

# Different weight shift trainings can improve the balance performance of patients with a chronic stroke

## A randomized controlled trial

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### Abstract

**Background:** Improving balance ability, increasing walking ability, and reducing the occurrence of falls are important objectives in the rehabilitation of stroke patients. Do the posture balance training and the intervention of lateral wedge insoles to improve of balance function and increase walking ability in patients with a chronic stroke?

**Methods:** A randomized, controlled trial with concealed allocation, intention-to-treat analysis, and blinded assessors. Participants who had a chronic stroke (onset >6 months) were recruited from the rehabilitation and neurology departments of a hospital in central Taiwan. Subjects were divided into 3 groups: a visual biofeedback balance training group, a lateral wedge group, and a control group; apart from their usual rehabilitation program, and both experimental groups received a 6-week training session program. The primary outcome was the balance computerized adaptive test (balance CAT), and secondary outcome was timed up and go (TUG) test. All subjects were evaluated at the baseline, posttraining (6-week), 1st follow-up (10-week), and 2nd follow-up (18-week).

**Results:** A total of 56 subjects were participated in this study, including 38 males and 18 females. The mean age of the subjects was 59.1 years old, and the mean time was 43.7 months after the onset of the stroke. This study found the interaction in groups and measurement time points reached statistical significance of the balance CAT and TUG test ( $F=5.740, P<.001$ ;  $F=2.926, P=.011$ ; respectively). In addition, the performance of both the visual biofeedback training and lateral wedge group was superior to that of the control group.

**Conclusion:** Six-week visual biofeedback training and intervention of 5° lateral wedge insoles can improve the balance ability of patients with a chronic stroke.

**Trial registry:** <http://www.chictr.org.cn>, ChiCTR-IPR-15007092.

**Abbreviations:** ANOVA = analysis of variance, balance CAT = balance computerized adaptive test, BT = balance training, CI = confidence interval, CIMT = constraint-induced movement therapy, LW = lateral wedge, TUG = timed up and go.

**Keywords:** outcome assessment, postural balance, rehabilitation, stroke

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WCL and CLL contributed equally to the study as first authors.

This study protocol was approved by the institutional review board of Jianan Mental Hospital (IRB no: 12-039), and the registration number of the clinical trial was ChiCTR-IPR-15007092. All participants gave written informed consent before data collection began.

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## 1. Introduction

Patients with stroke usually become complicated with sensory and motor dysfunctions. Although most patients are able to experience spontaneous recovery within 6 months after the onset and rehabilitation training can achieve a plain period of functional recovery, research data show that approximately 35% of patients with a chronic stroke still may be unable to stand and experience poor standing balance, asymmetric weight distribution, impaired weight shifting ability, or gait abnormality.<sup>[1,2]</sup> The risk of falls for patients may even increase, their daily living function may be reduced, or they may need assistance from others to complete daily living activities.<sup>[3–5]</sup> Therefore, one of the important objectives of rehabilitation in patients with stroke is to improve their balance and gait and to reduce the risk of falls.<sup>[6–8]</sup>

Past studies indicated that the use of visual biofeedback training to train stroke patients can significantly improve the weight bearing of the affected side, posture control, and balance ability in stroke patients, as well as reduce shaking during the standing posture.<sup>[9–11]</sup> To avoid and prevent learned non-use, Taub et al (1993) proposed the therapeutic mechanism of constraint-induced movement therapy (CIMT). The movements of a person's healthy side are limited, and the affected side

extremities forced to be used, and received continuous and long-term training.<sup>[12]</sup> Previous studies showed the upper limb of affected side was forced to receive functional training for 6 to 8 hours every day to improve the movement quality and functional ability and to reduce the time required to complete the activities.<sup>[13,14]</sup> CIMT can also achieve efficacy in patients with chronic stroke, a subsequent follow-up found that efficacy can be maintained for up to 6 months and even 2 years.<sup>[13,14]</sup>

In our knowledge, there are few studies applied the CIMT for lower limbs of patients with stroke. Such studies focused on the intervention of posture for weight bearing, such as standing and walking posture, which aim to force the use of the lower limb of the affected side and to shift the center of gravity to the affected side, and to symmetrically distribute the weight bearing in patients with stroke. The method is to enable patients to wear a lateral wedge insole or increase the height of shoe in the healthy side to improve the asymmetrical distribution of the center of gravity.<sup>[15,16]</sup> Past studies indicated that the placement of a lateral wedge insole at the lower limb of the healthy side of patients with stroke can force the use of the affected side which increases the weight bearing of the lower limb of the affected side and thus increases the ability to weight shifting and improved balance.<sup>[16–18]</sup>

Based on the research findings above, the application of visual biofeedback training and lateral wedge insole can significantly improve the weight bearing of stroke patients' affected side, posture control, and balance ability. However, the sample size in relevant past studies was insufficient or the convenience sampling method was used.<sup>[16–18]</sup> Although a few studies employed randomized control trials, their theoretical foundation was still insufficient. Moreover, most studies on the use of lateral wedge insole discussed short-term intervention and the immediate effects in patients with stroke.<sup>[16–18]</sup> Therefore, it is necessary to further investigate the application of these 2 intervention methods to the training of patients with a chronic stroke. This study utilizes 2 intervention methods to target to effectively improve the balance ability in patients with a chronic stroke and whether efficacy can be maintained for a period of time.

## 2. Materials and methods

A 3-arm, single-blind (the evaluator), randomized controlled trial was conducted, with the flow diagram shown as Figure 1. The research project was conducted according to the Declaration of Helsinki and was approved by the hospital's Institutional Review Board for research involving human subjects. The clinical trial

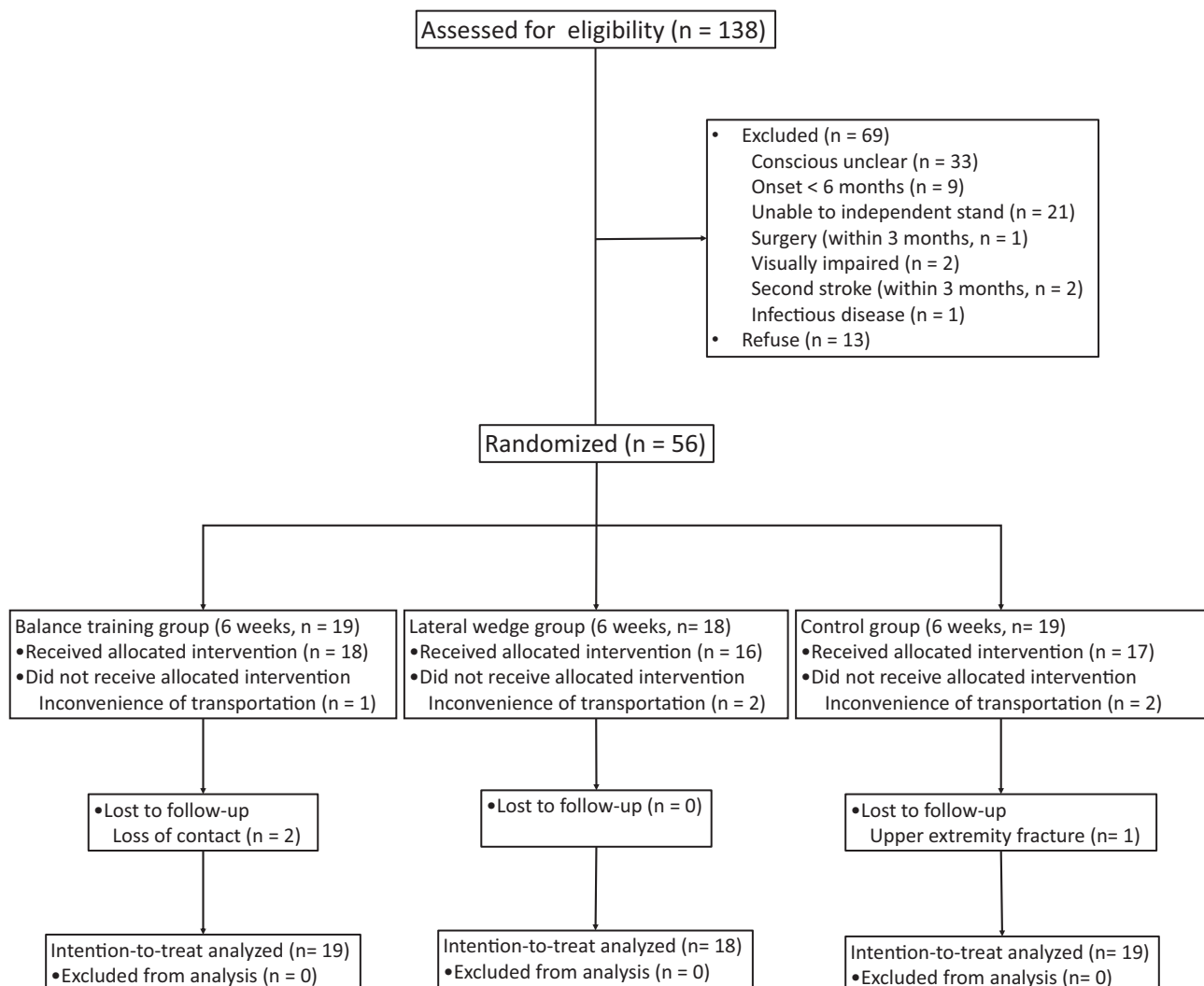


Figure 1. Study flow diagram.

registered number was ChiCTR-IPR-15007092. All of the participants received oral and written explanations of the objective and procedure of the study in his native language; those who agreed to participate were asked to sign an informed consent form and were entered into this study.

### 2.1. Participants

Participants were recruited from the rehabilitation and neurology departments of hospitals in central Taiwan from August 2013 to August 2014. The inclusion criteria were: experienced a single ischemic or hemorrhagic stroke in the cerebral hemisphere, as determined through computed tomography or magnetic resonance imaging; were >6 months poststroke onset, with diagnostic codes of the International Classification of Diseases, Ninth Revision (ICD-9) of 430-, 431-, 432-, 434-, 437-, 438-, etc; had a mini-mental state examination score >23 and able to follow verbal instructions; undergoing rehabilitation program activities at least once a week; and able to use aides to walk or can independently walk for more than 10 meters. The exclusion criteria were: a history of dizziness; experienced dizziness when changing posture or unable to maintain a standing posture balance; unable to identify a screen caused by visual disorder or poor vision; had undergone any surgery for treatment within 3 months; and a history of other neurological or orthopedic diseases that may affect balance ability.

### 2.2. Randomization and blinding

Each participant was asked to draw a folded piece of paper marked with a computer-generated random number from a box. Participants were assigned to groups per the number drawn. The trial was initiated immediately following group assignment. The assessors who evaluated patients were blinded to the group assignments.

### 2.3. Sample size estimation

The sample size calculation was determined using G-Power 3.1 (University of Kiel, Germany), based on an effect size  $f=0.25$  (medium effect size) and a statistical power of 0.95 (3 groups, 4 measurement times) with a repeated measures of analysis of variance (ANOVA) method (within-between interaction), and expected had a 20% attrition rate. A total of 56 participants were required for this study.

### 2.4. Intervention

The subjects were randomly divided into 3 groups (2 experimental groups: balance training group [BT] and lateral wedge group [LW]; and 1 control group), apart from their usual rehabilitation program; both experimental groups received a 6-week training session. The BT group received the weight shift training using the Biodex Balance System, as well as received visual biofeedback balance training (including 8 directions: front, back, left, right, left oblique front, right oblique front, left oblique rear, and right oblique rear). The training period was 20 minutes each time for 6 consecutive weeks, and the subjects received 3 times of balance training every week. The LW group used a 5° lateral wedge insole placed in the shoe of their healthy side for usual standing and walking for a total of 6 weeks. The control group only received routine rehabilitation program and did not receive any additional intervention.

### 2.5. Outcome measures

Outcome measures were taken at the baseline, after 6 weeks of training, at 10 weeks, and at 18 weeks following the study's beginning. All assessments were performed by a trained physical therapist who was blinded to the participants' allocation. Each participant was assessed by the same evaluator throughout the study.

The primary outcome was the balance computerized adaptive test (balance CAT), developed by Hsueh et al (2010).<sup>[19]</sup> It has been applied to the balance test of stroke patients. A balance item pool (41 items) was developed on the basis of predefined balance concepts, expert opinions, and field testing, including: posture shift, sitting posture balance, and standing posture balance. The highest total score of balance CAT is 10 points, and the lowest score is 0 points. The higher the score is, the better the balance ability is. The Pearson  $r$  value between the scores of the balance CAT and Berg balance scale was 0.90.<sup>[20]</sup> The test-retest reliabilities of the scores of the balance CAT (Pearson  $r=0.92$ ) were excellent.<sup>[21]</sup>

The secondary outcome measured was the timed up and go (TUG) test, which was 1st developed by Mathias et al (1986).<sup>[22]</sup> In 1991, it was modified by Podsiadlo and Richardson<sup>[23]</sup> and has been used until the present date. It is a simple and rapid functional mobility test, which can concurrently measure basic movement and balance abilities. The method is to mark a 3-meter distance with one side having a chair without armrest. The subject is requested to sit on the chair and complete the walking with a fast and safe speed. The total time it takes for the subject to stand up, walk for 3 meters to the marked end, turn back, walk back, and sit back on the chair is calculated. Ng et al and de Oliveira et al indicated in 2005 and 2008, respectively, that the test-retest reliability of standing up and walking test in patients with stroke is 0.95. The reliability of TUG is good.<sup>[24,25]</sup>

### 2.6. Statistical analysis

Data analysis was carried out using SPSS 14.0, and baseline characteristics were compared between groups using 1-way ANOVA and the Chi-squared test. For all outcome measures, intention-to-treat analysis was performed using the last observation carried forward method to account for missing data. The repeated measures of ANOVA were used to assess the intervention effects between groups. Alpha was set at 0.05, and the 95% confidence interval (CI) was calculated. If a significant difference was detected, then post hoc tests with the Scheffe method were conducted. The effect size between groups was calculated as partial eta-square ( $\eta^2$ ). The criteria for judging the estimated effect size were as follows: a large effect size was 0.14 or more, a medium effect size was 0.06 to 0.13, and a small effect size was 0.01 to 0.05.<sup>[26]</sup> The effect sizes within a group between different measure times were calculated as Cohen  $d$ , which is defined as the absolute difference between 2 means divided by a standard deviation for the data. An effect size ( $d$ ) > 0.8 is usually considered large; 0.5 to 0.8, medium; and 0.2 to 0.5, small.<sup>[26]</sup>

### 3. Results

This study's enrolled subjects came from Taichung Hospital, Ministry of Health and Welfare in Taiwan. During the enrollment period, a total of 138 outpatients and inpatients were diagnosed with a stroke using imaging examination by physicians. Sixty-nine of them were excluded from this study due

**Table 1**  
Baseline characteristics.

	BT (N=19)	LW (N=18)	Control (N=19)	P-value*
Age, y	59.21 ± 8.36	60.33 ± 8.00	57.79 ± 11.07	.706
Gender (male/female)	13/6	13/5	12/7	.838 <sup>†</sup>
Stroke type (hemorrhage/infarction)	9/10	10/8	7/12	.519 <sup>†</sup>
Affected side (right/left)	12/7	11/7	13/6	.891 <sup>†</sup>
Brunnstrom stroke recovery stage (L/E) III/IV/V	2/11/6	2/8/8	3/11/5	.808 <sup>†</sup>
Post-stroke onset, mo	42.66 ± 38.06	45.11 ± 32.96	43.68 ± 29.22	.976
Height, cm	163.74 ± 7.26	164.11 ± 6.76	164.05 ± 6.44	.984
Weight, kg	66.43 ± 12.26	70.83 ± 9.81	67.42 ± 12.73	.493
Body mass index	24.72 ± 3.91	26.40 ± 3.93	25.00 ± 4.25	.410
Balance CAT	7.41 ± 1.12	7.49 ± 0.90	7.42 ± 1.09	.969
Timed up and go test, s	26.17 ± 13.85	24.45 ± 8.55	25.06 ± 13.92	.912

Balance CAT = balance computerized adaptive test, BT = balance training group, L/E = lower extremity, LW = lateral wedge group.

\* Analyzed by 1-way analysis of variance.

<sup>†</sup> Analyzed by Chi-squared test.

to a failure to meet the inclusion criteria and 13 subjects refused to take part in this study. During the enrollment period, a total of 56 subjects met the inclusion criteria (19 subjects in the BT group, 18 subjects in the LW group, and 19 subjects in the control group). Eight subjects withdrew from the study, and a total of 48 subjects completed the 18-week subsequent follow-up (16 subjects in the BT group, 16 subjects in the LW group, and 16 subjects in the control group).

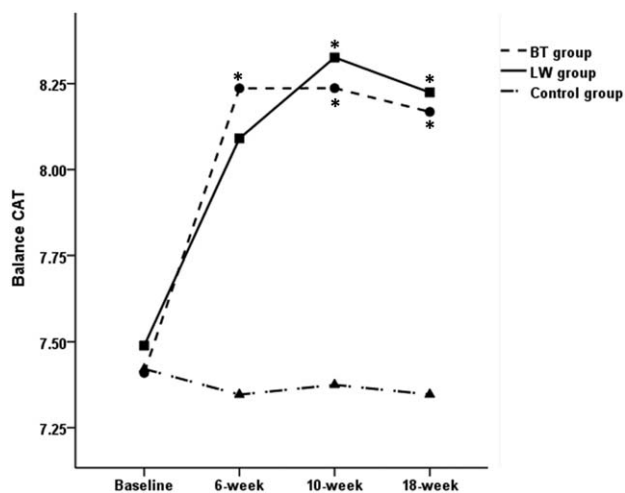
This study used intention-to-treat analysis to include the data of 56 subjects in the analysis, as shown in Figure 1. The mean age of all subjects was 59.08 ± 9.16 years old, the mean height was 163.96 ± 6.71 cm, the mean weight was 68.18 ± 11.64 kg, the mean body mass index was 25.35 ± 4.03, and the mean time of receiving rehabilitation after the stroke was 43.79 ± 33.02 months. A total of 38 males and 18 females participated in this study. There was no significant difference between groups in the baseline data ( $P > .05$ , as shown in Table 1).

There was a significant interaction between the measurement time point and the group, as reflected in the 4 measurement time points of balance CAT among 3 groups;  $F = 5.740$ ,  $P < .001$ , and effect size is large ( $\eta^2 = 0.252$ ). The performances of 2 groups, BT

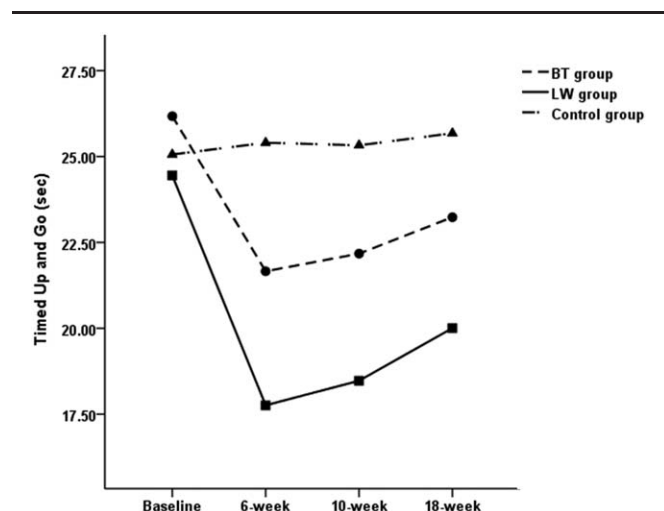
and LW, at 3 measurement time points, weeks 6, 10, and 18, were superior to that of the control group. However, there was no significant difference between the BT and LW groups (as shown in Fig. 2). There was a significant interaction between the measurement time point and the group, as reflected in the 4 measurement time points of the TUG test among 3 groups;  $F = 2.926$ ,  $P = .011$ , and effect size is large ( $\eta^2 = 0.147$ ). The performances of 2 groups, BT and LW, at 3 measurement time points, weeks 6, 10, and 18, were superior to that of control group. However, there was no significant difference between the BT and LW groups (as shown in Fig. 3).

For the change in each measurement time point of the BT group in the balance CAT, the comparison with the baseline showed that the effect sizes ( $d$ ) at weeks 6, 10, and 18 were 1.40, 1.37, and 1.15, respectively. The training efficacy could last to week 18. For the change in each measurement time point of the LW, the comparison with the baseline showed that the effect sizes ( $d$ ) at weeks 6, 10, and 18 were 0.96, 1.28, and 1.10, respectively. The training efficacy could also last to week 18. The effect sizes of the control group were 0.22, 0.13, and 0.22, respectively, and the change was not significant (as shown in Table 2).

For the change in each measurement time point of the BT group in the TUG test, the comparison with the baseline showed that the



**Figure 2.** Test results for balance computerized adaptive test of the 3 groups. \* Denotes having had a statistically significant difference in the BT and LW groups versus the control group ( $P < .05$ ); test by the Scheffe method.



**Figure 3.** Test results for timed up and go test of the 3 groups.

**Table 2**  
**Comparison of the effect size of the outcome measures within groups.**

	Balance CAT			TUG		
	BT	LW	Control	BT	LW	Control
Baseline to 6 wk	-0.83 (-1.11, -0.54)	-0.60 (-0.91, -0.29)	0.07 (-0.09, 0.24)	4.51 (1.71, 7.32)	6.69 (4.28, 9.11)	-0.34 (-2.31, 1.62)
Mean difference (95% CI)						
T-value, effect size ( <i>d</i> )	-6.089*, 1.40	-4.087*, 0.96	0.962, 0.22	3.382*, 0.78	5.857*, 1.38	-0.366, 0.08
Baseline to 10 wk	-0.83 (-1.12, -0.54)	-0.84 (-1.16, -0.51)	0.05 (-0.13, 0.22)	4.00 (1.50, 6.50)	5.98 (3.63, 8.33)	-0.27 (-2.17, 1.63)
Mean difference (95% CI)						
T-value, effect size ( <i>d</i> )	-5.972*, 1.37	-5.421*, 1.28	0.553, 0.13	3.357*, 0.77	5.374*, 1.27	-0.296, 0.07
Baseline to 18 wk	-0.76 (-1.08, -0.44)	-0.74 (-1.07, -0.40)	0.07 (-0.09, 0.24)	2.94 (0.55, 5.33)	4.45 (2.55, 6.35)	-0.62 (-2.37, 1.14)
Mean difference (95% CI)						
T-value, effect size ( <i>d</i> )	-5.027*, 1.15	-4.684*, 1.10	0.958, 0.22	2.584*, 0.59	4.935*, 1.16	-0.74, 0.17
6 to 10 wk	-0.00 (-0.17, 0.16)	-0.24 (-0.56, 0.09)	-0.03 (-0.15, 0.09)	-0.51 (-1.65, 0.62)	-0.72 (-1.94, 0.51)	0.08 (-0.46, 0.62)
Mean difference (95% CI)						
T-value, effect size ( <i>d</i> )	-0.007, 0.00	-1.54, 0.36	-0.496, 0.11	-0.951, 0.22	-1.235, 0.29	0.293, 0.07
6 to 18 wk	0.07 (-0.12, 0.26)	-0.13 (-0.49, 0.23)	0.00 (-0.11, 0.10)	-1.57 (-3.69, 0.54)	-2.25 (-3.09, -1.40)	-0.28 (-1.11, 0.55)
Mean difference (95% CI)						
T-value, effect size ( <i>d</i> )	0.744, 0.17	-0.782, 0.18	-0.011, 0.00	-1.562, 0.36	-5.600*, 1.32	-0.697, 0.16
10 to 18 wk	0.07 (-0.03, 0.17)	0.10 (-0.02, 0.22)	0.03 (-0.03, 0.09)	-1.06 (-2.43, 0.31)	-1.53 (-2.79, -0.28)	-0.35 (-1.16, 0.45)
Mean difference (95% CI)						
T-value, effect size ( <i>d</i> )	1.455, 0.33	1.834, 0.43	1.000, 0.23	-1.623, 0.37	-2.578*, 0.61	-0.915, 0.21

Balance CAT=balance computerized adaptive test, BT=balance training group, CI=confidence interval, LW=lateral wedge group, TUG=timed up and go test.

The values of mean difference were given as the change of 2 measures (95% CI).

\*  $P < .05$ , analyzed by paired *T* test.

effect sizes (*d*) at weeks 6, 10, and 18 were 0.78, 0.77, and 0.59, respectively. The training efficacy could last to week 18. For the change in each measurement time point of the LW, the comparison with the baseline showed that the effect sizes (*d*) at weeks 6, 10, and 18 were 1.38, 1.27, and 1.16, respectively. The training efficacy could also last to week 18. The effect sizes of the control group were 0.08, 0.07, and 0.17, respectively, and the change was not significant (as shown in Table 2).

#### 4. Discussion

This study is the 1st to investigate the influence of using 2 different weight shift training methods on the balance function of patients with stroke and performing a long-term subsequent efficacy follow-up. Past studies never used balance CAT for the evaluation of visual biofeedback balance training and intervention of lateral wedge insoles. The BT group's score increased from 7.41 to 8.24 points, suggesting that the patients progressed from jumping with both feet to jumping with the healthy side alone (1 foot) for 1 to 4 times, and they could still maintain it in the subsequent follow-up at week 10. The LW group's score also increased from 7.49 to 8.33 points, the patients could still maintain their balance ability, and the score even increased to 8.22 points in the subsequent follow-up. The functional performance results showed that the subjects' balance ability indeed improved.

The TUG test evaluation found that the number of seconds for the subjects in the BT and LW groups decreased, suggesting that the dynamic shift ability of these subjects improved after the training. However, the difference between them and the control group did not reach statistical significance. This result is similar to that of past studies on visual biofeedback balance training, although the standing balance can improve, patients' dynamic shift performance or walking does not directly improve.<sup>[27,28]</sup> The results showed that the placement of insoles at the affected side did not significantly impact gait performance. When the insoles were placed at the healthy side, the patients' gait was more

symmetric, but their walking speed did not improve.<sup>[17]</sup> The reason might be that the mean time of receiving rehabilitation of the subjects in our study was 4.8 years after the onset of the stroke. Their gait patterns were extremely fixed, and it was very difficult to significantly change.

Rodriguez and Aruin found that the weight bearing symmetric of lateral wedge insole at the healthy side was better than that of height increase insoles.<sup>[16]</sup> Pierrynowski and Smith (1996) indicated that there is a 5° eversion in the subtalar joint of normal people during passive activity. During the entire gait cycle, a 7.2° eversion is experienced by 44% of the people.<sup>[29]</sup> Rodriguez and Aruin (2002) found that the use of intervention of 5° lateral wedge insoles can generate a very good symmetric weight bearing effect. On the contrary, the use of 7° lateral wedge insoles lead to excessive weight bearing of the affected side.<sup>[16]</sup> Therefore, this study used 5° lateral wedge insoles for intervention.

For the 6-week intervention in this study, in the beginning, the LW group experienced muscle ache in the lower limb and trunk at the affected side during weeks 1 and 2 of the intervention. The reason might be that this intervention made the subjects' affected side and healthy side reach a balance, and thus the nerves and muscles had to be re-educated for weight bearing. The subjects did not experience other pain and discomforts afterwards, and neither did they experience falls, sprains, etc. Therefore, the intervention of 5° lateral wedge insoles is a safe and convenient approach whose effect can be maintained until the follow-up test at week 18. It is advised to clinically apply this approach to the shift in the center of gravity training in patients with stroke.

The training time of the BT group in this study was the intervention of 6-week visual biofeedback balance training (Biodex Balance System) for 3 days per week and 20 minutes per time. The subjects received visual biofeedback balance training for 360 minutes in total. For the study by Srivastava et al (2009),<sup>[11]</sup> in addition to the traditional rehabilitation therapy, the subjects also had to receive balance master and 4-week visual

biofeedback training, for 5 days per week and 20 minutes per time. The subjects received the intervention of visual biofeedback training for 400 minutes in total. In the study by Cheng et al (2001),<sup>[9]</sup> in addition to the traditional rehabilitation therapy, the experimental group also had to additionally use Balance Master to receive the 3-week visual biofeedback training for 5 days per week and 20 minutes per time. The experimental group received the visual biofeedback balance training for 300 minutes in total. The training time in this study was equivalent to that in these 3 aforementioned studies. In addition, none of the subjects participating in this study experienced adverse events, such as falls, pain and discomfort, and dizziness. Therefore, the design of training intensity and training time in this study is reasonable and effective.

Every subject in this study had to spend 6 weeks to complete the training. As a result, some of the subjects withdrew from this study early (8/56). This study adopted intention-to-treat analysis to include the data of 56 subjects in the analysis to conform to the spirit of RCT and avoid overestimating the effect of intervention. Moreover, to avoid any influence caused by the shoes worn by the subjects, the shoes worn by all of the subjects for 6 weeks were the same shoelace-free and nonslip shoes offered by the researcher. The weight distribution was not measured in the present study, but this factor can be incorporated into the research design for consideration in the future.

## 5. Conclusion

After the 6-week visual biofeedback training and the intervention of 5° lateral wedge insoles, the balance ability of patients with a chronic stroke improved. The 3-month subsequent follow-up after the research intervention also found that the patients maintained their balance ability. Although the visual biofeedback training and the intervention of 5° lateral wedge insoles both could improve the balance ability in patients with a chronic stroke, there was no significant between-group difference for comparison. The study did find that it is more convenient to use LW.

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## Author contributions

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