

# Effectiveness of Anti-Gravity Treadmill Training in Improving Walking Capacity and Balance in Hemiparetic Stroke Patients: A Randomized Controlled Trial

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**Objective:** To study the effect of anti-gravity treadmill training on walking capacity and balance in hemiparetic stroke patients.

**Materials and Methods:** A randomized controlled trial, assessor-blinded, was conducted in sub-acute to chronic hemiparetic stroke patients with impaired gait function at Department of Rehabilitation Medicine, King Chulalongkorn Memorial Hospital and Thai Red Cross Rehabilitation Center. Participants fulfilled criteria were randomly allocated by block randomization into two groups. In intervention group, ambulation training by anti-gravity treadmill was provided 30 minutes per day, five times per week for one month combined with conventional physiotherapy program. Control group received ambulation training with conventional physiotherapy program for one month. Baseline whole gait analysis, balance test, six-minute walk distance (6MWD), and functional ambulatory category (FAC) were assessed before and after treatment. Adverse events and satisfaction scale were assessed at the end of the study.

**Results:** Thirty-one participants were randomly assigned, 15 in the intervention group and 16 in the control group. One participant from each group dropped out due to personal problems. Both, intention to treat and per protocol analysis, were done. The intervention group revealed statistically significant improvements in standing balance when measured path length from balance test via force plate ( $p=0.050$ ), maximum voluntary isometric contraction (MVIC) of gluteus maximus muscle recorded by dynamic surface electromyography ( $p=0.004$ ), 6MWD ( $p=0.001$ ), and FAC ( $p=0.010$ ). Ambulation training by anti-gravity treadmill combined with conventional physiotherapy showed a statistically significant difference of improvement in eye closed standing balance test when compared with the control group ( $p=0.026$ ).

**Conclusion:** Both groups improved in standing balance, motor power, 6MWD, and FAC in sub-acute to chronic hemiparetic stroke patients. In the present study, ambulation training by anti-gravity treadmill combined with conventional physiotherapy was superior to the control group in balance training.

**Keywords:** Walking capacity, Balance, Anti-gravity treadmill, Stroke, FAC

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Nowadays, cerebrovascular disease is the second leading cause of death in elderly people worldwide according to the World Stroke Organization (WSO) (1,2). Furthermore, stroke is the sixth burden of disease in disability-adjusted life years (DALYs) worldwide (3).

Motor impairment defined by impaired or limited

ability to control movement of muscle, has been the most common impairment that is reported in stroke patients (4). One-third of stroke survivors are unable to walk even though they have been admitted for three months in a general hospital. Loss of ability to ambulate is one of the strongest risk factors of long-term disability in stroke patients (3,4).

Gait restoration has been one of the most important goals in non-ambulatory hemiparetic stroke patients. Conventional physiotherapy technique is an exercise that targets the strengthening of muscles. Other techniques such as Brunnstorm technique is

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also used. Many rehabilitation techniques are quite complex<sup>(5)</sup>. Another useful technique that provides gait training benefits in stroke patients is the task-specific, repetitive approach<sup>(6)</sup> including body weight support treadmill training (BWSTT) that relies on the theory of motor re-learning or task-specific training. Many studies have supported that task-specific training is useful in ambulation training in hemiparetic stroke patients<sup>(5-9)</sup>.

In 1995, Hesse et al<sup>(5)</sup> studied the effectiveness of ambulation training with partial body weight support compared with conventional physiotherapy by Bobath concept. They conducted an experimental study between two groups, single A-B-A case study design and allotted three weeks for each session. The study revealed that ambulation training with partial body weight support provided more benefit in gait restoration and walking speed with statistical significance, however, there were no statistically significant improvements of motor power and spasticity.

Then in 1997, Hesse et al<sup>(10)</sup> conducted another study and found that ambulation training with partial body weight support treadmill did not alter physiologic gait patterns of patients but stimulated balance training. Furthermore, ambulation training with partial body weight support treadmill led to 1,000 cycles of gait cycle when compared to conventional physiotherapy, where only 50 cycles were achieved in the same timing duration<sup>(11)</sup>. However, BWSTT requires two to three therapists per patient.

According to Cochrane review<sup>(12)</sup> published in August of 2017, ambulation training with body weight support in stroke patients improved walking capacity, especially in walking speed and walking endurance, specifically in stroke survivors who had more walking ability than non-ambulatory stroke patients. Corresponding with the recommendations from the American Heart Association and American Stroke Association<sup>(13)</sup> that classify ambulation training with body weight support as class IIb, this technique has been proven to yield more benefits than risk and may be recommended for stroke patients.

Recently, an anti-gravity treadmill<sup>(14)</sup>, a specialized treadmill with air supporting system to support the body weight of patients and reduce stress on lower limbs during gait training, has been developed<sup>(15)</sup>. The Air support system supports between 1% and 80% of the body weight. It makes it easier for patients to walk with less chances of injuries. Before training, patients are fitted with special pants tailor-made for this device. The U.S. Food and Drug Administration

(FDA) has cleared the G-trainer and it has been used for medical purposes since 2008<sup>(14)</sup>. Therefore, the anti-gravity treadmill is one medical device safely used for ambulation training in line with the principle of repetitive, task-specific training.

The anti-gravity treadmill has been used for rehabilitation in many diseases. For example, in 2014 Berthelsen et al<sup>(16)</sup> conducted a study about the use of anti-gravity treadmill for ambulation training in muscular dystrophy patients. They found that 10-weeks of anti-gravity treadmill training statistically improved walking capacity and balance when compared to before training without signs of muscular damage.

Up until now, there are no studies about anti-gravity treadmill training in stroke patients. The present research aimed to study the effect of ambulation training with anti-gravity treadmill combined with conventional physiotherapy on walking capacity and balance in hemiparetic stroke patients. Effect of training by whole gait analysis and patients' satisfaction of anti-gravity treadmill training were secondary outcomes in the present study. The assumption was ambulation training with anti-gravity treadmill combined with conventional physiotherapy improved walking capacity and balance in hemiparetic stroke patients more than conventional physiotherapy alone.

## **Materials and Methods**

### ***Research design***

The present study was an assessor-blinded randomized controlled trial.

### ***Population and sample***

Hemiparetic volunteer stroke patients who had ambulation problems and onset of stroke within one year were invited to join the study.

### ***Inclusion criteria***

1. First time diagnosis of either ischemic or hemorrhagic stroke
2. Evidence of stroke on imaging such as CT brain or MRI brain
3. Stable medical condition
4. Age less than 75 years old
5. Duration after onset between one month and one year
6. Able to stand and walk with or without gait aids and minimal assistance to under supervised level
7. No severe cognitive impairment

### **Exclusion criteria**

1. Patients who had orthopedic problem that interfered or inhibited ambulation
2. Predictable poor compliance
3. Unstable medical condition or exercise-contraindicated disease
4. Severe spasticity of both lower limbs or modified Ashworth scale of 3 or more
5. Joint contracture or amputee or active wound of lower limbs
6. History of arthritis of lower limbs in the past six months
7. Unable to walk prior to stroke onset
8. Peripheral arterial disease
9. SBP of greater than 200 mmHg and/or DBP of greater than 110 mmHg at resting period
10. History of severe osteoporosis.

### **Data collection and methods**

The present research was approved from the Institutional Review Board (IRB) of Faculty of Medicine, Chulalongkorn University, IRB Number 160/59. Volunteer stroke patients admitted at the Thai Red Cross Rehabilitation Center were recruited according to inclusion and exclusion criteria. After patients received information regarding to the research, consent forms were signed. Baseline data consisting of sex, age, type of stroke, side of lesion, onset, duration after onset, motor power, spasticity, and vital signs were collected.

Before starting the program, all volunteers would undergo a first whole gait analysis, computerized balance test, six-minute walk test<sup>(17,18)</sup>, and functional ambulatory category (FAC)<sup>(19,20)</sup> by an assessor at the Gait Laboratory, Faculty of Medicine, Chulalongkorn University. Then, randomization was done by block randomization technique.

The control group received a conventional physiotherapy program of five days per week, which consisted of 1) range of motion and strengthening exercise for 30 minutes, 2) gross motor function for 30 minutes, 3) balance training for 30 minutes, and 4) ambulation training for 60 minutes.

The intervention group received anti-gravity treadmill training combined with conventional physiotherapy of five days per week consisting of 1) range of motion and strengthening exercise for 30 minutes, 2) gross motor function for 30 minutes, 3) balance training for 30 minutes, 4) ambulation training for 30 minutes, and 5) anti-gravity treadmill training for 30 minutes.

Furthermore, both groups were provided with

other rehabilitation programs as the standard.

After one month of training, all volunteers underwent a second whole gait analysis, computerized balance test, six-minute walk test, and FAC by an assessor at the Gait Laboratory, Faculty of Medicine, Chulalongkorn University. The 5-level satisfaction scale was used in intervention group. Volunteers who had less than 80% of duration of training or needed to discontinue the study were considered as drop out.

### **Ambulation training by anti-gravity treadmill**

All subjects are required to wear special pants tailor-made for the anti-gravity treadmill. Then, the therapist proceeded to set up the training program. At first, the air supporting system released air around the subjects' lower limb area to support their body weight. In the present research, the authors' set body weight support at 50% of body weight for each subject with start speed of 0.1 m/second. The treadmill speed was gradually increased until reaching maximum walking capacity of each patient without losing lower limbs and treadmill track coordination. The ambulation training by anti-gravity treadmill program duration was set at 30 minutes per day and five days per week with a total of 20 sessions.

### **Randomization and binding technique**

Block randomization technique was used to divide volunteers into two groups. Sealed envelopes that contained the group number were sent to the physiotherapist. Then, all volunteer patients were allocated appropriate training according to their groups. Assessors in the present research were experienced gait laboratory therapists. The assessors were unaware of the volunteer patient classification. However, blinding of the intervention and the subjects could not be performed. For the researchers, all the data were revealed in the analytic process.

### **Outcome measurement**

Primary outcomes were six-minute walk distance (6MWD), FAC scale, and path length measured from computerized balance test<sup>(21)</sup>. Secondary outcomes were maximum voluntary isometric contraction (MVIC), root mean square or RMS<sub>average</sub> of each muscle in paretic limb from whole gait analysis<sup>(22,23)</sup>, and satisfaction of ambulation training by anti-gravity treadmill.

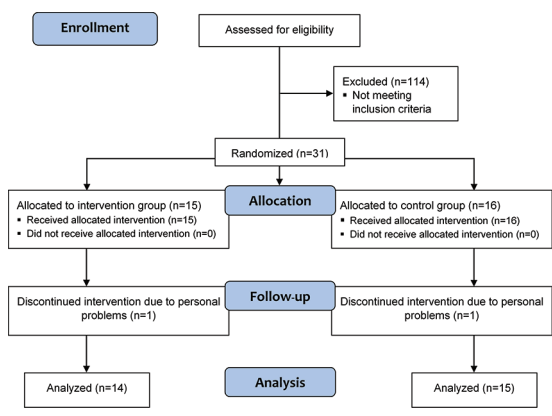
### **Sample size**

From all the literature reviewed, there were no previous studies about anti-gravity treadmill training

**Table 1.** Baseline characteristics

Variable	Intervention group (n=15) n (%)	Control group (n=16) n (%)	p-value
Age (years), Mean±SD	59.67±9.76	56±14.20	0.410
Sex			0.610
Male	11 (73.3)	13 (81.3)	
Female	4 (26.7)	3 (18.8)	
Diagnosis			0.910
Ischemic	10 (66.7)	11 (68.8)	
Hemorrhagic	5 (33.3)	5 (33.3)	
Side of lesion: right	8 (53.3)	11 (68.8)	0.390
Duration after onset (months), Mean±SD	4±3.27	3.25±2.08	0.450
Total score of MAS of affected leg, Mean±SD	1.07±0.34	1.04±0.31	0.520
FAC, Median (min, max)	4 (2, 5)	3 (2, 5)	0.090
Rest HR, Mean±SD	77.5±7.8	74.5±5.9	0.240
Rest SBP, Mean±SD	118±33.7	121.3±15.4	0.540
Rest DBP, Mean±SD	75.3±9.9	76.8±9.5	0.660

MAS=modified Ashworth scale; FAC=functional ambulation category; HR=heart rate; SBP=systolic blood pressure; DBP=diastolic blood pressure; SD=standard deviation



**Figure 1.** CONSORT 2010 flow diagram.

in stroke patients. The authors’ calculated sample size using Kumthornthip et al<sup>(8)</sup> study of the effectiveness of body weight supported treadmill training with a driven gait orthosis (Lokomat®) in stroke patients during rehabilitation phase: pilot study, by using the formula of two independent groups, confidence interval at 95% and power at 90%. After completing the calculations, 14 participants were needed for each group, thus 28 participants were invited to the study.

**Data analysis**

The present research was analyzed by intention

to treat analysis and last observation carried forward technique. SPSS version 22 was used for data analysis. Baseline characteristics were calculated by independent t-test and chi-square test. Within the group comparison, data were analyzed by paired t-test and Wilcoxon signed rank test. Between groups comparison was calculated by independent t-test and Mann Whitney U test. Patients’ satisfaction and adverse events were shown in numbers and percentages. Level of statistical significance was p-value of less than 0.050.

**Results**

Thirty-one volunteer-patients participated in the present study. They were randomized into two groups with 15 in the intervention group and 16 in the control group. One patient from each group dropped out due to personal issues (Figure 1). All baseline characteristics including sex, age, type of stroke, side of lesion, onset, duration after onset, motor power, spasticity and vital signs revealed no statistically significant difference between the two groups as shown in Table 1.

**Within the group comparison**

In the intervention group, the path length when standing with eyes closed measured from computerized balance test was significantly decreased after training. The path length when standing with

**Table 2.** Path length when standing eyes closed and eyes opened within and between group comparison, path length shown in millimeters

Balance test	Intervention group (n=15) Mean±SD	Control group (n=16) Mean±SD	p-value between group
Eye close			0.026*
Path length before training	2,982.24±413.68	2,805.93±332.47	
Path length after training	2,892.69±402.92	2,840.72±370.74	
p-value within group	0.050	0.300	
Eye open			0.310
Path length before training	2,923.59±420.85	2,753.34±335.52	
Path length after training	2,887.82±416.83	2,775.52±399.83	
p-value within group	0.400	0.560	

SD=standard deviation

\* Statistical significance,  $p < 0.050$

**Table 3.** 6MWD and FAC within and between group comparison, 6MWD shown in meters

Walking capacity	Intervention group (n=15)	Control group (n=16)	p-value between group
6MWD (m), Mean±SEM			
6MWD before training	88.25±18.3	67.79±9.3	0.330
6MWD after training	116.49±18.4	103.60±18.9	0.690
p-value within group	0.001*	0.028*	
6MWD change (after to before training)	28.24	32.86	0.730
FAC, Median (min, max)			0.780
FAC before training	4 (2, 5)	3 (2, 5)	
FAC after training	4 (2, 5)	4 (2, 5)	
p-value within group	0.010*	0.004*	

6MWD=six-minute walk distance; FAC=functional ambulation category; SEM=standard error of mean

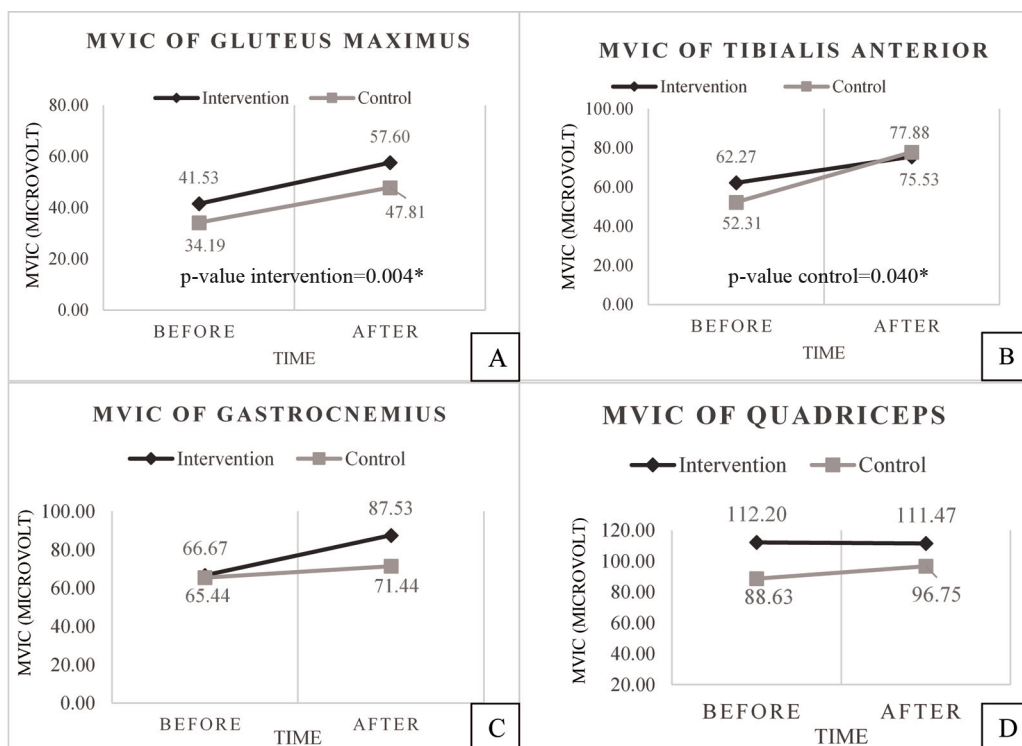
\* Statistical significance,  $p < 0.050$

eyes opened measured from computerized balance test showed no statistical difference after training, as shown in Table 2. In terms of the 6MWD, statistical significance increased after training to 28.24 m at  $p=0.001$  as shown in Table 3. Corresponding with the level of FAC, statistical significance increased after training in intervention group with  $p=0.010$ , as shown in Table 3. Dynamic surface electromyography (EMG) study showed MVIC of gluteus maximus muscles was statistically significantly improved after training at about 17.21 microvolts ( $p=0.004$ ) as seen in Figure 2A. There was improvement of MVIC in other tested muscles, however, no statistical significance was found (Figure 2B-D). Likewise, results also showed that  $RMS_{average}$  of all tested muscles were improved after training but not to a statistical significance level.

In the control group, 6MWD showed a statistically significance of improvement about 32.86 m at  $p=0.001$  (Table 3). The dynamic surface EMG study also revealed that MVIC of tibialis anterior muscles had statistically significant improvement after training at about 25.56 microvolts with  $p=0.041$  (Figure 2B). The level of FAC was also found to have statistical significance at  $p=0.004$  (Table 3). Considering the path length, there was no statistical significance improvement (Table 2). MVIC and  $RMS_{average}$  of all tested muscles were improved after training but not to a statistical significance as seen in Figure 2A, C, and D.

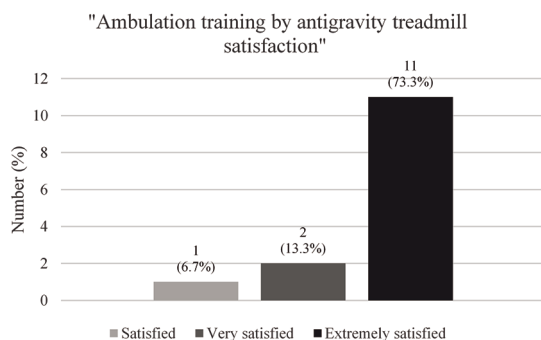
#### **Between group comparison**

There was statistically significant improvement



**Figure 2.** MVIC of all recorded muscles within and between group comparison.

\* Statistical significance,  $p < 0.050$



**Figure 3.** Satisfaction about “ambulation training by antigravity treadmill” in intervention group (n=14).

of path length when standing eyes closed in the intervention group when compared with the control group at  $p = 0.026$ , as seen in Table 2. Regardless, no significant difference of path length was found when standing with eyes opened, 6MWD, FAC, MVIC, and  $RMS_{average}$  of all tested muscles.

In the intervention group, the average satisfaction score was  $4.7 \pm 0.61$  from 5-level satisfaction scale as demonstrated in Figure 2. At the end of the study, no serious adverse events were reported.

## Discussion

From all literature review, this is the first randomized controlled trial that studied ambulation training by anti-gravity treadmill in stroke patients. The results of the present study corresponds with previous studies in the other diseases. For example, the study by Berthelsen et al<sup>(16)</sup> in 2014 reported significant improvements in walking capacity and dynamic balance found in anti-gravity training in patients with muscular dystrophy. In 2015, Malling and Jensen<sup>(24)</sup> studied Parkinson patients, and revealed that 8-week anti-gravity treadmill training improved dynamic standing balance. Many other emerging studies reported many benefits of anti-gravity treadmill training. Melbourn et al<sup>(25)</sup> in 2017, trained multiple sclerosis patients with anti-gravity treadmill for nine weeks and found benefits in muscle strength, ambulation, and balance. However, the present study is only a case report. The other preliminary studies in nine cerebral palsy patients from Kurz et al<sup>(26)</sup> in 2011 reported that six weeks of ambulation training by anti-gravity treadmill significantly improved walking speed, strength of lower extremities, and balance.

As mentioned above, the principle of BWSTT is motor re-learning or task-specific training leads

to brain re-organization. It stimulates central pattern generators that control ability to ambulate<sup>(5-9)</sup>. From the present study, the improvement of 6MWD could be explained from transfer effect. Ambulation training by anti-gravity treadmill improved ambulation performance either while training or after training when transferred to over-ground walking. Results showed 28.24 m of improvement of 6MWD in the intervention group versus 32.86 m in the control group. The lesser 6MWD of the intervention group maybe because of inadequate training duration. In fact, the control group was more compatible with real task-specific training. In the next study, the authors recommended more duration of training. This may help patients reach faster speeds of training than in this current study to yield different 6MWD results. The 6MWD of both groups in the present study did not reach minimal clinically important difference (MCID), as reported at 34.4 m from Tang et al<sup>(27)</sup> in 2012. However, they carried out their studied in the late recovery phase of stroke patients and had already trained for three months.

In terms of balance training, the significance of balance improvement may be explained from paralyzed patients who had limitations in moving their center of mass<sup>(16)</sup>. Anti-gravity treadmill helped make weightbearing easier on the affected side, improved patients' confidence, and helped transfer all the effect when switching to over-ground ambulation. Malling and Jensen<sup>(24)</sup> proposed that intensive ambulation training in people with gait impairment increased risk of falling. Therefore, the anti-gravity treadmill may be a safer treatment for advance gait and balance training.

Up until now, there is no definite protocol for anti-gravity treadmill training in stroke patients. In the present study, the authors used the studies of Hesse et al<sup>(10)</sup> in 1997 and Crompton et al<sup>(28)</sup> in 2001 as references. They reported that if supporting less than 30% body weight would lead to nearly physiologic walking, but weak patients required more, typically ranging between 0% to 50% of body weight support. In cases where supporting more than 50% of body weight, it would lead to a toe walking pattern. Therefore, the present study started at 50% of body weight support in all patients, and aimed at a speed goal first, then tried to reduce the body weight support later.

As for treadmill speed, the authors used Franceschini et al<sup>(29)</sup> in 2009 as the reference. They conducted the randomized controlled trial of 97 stroke patients to compare between BWSTT combined with conventional physiotherapy versus conventional

physiotherapy alone. Starting treadmill speed was at 0.1 m/second and the speed was adjusted as fast as possible to the point where patients still had adequate step length and swing phase of the affected leg. Lastly, patients' walking speed had to be consistent with treadmill speed<sup>(28)</sup>. After six weeks of training, motor power, balance, FAC, 10-minute walk test, and 6MWD were improved but with no statistical difference between the two groups. These results supported that BWSTT was indeed safe for stroke patients. In the present study, maximum speed was only at 0.8 m/second. This could be explained by inadequate treadmill training duration, therefore, in the future studies, the authors aim to increase time of treadmill training to promote more repetition and task specific training to create more effective motor re-learning. However, a study reported that 0.16 m/second improvement of walking speed in subacute stroke patients revealed clinical significance<sup>(30)</sup>. There are some limitations in the present study. First, all the outcomes were the result of a combined effect of ambulation training by anti-gravity treadmill combined with conventional physiotherapy. The authors intended to train patients according to the combination of new intervention, anti-gravity treadmill, and conventional physiotherapy, because no study had totally confirmed about benefits of anti-gravity treadmill in stroke patients before. In the future, the authors recommended a comparison between ambulation training by anti-gravity treadmill alone and conventional physiotherapy to exactly identify results and efficacy of the training. The other limitation was lack of long-term follow-up. All outcomes were followed up in short-term periods after training was completed. However, long-term effects also depend on many other factors. At the end of the present study, the authors evaluated patients' satisfaction after anti-gravity treadmill training. The results showed that most patients were extremely satisfied with the anti-gravity treadmill. The anti-gravity treadmill motivated patients in ambulation training, improved patients' self-esteem, and confidence.

Finally, the present research is one of the important steps for rehabilitation in stroke patients, because it is the first randomized controlled trial about ambulation training by anti-gravity treadmill. The authors hope that the present study will be useful to all patients in the future.

## Conclusion

As the result of a 1-month training, both intervention and control groups revealed the

improvements of standing balance, motor power, 6MWD, and FAC scale in subacute to chronic hemiparetic stroke patients within one year after onset. Furthermore, in the present study, ambulation training by anti-gravity treadmill combined with conventional physiotherapy seems to be superior to conventional physiotherapy alone in balance training. Lastly, the anti-gravity treadmill is another safe rehabilitative medical device to help patients improve clinical outcomes.

### What is already known on this topic?

Gait restoration has been one of the most important goals in non-ambulatory hemiparetic stroke patients. Gait training by BWSTT relies on the theory of motor re-learning or task-specific training provides benefits in stroke patients. U.S. FDA has cleared that G-trainer should be used for medical purposes since 2008.

### What this study adds?

Ambulation training by anti-gravity treadmill combined with conventional physiotherapy provides better outcomes compared with conventional physiotherapy alone in balance training for subacute to chronic hemiparetic stroke patients. Additionally, anti-gravity treadmill is another safe rehabilitative medical device.

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### Conflicts of interest

The authors declare no conflict of interest.

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