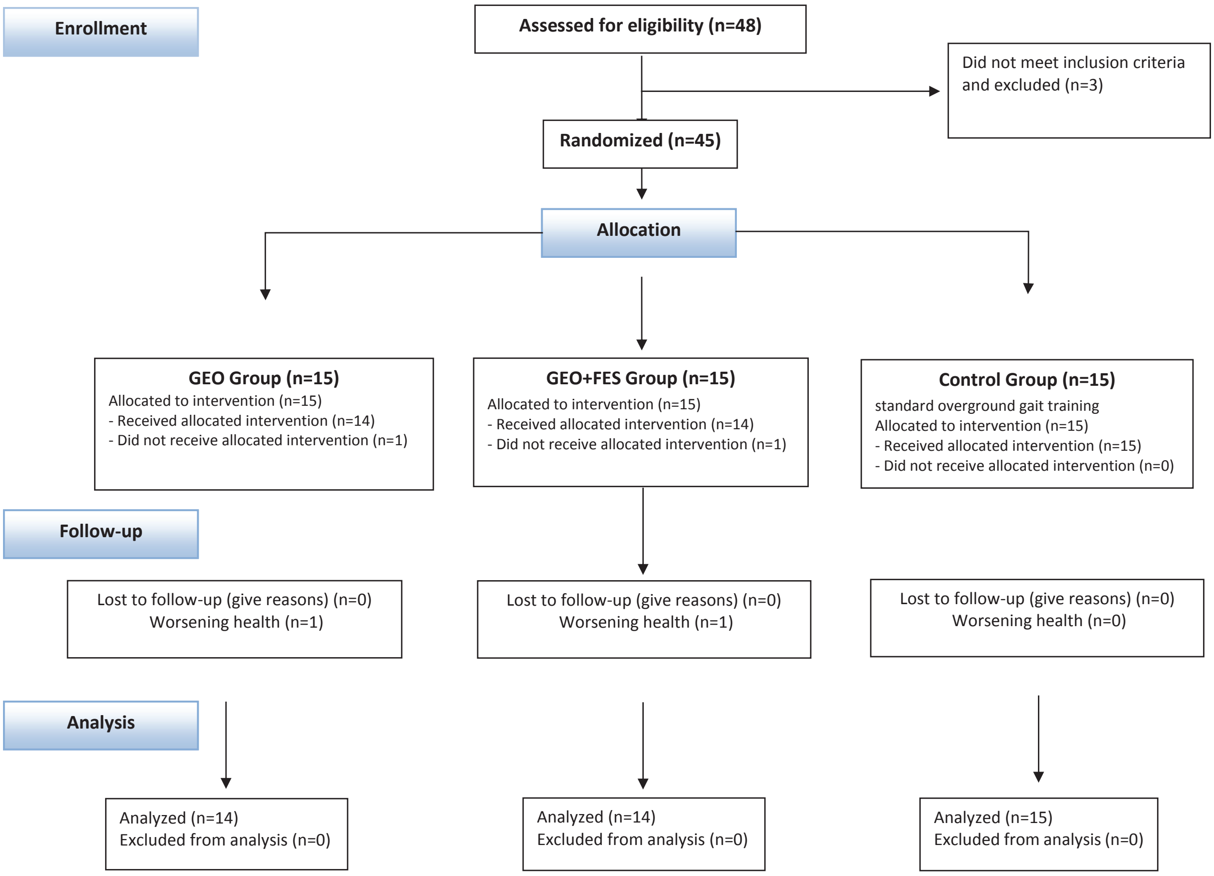

Figure 4. Flow diagram of the study (FES=functional electrical stimulation; GEO=stationary robot rehabilitation exercises)

There were no significant differences in patient characteristics between groups before therapy (p>0.05). Detailed data are presented in Tables 1 and 2.

Primary study outcomes for individual groups

Experimental groups

In both experimental groups, there was a significant reduction in stroke symptoms after treatment compared to before treatment (GEO, p=0.012 and GEO+FES, p=0.002). Patient quality of life improved significantly in the GEO Group (p=0.011), but not in the GEO+FES group (p=0.402). Functional Reach Test (FRT) range increased significantly in both experimental groups (GEO, p=0.008 and GEO+FES, p=0.005). Results are shown in Table 3.

None of the experimental groups experienced a significant change to independence in activities of daily living after treatment compared to before treatment (GEO, p=0.260 and GEO+FES, p=0.063), to static and dynamic balance (GEO, p=0.154 and GEO+FES, p=0.075), to dynamic balance and locomotion (GEO, p=0.093 and GEO+FES, p=0.155) or to time obtained in the 10MWT (GEO, p=0.285 and GEO+FES, p=0.066). Detailed results are shown in Table 3.

In stabilometric tests, there were no significant changes in the center of pressure (COP) path length (GEO, p=0.551 and GEO+FES, p=0.510) or COP surface area (p=0.507 and GEO+FES, p=0.845) after treatment compared to before treatment. However, there was a decrease in the length of maximum COP swings in the GEO+FES Group (p=0.009), which was not observed in the GEO Group (p=0.510). Results are shown in Table 4.

There were no changes to gait parameters in the experimental groups after therapy compared to before treatment. In all cases, the p-value was >0.05. Results are shown in Table 4.

Table 1. Characteristics of the groups before treatment (n=43)

Variables	Group		
	GEO (n=14)	**GEO+FES (n=14)**	**Control (n=15)**
*Gender: Female / Male [number of patients]	5 / 9	3 / 11	7 / 8
**Age: mean (SD) [years]	68.28 (9.38)	66.357 (9.920)	70.867 (10.357)
**BMI: mean (SD) [kg/m^2]	25.40 (4.15)	26.804 (4.925)	28.633 (5.676)
*Ischemic/hemorrhagic stroke [number of patients]	12 / 2	14 / 0	14 / 1
*Dominant limb: right/left [number of patients]	8 / 6	13 / 1	14 / 1
*Side affected: right/left [number of patients]	12 / 2	13 / 1	14 / 1
Brunnström Recovery Scale: III / IV / V / VI [number of patients]	1 / 3 / 6 / 4	1 / 3 / 5 / 5	0 / 1 / 8 / 6
Modified Ashworth Spasticity Scale: 0 / I / II / III [number of patients]	9 / 4 / 1 / 0	12 / 2 / 0 / 0	14 / 1 / 0 / 0
Questionnaires and functional tests			
**Stroke symptoms: mean (SD) [points][1]	4.36 (3.249)	3.71 (2.94)	3.26 (2.57)
**Independence in daily activities: mean (SD) [points][2]	87.14 (16.257)	91.42 (11.83)	94.33 (7.52)
**Quality of life: mean (SD) [points][3]	160.28 (45.69)	177.64 (46.28)	165.13 (45.16)
**Static and dynamic balance: mean (SD) [points][4]	41.64 (12.73)	45.85 (8.90)	45.13 (7.66)
**Dynamic balance and gait efficiency: mean (SD) [s][5]	17.35 (10.08)	13.21 (6.87)	15.33 (7.15)
**Functional reach test range: mean (SD) [cm][6]	26.71 (10.26)	28.85 (8.85)	29.73 (9.40)
**10 Meter Walk Test time: mean (SD) [s][7]	14.71 (9.80)	12.28 (6.19)	13.00 (5.94)
Stabilometric assessment			
**COP path length: mean (SD) [mm]	885.57 (485.03)	761.28 (404.01)	715.13 (482.93)
**COP surface area: mean (SD) [mm^2]	14.78 (7.92)	12.64 (6.82)	12.26 (7.93)
**Length of maximum COP swing: mean (SD) [mm]	33.58 (22.37)	44.84 (42.92)	38.93 (26.37)

GEO – experimental group in which stationary robotic exercise was conducted; GEO+FES – experimental group in which stationary robotic exercise combined with functional electrostimulation of lower limb muscles was conducted; Control – control group in which standard, overground gait training was conducted; [1] National Institutes of Health Stroke Scale; [2] Barthel Index; [3] Stroke Impact Scale; [4] Berg Balance Scale; [5] Timed Up and Go Test; [6] Functional Reach Test; [7] 10 Meter Walk Test; SD – standard deviation; COP – center of foot pressure; n – number of subjects. **In all cases, differences between groups were statistically insignificant (p>0.05); * Chi-square test of highest reliability; ** Kruskal-Wallis rank-sum ANOVA test.**

Table 2. Characteristics of groups before treatment cont. (n=43)

Variables	Group		
	GEO (n=14)	**GEO+FES (n=14)**	**Control (n=15)**
Gait parameters			
Step length on left leg: mean (SD) [cm]	20.28 (13.28)	29.92 (11.63)	26.66 (11.21)
Step length on right leg: mean (SD) [cm]	21.50 (12.05)	29.35 (11.00)	24.10 (15.60)
Double step length: mean (SD) [cm]	41.50 (24.66)	58.80 (20.01)	56.66 (38.58)
Step width: mean (SD) [cm]	13.21 (4.45)	17.27 (15.21)	13.80 (3.57)
Single support phase on left leg: mean (SD) [%]	70.35 (6.48)	69.23 (4.27)	66.46 (13.14)
Single support phase on right leg: mean (SD) [%]	68.11 (3.81)	68.05 (18.13)	69.06 (9.49)
Left leg swing phase: mean (SD) [%]	29.15 (6.77)	31.17 (4.15)	29.26 (7.59)
Right leg swing phase: mean (SD) [%]	31.92 (3.72)	27.67 (4.76)	31.51 (11.29)
Gait speed: mean (SD) [km/h]	1.04 (0.70)	0.62 (1.86)	1.09 (0.52)
Cadence: mean (SD) [number of steps per minute]	80.64 (23.99)	75.55 (29.39)	76.93 (17.77)

GEO – experimental group in which stationary robotic exercise was conducted; GEO+FES – experimental group in which stationary robotic exercise combined with functional electrostimulation of lower limb muscles was conducted; Control – control group in which standard, overground gait training was conducted; SD – standard deviation; n – number of subjects. **In all cases, differences between groups were statistically insignificant (p>0.05); Kruskal-Wallis rank-sum ANOVA test.**

Table 3. Treatment outcomes in the experimental groups (n = 28)

Variables	**Mean (SD); Median (lower quartile – upper quartile)**		**p-value***	**Mean (SD); Median (lower quartile – upper quartile)**		**p-value***
	Before therapy	**After therapy**		**Before therapy**	**After therapy**	
	GEO (n=14)			**GEO+FES (n=14)**		
Stroke symptoms [points][1]	4.35 (3.24); 4.00 (2.00-7.00)	2.78 (2.77); 2.50 (0.00-4.00)	0.012	3.71 (2.94); 3.00 (2.00-4.00)	1.15 (1.86); 0.00 (0.00-1.00)	0.002
Independence in daily activities [points][2]	87.14 (16.25); 95.00 (80.00-100.00)	90.71 (13.42); 97.50 (85.00-100.00)	0.260	91.42 (11.83); 95.00 (85.00-100.00)	97.30 (4.83); 100.00 (95.00-100.00)	0.063
Quality of life [points][3]	160.28 (45.69); 172.00 (118.00-195.00)	185.21 (44.49); 182.00 (165.00-227.00)	0.011	177.64 (46.28); 178.00 (144.00-207.00)	186.53 (44.40); 213.00 (162.00-222.00)	0.402
Static and dynamic balance [points][4]	41.64 (12.73); 43.00 (30.00-54.00)	45.50 (11.51); 49.50 (38.00-56.00)	0.154	45.85 (8.90); 46.50 (42.00-52.00)	50.07 (7.81); 55.00 (43.00-56.00)	0.075
Dynamic balance and gait efficiency [s][5]	17.35 (10.08); 16.50 (8.00-21.00)	15.00 (8.31); 13.000 (9.00-20.00)	0.093	13.21 (6.87); 10.00 (8.00-17.00)	10.61 (3.79); 9.00 (8.00-11.00)	0.155
Functional reach test range [cm][6]	26.71 (10.26); 24.00 (20.00-32.00)	37.21 (15.03); 34.00 (28.00-48.00)	0.008	28.85 (8.85); 30.00 (23.00-37.00)	39.15 (8.37); 41.00 (37.00-45.00)	0.005
10 Meter Walk Test time [s][7]	14.71 (9.80); 12.50 (7.00-19.00)	23.28 (39.58); 10.00 (8.00-20.00)	0.285	12.28 (6.19); 10.50 (8.00-13.00)	10.07 (4.38); 9.00 (8.00-11.00)	0.066

GEO – experimental group in which stationary robotic exercise was conducted; GEO+FES – experimental group in which stationary robotic exercise combined with functional electrostimulation of lower limb muscles was conducted; Control – control group in which standard, overground gait training was conducted; [1] National Institutes of Health Stroke Scale; [2] Barthel Scale; [3] Stroke Impact Scale; [4] Berg Balance Scale; [5] Timed Up and Go Test; [6] Functional Reach Test; [7] 10 Meter Walk Test; SD – standard deviation; n – number of subjects. *Wilcoxon signed-ranks test.

Table 4. Results of the stabilometric and gait quality assessments in the experimental groups (n=28)

Variables	Mean (SD); Median (lower quartile – upper quartile)		p value*	Mean (SD); Median (lower quartile – upper quartile)		p value*
	Before therapy	After therapy		Before therapy	After therapy	
	GEO (n=14)			GEO+FES (n=14)		
Stabilometric assessment						
COP path length [mm]	885.57 (485.03); 903.50 (462.00-1196.00)	784.28 (606.04); 587.50 (277.00-1273.00)	0.551	761.28 (404.01); 692.00 (566.00-933.00)	616.50 (401.33); 653.00 (226.00-770.00)	0.510
COP surface area [mm^2]	14.78 (7.92); 15.00 (8.00-20.00)	13.00 (10.06); 10.00 (5.00-21.00)	0.507	12.64 (6.82); 11.50 (9.00-16.00)	11.71 (6.60); 11.50 (6.00-16.00)	0.845
Length of maximum COP swings [mm]	33.58 (22.37); 23.75 (20.40-34.10)	26.00 (13.77); 28.35 (13.70-37.20)	0.510	44.84 (42.92); 29.55 (24.30-52.70)	23.55 (8.14); 22.55 (19.50-32.60)	0.009
Gait quality assessment						
Step length on left leg: mean (SD) [cm]	20.28 (13.28); 18.00 (10.00-31.00)	20.85 (15.76); 15.00 (9.00- 36.00)	0.706	29.92 (11.63); 32.00 (18.00-36.00)	30.78 (11.74); 31.000 (23.00-43.00)	0.576
Step length on right leg: mean (SD) [cm]	21.50 (12.05); 21.50 (12.00- 29.00)	22.00 (13.43); 17.50 (10.00-35.00)	0.660	29.35 (11.00); 29.50 (20.00-38.00)	29.92 (13.52); 30.00 (15.00-44.00)	0.807
Double step length: mean (SD) [cm]	41.50 (24.66); 43.00 (16.00- 60.00)	43.00 (27.99); 29.50 (19.00-72.00)	0.530	58.80 (20.01); 60.00 (41.00-72.00)	60.92 (24.41); 60.00 (45.00-90.00)	0.505
Step width: mean (SD) [cm]	13.21 (4.45); 13.50 (8.00- 16.00)	12.71 (5.18); 12.00 (8.00-17.00)	0.552	17.27 (15.21); 14.50 (9.00-17.00)	12.57 (4.84); 12.00 (10.00-15.00)	0.530
Single support phase on left leg: mean (SD) [%]	70.35 (6.48); 70.80 (65.10-75.10)	73.12 (6.71); 71.75 (69.00-78.00)	0.064	69.23 (4.27); 67.85 (67.10-72.80)	69.10 (5.51); 68.00 (65.40-70.80)	0.600
Single support phase on right leg: mean (SD) [%]	68.11 (3.81); 67.90 (65.70-70.40)	69.20 (5.63); 69.15 (67.10-73.20)	0.807	68.05 (18.13); 72.10 (67.90-75.20)	72.41 (5.22); 70.85 (69.40-75.20)	0.754
Left leg swing phase: mean (SD) [%]	29.15 (6.77); 28.90 (23.80- 34.90)	26.87 (6.70); 28.25 (22.00-31.00)	0.124	31.17 (4.15); 32.25 (29.80-32.90)	30.87 (5.50); 32.00 (29.20-34.40)	0.807
Right leg swing phase: mean (SD) [%]	31.92 (3.72); 32.10 (29.60- 34.30)	30.79 (5.63); 30.85 (26.80-32.90)	0.814	27.67 (4.76); 27.90 (24.80-32.10)	27.58 (5.22); 29.15 (24.80-30.60)	0.754
Gait speed: mean (SD) [km/h]	1.04 (0.70); 1.00 (0.40-1.50)	1.05 (0.89); 0.50 (0.50-1.800)	0.610	0.62 (1.86); 0.12 (0.11-0.15)	1.30 (0.44); 1.45 (1.10-1.60)	0.674
Cadence: mean (SD) [number of steps per minute]	80.64 (23.99); 84.50 (64.00- 97.00)	78.21 (19.67); 78.00 (66.00-91.00)	0.814	75.55 (29.39); 71.00 (62.00-102.00)	74.57 (17.82); 74.00 (65.00-85.00)	0.845

GEO – experimental group in which stationary robotic exercise was conducted; GEO+FES – experimental group in which stationary robotic exercise combined with functional electrostimulation of lower limb muscles was conducted; SD – standard deviation; COP – center of foot pressure; n – number of subjects; * Wilcoxon signed-ranks test.

Control group

In the Control Group, a significant reduction in stroke symptoms (p=0.016) and improvement in patient quality of life (p=0.001) were noted after therapy compared to baseline. There was also a significant increase in static and dynamic balance (p=0.029) and FRT (p=0.044). After therapy, the time to walk a distance of 10 meters was faster when compared to before therapy (p=0.026). Detailed results are shown in Table 5.

No significant change was found for independence in activities of daily living (p=0.374), and there was no change in dynamic balance and movement (p=0.279) after treatment compared to before treatment. Results are presented in Table 5.

In the stabilometric tests, the Control Group did not improve post-treatment. There were no changes recorded in COP path length (p=0.802), COP surface area (p=0.722), or the length of maximum COP swings (p=0.594). Results are shown in Table 6.

Gait analysis, assessed on a treadmill, demonstrated a significant increase in gait speed (p=0.041) and cadence (p=0.013) after therapy compared to before treatment. Values of the other gait parameters after therapy were no different from the pre-treatment values (p>0.05 in all cases). Detailed results are shown in Table 6.

Secondary study outcomes (comparison of results between groups)

There were no significant differences between the groups in stroke symptom severity, independence in daily activities, or quality of life. There were also no differences between the groups for changes in locomotion, static and dynamic balance, or FRT range. Furthermore, no differences were recorded between the groups for postural control parameters or gait quality indices. Details of data are shown in Table 7 and Table 8.

Discussion

Exercise on a stationary robot, either with or without FES of the lower limb muscles, contributed to a significant reduction of stroke symptoms according to the NIHSS (p<0.05). Furthermore, stationary robot exercise without the addition of FES significantly improved patient quality of life (p<0.05). However, these effects were not significantly different from the results found for the Control Group, in which conventional overground gait training was used. This allows us to conclude that for patients in the first six months post-stroke, stationary robotic exercises, with or without FES supplementation, can be used as a substitute for overground gait training to reduce stroke symptoms and improve patient quality of life. Also, stationary robotic exercises, with or without FES, can be used as an extension to standard post-stroke therapy.

Three weeks of stationary robotic exercise, both with and without the use of FES, did not affect the patient's functional performance in activities of daily living (p>0.05). Ng et al. [16] also included patients in the subacute period after stroke in their study and reported no improvement of functional performance in activities of daily living after four weeks of stationary robot exercises either with or without the use of FES. However, in three other studies [7, 9, 12]

Table 5. Results of therapy in the control group (n=15)

Variables	Mean (SD); Median (lower quartile – upper quartile)		p-value*
	Before therapy	After therapy	
Stroke symptoms [points][1]	3.26 (2.57); 2.00 (1.00-6.00)	1.53 (1.80); 1.00 (0.00-2.00)	0.016
Independence in daily activities [points][2]	94.33 (7.52); 95.00 (95.00-100.00)	96.00 (7.12); 100.00 (95.00-100.00)	0.374
Quality of life [points][3]	165.13 (45.16); 185.00 (125.00-205.00)	196.60 (42.53); 214.00 (147.00-228.00)	0.001
Static and dynamic balance [points][4]	45.13 (7.66); 45.00 (38.00-52.00)	49.60 (6.58); 53.00 (43.00-56.00)	0.029
Dynamic balance and gait efficiency [s][5]	15.33 (7.15); 13.00 (11.00-21.00)	14.20 (8.17); 12.00 (8.00-18.00)	0.279
Functional reach test range [cm][6]	29.73 (9.40); 28.00 (21.00-35.00)	34.73 (5.40); 35.00 (33.00-39.00)	0.044
10 Meter Walk Test time [s][7]	13.00 (5.94); 11.00 (9.00-18.00)	10.86 (5.06); 10.00 (7.00-14.00)	0.026

Control – control group in which standard, overground gait training was conducted; [1] National Institutes of Health Stroke Scale; [2] Barthel Scale; [3] Stroke Impact Scale; [4] Berg Balance Scale; [5] Timed Up and Go Test; [6] Functional Reach Test; [7] 10 Meter Walk Test; SD – standard deviation; n – number of subjects; * Wilcoxon signed-ranks test.

Table 6. Results of stabilometric assessment and gait quality in the control group (n=15)

Variables	Mean (SD); Median (lower quartile – upper quartile)		p-value*
	Before therapy	After therapy	
	Control (n=15)		
Stabilometric assessment			
COP path length [mm]	715.13 (482.93); 560.00 (355.00-964.00)	721.53 (511.16); 545.00 (443.00-836.00)	0.802
COP surface area [mm^2]	12.26 (7.93); 13.00 (6.00-16.00)	11.93 (8.43); 9.00 (7.00-14.00)	0.722
Length of maximum COP swings [mm]	38.93 (26.37); 29.20 (16.80-47.70)	32.74 (29.97); 28.50 (18.60-31.90)	0.594
Gait quality assessment			
Step length on left leg: mean (SD) [cm]	26.66 (11.21); 26.00 (19.00-34.00)	25.86 (9.44); 27.00 (18.00-34.00)	0.594
Step length on right leg: mean (SD) [cm]	24.10 (15.60); 21.00 (15.50-32.00)	24.86 (11.98); 26.00 (21.00-36.00)	0.695
Double step length: mean (SD) [cm]	56.66 (38.58); 46.00 (31.00-70.00)	51.00 (20.65); 52.00 (36.00-70.00)	0.600
Step width: mean (SD) [cm]	13.80 (3.57); 14.00 (10.00-16.00)	13.60 (4.22); 14.00 (10.00-16.00)	0.851
Single support phase on left leg: mean (SD) [%]	66.46 (13.14); 69.40 (62.80-73.80)	68.36 (6.91); 69.80 (64.10-76.30)	0.638
Single support phase on right leg: mean (SD) [%]	69.06 (9.49); 67.50 (65.40-73.70)	66.23 (15.28); 66.00 (63.60-74.60)	0.363
Left leg swing phase: mean (SD) [%]	29.26 (7.59); 30.00 (25.40-37.10)	30.38 (5.48); 29.90 (23.70-35.60)	0.826
Right leg swing phase: mean (SD) [%]	31.51 (11.29); 32.50 (26.30-34.60)	29.93 (6.43); 30.10 (25.40-35.00)	0.551
Gait speed: mean (SD) [km/h]	1.09 (0.52); 1.00 (0.90-1.20)	1.26 (0.61); 1.20 (0.80-1.50)	0.041
Cadence: mean (SD) [number of steps per minute]	76.93 (17.77); 75.00 (63.00-87.00)	82.93 (18.37); 83.00 (66.00-94.00)	0.013

Control – control group in which standard, overground gait training was conducted; SD – standard deviation; COP – center of foot pressure; n – number of subjects;* Wilcoxon signed-ranks test.

Table 7. Comparison of percentage rates of change in diagnostic results between groups (n=43)

Variables	Percentage rates of change after therapy compared to before treatment [%] Mean (SD); Median (lower quartile – upper quartile)			Statistical significance
	GEO (n=14)	GEO+FES (n=14)	Control (n=15)	p*
Stroke symptoms [points][1]	–1.57 (2.02); –1.00 (–2.00-0.00)	–2.64 (1.55); –2.50 (–4.00 – -2.00)	–1.73 (2.25); –1.00 (–4.00-0.00)	0.171
Independence in daily activities [points][2]	3.57 (11.67); 2.50 (0.00-5.00)	–1.07 (19.72); 0.00 (0.00-5.00)	1.66 (8.59); 0.00 (0.00-5.00)	0.909
Quality of life [points][3]	24.92 (29.33); 21.50 (0.00-50.00)	–4.42 (70.14); 15.50 (–34.00-26.00)	31.46 (32.29); 22.00 (16.00-41.00)	0.370
Static and dynamic balance [points][4]	3.85 (11.96); 2.00 (0.00-11.00)	0.64 (8.36); 1.50 (–1.00-5.00)	4.46 (7.37); 3.00 (0.00 10.00)	0.650-
Dynamic balance and gait efficiency [s][5]	–2.35 (5.48); –2.500 (–5.00- –1.00)	–3.35 (7.91); –1.00 (–3.00-0.00)	–1.13 (4.83); –1.00 (–4.00-1.00)	0.693
Functional reach test range [cm][6]	10.50 (13.08); 5.50 (3.00-22.00)	7.50 (14.12); 9.00 (3.00-12.00)	5.00 (8.36); 5.00 (2.00-14.00)	0.675
10 Meter Walk Test time [s][7]	8.57 (30.18); 0.000 (–1.00-5.00)	–2.92 (6.68); –1.00 (–3.00-0.00)	–2.13 (3.09); –2.00 (–5.00-1.00)	0.073

GEO – experimental group in which stationary robotic exercise was conducted; GEO+FES – experimental group in which stationary robotic exercise combined with functional electrostimulation of lower limb muscles was conducted; Control – control group in which standard, overground gait training was conducted; [1] National Institutes of Health Stroke Scale; [2] Barthel Scale; [3] Stroke Impact Scale; [4] Berg Balance Scale; [5] Timed Up And Go Test; [6] Functional Reach Test; [7] 10 Meter Walk Test, SD – standard deviation; n – number of subjects; * Kruskal-Wallis rank-sum ANOVA test.

Table 8. Comparison of percentage rates of change in diagnostic results between groups (n = 43)

Variables	Percentage rates of change after therapy compared to before treatment [%] Mean (SD); Median (lower quartile - upper quartile)			Statistical significance
	GEO (n=14)	GEO+FES (n=14)	Control (n=15)	p*
Stabilometric assessment				
COP path length [mm]	−101.28 (562.99); −43.00 (−466.00-293.00)	−144.78 (529.05); −18.00 (−707.00-125.00)	6.40 (351.00); 9.00 (−294.00-213.00)	0.636
COP surface area [mm^2]	−1.78 (9.22); −1.00 (−8.00-5.00)	−0.92 (8.38); 0.50 (−7.00-3.00)	−0.33 (5.39); 0.00 (−5.00-3.00)	0.867
Length of maximum COP swings [mm]	−7.57 (26.90); −1.90 (−28.70-10.200)	−21.29 (42.96); −6.35 (−32.80- −0.50)	−6.19 (30.88); 0.00 (−10.90-8.00)	0.360
Gait quality assessment				
Step length on left leg: mean (SD) [cm]	0.57 (7.90); 0.00 (−2.00-7.00)	0.85 (6.70); 1.00 (−3.00-7.00)	−0.80 (7.48); −1.00 (−6.00-4.00)	0.731
Step length on right leg: mean (SD) [cm]	0.50 (7.28); 1.00 (−3.00-5.00)	0.57 (6.27); 0.50 (−5.00-7.00)	0.76 (14.90); 0.00 (−4.00-10.00)	0.975
Double step length: mean (SD) [cm]	1.50 (14.08); 4.00 (−6.00-10.00)	2.12 (10.01); 0.50 (−4.00-6.00)	−5.66 (29.54); −3.00 (−8.00-6.00)	0.590
Step width: mean (SD) [cm]	−0.50 (3.79); −1.00 (−4.00-2.00)	−4.70 (15.38); 0.00 (−3.00-1.00)	−0.20 (4.42); −1.00 (−5.00-2.00)	0.974
Single support phase on left leg: mean (SD) [%]	2.77 (4.18); 0.90 (−0.20-6.80)	−0.12 (2.37); −0.20 (−1.80-0.70)	1.89 (13.71); 0.40 (−1.20-2.10)	0.155
Single support phase on right leg: mean (SD) [%]	1.09 (5.92); 0.35 (−2.50-2.20)	4.36 (17.28); −0.60 (−1.20-1.00)	−2.833 (16.994); −1.10 (−2.60-1.30)	0.732
Left leg swing phase: mean (SD) [%]	−2.27 (4.06); −0.65 (−5.60-0.20)	−0.12 (2.37); −0.2 (−1.80-0.70)	1.89 (13.71); 0.40 (−1.20-2.10)	0.345
Right leg swing phase: mean (SD) [%]	−1.13 (5.91); −0.35 (−2.20-2.50)	−0.29 (2.33); 0.10 (−1.00-1.10)	1.11 (5.06); −0.10 (−1.80-1.90)	0.874
Gait speed: mean (SD) [km/h]	0.01 (0.46); 0.10 (−0.10-0.20)	−0.09 (2.33); 0.60 (−1.00-1.20)	−1.58 (9.78); 0.20 (−1.30-2.30)	0.374
Cadence: mean (SD) [number of steps per minute]	−2.42 (20.36); 0.00 (−10.00-16.00)	−0.97 (27.25); −0.50 (−12.00-6.00)	6.00 (7.37); 6.00 (−1.00-11.00)	0.306

GEO – experimental group in which stationary robotic exercise was conducted; GEO+FES – experimental group in which stationary robotic exercise combined with functional electrostimulation of lower limb muscles was conducted; Control – control group in which standard, overground gait training was conducted; SD – standard deviation; COP – center of foot pressure; n – number of subjects; * Kruskal-Wallis rank-sum ANOVA test.

conducted in subacute post-acute patients, 4-week therapy conducted on a stationary robot (including robot therapy in combination with FES [7]) resulted in a significant improvement in the performance of daily living activities compared to overground gait training [7, 12] and conventional therapy not specifically aimed at gait training (p>0.05) [9]. Ng et al. [10] and others [7, 9, 12] used the same methods as the present study, the BI, to assess functional performance in activities of daily living.

In functional tests, there was a significant increase in the FRT after exercise on the stationary robot, both with and without the use of FES. This may be related to improvements in body balance, as well as improved mobility of the spine, hip girdle, and lower limbs. The improvement was at a similar level to the change found in the Control Group who had undergone traditional overground gait training. It can therefore be concluded that stationary robotic exercises, including robotic exercises combined with FES of the lower limb muscles, can be used to improve functional reaching range as a substitute for overground gait training in patients in the subacute post-stroke period.

Results of the other functional tests did not indicate any improvement in gait performance or body balance (TUG, 10MWT, and BBS) (all p>0.05). Also, the treadmill test did not show an improvement in gait quality after exercises on the stationary robot, either with or without FES. These results differ from those obtained in other studies of patients in the subacute post-stroke period, who demonstrated improvements in mobility (Rivermead Motor Assessment) [5, 11-13], functional independence (Functional Independence Measure) [7], gait [5, 7, 9-14], walking speed time in the 10MWT [5, 7, 10, 11], and static and dynamic balance (BBS) [7], after rehabilitation exercises on a stationary robot. Nonetheless, Ng et al. [10] and Ochi et al. [14], also found no improvements in body balance [10], walking speed in the 10MWT, or functional independence [10, 14], after exercises on a stationary robot.

In studies in which FES was applied to the lower limb muscles during stationary robot exercises [7, 10], the results of the therapy did not differ from those obtained in the groups in which only the robot exercises were conducted without FES application. However, it is worth noting that the GEO+FES Group in the current study demonstrated a significant decrease in the range of COP swings. This may be due to an increase in lower limb muscle strength under the influence of FES, and thus represent an increase in body stabilization. Further clinical studies should be conducted to test this hypothesis further.

It is currently difficult to unequivocally explain the discrepancies between the results of our study and those found by others. However, it should be noted that the robotic treatment methodology used in the current study differed to some extent from that used in previous studies. In both experimental groups, the robotic exercises were conducted for three weeks, which was determined by the 3-week stay of the patients at the resort treatment facility. Exercises lasted 20 minutes per day and were conducted six days per week (18 exercises in total). In the first experimental group, only robotic exercises were conducted and in the second experimental group, FES of the lower limb muscles was applied during the robotic exercises. In most other previous studies, robotic exercises were conducted for 20 minutes per day [5, 7, 9-11, 14], five days per week [5, 7, 9-14], and over four weeks [7, 9, 10, 12-14]. This amounts to a total of 20 treatments for each patient. Fewer studies provided therapy for three [11] or six weeks [5], and 30 [13] or 40 minutes per day [12].

In the current study, simultaneous FES of the thigh and shin muscles of both lower limbs was performed during robotic training. A similar FES methodology was used by Ng [10] and Tong [7]. In these studies, FES was also performed with an alternating rectangular current with a pulse duration of 400 μs. Meanwhile, simultaneous electrical stimulation of the quadriceps and the fibular nerve of the paretic side was also performed. The current intensity was dosed individually for each patient to obtain non-painful muscle contractions, the amplitude of the current was modulated to allow contraction and relaxation of individual muscle groups depending on the gait phase, and the current intensity was modulated to allow >20° of knee joint extension during gait.

During robotic exercises, partial support of body weight was used as necessary, the value of which was individually adjusted so that the patient's knee joints became extended. In other studies, partial support of body weight was also applied, but the degree of support was different or not within the stated range [11, 13]. The value of patient weight support ranged from 10% to 20% of body weight [9], from 10% to 50% of body weight [12], or the value was adjusted to achieve knee joint extension [5, 7, 10, 14].

Robotic walking speed and stride length were individually selected for each patient in this study, ranging from 0.7-2.5 km/h for gait speed, and 34 - 48 cm for stride length. The stance and swing phases were 60% and 40% of the total gait cycle time, respectively. In other studies, values were also selected individually for each patient. Indeed, Wener et al. [5] varied the gait speed from 0.90-1.44 km/h, and stance and swing phases were 60% and 40% of the duration of the entire gait cycle, respectively. In a study by Pohl [9], gait speed was 1.4-1.8 km/h, and stride length was 48 cm. In another study by Peurala et al. [6], gait speed was up to 2 km/h, though step length was not mentioned. Monroe et al. [12] used a step length of 38-44 cm, and gait speed of 1.4-1.6 km/h, whilst Hesse et al. [13] did not report these gait parameters, and only stated that patients practiced 5 to 15 minutes of walking and 5 to 10 minutes of ascending (minimum 300 steps) and descending steps (minimum 50 steps) in each session. In the Ochi et al. [14] study, gait speed was 0.76 km/h, step length was 64 cm and cadence was 0.33 steps/sec. Parameters selected in the study by Tong [7] were 34-48 cm for step length, 0.72-2.16 km/h for gait speed, and stance and swing phases were 60% and 40% of the total gait cycle time, respectively. In the Ng et al. [10] study, no step length was mentioned, the gait speed was 0.72-2.16 km/h, and stance and swing phases were 60% and 40% of the duration of the entire gait cycle, respectively.

In the current study, basic post-stroke therapy based on best clinical practice principles was provided to all groups for three weeks, six days a week. The therapy included exercises focused on re-education and improvement of movement patterns. Similar to our study, other studies [5, 7, 9-14] also conducted basic post-stroke therapy based on principles of best clinical practice in all groups during the intervention, except that it was conducted once a day, five days a week.

Gait and postural control training is a therapeutic procedure that is recommended in standard rehabilitation of patients at various times after stroke, and its effectiveness has been confirmed by many clinical studies. However, given that the rehabilitation of post-stroke patients is generally long-lasting (often many years), new methods of post-stroke therapy are still being sought. These new methods should be effective and attractive to patients and should contribute to reducing the time of rehabilitation therapy. Modern technologies in rehabilitation can help, but they should be implemented according to the principles of evidence-based medicine and physical therapy. One of the modern therapies that could be implemented into general clinical practice in post-stroke rehabilitation is the use of stationary rehabilitation robots, which can be combined with FES. However, evidence-based knowledge of their impact on the treatment of post-stroke patients is still insufficient and exercise methodologies are inconsistent. Further research in this area is therefore needed.

Results of the study indicate that post-stroke rehabilitation enriched with exercises on a stationary rehabilitation robot, together with FES, may be as effective as conventional gait training in subacute post-stroke patients. Therefore, this approach can be recommended as an alternative to conventional post-stroke therapy. However, it should be highlighted that this was a pilot study (preliminary study with single-group) with a small sample size, and the results should be verified in a high-quality randomized controlled trial in the future.

Limitations

limitations of the current study include the lack of blinding of patients and medical personnel and the lack of a placebo. The introduction of placebo and blinding was not possible due to the study topic. Also, relatively few patients (n=15) were treated in each group and there was no long-term follow-up on the effects of therapy after the completion of the robot exercises. Follow-up was not possible as the patients traveled to the therapy location, Solanki Inowrocław Health Resort, from all over Poland. After completing their therapy, the patients returned to their homes, which are generally located at a great distance from the place of the study. Statistical analysis was based on the «p» value as a measure of statistical significance, but no analysis of the effect size was performed [16]. The «intention-to-treat» analysis was not included in the statistical analysis [17].

Conclusions

Inclusion of stationary robotic exercises, including robotic exercises in combination with FES of the lower limb muscles, in standard post-stroke therapy for patients between one and six months after stroke reduced stroke symptoms and improved quality of life. Exercises on a stationary robot, both with and without FES application, also contributed to an increase in functional reaching range. Furthermore, the effectiveness of robotic exercises alone and in combination with FES was similar to that of traditional overground gait training. Therefore, stationary robotic exercises could be used independently or in combination with FES including as a substitute for overground gait rehabilitation exercises to reduce stroke symptoms, increase functional reaching range, and improve quality of life.

FES of lower limb muscles applied during exercises on a stationary rehabilitation robot may reduce the amount of patient postural COP sway and improve postural stability, but this observation needs to be confirmed in further clinical studies.

Three weeks of stationary robotic exercises, with or without concurrent FES of the lower limb muscles, applied for 20 minutes a day, six days a week, did not improve gait quality or body balance in patients between one and six months after stroke.

Application conclusion: to reduce stroke symptoms, increase functional reaching range, and improve patient quality of life, exercise on a stationary robot is recommended to be carried out for 20 minutes a day, six days a week, for three weeks.

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