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Repetitive locomotor training and physiotherapy improve walking and basic activities of daily living after stroke: a single-blind, randomized multicentre trial (DEutsche GAngtrainerStudie, DEGAS)

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Objective: To evaluate the effect of repetitive locomotor training on an electromechanical gait trainer plus physiotherapy in subacute stroke patients.

Design: Randomized controlled trial.

Setting: Four German neurological rehabilitation centres.

Subjects: One hundred and fifty-five non-ambulatory patients (first-time stroke < 60 days).

Intervention: Group A received 20 min locomotor training and 25 min physiotherapy; group B had 45 min physiotherapy every week day for four weeks.

Main outcome measures: Primary variables were gait ability (Functional Ambulation Category, 0–5) and the Barthel Index (0–100), blindly assessed at study onset, end, and six months later for follow-up. Responders to the therapy had to become ambulatory (Functional Ambulation Category 4 or 5) or reach a Barthel Index of ≥ 75 . Secondary variables were walking velocity, endurance, mobility and leg power.

Results: The intention-to-treat analysis revealed that significantly greater number of patients in group A could walk independently: 41 of 77 versus 17 of 78 in group B ($P < 0.0001$) at treatment end. Also, significantly more group A patients had reached a Barthel Index ≥ 75 : 44 of 77 versus 21 of 78 ($P < 0.0001$). At six-month follow-up, the superior gait ability in group A persisted (54 of 77 versus 28 of 78, $P < 0.0001$), while the Barthel Index responder rate did not differ. For all secondary variables, group A patients had improved significantly more ($P < 0.0001$) during the treatment period, but not during follow-up.

Conclusions: Intensive locomotor training plus physiotherapy resulted in a significantly better gait ability and daily living competence in subacute stroke patients compared with physiotherapy alone.

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Introduction

The annual stroke incidence is approximately 180 patients per 100 000 inhabitants in the industrialized world.¹ For the surviving patients, restoration of stance and gait is a high priority. Three months after stroke onset, 20% of the patients remain wheelchair-bound, and approximately 70% walk at a reduced walking velocity and capacity.²

In gait rehabilitation, no conventional treatment approach has so far proven superior.³

Modern concepts favour a task-specific repetitive approach. Treadmill training with partial body weight support was a first step in this direction, enabling chronic paraparetic^{4–6} and hemiparetic⁷ patients the repetitive practice of complex gait cycles. Randomized studies of subacute stroke patients, however, failed to show a superiority of treadmill training compared with physiotherapy stressing gait practice on the floor.^{8,9}

One disadvantage of treadmill training was the effort needed by the therapist to set the paretic limbs and to control weight shift, thereby likely limiting therapy intensity.

Gait machines, consisting either of a robot-driven orthosis and a treadmill¹⁰ or an electromechanical solution with two driven footplates simulating the phases of gait¹¹ were intended to reduce the therapist's exertions. For subacute stroke patients, the latter device brought about significantly more improvement in walking ability when compared to treadmill training in a randomized cross-over study.¹²

The goal of the present multicentre trial was to compare the effect of repetitive locomotor training using the electromechanical gait trainer (Gait Trainer GT I; Reha-Stim, Berlin, Germany) in combination with physiotherapy to the effect of physiotherapy alone. Gait function and competence in basic activities of daily living (ADL) were assessed for subacute, non-ambulatory stroke patients. The hypothesis was that the combined treatment would be superior with respect to the restoration of gait ability and ADL competence.

Methods

Over the course of 21 months (August 2001–May 2003) all eligible stroke patients at four German rehabilitation centres were recruited. Participating patients had suffered a first-time supratentorial stroke, either ischaemic or haemorrhagic, their ages ranged from 18 to 79 years, and the interval between stroke and study onset was less than 60 days. They were able to sit unsupported (i.e. without holding onto supports such as the edge of the bed), with feet supported, could not walk at all, or required the help of one or two therapists irrespective of the use of an ankle-foot orthosis or a walking aid. They could understand the meaning of the study and follow instructions, and gave their written informed consent of participation in the study approved by the local ethical committee.

An unstable cardiovascular condition, following a 12-lead electrocardiogram and examined by a cardiologist, a restricted passive range of motion in the major lower limb joints (i.e. an extension deficit of $> 20^\circ$ for the affected hip or knee joints, or a dorsiflexion deficit of $> 20^\circ$ for the affected ankle, tested while lying supine and on the non-affected side), and the existence of other neurological or orthopaedic diseases impairing walking ability excluded the patients from participation.

A consultant enrolled the patients. Lots, indicating A or B, had been prepared in sealed envelopes. Immediately prior to the first treatment session, the patient drew a lot from the envelope presented by an independent person, who then informed him or her of the group allocation.

The sample size was calculated to corroborate a minimal clinically important difference of 10 points in the Barthel Index¹³ (0–100), assuming a mean (\pm SD) Barthel Index of 50 ± 23 points, an alpha of 0.05, a power of 0.8, and a drop-out rate of 20%.

Intervention

Group A patients received 20 min of repetitive locomotor therapy on the gait trainer, immediately followed by 25 min of one-on-one physiotherapy every week day for four weeks (i.e. 20 45-min sessions). Group B patients received 20 45-min sessions of physiotherapy in the same period.

Additional time for preparation was not to exceed a total of 15 min in both groups, limiting the total patient–therapist contact time to 60 min daily. The remaining comprehensive rehabilitation programme, including group but no additional individual physiotherapy sessions, was the same for both groups.

The gait training machine consisted of two footplates whose driven movements simulated stance and swing; the movements of the centre of mass were controlled in a phase-dependent manner by ropes attached to the harness (Figure 1). During the locomotor training, patients wore a harness, were initially transferred onto the machine with the help of a lifter, and later stepped into it. They practised up to 20 min, with the option of a break in between, and were then reseated into the wheelchair. The step length was 48 cm, the cadence was individually adjusted to a comfortable training velocity ranging from 1.4 to 1.8 km/h. The initial



Figure 1 A harness-secured left hemiparetic patient is practising on the electromechanical gait trainer.

weight support ranged from 10% to 20% body weight, being reduced as rapidly as possible. Initially one therapist sat in front of the patient assisting the paretic knee control, but with further improvement patients practised independently in the gait trainer.

The physiotherapy in both groups concentrated exclusively on the restoration of stance and gait, comprising at least 60% of the net therapy time. Initially two therapists assisted the patient's gait on the floor and on the stairs; with further improvement less and less help was required. A data sheet asked the therapists to tick off the specific content and time needed. Occupational therapy was implemented for upper limb rehabilitation.

Outcome measures

Primary outcome variables were gait ability and basic ADL, assessed before study onset (T_{begin}), at the end of the four-week treatment period (T_{end}) and at follow-up six months after study end ($T_{6\text{-months}}$).

The Functional Ambulation Category (0–5¹⁴), a reliable and valid score, helped to assess gait ability. Six categories (0–5) were distinguished to give detail on the physical support needed by patients while walking, irrespective of the technical aids used. Level 0 indicates a patient who cannot walk at all or needs the help of two therapists. Level 5 indicates a patient who can walk everywhere, including stairs, independently.

A blind assessor assessed the Functional Ambulation Category with the help of randomized videos taken from the rear and from the side while the patients walked a 15 m distance. When the patient could climb stairs, an additional video helped to distinguish between level 4 and 5. For follow-up, most of the patients came into the clinic, but if this was not possible, a suitable walking floor of at least 10 m either at the patient's home or in the physiotherapy outpatient service was taken for the video.

The Barthel Index (0–100) is a valid and reliable index commonly applied to assess ADL. Ten items were used to assess the degree of independence from any form of help, whether physical or verbal. One hundred points described a fully competent patient.

The head nurses routinely assessed the Barthel Index in their respective wards in each centre weekly, he or she was blind with respect to the group assignment. For follow-up, caretakers were

sources of information in addition to direct observation.

Secondary outcome variables were walking velocity, walking endurance, the Rivermead Mobility Index¹⁵ and motor power of the paretic lower limb.

The 10-m walking time¹⁶ and the 6-min walking test¹⁷ helped to assess walking velocity and endurance. Patients twice walked a distance of 10 m at their maximum speed, the time was taken and the mean maximum velocity calculated. Further, the patients walked for 6 min without interruption, and the maximum distance was noted. If the patients had to stop during the 6-min test because to exhaustion, the distance covered so far was considered. Stumbling was not considered a cause for stopping the test.

The Rivermead Mobility Index (0–15) covers 15 mobility-related items, from turning over in bed to running, each item scored as a dichotomous score (0 for unable and 1 for able to perform the item).

The Motricity Index (1–100)¹⁸ assessed the motor power of the affected lower limb. Ankle dorsiflexion, knee extension and hip flexion were rated according to the motor strength grades 0–5 of the Medical Research Council (0–5, 0 = no movement, 5 = normal power), and then converted to arrive at a leg score ranging from 1 (plegic) to 100 (normal power).

Two physiotherapists at each centre not involved in the treatment assessed the secondary outcome variables, with the exception of the Rivermead Mobility Index together. They were not blind to the study conditions. The patients themselves rated the Rivermead Mobility Index. The principal investigator, CW, had trained all assessors in workshops before the onset of the trial.

Statistical analysis

Primary and secondary outcome data were analysed as intended to treat. If a subject dropped out, assessment continued, if this was not possible, the last score was used. Homogeneity at T_{begin} was tested with the help of the Mann–Whitney test.

Responders at T_{end} and $T_{6\text{-months}}$ were defined as patients with a Functional Ambulation Category of 4 or 5 (ambulatory without physical help), and with a Barthel Index of at least 75. According to national guidelines¹⁹ patients switch into a less costly rehabilitation phase at this ADL level, as they require only minor assistance and medical

supervision on the ward. The global alpha for both primary outcome variables was set to 0.05, chi-squared test with Bonferroni adjustment ($P < 0.0125$) of the two time-points after therapy and approximated confidence intervals for the estimated probabilities were calculated.

For the four secondary variables, we calculated intraindividual differences $T_{\text{end}} - T_{\text{begin}}$, and $T_{6\text{-months}} - T_{\text{end}}$. All differences were not normally distributed, accordingly between-group differences were calculated with the help of the non-parametric Mann–Whitney test (Bonferroni adjustment, $P < 0.00625$). SPSS software program version 13.0 was applied.

Results

Over a period of 21 months, 155 patients entered the trial, 77 in group A and 78 in group B. In group A, all but five patients completed the treatment block, and in group B all but six patients completed the treatment block. Sixty-four patients of both groups made it to the follow-up (Figure 2). The drop-outs did not differ with respect to their demographic data, initial outcome scores and reasons of losses.

Patients of group A practised a mean of 851 steps in the first half and 1076 steps in the second half of the locomotor therapy on the gait trainer. Their 25-min physiotherapy sessions compromised a mean of 81.8% in the first and of 82.8% in the second two weeks for standing and walking. In absolute numbers, standing tasks took a mean of 6.0 min in the first two weeks and 6.4 min in the second two weeks of the study (numbers for the second two weeks in brackets consecutively), walking on even surfaces 10.1 (10.5) min, and stair climbing 4.4 (3.9) min. Therapy-related side effects did not occur.

For group B patients, the 45-min physiotherapy sessions compromised a mean of 73.1% in the first and of 77.1% in the second two weeks for standing and walking. Standing tasks took a mean of 14.6 (12.8) min, walking on even surfaces 15.3 (17.4) min, and stair climbing 3.2 (4.2) min. One patient in group B reported therapy-related lower limb pain and refused further participation in the study.

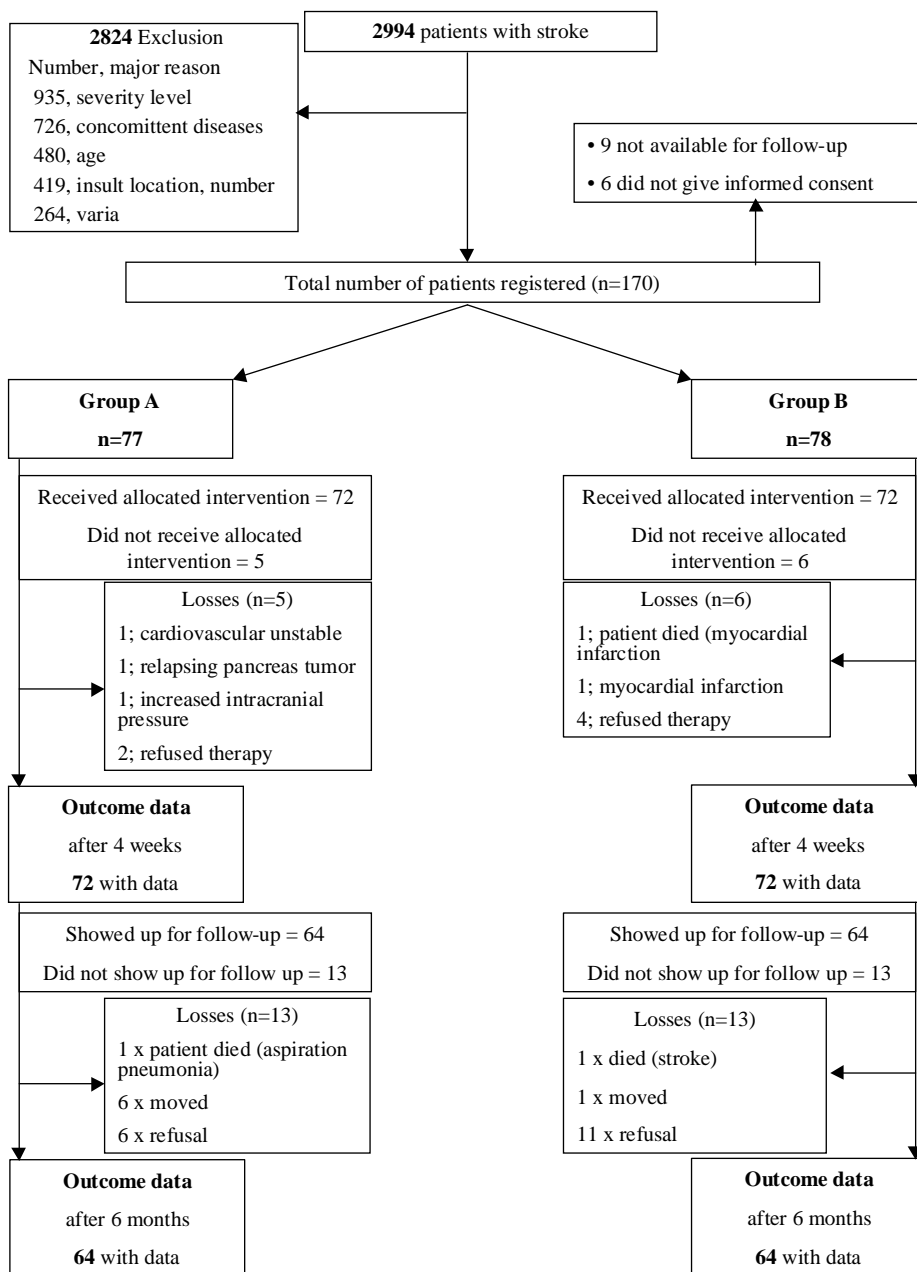


Figure 2 Flowchart of the study.

At study onset the groups were homogeneous (Table 1). At T_{end} , significantly more patients in group A could walk independently: 41 of 77 (53.2%) in group A versus 17 of 78 (21.8%) in

group B, $P < 0.0001$ (Table 2, Figure 3). The corresponding 95% confidence interval (CI) probabilities were: 42.1–64.4% versus 12.8–31.3.0%. Also, significantly more patients in group A had

Table 1 Clinical data and initial assessment scores of both groups

	Group A (RLT+PT)	Group B (PT)	<i>P</i> -value
<i>n</i>	77	78	
Diagnosis (ischaemic/haemorrhagic)	61/16	63/15	0.710
Hemiparesis (left/right)	41/36	45/33	0.936
Stroke interval (weeks)	4.2 (\pm 1.8)	4.5 (\pm 1.9)	0.265
Age (years)	62.3 (\pm 12.0) (range: 26–79)	64.0 (\pm 11.6) (range: 37–79)	0.565
Sex (female/male)	27/50	24/54	0.469
Initial Barthel Index (0–100)	37.9 (\pm 12.9); median 35, IQR (25–45)	36.8 (\pm 12.7), median 30, IQR (25–46)	0.555
Initial Functional Ambulation Category (0–5)	0.99 (\pm 0.89); median 1.0, IQR (0–2)	1.19 (\pm 1.12); median 1.0, IQR (0–2)	0.392
Initial gait velocity (m/s)	0.13 (\pm 0.17); median 0.08, IQR (0–0.18)	0.14 (\pm 0.19), median 0.1, IQR (0–0.19)	0.730
Initial maximum walking distance (m)	32.3 (\pm 49.3); median 15, IQR (0–46)	32.9 (\pm 49.9), median 15, IQR (0–41)	0.940
Initial Mobility Index (0–15)	3.5 (\pm 1.8); median 4, IQR (2–5)	3.4 (\pm 2.2), median 3, IQR (2–5)	0.554
Initial Motricity Index (1–100)	32.3 (\pm 22.6); median 28, IQR(15–48)	33.4 (\pm 24.0), median 38, IQR (8–50)	0.737

RLT, repetitive locomotor training; PT, physiotherapy.

Values are means (\pm SD), median and interquartile ranges (IQR). *P*-value of the Mann–Whitney test.

reached a Barthel Index of 75 or more at study end: 44 of 77 (57.1%) in group A versus 21 of 78 (26.9%) in group B, $P < 0.0001$ (Table 2, Figure 4). The 95% CI probabilities were 46.1–68.2% versus 17.3–37.2%.

At $T_{6\text{-months}}$, significantly more patients could walk independently in group A: 54 of 77 (70.1%) versus 28 of 78 (35.9%), $P < 0.0001$ (Table 2, Figure 3). The 95% CI probabilities were: 68.0–88.3% versus 31.6–55.9%. Among the patients

Table 2 Mean (SD), median (IQR) and responder–non-responder rate of both groups at T_{begin} , T_{end} and $T_{6\text{-months}}$

Primary outcome variables	T_{begin}		T_{end}		$T_{6\text{-months}}$	
	A (RLT+PT)	B (PT)	A (RLT+PT)	B (PT)	A (RLT+PT)	B (PT)
Functional Ambulation Category (FAC, 0–5)						
Mean (SD)	0.99 (\pm 0.88)	1.2 (\pm 1.1)	3.2 (\pm 1.4)	2.1 (\pm 1.5)	3.8 (\pm 1.7)	2.6 (\pm 1.8)
Median (IQR)	1 (0–2)	1 (0–2)	4 (2–4)	2 (1–3)	5 (3.5–5)	3 (1–4)
FAC 4 or 5, i.e. responder (<i>n</i>)	0	0	41	17	54	28
FAC 0–3, i.e. non-responder (<i>n</i>)	77	78	36	61	23	50
Barthel Index (BI, 0–100)						
Mean (SD)	37.9 (\pm 12.9)	36.9 (\pm 12.7)	72.3 (\pm 21.0)	58.7 (\pm 21.6)	77.5 (\pm 23.1)	65.1 (\pm 28.0)
Median (IQR)	35 (35–45)	30 (25–46)	75 (55–87.5)	55 (39–76)	85 (65–97.5)	75 (35–86)
BI > 75, i.e. responder (<i>n</i>)	0	0	44	21	45	36
BI < 75, i.e. non-responder (<i>n</i>)	77	78	33	57	32	42

RLT, repetitive locomotor training; PT, physiotherapy.

*Significant difference (chi-squared test, $P < 0.0125$) in favour of group A.

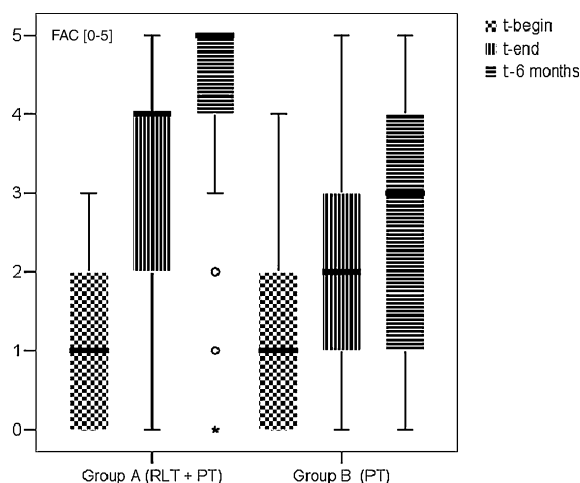


Figure 3 Box plot of the Functional Ambulation Categories (FAC, 0–5) of patients of group A (RLT+PT, left, $n = 77$) and group B (PT, right, $n = 78$) at T_{begin} , T_{end} and $T_{6\text{-months}}$. RLT, repetitive locomotor training; PT, physiotherapy; \circ indicates values larger than one and a half of the box, * indicates values larger than three times of the box.

with an Functional Ambulation Category of 0 at T_{end} in group A ($n = 5$) and group B ($n = 12$), only one patient from group B could further improve his gait ability.

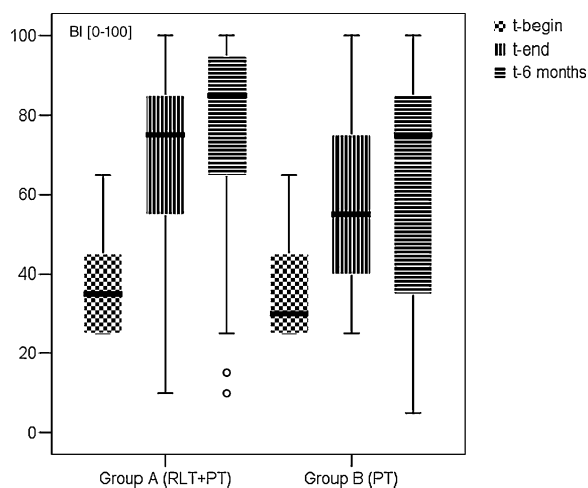


Figure 4 Box plot of the Barthel Index (BI, 0–100) of patients of group A (RLT+PT, left, $n = 77$) and group B (PT, right, $n = 78$) at T_{begin} , T_{end} and $T_{6\text{-months}}$. RLT, repetitive locomotor training; PT, physiotherapy; \circ indicates values larger than one and a half of the box.

The Barthel Index responder rate no longer differed between groups at follow-up ($P = 0.025$). In group A, 45 of 77 patients and 36 of 78 in group B had reached a Barthel Index of at least 75 (Table 2, Figure 4).

For all secondary variables (Tables 3 and 4), group A patients had improved significantly more in the time interval from T_{begin} to T_{end} (uniform $P < 0.0001$). For the period from T_{end} to $T_{6\text{-months}}$, the changes of all four variables did not differ between the two groups.

At follow-up, 54 patients of group A and 53 patients of group B were living at home; 10 of group A and 11 of group B were in a nursing home. The living situation of the remaining patients was unknown. They had all received ongoing physiotherapy since discharge from the clinic with a mean of 2.6 (group A) and 2.4 (group B) sessions per week respectively.

Discussion

Significantly more subacute stroke patients could walk independently and had reached a Barthel Index (0–100) of at least 75 following four weeks of repetitive locomotor training plus physiotherapy, compared with physiotherapy alone. At follow-up the effects in favour of the locomotor group were persistent except for the number of patients having reached a Barthel Index of at least 75.

The study groups were homogeneous at study onset, the absolute treatment duration and the relative content of physiotherapy were comparable in both groups. On the gait training machine, the non-ambulatory patients practised 800 to 1200 steps at each session, whereas the patients of the control group rarely exceeded 150–200 steps during their daily 45-min physiotherapy sessions. The latter was calculated on the basis of the therapists' estimation of the walking distance covered during each single physiotherapy session. Accordingly, the known positive correlation between therapy intensity and motor outcome of stroke rehabilitation most likely explained the superior gait function, walking velocity and endurance in the locomotor group.²⁰ With respect to the Barthel Index, six of the ten items are mobility-related (see also the results of the Rivermead Mobility Index), and bowel and bladder function are known to profit

Table 3 Mean (SD), median (IQR) of the secondary outcome variables of both groups at T_{begin} , T_{end} and $T_{6\text{-months}}$

Secondary outcome variables Group	T_{begin}		T_{end}		$T_{6\text{-months}}$	
	A (RLT+PT)	B (PT)	A (RLT+PT)	B (PT)	A (RLT+PT)	B (PT)
Gait velocity (m/s)						
Mean (SD)	0.13 (± 0.17)	0.14 (± 0.19)	0.44 (± 0.47)	0.32 (± 0.36)	0.53 (± 0.31)	0.36 (± 0.42)
Median (IQR)	0.08 (0–0.18)	0.10 (0–0.19)	0.32 (0.16–0.50)	0.2 (0.1–0.4)	0.34 (0.17–0.80)	0.19 (0–0.63)
Gait endurance (m)						
Mean (SD)	32.3 (± 49.3)	32.9 (± 49.9)	134.4 (± 125.5)	92.5 (± 104.9)	165.5 (± 152.5)	112.1 (± 127.7)
Median (IQR)	15 (0–46)	15 (0–41)	102. (40–190)	56 (18–130.5)	118 (50.5–267.5)	60 (0–192.0)
Rivermead Mobility Index (0–15)						
Mean (SD)	3.5 (± 1.8)	3.4 (± 2.2)	8.5 (± 3.9)	6.3 (± 3.7)	10.0 (± 4.1)	7.8 (± 4.8)
Median (IQR)	4 (2–5)	3 (2–5)	9 (5–12)	6 (3–9)	11 (7.5–13)	9 (2–13)
Motricity Index (1–100)						
Mean (SD)	32.3 (± 22.6)	33.4 (± 24.0)	53.8 (± 25.1)	42.2 (± 26.1)	58.9 (± 26.6)	47.0 (± 25.9)
Median (IQR)	28 (15–48)	38 (8–50)	54 (35–76)	46.5 (23–64)	62 (40–76)	43 (32–70)

RLT, repetitive locomotor training; PT, physiotherapy.

from improved stance and gait in immobilized patients.²¹ Walking velocity and endurance correlate positively with gait ability in stroke patients.²²

Previous controlled trials on the locomotor therapy with the help of a treadmill and manual assistance failed to show superior gait function and walking velocity in non-ambulatory stroke

patients.^{8,9} The patients may have made too few steps on the belt, attributable to the effort for the therapists (e.g. when setting the paretic limbs). None of the trials reported exact numbers.

Repetitive locomotor training is in line with modern principles of motor learning favouring a task-specific, repetitive approach. The so-called

Table 4 Intra-individual differences of the secondary outcome variables of both groups in the time intervals $T_{\text{end}} - T_{\text{begin}}$, and $T_{6\text{-months}} - T_{\text{end}}$

Secondary outcome variables Group	$T_{\text{end}} - T_{\text{begin}}$			$T_{6\text{-months}} - T_{\text{end}}$		
	A (RLT+PT)	B (PT)	<i>P</i> -value	A (RLT+PT)	B (PT)	<i>P</i> -value
Δ Gait velocity (m/s)						
Mean (SD)	0.31 (± 0.40)	0.18 (± 0.28)	< 0.0001	0.09 (± 0.15)	0.04 (± 0.17)	n.s.
Median (IQR)	0.2 (0.09–0.41)	0.11 (0–0.22)		0.04 (0–0.2)	0 (–0.02–0.07)	
Δ Gait endurance (log m)						
Mean (SD)	102.2 (± 97.1)	59.6 (± 72.9)	< 0.0001	31.1 (± 55.7)	19.6 (± 52.6)	n.s.
Median (IQR)	76 (33.5–137.5)	35 (9–73)		12 (0–49)	0 (–3–41)	
Δ Rivermead Mobility Index (0–15)						
Mean (SD)	5.0 (± 2.9)	2.9 (± 2.6)	< 0.0001	1.5 (± 2.2)	1.5 (± 3.1)	n.s.
Median (IQR)	5 (3–7)	2 (1–5)		1 (0–3)	0 (0–3)	
Δ Motricity Index (1–100)						
Mean (SD)	21.5 (± 15.1)	8.8 (± 12.2)	< 0.0001	5.1 (± 10.8)	4.8 (± 13.3)	n.s.
Median (IQR)	20 (9–30)	7.5 (0–16.5)		6 (0–12)	5 (0–11)	

RLT, repetitive locomotor training; PT, physiotherapy. *P*-value of the Mann–Whitney test, Bonferroni adjusted $P < 0.00625$.

Clinical messages

- Intensive locomotor training on an electro-mechanical gait trainer plus physiotherapy resulted in a significantly better gait ability and daily living competence in subacute stroke patients compared with physiotherapy alone.
- A higher intensity of gait practice, in line with modern principles of motor learning, probably explains the superior result.

motor relearning programme, a physiotherapy approach also based on task-oriented treatment principles,²³ proved to be better than the Bobath approach²⁴ with respect to the improvement of motor functions in acute stroke patients.

Neurophysiologically, the repetitive locomotor training aims at an activation of spinal and supraspinal pattern generators, according to animal²⁵ and clinical studies in spinal cord injury patients.^{4–6} For stroke patients after a supratentorial lesion, with descending fibres originating from brainstem centres intact, Miyai and colleagues showed that locomotor recovery was associated with improvement of asymmetry in primary sensorimotor cortex activation and enhanced premotor cortex activation in the affected hemisphere.²⁶

The sustained favourable treatment effects at follow-up supports the argument that an early intensive therapy translates to long-lasting effects, as was recently shown by Feys *et al.* for an early and repetitive stimulation of the arm.²⁷ With a rather low-frequency professional therapy programme after discharge in both groups, one may speculate that the then ambulatory patients of the experimental group may have continued a more intensive practice on their own at home, as was already discussed for ambulatory stroke patients following treadmill training.^{28,29} With respect to the Barthel Index, a ceiling effect in the experimental group may explain the no longer significant difference between the two groups at follow-up.

A minor group of patients (7%) experienced deterioration in gait ability during the six-month follow-up period. Besides a worsening of health conditions, the partner's attitude seemed to have influenced the development of gait ability. Some of

them may have advised their partners to refrain from walking and to remain in the wheelchair in order to prevent falls. For a total of 205 first-ever stroke patients, van de Port *et al.* reported a mobility decline in 21% of the patients over a period of 1–3 years after stroke.³⁰

The study has certain limiting factors. The assessment and rating of the secondary outcome variables was not blind, the close co-operation of therapists made concealing impossible. Patients in the experimental group may have had the impression of a double therapy, although the net treatment time did not differ and the locomotor therapy and the physiotherapy followed each other immediately. An exclusive treatment on the machine would have not reflected the current use of the locomotor approach as supplementary in most clinics. Furthermore, an inclusion rate of 5% of all patients, comparable to the one reported by Kwakkel *et al.*,²⁰ limited its generalizability.

In conclusion, four weeks of repetitive locomotor training plus physiotherapy led to better gait ability and ADL competence at study end and gait ability at follow-up in subacute, non-ambulatory stroke patients as compared to physiotherapy of equal treatment duration. The higher intensity of gait practice, in line with modern principles of motor learning, probably explains the superior result.

Role of the funding source

A BioFuture grant of the Bundesministerium für Bildung und Forschung (BMBF) and the Reha-Stim company sponsored the DEGAS study (Deutsche Gangtrainerstudie). The study sponsors had no influence on the study setting.

Competing interests

Reha-Stim, which holds the national patent for the gait trainer device, is owned by Dr Brandl-Hesse, the spouse of the author Stefan Hesse.

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