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# Early Intensive Gait Training vs. Conventional Low Intensity Gait Training in Individuals Post Stroke

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## Early Intensive Gait Training vs. Conventional Low Intensity Gait Training in Individuals Post Stroke

### Disciplines

Physical Therapy

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## **Early Intensive Gait Training vs. Conventional Low Intensity Gait Training in Individuals Post Stroke.**

**Clinical Scenario:** The patients that led us to pursue this question included several male patients between the ages of 50 and 70 with a diagnosis of sub-acute cerebral vascular accident that presented with difficulty walking. Medical treatment to date has included occupational therapy, speech therapy, physical therapy in the acute and sub-acute settings, and nursing and physician care. Challenges identified included neglect, difficulty with ambulation, difficulty with transfers, decreased functional mobility and strength, and difficulty communicating. We would like to know if there is an optimal amount of walking training that should be implemented during rehabilitation to maximize walking outcomes.

**Brief Introduction:** For the purposes of our clinical question, we want to know what the research says about the use of early intensive gait training on patients with acute or sub-acute CVA. The patients in the skilled nursing facilities we have worked in often have difficulty with ambulation post-stroke. While intensive gait training has been rigorously studied in patients with chronic stroke, there has not been a great deal of research in this area with patients that are acute or sub-acute.

**Clinical Question:** Does early intensive gait training with patients after acute or sub-acute stroke improve gait performance as compared to conventional post-stroke rehabilitation?

### **PICO**

**Population** – Adults ages 50-75 years old in a skilled nursing or rehabilitation facility with a diagnosis of acute or sub-acute CVA.

**Intervention** – Early intensive gait training with or without the use of assistive devices.

**Comparison** – Conventional or low intensity stroke rehabilitation, which includes strengthening, balance, and motor control exercises.

**Outcome** – Gait velocity, walking capacity and endurance, functional ambulation, and mobility.

**Overall Clinical Bottom Line:** Results from Outermans et al., Peurala et al., and Pohl et al., show that early intensive gait training result in both statistically significant and clinically meaningful improvements in ambulation endurance and velocity in patients with hemiplegic acute or sub-acute stroke. Outermans et al. showed that early intensive over ground gait training, strengthening, and cardiorespiratory training improve ambulation velocity and endurance in high functioning patients significantly more than low intensity physical therapy focused on motor control and balance. Peurala et al.'s results demonstrated that early intensive gait-training either over ground or with a body weight supported gait trainer along with traditional stroke therapy significantly improved ambulation velocity and endurance from baseline, and significantly improved FAC scores and MMA scores over the low intensive control group. The study by Pohl et al. showed that early intensive repetitive locomotor training with an electromechanical gait trainer and additional therapy in non-ambulatory patients significantly improved gait speed, velocity, and independent ambulation abilities more than traditional physical therapy alone. From the three studies, we can generalize these results to acute and sub-acute populations ranging from non-ambulatory to high functioning within the age groups of 18-80 within the inpatient rehabilitation setting. More research in this field is needed with regards to differentiation between acute and sub-acute populations, as well as developing a standard of care within all rehabilitation centers for early intensive gait training.

Components of our clinical question that were not answered include: learning details of therapeutic treatment protocols for over ground gait training, and a lack of discussion of feasibility of treatments within a normal clinic setting, such as cost of equipment, space and equipment required for specific treatments, and applicability to different individuals within the post-stroke category.

**Search Terms:** high-intensity gait training, acute stroke, task-oriented gait training, CVA, lower extremity, early intensive gait training

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### **Rationale for Our Chosen Articles**

While there are many articles on intensive gait training, most of the research to date has been on patients with chronic stroke. Through our literature search we were only able to identify a few articles that researched the effects of early intensive gait training on patients in the acute or sub-acute phase post-stroke. The following articles were the ones that we found that most closely matched our PICO, specifically the population's diagnosis and age group, and the intervention. Due to the lack of research in this area, the level of function of some of the subjects varies from our chosen population and we included articles that researched body-weight supported gait training as a part of the high-

intensity training, which was not initially our plan. Below is an overview of the study designs and Table 1 shows the PEDro scoring for each chosen article.

Outermans, J.C., van Peppen, R.P.S., Wittink, H., Takken, T., Kwakkel G. Effects of a high-intensity task-oriented training on gait performance early after stroke: a pilot study. *Clinical Rehabilitation* 2010; 24: 979-987.

PEDro Score: 6/10

**Patient:** All participants were inpatients at a neurorehabilitation clinic and diagnosed with hemiplegia resulting from first or recurrent stroke. The time elapsed from the CVA was between 2 and 8 weeks, which was similar to our patient population. However, all participants were required to be able to walk 10 meters without assistance prior to the study, which did not match our patients' experiences. Participants also had functional ambulation categories greater than or equal to 3, which was also at a higher skill level than our patients.

**Intervention:** The experimental group participated in conventional physical therapy for ½ an hour each day, in addition to high-intensity task-oriented gait training for 45 minutes three times a week for four weeks. They also performed walking relays and races for 10 minutes after each 45-minute session. The control group also received 30 minutes of conventional physical therapy a day, and participated in a 45 minute low intensity group exercise program 3 days a week for four weeks. Afterwards, the participants joined in games for 10 minutes after the 45-minute session.

**Outcome Measures:** Six-minute walk test, Borg scale of perceived exertion, 10 meter timed walking tests, and Berg balance score

Peurala, S.H., Airaksinen, O., Huuskonen, P., Jäkälä P., Juhakoski M., Sandell, K., Tarkka, I.M., Sivenius, J. Effects of Intensive Therapy Using Gait Trainer or Floor Walking Exercises Early After Stroke. *Journal of Rehabilitation Medicine* 2009; 41:166-173.

PEDro score: 5/10

**Patient:** All patients were inpatients at an acute care hospital with a diagnosis of either their first stroke or stroke with no significant disturbances from a previous stroke.

Patients were a mean of 8 days post CVA. The age range of patients was between 18 and 85, with an average age of 71.4 years. Unlike the patients that we saw, all participants were required to have voluntary movement with their affected leg at 8 days post stroke, and could not have any severe communication or cognitive disorders.

**Intervention:** There were two experimental groups and one control group. The Gait Trainer (GT) experimental group walked with body-weight supported on motor driven footplates. The Walking experimental group (WALK) practiced walking over ground using their personal assistive devices and with assistance from one or two therapists. Both groups received one hour of therapy each day in order to achieve 20 minutes of actual walking during that time. The control group transferred to a health center and received one to two physical therapy sessions per day at low intensity.

**Outcome Measures:** Functional Ambulatory Category, Borg scale of perceived exertion, 10 meter timed walk test, modified motor assessment scale, Rivermead motor assessment scale, Rivermead mobility index, and 6 minute walk test

Pohl M., Werner C., Holzgraefe M., Kroczeck G., Wingendorf I., Hoolig G., Koch R., Hesse S. Repetitive Locomotor Training and Physiotherapy Improve Walking and Basic Activities of Daily Living After Stroke: a Single-Blind, Randomized Multicentre Trial (DEutsche GAngtrainerStudie, DEGAS). *Clinical Rehabilitation* 2007; 21(1): 17-27.

PEDro Score: 8/10

**Patient:** All patients were inpatients at four German Rehabilitation centers that had suffered a first-time stroke within the last 60 days, which was similar to our patient population. The age range was 18-79 years and patients had to be able to sit unsupported with feet supported, could not walk at all, or required the help of one or two physical therapists irrespective of a walking aid or ankle foot orthoses (AFOs). These criteria were also very similar to the patients that we saw in the inpatient setting. Participating patients could not have an unstable cardiovascular condition, restricted passive range of motion in the major lower limb joints, or the existence of other neurological or orthopedic diseases that impaired walking ability.

**Intervention:** The experimental group received 20 minutes of repetitive locomotor therapy on a gait trainer that consisted of two motor driven footplates with bodyweight support, followed by 25 minutes of physical therapy that emphasized gait training 5 days a week for four weeks. The control group received 45 minutes of gait and stance training focused physical therapy 5 days a week for four weeks, but without the use of a gait trainer. Both groups also received the same amount of group rehabilitation sessions during the four weeks of the study.

**Outcome Measures:** Functional Ambulation Category, Rivermead Mobility Index, Barthel Index, 10 meter timed walk test, and 6-minute walk test

Table 1: Comparison of PEDro scores

	Outermans et al.	Peurala et al.	Pohl et al.
Random	Yes	Yes	Yes
Concealed Allocation	Yes	Yes	Yes
Baseline comparability	Yes	Yes	Yes
Blind subjects	No	No	No
Blind therapist	No	No	No
Blind Assessors	No	No	Yes
Adequate Follow-up	No	No	Yes
Intention to Treat	Yes	No	Yes
Between Group	Yes	Yes	Yes
Point estimated and variability	Yes	Yes	Yes
Total score	6/10	5/10	8/10

Outermans, J.C., van Peppen, R.P.S., Wittink, H., Takken, T., Kwakkel G. Effects of a high-intensity task-oriented training on gait performance early after stroke: a pilot study.

*Clinical Rehabilitation* 2010; 24: 979-987.

**Clinical Bottom Line:** This study researched the effects of high-intensity task-oriented gait training as an addition to conventional physical therapy in high-functioning patients that had acute hemiplegic strokes. The intervention was compared with low-intensity physical therapy that focused on motor control and balance of the paretic lower extremity in addition to conventional physical therapy. The experimental group improved significantly from pre- to post-treatment with a mean difference of 54 meters (m) ( $p = 0.02$ ) on the Six Minute Walk Test (6MWT), with a 95% confidence interval (CI) of -73.6. 181.6 m. This distance is clinically meaningful as it meets the MCID for the 6MWT. When the two groups were compared post-treatment, the experimental group met the MCID with a mean difference of 96.3 m (95% CI = 0.43 – 192.17) over the control group. The MCID for the 10MTWT is 0.3 m/s. The experimental group did not meet this

from pre- to post-treatment with a mean difference of 0.2 m/s (95% CI = -0.12 – 0.52). The experimental group improved significantly ( $p = 0.03$ ) over the control group in the Ten Minute Timed Walking Test (10MTWT), with a mean difference of 0.3 m/s (95% CI = -0.48 - 1.48 m/s) faster than the control group, which also met the MCID.

There were significant threats to the study's internal validity. The subjects, therapists, and assessors were not blinded. In addition, there may not have been enough subjects in the study in order to achieve adequate statistical power. There was no follow-up of the subjects once the intervention was completed. There were no adverse effects reported to be due to the intervention, and the group circuit class format for high-intensity gait training does not have a high cost financially or in regards to therapist and patient time. This study showed that the intervention is more effective than low-intensity training in this population, but it is difficult to determine if the results can be applied to patients with chronic stroke or more severe hemiplegia resulting from a stroke.

**Article PICO:**

**Population:** The population consisted of patients with hemiplegic strokes that occurred between 2 and 8 weeks previously, residing at an inpatient neurorehabilitation, and independently ambulatory for at least 10 meters.

**Intervention:** The intervention was conventional physical therapy with additional high-intensity task-oriented gait training that emphasized gait-related activities, strengthening, and cardiorespiratory training.

**Comparison:** The comparison was conventional physical therapy with additional low-intensity physical therapy that focused on improving motor control of the paretic limb and balance.

**Outcomes:** Outcomes measured were the six-minute walk test (6MWT) and 10 meter timed walking tests (10MTWT).

**Blinding:** No blinding was performed in this study. To minimize bias the assessor was not present at any of the group training sessions during the study. In addition, previous assessments were not available during the post-test measurements and all instructions were standardized. Due to this lack of blinding, there is a higher risk for rater bias favoring the high-intensity training group. There is also the risk of both the Rosenthal effect and the Hawthorne effect on the participants, since they were aware of which group they were in. These are all threats to the construct validity of the study.

**Controls:** There was a control group that served as a comparison to the experimental group. In place of the high-intensity training, they received low-intensity circuit training that focused on improving motor control and balance instead of improving walking competency. Total treatment time and contact time with researchers were equal.

**Randomization:** The subjects that met the inclusion criteria were randomly assigned to two groups after baseline measurements were taken. Allocation to each group was performed by drawing randomly generated lots from opaque envelopes. No statistically significant differences were found between the groups at baseline in regard to age, body mass index (BMI), mean time since onset of stroke, mean participation duration, or in the measurements of the 6 Minute Walk Test (6MWT), the 10 Minute Walk Test (10MWT), Berg Balance Scale, and the Functional Reach Test. There were no additional details regarding the process or methods of randomization.

**Study:** This was a randomized controlled pilot study that evaluated the effects of high-intensity task oriented gait training in patients early after stroke as compared with a low-

intensity motor control and balance focused program. There were 44 subjects with hemiplegic stroke that met the inclusion criteria of the study. All subjects had suffered a stroke between two and eight weeks before the study, were able to walk 10 meters without assistance, and had Functional Ambulation categories of at least three. Patients were excluded if they had any cardiovascular instability, sensory communicative disorders, or impairments of the lower extremities that influenced walking ability.

There were 21 patients in the control group that received low-intensity physical therapy group. They received 45 minutes of circuit training, with 10 stations, three times a week for four weeks. The individual stations were not described in the study. The therapy focused more on improving motor control of the hemiparetic leg and on improving balance. No components of strengthening or cardiovascular exercises were included in the circuit. After the circuit session, the patients participated in games for 10 minutes. The 22 patients (see study losses below) in the experimental group received high-intensity task-oriented gait training from a 10-station circuit class. They performed 45 minutes of training three times a week for four weeks. Their training focused on improving walking skills such as climbing stairs, turning, making transfers, and improving gait speed and distance. Postural control, strengthening, and cardiorespiratory training were also incorporated in the intervention. At the end of each session, the subjects participated in walking relays and races for 10 minutes. In addition to the circuit class training, both groups received usual individual physical therapy every day for 30 minutes. It is not clear what was practiced during these sessions, but therapists were instructed not to depart from their usual practice during the study.

Outcome Measures: The researchers assessed gait performance via the six-minute walk test (6MWT) and the ten-minute timed walk test (10MTWT). The 6MWT was chosen as a measure of walking capacity, and the authors stated that it is reliable and valid in a stroke population. The 10MTWT was used to assess maximal gait speed. The test was performed three times and the mean was used in the analysis. In patients with stroke, the 10MTWT has shown high intra-rater reliability (intraclass correlation coefficient = 0.95), and validity ( $r_s = 0.79$ ). Reliability of the assessors in this study was not established. Both tests were measured at baseline and post-intervention. According to the authors, the minimally clinical important difference (MCID) is 54.1 meters for the 6MWT. The MCID given by the authors for the 10MWT is 0.3 m/s. During each test the assessor remained behind the patient in order to avoid influencing performance.

Study Losses: Twelve patients were lost during the study, or 28% of the total subjects. One patient was excluded due to a wrong diagnosis and was not included in the statistical analysis, one participant suffered a recurrent stroke, one experienced a case of acute gonarthritis, one did not receive treatment as allocated, four participants dropped out for motivational reasons, and five participated for less than 20 days but could be assessed post-trial. Analyses were performed using an intention-to treat analysis, and the researchers assumed the worst-case scenario (baseline values were carried forward) when imputing values for the subjects that had an early discharge from the study. The study losses do not appear to be due to the intervention itself, and all subjects were analyzed in the group that they were randomized into.

**Summary of Internal Validity:** The internal validity of this study was fair. One significant threat to the internal validity was the lack of any blinding, which may have

resulted in a Hawthorne effect and rater bias in favor of the high-intensity gait-training group. Due to the small numbers used in the study, the results may not have adequate statistical power to prove the effectiveness of the treatment. The authors did not do a power analysis to determine sufficient sample size. In addition, there was no follow-up in the study to determine if the effects of the intervention were lasting or not.

Strengths of the study design included use of randomization, the presence of a control group, and the use of appropriate statistical tests for the evaluation of the data. There were also no significant differences between the patients in regard to age, BMI, mean time since onset of stroke or with respect to measurements of the 6MWT and 10MWT at baseline.

**Evidence:** The high-intensity gait-training group showed an improvement of 54.0 meters (SD 65.1) walked during the 6MWT from baseline to post-treatment analysis, while the low-intensity group showed an increase of 21.4 (SD 43.2) meters walked during the 6MWT (Table 2). Using a between group analysis of post-treatment scores with a Mann-Whitney U test found a significant difference in the improvement of the high-intensity training group over the control group ( $Z = -2.26$ ,  $p = 0.02$ ). For the maximum speed 10MWT, the experimental group showed an improvement of 0.2 m/s (SD 0.5), while the control did not improve at all, remaining at a mean of 1.4 m/s (SD 0.4) after treatment. The mean improvement of the experimental group over the control group was 0.3 m/s, also found to be statistically significant ( $Z = -2.13$ ,  $p = 0.03$ ).

Table 2: pre-and post treatment results of 6MWT and 10MWT with standard deviations

	<b>Pre-treat 6MWT (SD) (m)</b>	<b>Post-treat 6MWT (SD) (m)</b>	<b>Pre-treat 10MTWT (SD) (m/s)</b>	<b>Post-treat 10MTWT (SD) (m/s)</b>
<b>Control Group</b>	401.0 (131.5)	422.4 (127.9)	1.4 (0.5)	1.4 (0.5)
<b>Experimental Group</b>	459.8 (145.8)	518.7 (165.2)	1.5 (0.5)	1.7 (0.5)

The authors stated that the minimum clinically important difference (MCID) for the 6MWT is 54.1 meters. The mean difference for the experimental group was 54 meters, (95% Confidence Interval (CI) = -73.6 – 181.6 m) which, while 0.1 m below the MCID value, is close enough to be clinically meaningful. The control group had a mean change of 21.4 m, from pre- to post-treatment, which did not meet the MCID. Comparison between the two groups post-treatment showed a 96.3 m (95% CI = 0.43 – 192.17) difference in favor of the experimental group, which is a clinically important difference. When comparing the change scores of 54 m for the experimental group and 21.4 m for the control group, the difference is 32.6 m (95% CI = -3.35 – 68.55), which does not meet the MCID. The relatively small number of subjects in the study accounts for the large confidence interval, but it raises concerns about accuracy and the effectiveness of the intervention in a larger population. The MCID for the 10MTWT given by the authors is 0.3 m/s, which the experimental group did not meet from pre- to post-treatment with a change of 0.2 m/s (95% CI = -0.12 – 0.52). The control group did not meet the MCID in a within-group analysis, since they did not change at all from pre- to post-treatment. The experimental group did meet the MCID when compared to the post-treatment control group, with a mean difference of 0.3 m/s (95% CI = -0.48 - 1.48

m/s). The difference between the change scores from the two groups was also 0.3 m/s, which met the MCID as well.

*Table 3: Statistical Analysis of Mean Difference and Confidence Intervals (calculated by the appraiser)*

	<b>Mean Difference</b>	<b>95% Confidence Interval</b>	<b>MCID Met:</b>
<b>6MWT (within experimental group)</b>	54.0 m	-73.6 – 181.6 m	Yes
<b>6MWT (between groups)</b>	96.3 m	0.43 – 192.17	Yes
<b>10 MTWT (within experimental group)</b>	0.2 m	-0.12 – 0.52	No
<b>10 MTWT (between groups)</b>	0.3 m/s	-0.48 - 1.48 m/s	Yes

### **Applicability of Study Results:**

Benefits vs. Costs: The results of this study suggest that, in individuals that are high functioning acute stroke survivors, high-intensity task-oriented gait training is more effective than a low-intensity physical therapy program. The financial costs of this treatment do not seem to be too great for most rehabilitation settings; the main concern would be having enough space to have a group circuit training area with 10 stations. This treatment method could potentially save time for the therapist and patients, since the treatment included only ½ an hour of regular physical therapy a day for each patient, and 55 minutes total time of group circuit training three times a week. This format allows the therapist to oversee multiple patients at one time, and creates a positive social environment for the patients as well. There were no recorded adverse events due to treatment. Since the control group received the same amount of time and the same

number of sessions as the experimental group, the improvements seen in the high-intensity group are more likely to be from the intervention than other factors.

Feasibility of Treatment: This treatment is feasible for facilities that have the space and equipment for the intervention, and for patients that are very high-functioning post-stroke. While the intervention of high-intensity task-oriented gait training could be generally reproduced from this study, it could not be exactly replicated since the authors did not describe each individual station of the circuit training classes. From their description, however, the requirements of equipment, time, and expertise would be well within what is available in most inpatient rehabilitation settings.

Summary of External Validity: This study can only be generalized to patients with hemiplegic stroke that occurred between 2 and 8 weeks prior, with the ability to walk at least 10 meters without assistance. It is therefore difficult to determine if the results of this study can be applied to sub-acute or chronic patients with hemiplegic stroke, or to patients that suffered an acute stroke with more resultant disability. There are numerous threats to the internal validity of this study, which weaken the external validity as well. Despite these limitations, this study did show a significant improvement in gait speed and walking capacity, and this is important to take into account.

Peurala, S.H., Airaksinen, O., Huuskonen, P., Jäkälä P., Juhakoski M., Sandell, K., Tarkka, I.M., Sivenius, J. Effects of Intensive Therapy Using Gait Trainer or Floor Walking Exercises Early After Stroke. *Journal of Rehabilitation Medicine* 2009; 41:166-173.

**Clinical Bottom Line:** The evidence presented in this article suggest that patients with an acute stroke in an inpatient setting who received early intensive gait training had improvements in walking speed, distance, and had greater improvements in the functional ambulatory category (FAC) in comparison to those who just received standard low intensity stroke rehabilitation therapy. The high intensity gait-training group had greater improvements in their FAC median scores by 2.5 in comparison to the conventional therapy group. This improvement in FAC scores took the intervention group from a zero, which is a complete assist of two and inability to walk, to a four, which is independent walking on uneven surfaces. The MCID for this population is 54.1 meters for the six-minute walk test (6MWT) and 0.3 m/s for the ten meter timed walk test (10MTWT). The GT group improved their 10MTWT by 0.23 m/sec at 3 weeks and 0.42 m/sec at 6 months, and 6MWT by 93.4 m at 3 weeks and 188.6 m at 6 months. The WALK group improved their 10MTWT by 0.44 m/sec at 3 weeks and 0.46m/sec at 6 months, and 6MWT by 135 m at 3 weeks and 117 m at 6 months. The authors were unable to provide 6MWT and 10MWT scores for the conventional stroke therapy group. This makes it difficult to know the extent to which gains made by the intervention groups could be attributed solely to the intervention itself. The study had a similar population to the population in our PICO, but lacked sufficient evidence to answer the PICO question.

More research is needed with times and distances for the 10MWT and 6MWT for the low intensity stroke rehabilitation group to fully answer our PICO question.

**Article PICO:**

**Population:** Patients in the acute care hospital between the ages of 18-85 years old with a diagnosis of acute CVA.

**Intervention:** Either an early intensive walking over ground intervention or a gait trainer intervention; both resulting in 20 minutes of walking per session with assistance from physical therapist and assistive devices. Both groups also received additional standard gait directed physical therapy.

**Comparison:** Low intensity stroke rehabilitation therapy.

**Outcomes:** The outcome measures are the functional ambulatory category (FAC), ten meter timed walk test (10MTWT), six-minute walk test (6MWT), Modified Motor Assessment Scale (MMAS), Rivermead Motor Assessment Scale (RMA), and Rivermead Mobility Index (RMI).

**Blinding:** Subjects, therapists and assessors were not blinded to the study. The lack of blinding of both the subjects and assessors can be considered a threat to validity due to the possibility of the Hawthorne effect occurring with the subjects, rater bias occurring with the assessors, and Rosenthal effect occurring with the therapist.

**Controls:** There was a control group that received one to two low intensity physical therapy sessions a day at an inpatient health center, and two different intervention groups that received high intensity gait directed physical therapy and 20 minutes of actual walking either in a gait trainer or over ground once a day. The exact amount of time spent with the control group as well as the description of their therapy session was not

provided, which makes it difficult to state whether or no the groups received similar amount of total therapy time.

**Randomization:** The randomization process was stratified allocation. After meeting inclusion criteria and submitting themselves to baseline testing, subjects were randomly assigned to either the gait trainer group, over ground walking group, or low intensity physical therapy group. The author stated that stratified allocation was sealed and carried out by an individual who did not have connections to the patients. Demographics (age, gender, BMI, post-stroke days, Scandinavian Stroke Scale, Barthel Index, type of stroke, stroke side, presence of aphasia, neglect, FAC scores) of each group were collected at baseline. Group demographics were compared using one-way ANOVA, Man-Whitney U test and Kruskal Wallis statistical analyses. There was no statistically significant difference found between groups at baseline, which indicates a successful randomization.

**Study:** The study is a randomized controlled clinical trial performed over the span of a year and a half. The authors evaluated the effects of early intensive gait therapy using a gait trainer or over ground walking on individuals who experienced an acute stroke. Patients were recruited from an acute care hospital if they experienced their first stroke or had no significant disorder from an earlier stroke, scored zero to three on the Functional Ambulatory Scale (FAC), had voluntary movement in the leg on the affected side, no uncontrolled cardiovascular problems, were between the ages of 18-85 years, had a Body Mass Index (BMI) less than 32, no severe problematic joint disorders, and no severe communication or cognitive problems. Each patient underwent an MRI to confirm a recent stroke. Fifty-six patients were initially in the study; 22 patients in the gait trainer

group, 21 patients in the over ground walking group, and 13 patients in the control group. The intervention period lasted three weeks.

Patients in the control group received low intensity stroke physical therapy at a health center one to two times a week. The gait trainer group (GT) received 20 minutes of walking in the gait trainer with additional gait directed physical therapy for 55 minutes. The over ground walking group (WALK) received 20 minutes of walking with additional gait directed physical therapy for 55 minutes. Both the gait trainer and over ground walking groups were seen daily during the intervention period.

Outcome measures: An assessment was performed before, at two weeks, at three weeks, and six months after the three-week intervention. The assessment consisted of the FAC, 10MTWT, 6MWT, MMAS, RMA score, RMI score, RMA gross motor function (RMAg), and the RMA lower limb function plus trunk control (RMA l&t). Baseline levels were established at the beginning to monitor improvement overtime. A physical therapist or an independent observer performed the measurements alone. The inter-rater reliability of the measures was analyzed prior to collecting measurements and ranged from good to excellent.

Study losses: Of the original 56 patients, five patients from the GT group were lost, one patient from the WALK group was lost, and three patients from the control group were lost at the end of the three-week intervention. Overall, four patients dropped out due to worsening of their condition after treatment, one patient was lost due to unsuccessful attempts in a gait trainer, one patient due to scheduling problems after five treatments, two patients were lost because they felt the therapy sessions were too demanding, and two passed away during the study. It is important to note the two subjects that withdrew

from the study due to inability to tolerate treatment and how it may affect feasibility of the treatment. At the six-month follow up, one patient from the GT group was lost and one patient from the WT group was lost. Authors did not include the data of those patients who were lost. Overall, there was a 16% subject loss from the study indicating the need for intention to treat analysis to be performed. The lack of intention to treat serves as a major threat to validity.

**Summary of internal validity:** The internal validity of the study is fair. Strengths included that subjects were randomized and they had a control group. Patients were screened to account for inter-subject differences and were randomly allocated. The individual who performed patient allocation was blinded, which left no possibility of allocation bias. There were several threats to validity. The authors failed to perform a power analysis test to properly estimate an adequate power; therefore, if lack of a difference is found, it will not be clear if it is because of inadequate power or no actual effect of the intervention. Authors failed to state whether or not patients, therapist and assessors were blinded to the treatments, which left the possibility of the Hawthorne effect, Rosenthal effect and rater bias. During the follow up measurements at 6 months post intervention, two patients were lost and data was not collected. The author did not use intention to treat for all lost patients, which could harm the integrity of randomization. The authors failed to provide SD values for FAC, 6MWT and 10MWT, which made it difficult to find the effect size for this measurement. The authors provided 95% confidence intervals (CI) for the FAC scores and stated that the values are median inter-quartile ranges, which limits the ability to perform further statistical analysis. The

study had a 16% drop out rate during the intervention period (3 weeks) which can be considered in some cases quite high, which leads to more uncertainty in the study.

**Evidence:** After the three-week intervention period, the GT and WALK groups appear to have greater improvement with FAC compared to the low intensity conventional group (Table 4). The authors used both parametric and non-parametric test to analyze the data. While the repeated measures ANOVA showed significant group differences, the non-parametric test did not identify significant differences for different time-points or group differences. It is unclear at this time, based on the way data was presented, to determine if there is a statistically significant difference between groups for FAC scores.

*Table 4: Comparison of Gait-trainer, High-intensity group and low-intensity group for FAC (median scores and inter-quartile ranges)*

<b>Groups</b>	<b>Initial FAC</b>	<b>3 weeks FAC</b>	<b>6 months FAC</b>
<b>GT Group</b>	0	3 (1- 4.75)	4 (1-5)
<b>WALK group</b>	0	3 (1-3)	4 (3-4)
<b>Control</b>	0	0.5 (0-3)	2.5 (1-3.25)

Significant group differences ( $F = 4.036$ ,  $p = 0.025$ ) and rehabilitation improvements ( $F = 4.036$ ,  $p < 0.0001$ ) in FAC scores were found between the groups using ANOVA. No significant differences were found when the data was analyzed with the Kruskal-Wallis test.

Scores for GT and WALK groups were recorded at baseline, three weeks and six months post-intervention for the 10MWT and 6MWT (Tables 5&6). To take into account the patients who were unable to perform any walking test at baseline, the authors

performed a data transformation by calculating the relative difference (Equations 1&2) between the walking parameters at baseline and at the end of the intervention.

*Equation 1. Example for 10MTWT Relative difference (10MTWTrf)*

$$\frac{(\text{mean 10MTWT at end} - \text{mean 10MTWT at the start}) \times 100}{\text{Mean 10MTWT at the end}}$$

*Equation 2. equation if parameters at start were missing*

$$\frac{(100 - 10\text{MTWTrf}) \times \text{mean 10MTWT at the end}}{100}$$

Results were considered significant if  $p < 0.05$ .

Groups	Initial time (sec.)	CI at 95%	3 weeks (sec.)	CI at 95%	6 months (sec.)	CI at 95%	p-value
<b>GT group</b>	29.4	0.0-62.1	17.4	12.1-22.7	13.1	7.9-18.3	
<b>Velocity (m/s)</b>	.34		.57		.76		
<b>Change in velocity from baseline (m/s)</b>			.23		.42		
<b>WALK group</b>	44.2	18.0-70.4	15	10.2-19.4	14.6	9.9-19.3	0.016
<b>Velocity (m/s)</b>	.22		.66		.68		
<b>Change in velocity from baseline (m/s)</b>			.44		.46		

*Table 5: Comparison of 10MTWT (95% confidence intervals)*

The p-value for the 10MTWT was  $>0.05$ , indicating no significant difference between the GT and WALK groups. The authors did not compare either of the intervention groups to the control group, so it is not known if there was a significant difference.

Table 6: Comparison of 6MWT (95% confidence intervals)

<b>Groups</b>	<b>Initial Distance (meters)</b>	<b>CI 95%</b>	<b>3 weeks (meters)</b>	<b>CI 95%</b>	<b>6 months (meters)</b>	<b>CI 95%</b>	<b>p-value</b>
<b>GT group</b>	196.4	14.6-25.3	289.8	201.8-377.9	385.0	306.3-463.7	
<b>Change from baseline</b>			93.4		188.6		
<b>WALK Group</b>	220.1	174.7-265.6	355.5	280.1-430.9	337.1	269.7-404.5	< 0.001
<b>Change from baseline</b>			135		117		

The p-value for the 6MWT was >0.05 indicating no significant difference between the GT and WALK groups. No comparison was made to the control group, so it is not known if a difference exists.

Following the three-week intervention, both the GT and WALK groups showed significant improvements in 10MTWT and 6MWT (Table 5, Table 6). The GT group had a mean improvement in the 10MWT of 12 seconds ( $F = 6.862$ ,  $p = 0.016$ ), a mean increase in gait speed of 0.23 m/sec, and a 93.4 ( $F = 45.675$ ,  $p = <0.0001$ ) meter increase in the 6MWT. The WALK group had a mean improvement in the 10MWT time by 29.2 seconds ( $F = 6.862$ ,  $p = 0.016$ ), a mean increase in gait speed of 0.66 m/sec, and a 135 meter increase ( $F = 45.675$ ,  $p = <0.0001$ ) in the 6MWT.

At six months post-intervention the mean improvement in the 10MTWT from baseline for the GT group was .42 sec ( $p=0.045$ ) and .46 sec ( $p=0.045$ ) sec in the WALK group. At six months post-intervention the mean improvement in the 6MWT from

baseline for the GT group was 188.8 meters ( $p=0.082$ ) and 117 meters ( $p=0.082$ ) in the WALK group. Only the GT group had an improvement in their mean 6MWT from three weeks to six months ( $p=0.013$ ). The authors did not provide scores for the 6MWT and 10MWT for the Control group because too many patients were unable to perform any of the walking exams.

The minimum clinically important difference (MCID) for the 6MWT is 54.1 meters and for the 10MTWT is 0.3 m/sec. MCID is the smallest level of change that needs to occur due to an intervention to consider in worthwhile for patients. Differences for WALK and GT groups were calculated using the mean scores at three weeks and 6 months (Table 5).

*Table 7: Mean change relative to baseline for 6MWT and 10MWT in comparison to the MCID*

<b>Groups</b>	<b>6MWT at 3 weeks</b>	<b>6MWT at 6 months</b>	<b>10MTWT at 3 weeks</b>	<b>10MTWT at 6 months</b>
<b>GT group</b>	93.4 meters	188.6 meters	.23 m/sec	.42 m/sec
<b>MCID met</b>	Yes	Yes	No	Yes
<b>WALK group</b>	135 meter	117 meters	.44 m/sec	.46 m/sec
<b>MCID met</b>	Yes	Yes	Yea	Yes

Based on these results and the MCIDs for the 6MWT and 10MWT, both the GT and WALK groups met the MCID (54.1 meters) for the 6MWT at both three weeks and six months. The WALK group met the MCID (0.3 m/sec) for the 10MTWT at both three weeks and six months, while the GT group only met the MCID for the 10MTWT at six months.

### **Applicability of study results:**

Benefits vs. Costs: The cost and time spent on the WALK therapy group was greater than that of the control group. The WALK therapy group required more space to perform 20 minutes of walking, and a total of 40 hours and 15 minutes of therapy, which required more of both the patient's and therapist's time than did the control group. The benefits gained the high-intensity over ground gait training (WALK) are significantly better than those of the control group. Because of the greater amount of time spent in the WALK program, it is difficult to distinguish whether the benefits are due to the type of therapy performed or the amount of time spent in therapy or some combination. The costs of the GT group were greater than the costs of both the control and WALK group. The time spent with both the WALK and GT group was the same but the cost of the gait-trainer equipment and training ranges from \$19,000-20,000<sup>1</sup>. As a result, for several measures, we don't really know to what extent maturation contributed to the outcomes.

Feasibility of Treatment: The authors failed to describe the requirements of equipment, clinician expertise and what intensive gait therapy consisted of, which makes the study procedures hard to reproduce. The duration and number of the physical therapy sessions were within the allowed amount that would be covered by insurance companies.

Intensive gait training is feasible for patients within a skilled nursing facility or inpatient settings. Although treatment for early intensive gait training was not thoroughly described, early intensive gait training in combination with physical therapy with patients who suffered an acute stroke appears to result in superior walking ability and increase muscle strength compared to conventional therapy six months post treatment.

Summary of external validity: The results of the intensive gait training early after stroke appear to be applicable to adults who have experienced an acute stroke no more than 10 days post-stroke. The subject samples within the study appear to be similar to patients treated in the skilled nursing facilities. The author failed to provide a detailed description of therapy procedures, which makes it slightly difficult to apply in a clinical setting. No adverse effects due treatment were reported by the author. The internal validity of the study was fair. The population size was small, and lost patient's scores were not taken in to account. More research with a larger population and an intention-to-treat analysis for lost patients is needed. Although the internal validity is only fair, the data showed that improvements in functional ambulatory scale and motor ability, FAC scores and MMAS scores for the GT and WALK groups were significantly better than the Control group's scores. The study results suggest that early intensive gait training is a valid treatment in improving FAC and MMAS three weeks and six months post treatment in patients with an acute stroke.

Pohl M, Werner C, Holzgraefe M, Kroczeck G, Wingendorf I, Hoolig G, Koch R, Hesse S. Repetitive Locomotor Training and Physiotherapy Improve Walking and Basic Activities of Daily Living After Stroke: a Single-Blind, Randomized Multicentre Trial (DEutsche GAngtrainerStudie, DEGAS). *Clinical Rehabilitation* 2007; 21(1): 17-27.

**Clinical Bottom Line:** This study researched the effects of repetitive locomotor training, in addition to conventional gait and stance training – focused physical therapy, versus the effects of conventional physical therapy alone on patients with sub-acute hemiplegic stroke that were non-ambulatory at baseline. Both groups received 20 therapy sessions,

each 45-60 minutes long, within a period of four weeks. The intervention group improved significantly from pre- to post-treatment in the ability to walk independently according to the Functional Ambulatory category (FAC), with 53.2% ambulatory at four weeks (95% Confidence Interval (CI) 42.1 – 64.4%), and 70.1% ambulatory at a six-month follow-up (95% CI 68.0% - 88.3%). Of the control group, 21.8% were ambulatory at four weeks (95% CI 12.8 – 31.30%), and 35.9% were independently ambulatory at six months (95% CI 31.6% - 55.9%). The Number Needed to Treat in order to achieve independent ambulation from repetitive locomotor training at four weeks is 3.18 (95% CI 2.2 – 5.9), and at six months is 2.92 (95% CI 2.0 – 5.1). The intervention group also improved significantly on the Ten Minute Timed Walking Test (10MTWT), with a mean difference of 0.31 m/s at four weeks, which meets the MCID for the 10 MTWT, which is 0.3 meters/second (m/s); they also maintained this improvement, with a total mean difference of 0.4 m/s from baseline to six months after treatment. The control group did not meet the MCID for the 10MTWT at four weeks or at the six-month follow-up. For the Six Minute Walk Test (6MWT), both groups met the MCID of 54.1 meters (m), but the intervention group improved significantly more than the control group at four weeks. At six months, the improvements in the treatment group met the MCID with a mean difference of 54.1 m when compared with the control group mean change at six months.

There were minor threats to the study's internal validity, but no significant ones. There were no adverse effects reported to be due to the intervention, but this intervention would initially be very expensive to purchase the equipment needed and train all therapists and staff how to use and maintain it. In addition, this intervention may take more time than other forms of therapy, since it may take longer to get the patient set up in

the harness before beginning therapy. This study showed that repetitive locomotor training is more effective than conventional physical therapy in this population, but this cannot be generalized to patients with acute or chronic stroke, or patients with sub-acute stroke that are higher functioning. More research is necessary to determine if a less expensive method of intensive walking training would result in similar outcomes.

**Article PICO:**

**Population:** The population consisted of 155 non-ambulatory patients that had suffered a stroke for the first time within the last 60 days and resided in one of four neurological rehabilitation centers.

**Intervention:** The intervention consisted of 20 minutes of locomotor training on a gait trainer and 25 minutes of gait and stance training – focused physical therapy immediately following, 5 days a week for four weeks.

**Comparison:** The comparison was 45 minutes of gait and stance training – focused physical therapy 5 days a week for four weeks, without the use of a gait trainer.

**Outcomes:** The outcomes measures were: the Functional Ambulation Category (FAC), the 10 Meter Timed Walk Test (10MTWT), and the Six-Minute Walk Test (6MWT).

**Blinding:** The assessors of the FAC were blinded with respect to group assignment at study onset, at the end of the four-week treatment period, and at the six-month follow up. Two therapists at each rehabilitation center that were not involved in the treatments assessed the 10MTWT and the 6MWT; however, they were not blinded to the study conditions. The therapists and the subjects were not blinded; this may have increased the risk of the Hawthorne effect and the Rosenthal effect on the participants. These effects are threats to the construct validity of the study.

**Controls:** There was a control group that served as a comparison to the experimental group. The control group received the same type of physical therapy as the experimental group with emphasis on the restoration of stance and gait, with the exclusion of repetitive locomotor training on a gait trainer. Both groups received the same amount of time of physical therapy each day as well.

**Randomization:** The subjects that met the inclusion criteria were randomly assigned to two groups. Prior to the first intervention, each patient randomly drew a lot that indicated A or B out of an envelope that had previously been sealed. There were no statistically significant differences between the two groups at baseline in regards to age, gender, mean time since onset of stroke, mean participation duration, or in the measurements of the FAC, 6MWT or the 10 MTWT. There were no additional details regarding the process or methods of randomization.

**Study:** This was a randomized controlled trial that evaluated the effects of repetitive locomotor training with additional physical therapy as compared to physical therapy alone in patients with sub-acute stroke. There were 155 subjects that met the inclusion criteria of the study. All subjects had suffered a first- time stroke within the last 60 days, were able to sit with their upper extremities unsupported (i.e. without holding on to supports, but with feet supported), and could not walk at all or required the assistance of one or two therapists regardless of the use of a walking aid or ankle-foot orthosis. Patients were excluded if they had an unstable cardiovascular condition, a restricted passive range of motion in any of the major joints of the lower extremity, and/or the existence of other neurological or orthopedic diseases that would impair walking ability.

There were 78 patients in the control group that received 45 minutes of physical therapy five days a week for four weeks. Therapeutic interventions focused at least 60% of therapy time on the restoration of stance and gait both over ground and on stairs. Preparation time before therapy could not exceed 15 minutes in either group, so that total patient-therapist time was limited to 60 minutes daily. The 78 subjects in the intervention group received 20 minutes of repetitive locomotor therapy on an electromechanical gait trainer, immediately followed by 25 minutes of physical therapy with the same parameters of the control group. Thus, both groups received 20 sessions lasting between 45 and 60 minutes in the four-week period. The gait trainer consisted of two motor-driven footplates whose movements simulated the stance and swing phases of gait. During the locomotor training, patients wore a harness that initially supported 10-20% of their body weight, with the support being reduced as rapidly as possible in successive treatments. Both groups also received the same amount of group physical therapy sessions. It was not stated what type of interventions were performed in the group classes.

Outcome Measures: The researchers assessed gait ability with the Functional Ambulatory Category (FAC), a reliable and valid measure (as stated, but not cited, by the authors) with six categories (0-5) to determine the amount of physical support needed by patients while walking. A score of 0 indicates a patient that either cannot walk or needs assistance from two therapists. A score of 5 indicates a patient that can walk independently, including stairs. The 10MTWT was used to determine walking velocity; patients were timed as they walked 10 meters twice at their maximum speed, and the mean maximum velocity was calculated from the results. According to Outermans et al, the minimal clinically important difference (MCID) for the 10MTWT is 0.3 meters per second (m/s).<sup>1</sup>

The 6MWT was used to determine walking endurance. The patients walked for 6 minutes, and the maximum distance they were able to walk within this time frame was measured. The MCID for the 6MWT in the literature is 54.1 meters (m).<sup>1</sup>

Study Losses: There were eleven subjects lost out of 155 during the treatment block, five from group A and six from group B. Of the five subjects lost from group A, the treatment group, three stopped therapy due to unrelated medical issues and two refused therapy. Of the six lost from group B, the control group, two had unrelated medical issues and four refused therapy. At the follow-up testing six months after the intervention, 13 patients were lost in each group due to medical issues, moving away from the area, or refusal to participate. Thus, 64 patients in each group participated in the follow-up testing.

According to the authors, the dropouts did not differ with respect to their demographic data or initial outcome scores. An intention-to-treat analysis was performed by using the last score given for patients that dropped out.

**Summary of Internal Validity:** The internal validity of this study was good, but it had some minor threats. While the raters of the FAC were blinded, the treating therapists and the subjects were not, which could have resulted in a Hawthorne effect or Rosenthal effect. The authors chose the sample size of subjects based on a power analysis. The analysis used one of their outcome measures, the Barthel Index (BI) for independence of activities of daily living (ADLs), to determine the size necessary to detect the MCID of 10 points in the BI. While this increases the internal validity for that particular measure, it is unclear whether the number of subjects that participated was sufficient to detect differences found in the other outcome measures such as the FAC. Another potential threat to this study's validity is the fact that the wife of one of the authors is the owner of

Reha-Stim, the company that designed the gait trainer used in the study. In addition, Reha-Stim partially funded the research study, which could have influenced the interpretation or design of the study.

The study strengths included use of randomization, the presence of a control group, blinding of the raters, and the use of appropriate statistical tests for the evaluation of the data. The authors used an intention-to-treat analysis, and the two groups were homogeneous at study outset in regards to age, gender, diagnosis, and initial assessment results.

**Evidence:** After the four-week intervention period, 41 patients out of 77, or 53.2% of the subjects, (95% Confidence Interval (CI) = 42.1% – 64.4%) in the repetitive locomotor training group could walk independently (based on achievement of FAC score of 4 or 5). In the control group, only 17 patients out of 78, or 21.8% of the subjects, (95% CI = 12.8% – 31.30%) could ambulate independently ( $P < 0.0001$ ). At the six-month follow-up, 54 out of the 77 patients in the intervention group, or 70.1% (95% CI = 68.0% - 88.3%) were independent ambulators. In contrast, 28 of the 78 patients in the control group, or 35.9% (95% CI = 31.6% - 55.9%) could walk independently according to the FAC ( $P < 0.0001$ ). At four weeks and at six months, the confidence intervals between the two groups do not overlap at all, which means that the difference in the treatment group is more likely to be from the intervention instead of random chance or other factors (Table 8).

*Table 8: Percentage of Ambulatory patients at Four Weeks and Six Months, with 95% Confidence Intervals*

	<b>Percentage ambulatory at four weeks</b>	<b>95% Confidence Interval</b>	<b>Percentage ambulatory At six months</b>	<b>95% Confidence Interval</b>
<b>Intervention Group (Group A)</b>	53.2%	42.1 – 64.4%	70.1%	68.0% - 88.3%
<b>Control Group (Group B)</b>	21.8%	12.8 – 31.30%	35.9%	31.6% - 55.9%

With these numbers, it is possible to calculate the number needed to treat (NNT), or the number of patients that would need to receive repetitive locomotor training in order to have one more patient gain the ability to walk independently (Table 9). At the end of the treatment period, with 41 patients of the 77 able to walk in the treatment group and 17 of 78 able to walk in the control group, the NNT is 3.18, with a 95% CI of 2.2 – 5.9. This means that about 3 patients would need to be treated with this intervention for one additional patient to achieve independent ambulation. At the six-month follow-up, with 54 out of 77 patients in the treatment group ambulatory and 28 of the 78 patients in the control group ambulatory, the NNT decreases to 2.92, with a 95% CI ranging from 2.0 to 5.1. Overall, this means that compared to standard rehabilitation, for every three patients treated with the locomotor trainer, one additional patient will be able to reach independent ambulation with treatment after six months. The high end of the 95% CI indicates that if this study was repeated, the highest the NNT would be 5.

*Table 9: NNT to Achieve Independent Ambulation with Repetitive Locomotor Training at Four Weeks and Six Months*

	<b>NNT at 4 Weeks</b>	<b>95% CI</b>	<b>NNT at 6 months</b>	<b>95% CI</b>
<b>Locomotor Training compared to standard physical therapy</b>	3.18	2.2 – 5.9	2.92	2.0 – 5.1

According to the authors, the treatment group improved significantly in all secondary variables, including the 6MWT and the 10MTWT at the end of the four-week intervention period. Before treatment, the intervention group mean gait velocity for the 10MTWT was 0.13 m/s (standard deviation (SD)  $\pm$  0.17). At the end of the four-week intervention period, mean gait velocity was 0.44 m/s (SD  $\pm$  0.47), and at the end of six months it was 0.53 m/s (SD  $\pm$  0.31). For the control group, baseline measurements showed a mean of 0.14 m/s (SD  $\pm$  0.19). At four weeks, mean gait velocity increased to 0.32 m/s (SD  $\pm$  0.36), and at six months, it was 0.36 m/s (SD  $\pm$  0.42). Based on these measurements, it can be extrapolated that the treatment group had a mean difference of 0.31 m/s (SD  $\pm$  0.40) from beginning of treatment to the end, and a mean difference of 0.09 m/s (SD  $\pm$  0.15) from the end of the treatment to the six-month follow-up period. The MCID for the 10MTWT is 0.3 m/s, which the patients in the intervention group met at the end of treatment, and were able to maintain 6 months after the study. The control group had a mean difference of 0.18 m/s between baseline and four weeks, and a mean difference of 0.04 m/s between the end of treatment and six months later. Even with the

additional 0.04 m/s gain by six months, the control group did not meet the MCID for the 10MTWT (Table 10).

*Table 10: Mean Differences for the 10MTWT at Four Weeks and Six Months*

	<b>Mean Difference at Four Weeks (m/s)</b>	<b>Total Mean Difference at Six Months (m/s)</b>	<b>MCID Met (yes/no)</b>
<b>Intervention Group</b>	0.31	0.4	Yes
<b>Control Group</b>	0.18	0.22	No

The 6MWT also improved significantly more in the treatment group than the control group. At baseline, the intervention group's mean distance was 32.3 m (SD  $\pm$  49.3). At the end of four weeks, it increased to 134.2 m (SD  $\pm$  125.5), and at six months mean endurance was 165.5 m (SD  $\pm$  152.5). For the control group, mean baseline endurance was 32.9 m (SD  $\pm$  49.9). After four weeks of treatment, mean endurance was measured at 92.5 m (SD  $\pm$  104.9), and at the six-month follow-up it was 112.1 m (SD  $\pm$  127.7). Thus, from baseline to the end to treatment, the intervention group had a mean difference of 102.2 m (SD  $\pm$  97.1) as measured by the 6MWT and the control group had a mean difference of 59.6 m (SD  $\pm$  72.9) between baseline and four weeks. The MCID for the 6MWT is 54.1 m, which both groups met at the end of treatment. According to the authors, the intervention group improved significantly more than the control group at the four-week measurement ( $P < 0.0001$ ), with a mean difference between the groups of 41.9 m (95% CI = 1.01 – 82.79). Between four weeks and six months, the intervention group had a mean difference of 31.1 m (SD  $\pm$  55.7), and the control group had a mean

difference of 19.6 m (SD  $\pm$  52.6). While there was not a statistically significant difference in the comparisons between the groups at six months, the between-group mean difference from baseline to six months was 54.1 m in favor of the treatment group, which is a clinically important difference.

*Table 11: Mean Differences for the 6MWT at Four Weeks and Six Months*

	<b>Mean Difference at Four Weeks (m)</b>	<b>Total Mean Difference at Six Months (m)</b>	<b>MCID Met (yes/no)</b>
<b>Intervention Group</b>	102.2	133.3	Yes
<b>Control Group</b>	59.6	79.2	Yes
<b>Between Group Analysis</b>	41.9	54.1	Four Weeks: No Six Months: Yes

**Applicability of Study Results:**

Benefits vs. Costs: The results of this study suggest that, in individuals that are non-ambulatory sub-acute stroke survivors, the addition of intensive repetitive locomotor training on an electromechanical gait trainer is more effective than gait and stance-focused physical therapy without the use of a gait trainer. The initial financial costs of this treatment can be quite high, as the clinic would have to purchase a gait trainer to perform this type of therapy. However, in a clinic that primarily sees patients that are recovering from sub-acute strokes, it may be a worthwhile investment. The cost required for the control group therapy was much less, since they only required conventional physical therapy tools as needed. Using a gait trainer may also increase the time needed for therapy for both the therapist and the patient, due to the time needed to set up the patient in the harness before starting each session. There were no recorded adverse events due to this treatment, and the control group received the same amount of sessions that

were the same total amount of time as the control group. The strength in the study design increases our confidence that the differences seen in the intervention group were due to the repetitive locomotor training, and not any other factor.

Feasibility of Treatment: This treatment is feasible for facilities that have the space, equipment, and/or adequate funding to purchase the needed equipment needed for repetitive locomotor training. The authors provided specific directions for the gait trainer in regards to step length, initial cadence and body weight support, and how the therapist assisted the patient as needed; therefore, reproduction of that aspect of the intervention is possible. The conventional therapy that both groups received was described generally, but not in enough detail to be exactly reproduced. The number of sessions and the time needed for the intervention is possible in most inpatient rehab settings such as a skilled nursing facility, but would be difficult to maintain in an outpatient facility unless 60-minute treatment sessions were possible. Therapists would need to be trained to use the gait trainer, but this should not take undue time or expertise. This treatment seems to be feasible for all patients, since all that participated in the study were initially non-ambulatory. The authors did not report any losses due to increased pain from the intervention. This study does not determine the feasibility of this treatment for patients that have acute or chronic conditions, or are at a higher level of function.

Summary of External Validity: The results of this study can be generalized to patients with first-time, sub-acute hemiplegic stroke that occurred less than 60 days prior to treatment, and are non-ambulatory. It is difficult to determine if the results can be generalized to patients with acute or chronic stroke, or to patients with sub-acute strokes that are higher functioning. There were minor threats to internal validity, but none so

great that they would severely compromise the ability to generalize the results. The subject sample is similar to those that would be seen in an inpatient rehabilitation clinic. From these factors, it can be extrapolated that patients with sub-acute hemiplegic stroke that are non-ambulatory would benefit significantly from repetitive locomotor training in regards to functional ambulation, gait speed, and walking endurance.

**Synthesis/Discussion:** The study methods for all three articles ranged from fair to very good. Overall the internal validity of the studies did not compromise our ability to generalize their results to our patient population. While all studies had threats to internal validity to some degree, none of these threats were significant enough to disallow their use in forming a clinical decision about early intensive gait training. The populations of each article were fairly similar to our population group. While some criteria did not reflect our population, for example Outermans et al's population of high-functioning independent ambulators, we feel that these differences allow us to generalize results to a broader population than our original one.

In addition, while all three studies used early intensive gait training as an intervention, they used different specific interventions such as circuit training, the use of a body-weight support system, and over-ground gait training. Despite these differences, all interventions showed significant improvement with ambulation for the treatment groups from pre-to post-treatment, at follow up periods, and when compared to the control groups. Outermans et al. and Peurala et al. both had small study sizes, which could potentially decrease the power of their statistics; however, even if the differences aren't as large as the results seem to suggest, the studies still showed greater improvements with early intensive therapy than traditional low-intensity therapy. Pohl et

al. had a large sample size for their subjects, which increases the statistical power of their analysis, and makes it more likely that the changes seen are truly significant. Due to all of these factors, we are confident in recommending early intensive gait training, in whatever form is most available and cost-effective for each clinic, as a valid and necessary part of early stroke rehabilitation.

Future research is needed with details on therapeutic treatment for high-intensity gait training, larger study size, and discussion on the feasibility of treatments within a normal clinic setting.

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*All MCIDs taken from:*

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