

# Effect of Customized Insoles on Gait in Post-stroke Hemiparetic Individuals: A Randomized Controlled Trial

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## Research

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# Abstract

**Background:** Insoles were considered to be a beneficial adjunctive treatment option for gait rehabilitation, which could provide a proper basic support for walking. The purpose of this study was to evaluate the effect of customized insoles (Jiangsu Suyun Medical Equipment Co. Ltd, Jiangsu, China) on the gait of patients with hemiplegia.

**Methods:** This randomized controlled trial was set in the rehabilitation department of a hospital. A total of 50 stroke patients were randomized into an experimental group (n=25) or a control group (n=25). Both groups received 40-min conventional gait training, which was conducted 5 times a week, for 4 weeks and patients in the experimental group were required to wear customized insoles for at least 1 h per day for 4 weeks. The primary outcome measure was Tinetti Gait Scale (TGS), which was assessed three times (baseline[T<sub>0</sub>], 4 weeks from baseline[T<sub>1</sub>] and 4 weeks after completion of the intervention[T<sub>2</sub>]), and the secondary outcome measures were the plantar pressure test, 6-min walking test (6MWT), Lower Extremity Fugl-Meyer assessment (FMA-LE), Berg Balance Scale (BBS) and Barthel Index (BI), which was assessed twice (baseline[T<sub>0</sub>] and 4 weeks from baseline[T<sub>1</sub>]).

**Results:** Compared to the control group, there were significant increases in the experimental group after 4 weeks ( $P = 0.014$ ) and 4 weeks follow-up ( $P = 0.001$ ) in the change of TGS, weight-bearing on the involved side ( $P = 0.012$ ) or forefoot ( $P = 0.028$ ) when standing, weight-bearing on the involved side ( $P = 0.016$ ) or forefoot ( $P = 0.043$ ) when walking, early stance phase ( $P = 0.023$ ) and mid stance phase ( $P = 0.013$ ) on the involved side, FMA-LE ( $P = 0.029$ ), BBS ( $P = 0.005$ ) and BI ( $P = 0.009$ ), but no difference in late stance phase ( $P = 0.472$ ) on the involved side when walking and in the 6MWT ( $P = 0.069$ ).

**Conclusions:** Customized insoles had great efficacy in enhancing gait performance.

**Clinical Trial Registration:** ChiCTR1900024843. Registered 30 July 2019 <http://www.chictr.org.cn/edit.aspx?pid=41003&htm=4>.

## Background

Approximately 80% of stroke patients suffer from hemiplegic gait[1]. Hemiplegic gait includes a prolonged swing phase, shortened stance phase, increased asymmetry in time and space on the involved side[2], and the lower extremity often presents as hip external rotation, knee hyperextension, foot drop and varus[3]. Moreover, the increasing incidence of falls caused by hemiplegia greatly lowers patients' quality of life and causes an economic burden for health and social services[4].

A wide range of strategies in conventional gait therapy has been developed[5], such as manipulation provided by physical therapists and technological approaches including Functional Electric Stimulation (FES)[6] or Treadmill Training[7]. Stroke patients who receive conventional gait therapy have to stick with certain therapists or specific locations. Therefore, losing access to rehabilitation facilities or therapists may result in a relapse of gait pattern, which should be particularly noticeable [8]. Previous studies reported that hemiplegic patients often experienced changes in plantar pressure due to biomechanical abnormalities of the lower extremities. These abnormalities alter the closed chain movement of the upper segment of the body, eventually aggravating abnormal gait[9][10][11]. However, few studies have focused on rehabilitation techniques based on abnormal plantar pressure for hemiplegic patients.

In recent years, treatments with corrective insoles have been widely applied to many diseases such as flatfoot, plantar fasciitis, diabetic foot, posterior tibial tendonitis, lower back pain and others[12][13][14][15][16]. Corrective insoles can change pressure distribution of the sole to provide an appropriate base of support, maintain correct positioning of the foot to limit or facilitate the movement of the lower limbs, as well as enhance shock absorption and stability to alleviate pain or other specific pathologies while standing or walking[17]. Previous research has demonstrated that lateral-wedged and heel-lift insoles had a positive effect on increasing the weight-bearing of hemiplegic side and bilateral symmetry during standing, but these effects were not felt during ambulation[18][19]. Kusumoto et al. confirmed that the insoles combined with metatarsal pad promoted static and dynamic balance in patients with cerebral palsy[20]. Based on the previously mentioned studies, it

was found that the insoles had only one additional modification that had been applied for the correction of lower limb kinematic and kinetic abnormalities in most studies on hemiplegic gait[21][22]. In fact, patients with hemiplegia usually had variable abnormal gait performances, which were caused by different foot structures and movement defects, such as a collapsed transverse arch, spastic clawing of toes, restricted ankle dorsiflexion and plantarflexion[23]. These problems often could not be solved with a single additional modification for insoles, which was not conducive to the patient's gait smoothness and stability.

As a type of corrective insoles, customized insoles were individually and specifically applied to biomechanical deformities by adding various pads (e.g., inversion ramp pad, forefoot pad, metatarsal dome pad, hallux valgus pad, etc.) to prefabricated insoles, and each pad had its own function [22]. The technique took the personal biomechanical problems of each patient into account. Additionally, one of the prominent advantages of customized insoles was that they could be further modified after production, unlike 3D-printed insoles, which could not be changed once the product was formed[24]. Therefore, the purpose of the present study was to evaluate whether wearing customized insoles could improve gait in stroke patients and the impact of this technique on plantar pressure distribution, lower limb motor function, balance function, daily life ability and walking endurance.

## Methods

### Study design

We designed a single-blind, randomized clinical trial to examine the effects of customized insoles on gait in patients with hemiplegia. Eligible patients were randomized into 'conventional gait training + customized insoles' (Group A) or 'conventional training' (Group B) at a 1:1 ratio using a computer-generated random table. We put trial instructions and groupings in sealed envelopes and the participants were randomly assigned in order.

Each patient was evaluated by the same assessor who was unaware of the group assignment. The primary outcome measures were conducted three times (baseline[T<sub>0</sub>], 4 weeks from baseline[T<sub>1</sub>] and 4 weeks after completion of the intervention[T<sub>2</sub>]) and the secondary were performed twice(baseline[T<sub>0</sub>] and 4 weeks from baseline[T<sub>1</sub>]).

### Participants

From July 2019 to July 2020, a total of 50 patients were recruited in the outpatient and ward of the rehabilitation department of our hospital. Patient recruitment included the following steps: (1) a patient's attending doctor was required to be acquainted with the inclusion and exclusion criteria, as well as the screening of potential participants and recommending them to the primary researcher; (2) the patients were then judged on their clinical characteristics; (3) the primary researcher explained the trial aims to a potential patient and discussed the rehabilitation objectives with them; and (4) the patients or their relatives were required to sign informed consent forms.

Inclusion criteria for subjects were as follows: (1) meeting the diagnostic criteria for cerebral infarction or cerebral hemorrhage; (2) unilateral limb paralysis from the first stroke; (3) time of onset: 1–12 months after stroke; (4) aged 40–80 years; (5) involved lower limb motor function  $\geq$  Brunnstrom grade III; (6) ability to walk at least 10 meters with or without auxiliary tools; (7) no other diseases or complications that might affect rehabilitation training; (8) stable vital signs.

Exclusion criteria were: (1) a history of any other additional diseases that could influence ambulation; (2) diabetic foot and peripheral neuropathy; (3) MMSE < 17 points; (4) severe communication impairment; and (5) other factors that might prevent participation in the experiment.

### Intervention

All patients underwent conventional gait training. During ambulation, sophisticated therapists performed manipulations to help patients suppress excessive muscle tension, stimulate muscle activity and promote normal movement patterns. In

addition, patients received instructions about weight-shifting, involved limb weight-bearing, balance training and various intensive exercises, as functional activities (such as standing up from a chair, turning around, crossing obstacles). Both groups received 40-min training sessions each week for 4 weeks. Only patients in the experimental group were required to wear insoles for a minimum of 1 hour every day and recommended to continue wearing at 4 weeks follow-up after the completion of treatment, but it was not mandatory.

### **Customization processes of insoles**

The process included relevant biomechanical assessments, prescription formulation and the manufacture of insoles (see **Figure 1**).

Step 1: The assessment mainly consisted of gait observation, plantar pressure test (F-Scan®, Techstrom, Korea), and the use of the Najjarine Assessment System (NAS)[25]. Gait observation required the therapist to observe condition of each segment of movement chain from the front, back and side respectively, especially the movement of the involved lower limb and foot[26]. During the plantar pressure test, the patient stood naturally on the electronic plantar pressure plate and remained while static data were collected, then stepped over the plate to collect dynamic data[27]. Gait observation and plantar pressure test can reveal neuromuscular abnormalities of the foot and ankle after central nervous system injury. With NAS, leg length, forefoot to rearfoot position and the calcaneal angle when standing, which reflects patients' foot structure and the biomechanical status of lower limbs, can be obtained.

Step 2: Based on the results of above assessments, the individualized prescription of insoles could be determined for stroke patients with hemiplegia. A pair of prefabricated insoles, with a 5° lateral wedge, and an arch support made from high-density ethyl vinyl acetate (produced by Jiangsu Suyun Medical Equipment Co. Ltd, Jiangsu, China), were distributed to each patient in the experimental group. Typically, we added a 2° or 4° forefoot pad on the paretic forefoot to promote ankle dorsiflexion, a 4° or 6° inversion ramp pad to promote the paretic foot's pronation movement and a metatarsal dome pad to alleviate paretic forefoot plantar pressure on the involved side. In addition, a 4° forefoot pad was added on the lateral of the non-paretic forefoot to increase the stability of the uninvolved foot. All the above pads were attached to the plantar surface of the insoles (see **Figure 2**).

Step 3: The producers chose and cut appropriate-size prefabricated insoles to suit patients' shoes. All pads were pre-cut and attached to the insole with double-sided tape. After the insoles were made, each patient tried them on and appropriate adjustments and corrections were performed if necessary. Finally, the insoles were molded specifically by heating for 40 seconds with a heat gun and were then shaped by a qualified physiotherapist to maintain the subtalar joint in a neutral standing position[28]. Furthermore, some modifications could be made according to the patient's condition in the later period.

All of the above steps were performed by qualified therapists.

### **Outcome measures**

Tinetti Gait Scale (TGS) measurement was our primary indicator [29], which was used to evaluate the patient's gait. It consisted of 6 items, including 2 items related to coordinated gait components, 5 items related to compensation strategies and 1 item related to temporal aspects of gait. TGS ranged from 0 to 12 points, representing most deviations to normal.

#### **Secondary outcomes**

- i. Plantar pressure test (%) [30]: Items included weight-bearing of the involved foot (normal: 50%) and the involved forefoot (normal: 27.5%) during static standing, weight-bearing of the involved foot (normal: 50%) and the involved forefoot (normal: 35%) during walking, and gait cycle percentage (early stance phase, normal: 20%; mid-stance phase, normal: 40%; and late stance phase, normal: 20%).
- ii. 6-min walking test (6MWT)[31]: It was carried out indoors along a long, flat, straight enclosed corridor. The length of the walking track was 30 meters and subjects walked as fast as they could for 6 min, and the walking distance was

measured.

- iii. Lower Extremity Fugl-Meyer assessment (FMA-LE)[32] : There were 17 items in this assessment, of which 2 items related to reflex activity, 11 items to synergistic movements and 3 items to coordination. The scoring of each item was based on a sequential score of 3 points (0, unable to complete; 1, partially completed; 2, completely completed), except for the 2 reflection items.
- iv. Berg Balance Scale (BBS) [33]: It was a list of 14 items, and each item was composed of a five-point ordinal scale from 0 to 4; 0 represented the lowest level of function and 4 the highest level of function.
- v. Barthel Index (BI) assessment [34]: It covered 10 domains of functioning (activities): bowel and bladder control, as well as assistance with grooming, toilet use, feeding, transfer, walking, dressing, climbing stairs and bathing. Each activity had 5 dependency levels, ranging from 0 (unable to perform) to 5, 10 or 15 (completely independent).

The sample size calculation was detailed in the **Appendix 1(Figure 304)**.

## Statistical analysis

Data analysis was performed using SPSS Statistics (version 20.0, IBM, USA). Patients' demographic and clinical characteristics, including age, gender, course and classification of stroke, involved side (left/right) and the Brunnstrom stage, are given by the number of cases (%) for categorical data and mean (SD) for continuous variables (**Table 1**). Tinetti Gait Scale was described as the number of cases (%) and the plantar pressure test, Lower Extremity Fugl-Meyer assessment (FMA-LE) and Berg Balance Scale (BBS), which did not conform to a normal distribution, as well as discontinuous variables such as the Barthel Index (BI) assessment, are presented as the mean (95% confidence interval (CI)). Continuous variables such as the 6-min walking test (6MWT) with a normal distribution are reported as the mean (SD).

Chi-square test was conducted for the comparison in the change of Tinetti Gait Scale (TGS). The Wilcoxon rank sum test was used to analyze differences between the two groups and the Wilcoxon signed-rank test was employed within the groups for discontinuous variables such as Tinetti Gait Scale (TGS) and Barthel Index (BI) assessments. Based on the assumption of normal distribution and homogeneity of variance, we conducted an independent sample t-test to analyze the difference in the change of 6-min walking test (6MWT) between the two groups. Continuous variables, such as the change in plantar pressure test, Lower Extremity Fugl-Meyer assessment (FMA-LE) assessment and Berg Balance Scale (BBS) did not exhibit a normal distribution and Wilcoxon signed-rank test was used within the groups and Wilcoxon rank sum test between groups. The significant level was set as  $\alpha = 0.05$ .

## Results

As shown in **Figure 5**, a total of 50 patients met the inclusion criteria were enrolled in the study and 47 patients completed the experimental procedures and follow-up measurement data were available. Analysis was by intention to treat and three patients (one in the experimental group and two in the control group) dropped out and their missing data was filled with the most recent data. All were included in the statistical analysis and there was no significant difference between the experimental group and the control group for baseline demographic data and all outcome measures. No serious adverse events were observed.

After 4 weeks of intervention, the change in the Tinetti Gait Scale in the experimental group was significantly different from the control group ( $P = 0.014$ ). Furthermore, a comparison of the changes in the Tinetti Gait Scale after 4 weeks follow-up also showed that the experimental group was higher than the control group ( $P = 0.001$ ) (**Table 203**). After 4 weeks of intervention, changes of weight-bearing on the involved side ( $P = 0.012$ ) and forefoot ( $P = 0.028$ ) when standing between groups exhibited a significant difference, and statistically significant differences were found in the change of weight bearing on the involved side ( $P = 0.016$ ) and forefoot ( $P = 0.043$ ) when walking. The change of the early stance phase ( $P = 0.023$ ) and mid stance phase ( $P = 0.013$ ) on the involved side had statistical differences between groups, but no statistical difference in the change of the late stance phase on the involved side ( $P = 0.472$ ). In addition, there were significant differences in the change of

Lower Extremity Fugl-Meyer assessment (FMA-LE) between the two groups ( $P = 0.029$ ), Berg Balance Scale (BBS) ( $P = 0.005$ ) and Barthel Index (BI) ( $P = 0.009$ ), while the 6-min walking test(6MWT) exhibited no significant differences between the two groups ( $P = 0.069$ ) (**Table 4**).

## Discussion

The study results revealed that patients in the experimental group exhibited significantly improved gait performance compared with the control group, after the treatment period and the 4-week follow-ups. In addition, after 4 weeks of the intervention, weight-bearing on the involved foot or forefoot was increased no matter whether the patient was standing or walking. The early stance phase was prolonged and the mid-stance phase was shortened. Furthermore, the use of customized insoles was more effective in enhancing lower limb motor function, balance and activities of daily life except for patients' walking endurance.

Studies have found that joint kinematics and temporospatial features of hemiplegia patients are different from those of healthy people during the stance and swing phase[35] [36]. In the early stance phase, the subtalar joint is in a supination position and the limited dorsiflexion of the ankle causes the involved foot to tend to land on the lateral heel, forefoot or flat-foot at initial contact, which would further impede knee flexion [37]. In the mid-stance phase, due to limited ankle dorsiflexion, forward progression of the leg cannot be allowed, thus, patients with hemiparesis often present with compensatory hip flexion and trunk forward leaning[38]. When the involved side was in the prolonged swing phase [37], the uninvolved side was exactly in the middle and late phase of standing. The dynamic transformation under this condition was that the center of gravity should be moved to the involved side, while the uninvolved side would be moved forward simultaneously, which was a necessary requirement for patient balance. We found that the center of gravity moved back-and-forth, inward-and-outward not only on the involved side but also on the uninvolved side in the forefoot and midfoot (**Appendix 2**). Therefore, the uninvolved foot is also in an unstable state, which is very worthy of attention and the same stated phenomenon is consistent with the findings of Merying et al.'s research [39][40].

The way to modify the insoles was by adding different combinations of pads to a pair of full-length prefabricated insoles in our study. The inversion ramp on the lateral region of the involved foot encouraged the paretic foot to move from supination at heel contact into maximum pronation by the time the forefoot has contacted the floor. The inversion ramp also reestablished the heel as an appropriate base of support, promoted forward motion of the tibia and restored the rocker action of the ankle, thus assisting in propulsion [41]. Moreover, we modified the insole with a forefoot pad under the paretic forefoot to induce ankle dorsiflexion in the mid-stance phase. Simultaneously, knee flexion should also be improved along the human movement chain. A metatarsal dome was added, slightly posterior to metatarsal heads, to mend claw toe, alleviating the hypertonicity and abnormal pressure distribution of the forefoot. As mentioned above, there was instability in the uninvolved foot and previous literature has reported that lateral pads could alleviate instability in the elderly during walking[42]. With this in mind, we added a lateral forefoot pad to the uninvolved forefoot to enhance its stability, consequently improving the balance of the individual and making the gait smooth.

The results of the Tinetti Gait Scale analysis indicated the improvement of gait performance in the experimental group. The advantages of the customized insoles were as follows: 1) they maintained good foot posture by providing an appropriate base of support, reducing compensatory movement; 2) they enhanced the stability of the uninvolved side[43]. Indeed, patients with the customized insoles showed a smoother gait after 4-weeks of intervention, and the daily logs of patients showed an average of 2.87 hours spent wearing insoles per day during the intervention period. Surprisingly, most patients in the experimental group were willing to voluntarily wear the customized insoles for an average of 2.59 hours per day during the 4 weeks follow-up period. Thus, wearing customized insoles was a constant and convenient treatment for stroke patients rather than conventional gait therapy, which clearly had restrictions on locations and access to professionals.

A major reason for the success of the customized insoles was that they were designed to redistribute the load of the foot, resulting in a better distribution of plantar pressure. The inversion ramp on the lateral region increased plantar foot contact

area during the phase of initial heel contact from flat foot to floor. As a consequence, the results of the plantar pressure test showed that wearing customized insoles promoted weight-bearing on the involved foot or forefoot during a movement of static standing or dynamic walking. Certainly, the early stance phase was also prolonged for the paretic foot. In addition, the forefoot pad induced active dorsiflexion of the involved foot and the metatarsal dome relieved the excessive pressure of the toe, which made the center of gravity move forward more easily. Consequently, this shortened the mid-stance phase of the involved side.

Based on the above reason, the customized insoles also promoted the motor function of the lower limbs for hemiplegia patients. So the results of the present study demonstrated that the experimental group yielded greater benefits than the control group in the case of the Lower Extremity Fugl-Meyer assessment (FMA-LE) assessment, which was consistent with Li's research[44].

The experimental group had further gained greater results in comparison to the control group when we investigated the changes associated with the Berg Balance Scale (BBS) and Barthel Index (BI) scores after 4 weeks of intervention, which illustrated that the insoles were effective in improving the balance of stroke patients as well as contributing to an overall improvement in daily life. Clinically, the customized insole reestablished a proper and steady foundation for hemiplegic patients during the gait cycle, thus improving a patient's balance function. Studies have determined that due to the improvements associated with lower limb and balance function, the ability of toileting, transferring, ambulating and stair climbing were also enhanced [45][46].

6-min walking test(6MWT) was a long walking task, which was designed to measure the endurance of the patient and was thought to correlate to community activities. In this assessment, the subject was asked to walk as far as possible in 6 minutes [33]. Stroke patients already had a slower gait speed and previous studies have shown that 6MWT was a poor predictor for people with a slower walking speed[47]. Therefore, our study found that there was no significant difference in the performances for the 6MWT between the experimental and control groups after 4 weeks of intervention.

### **Study limitations**

First, the primary observed indicator used was scale, so three-dimensional gait analysis may be considered to quantify objectively the gait performance. Second, the sample size of this study was relatively small, which may cause uncertainty; more patients will be included to verify the efficacy of the customized insoles. Finally, in future studies, positive control studies can be used, such as comparison with ankle-foot orthoses, which may have more clinical significance in evaluating the effect of customized insoles. A stratified study should be carried out according to different levels of lower extremity motor function of patients to determine which level or levels the customized insoles are more suitable for, and to provide further evidence for the clinical application of insoles in stroke hemiplegia.

## **Conclusions**

Customized insoles were effective as a type of orthotic treatment designed to improve the gait performance of patients with hemiplegia. Their benefits included improved gait cycle, increased weight-bearing on the involved side when static standing and dynamic walking, better motor function of lower limbs, balance and abilities in daily life.

## **Abbreviations**

Berg Balance Scale BBS Barthel Index BI confidence interval CI Functional Electric Stimulation FES Lower Extremity Fugl-Meyer assessment FMA-LE Najjarine Assessment System NAS 6-min walking test 6MWT Tinetti Gait Scale TGS.

## **Declarations**

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### **Authors' contributions**

WJ conducted insole production, data analysis and the entire manuscript. ZY and FWJ were responsible for the research design and review of the final draft. QL performed conventional gait training, YL recruited patients and collected data. WYM was committed to evaluation. All authors unanimously approved the final draft.

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### **Availability of data and materials**

Upon reasonable request, the data set used in this study can be obtained from the corresponding author.

### **Ethics approval**

The study was approved by the Ethics Committee of the hospital (No. 2019-54), and the registration of China clinical trial registration platform was completed (Identification: ChiCTR1900024843), which followed the guidelines and procedures of the Comprehensive Standard for Test Reports (CONSORT) and acted up to the consistent ethical standards of the Declaration of Helsinki.

### **Consent for publication**

Not applicable.

**Conflict of Interest:** None declared.

**Competing interests:** None.

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## Tables

**TABLE 1.** Participant Characteristics at Baseline.

Characteristic	Group A	Group B	<i>P</i> value
Participants, <i>n</i>	25	25	
Age (years), median (IQR)	56.00(49.50 to 66.50)	60.00(54.00 to 65.00)	0.303
Duration of stroke (days), mean (SD)	130.36(64.87)	123.08(54.06)	0.668
Male, <i>n</i> (%)	19(76%)	18(72%)	0.747
Classification, <i>n</i> (%)			
Cerebral infarction	13(52%)	16(64%)	0.390
Cerebral hemorrhage	12(48%)	9(36%)	
Affected body side, <i>n</i> (%)			
Left	17(68%)	18(72%)	0.758
Right	8(34%)	7(28%)	
Brunnstrom $\square$ <i>n</i> (%)			
III	5(20%)	4(16%)	0.762
IV	16(64%)	15(60%)	
V	4(16%)	6(24%)	

Group A: experimental group; Group B: control group.

**TABLE 2.** Results of Tinetti Gait Scale.

Scores of Tinetti Gait Scale, <i>n</i> (%)	T <sub>0</sub>		T <sub>1</sub>		T <sub>2</sub>	
	Group A, (n=25)	Group B (n=25)	Group A (n=25)	Group B (n=25)	Group A (n=25)	Group B (n=25)
4	1(4%)	1(4%)	1(4%)	0	1(4%)	0
5	10(40%)	4(16%)	1(4%)	0	0	1(4%)
6	4(16%)	9(36%)	2(8%)	6(24%)	0	4(16%)
7	5(20%)	7(28%)	1(4%)	6(24%)	3(12%)	8(32%)
8	4(16%)	3(12%)	9(36%)	7(28%)	13(52%)	9(36%)
9	1(4%)	1(4%)	8(32%)	6(24%)	7(28%)	3(12%)
10			3(12%)	0	1(4%)	0

Group A: experimental group; Group B: control group.

T<sub>0</sub>: baseline measurement; T<sub>1</sub>: 4 weeks from baseline; T<sub>2</sub>: 4 weeks after completion of the intervention.

**TABLE 3.** Changes in Tinetti Gait Scale.

Changes in Tinetti Gait Scale, <i>n</i> (%)	T <sub>1</sub> -T <sub>0</sub>		T <sub>2</sub> -T <sub>0</sub>	
	Group A (n=25)	Group B (n=25)	Group A (n=25)	Group B (n=25)
0	3(12%)	5(20%)	1(4%)	4(16%)
1	5(20%)	14(56%)	3(12%)	1(4%)
2	8(32%)	4(16%)	2(8%)	13(52%)
3	9(36%)	2(8%)	10(40%)	6(24%)
4			9(36%)	1(4%)
<b><i>p</i>-value</b>	0.014		0.001	

Group A: experimental group; Group B: control group.

T<sub>0</sub>: baseline measurement; T<sub>1</sub>:4 weeks from baseline; T<sub>2</sub>: 4 weeks after completion of the intervention

The *p*-values refer the differences of the change of the outcome measures between the two groups P<0.05.

**TABLE 4.** Results of secondary outcomes.

	Group A (n=25)		Group B (n=25)		T <sub>1</sub> -T <sub>0</sub>		P value
	T <sub>0</sub>	T <sub>1</sub>	T <sub>0</sub>	T <sub>1</sub>	Group A	Group B	
<b>Weight-bearing on the affected side, standing, %, mean (95%CI)</b>	41.57 (39.70 to 43.45)	45.02 (43.45 to 46.62)	43.85 (41.72 to 45.98)	45.34 (43.32 to 47.37)	3.46 (2.37 to 4.55)	1.49 (0.48 to 2.49)	0.012
<b>Weight-bearing on the forefoot of the affected side, standing, %, mean (95%CI)</b>	17.00 (14.69 to 19.31)	19.73 (17.83 to 21.63)	17.72 (15.67 to 19.78)	19.22 (17.15 to 21.28)	2.73 (1.67 to 3.79)	1.49 (0.65 to 2.34)	0.028
<b>Weight-bearing on the affected side, walking, %, mean (95%CI)</b>	42.73 (40.88 to 44.58)	45.88 (44.30 to 47.47)	45.71 (43.86 to 47.56)	47.04 (45.38 to 48.70)	3.15 (1.53 to 4.77)	1.33 (0.49 to 2.17)	0.016
<b>Weight-bearing on the forefoot, walking, %, mean (95%CI)</b>	20.78 (18.04 to 23.52)	24.84 (22.42 to 27.26)	21.57 (19.42 to 23.72)	23.50 (21.78 to 25.23)	4.06 (2.14 to 5.99)	1.93 (0.67 to 3.20)	0.043
<b>Gait cycle</b>							
<b>Early stance phase, %, mean (95%CI)</b>	3.52 (2.35 to 4.69)	8.52 (6.54 to 10.50)	3.40 (1.83 to 4.97)	6.08 (4.44 to 7.72)	5.00 [3.21 to 6.79]	2.68 [1.86 to 3.50]	0.023
<b>Mid stance phase, %, mean (95%CI)</b>	79.68 (74.12 to 85.24)	74.00 (69.19 to 78.81)	74.92 [70.93 to 78.91]	73.56 (69.73 to 77.39)	-5.68 [-8.29 to -3.07]	-1.36 [-3.10 to 0.38]	0.013
<b>Late stance phase, %, mean (95%CI)</b>	16.80 [10.84 to 22.76]	17.48 [11.98 to 22.98]	21.68 [17.21 to 26.15]	20.36 [16.12 to 24.60]	0.68 [-2.28 to 3.64]	-1.32 [-3.23 to 0.59]	0.472
<b>6MWT, mean (SD)</b>	135.60(28.45)	200.28(26.70)	124.56(26.14)	172.44(40.33)	64.68(32.12)	47.88(31.67)	0.069
<b>FMA-L,</b>	18.80	25.80	19.52	25.00	7.00	5.48	0.029

<b>mean (95%CI)</b>	(17.34 to 20.26)	(24.06 to 27.54)	(17.97 to 21.07)	(23.27 to 26.73)	(5.97 to 8.03)	(4.52 to 6.44)	
<b>BBS, mean (SD)</b>	41.04(4.04)	47.32(4.31)	40.04(3.58)	44.08(3.97)	6.28(2.99)	4.04(2.35)	0.005
<b>BI, mean (95%CI)</b>	66.20 (63.03 to 69.37)	78.60 (75.84 to 81.36)	63.60 (60.05 to 67.15)	72.60 (69.93 to 75.27)	12.40 (10.24 to 14.56)	9.00 (7.31 to 10.69)	0.009

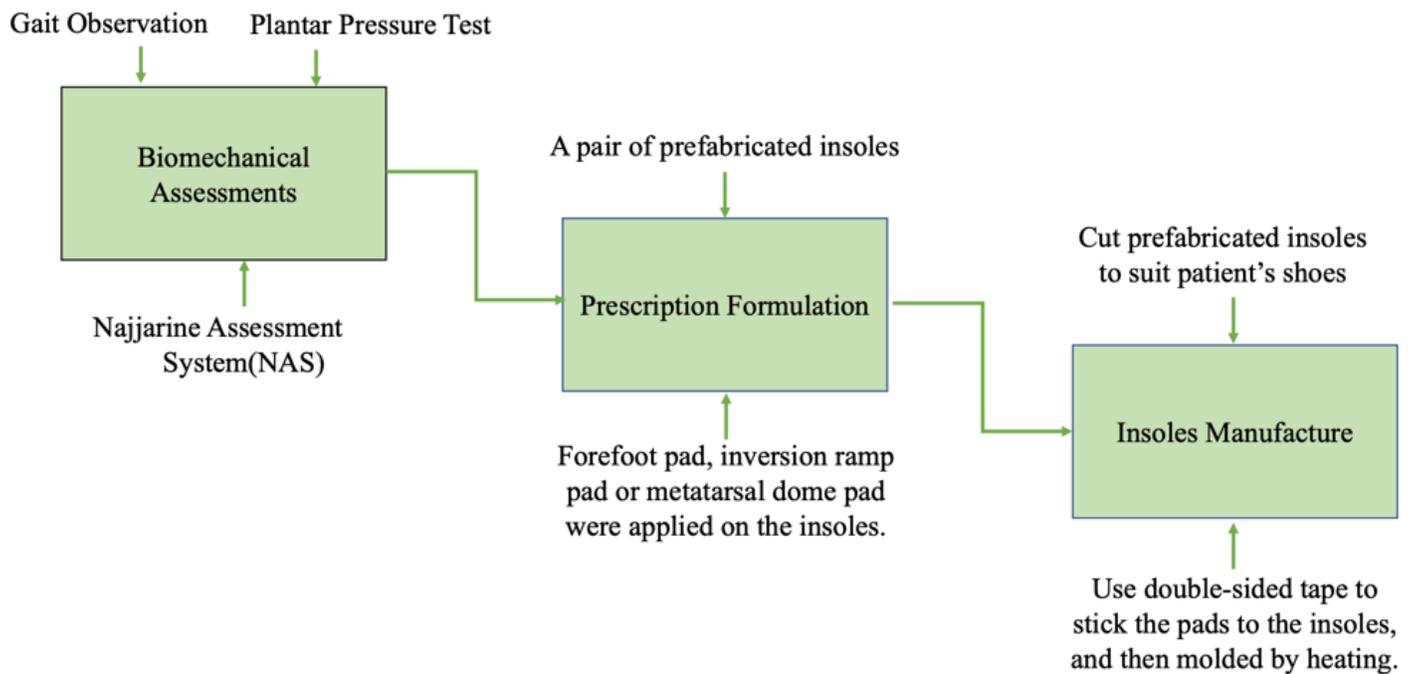
Group A: experimental group; Group B: control group.

6MWT:6-minute walking test; FMA-LE: Lower Extremity Fugl-Meyer assessment; BBS:Berg Balance Scale; BI : Barthel Index.

T<sub>0</sub>: baseline measurement; T<sub>1</sub>:4weeks from baseline;

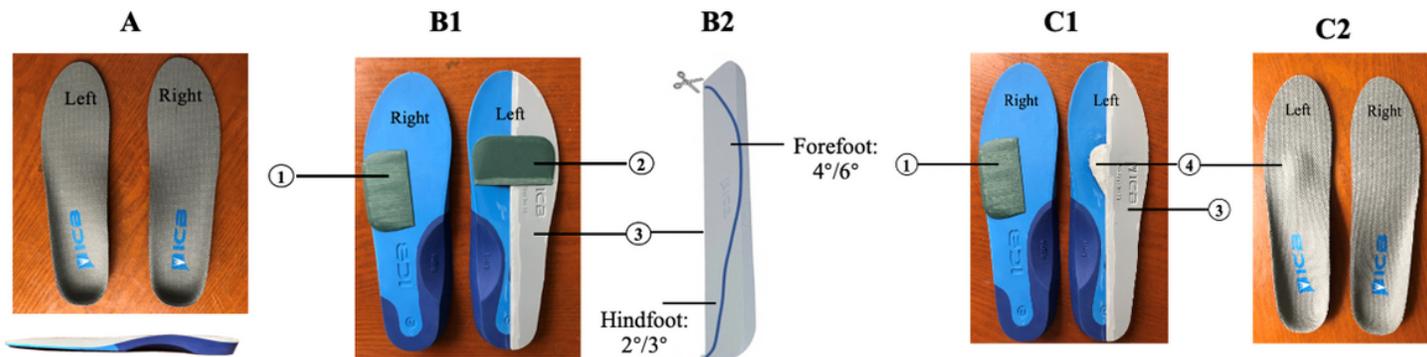
The p-values refer the differences of the change of the outcome measures between the two groups, P<0.05.

## Figures



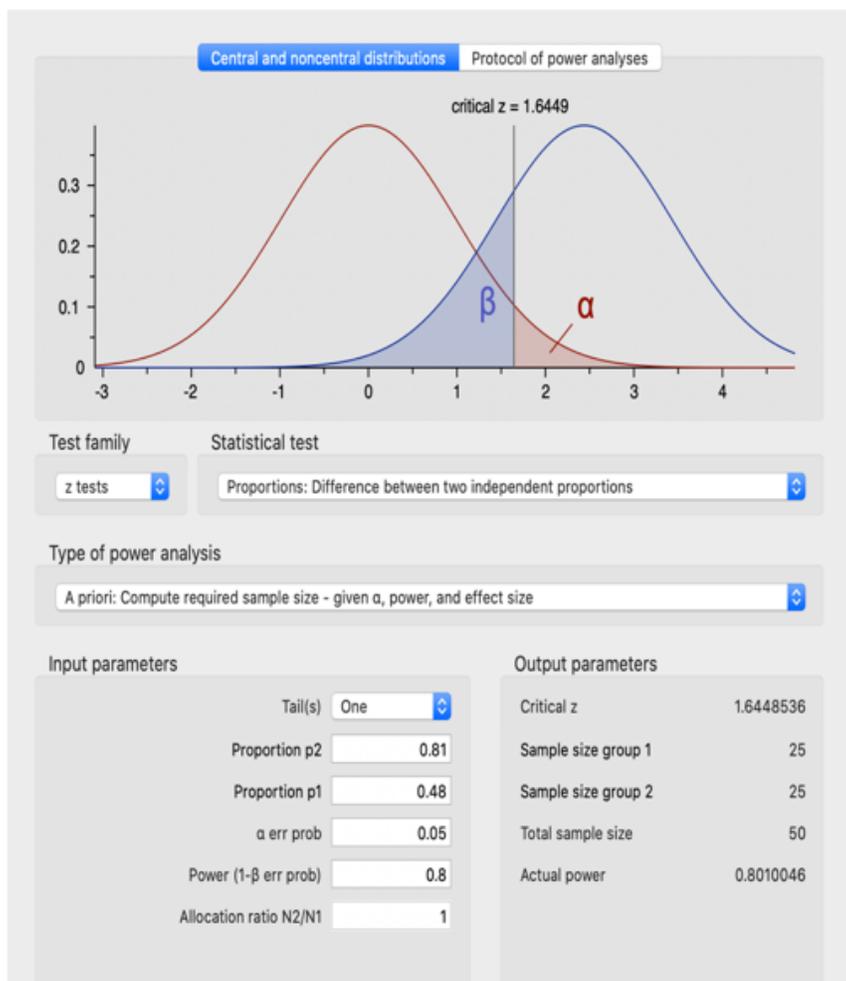
**Figure 1**

Customization process of insoles.



**Figure 2**

Conventional prescriptions for hemiplegia (left-sided hemiplegia). Figure A demonstrated a pair of prefabricated insoles with a 5° lateral wedge and arch support. Figure B1, B2, C1, C2 demonstrated two typical prescriptions for hemiplegia: forefoot pad (2° or 4°): it was stuck on the lateral of unparetic forefoot, this was to increase the stability of unaffected foot; forefoot pad (2° or 4°): it was stuck on the paretic forefoot in order to promote ankle dorsiflexion; inversion ramp pad (4° or 6°): it was stuck on the lateral of paretic foot, the whole pad was trimmed along the line to reach forefoot 4°-hindfoot 2° or forefoot 6°-hindfoot 3°, and its medial edge was polished into a slope, this was to promote paretic foot's pronation movement; metatarsal dome pad: it was stuck slightly posterior to the metatarsal heads in order to alleviate paretic forefoot plantar pressure on the paretic side. All the above pads were stuck to the plantar surface of insole.



**Figure 3**

## Sample size estimation

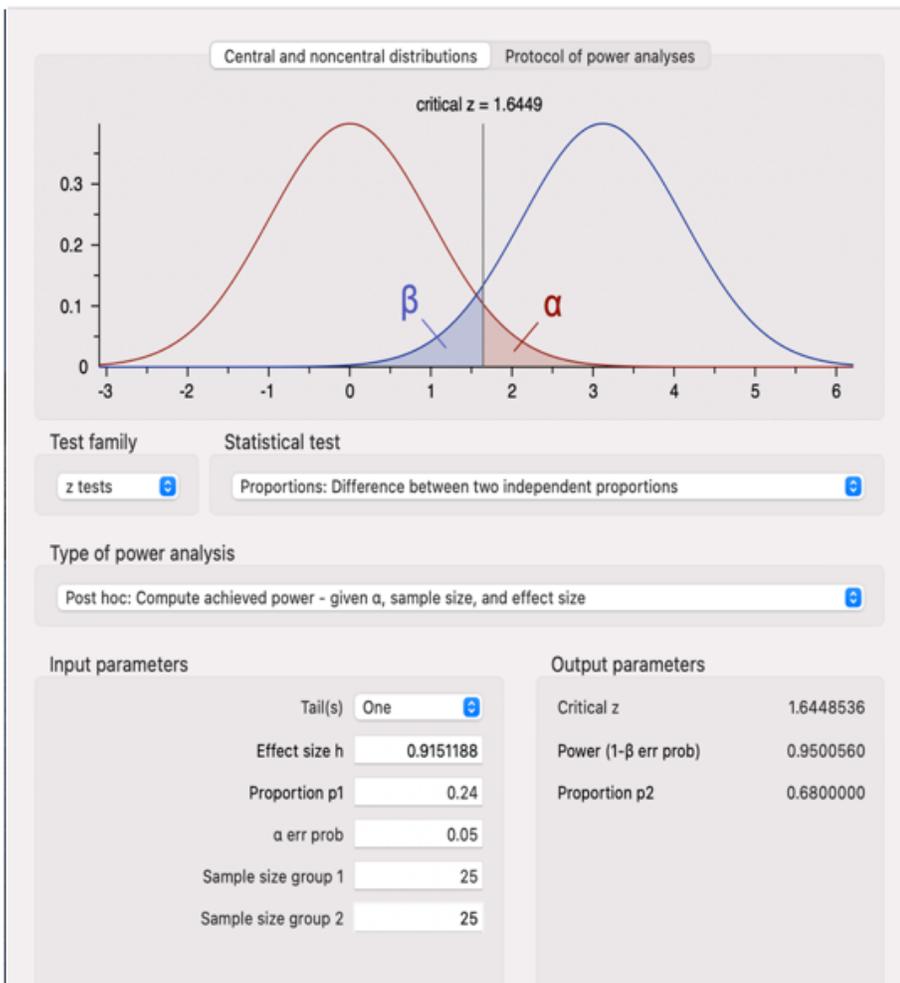
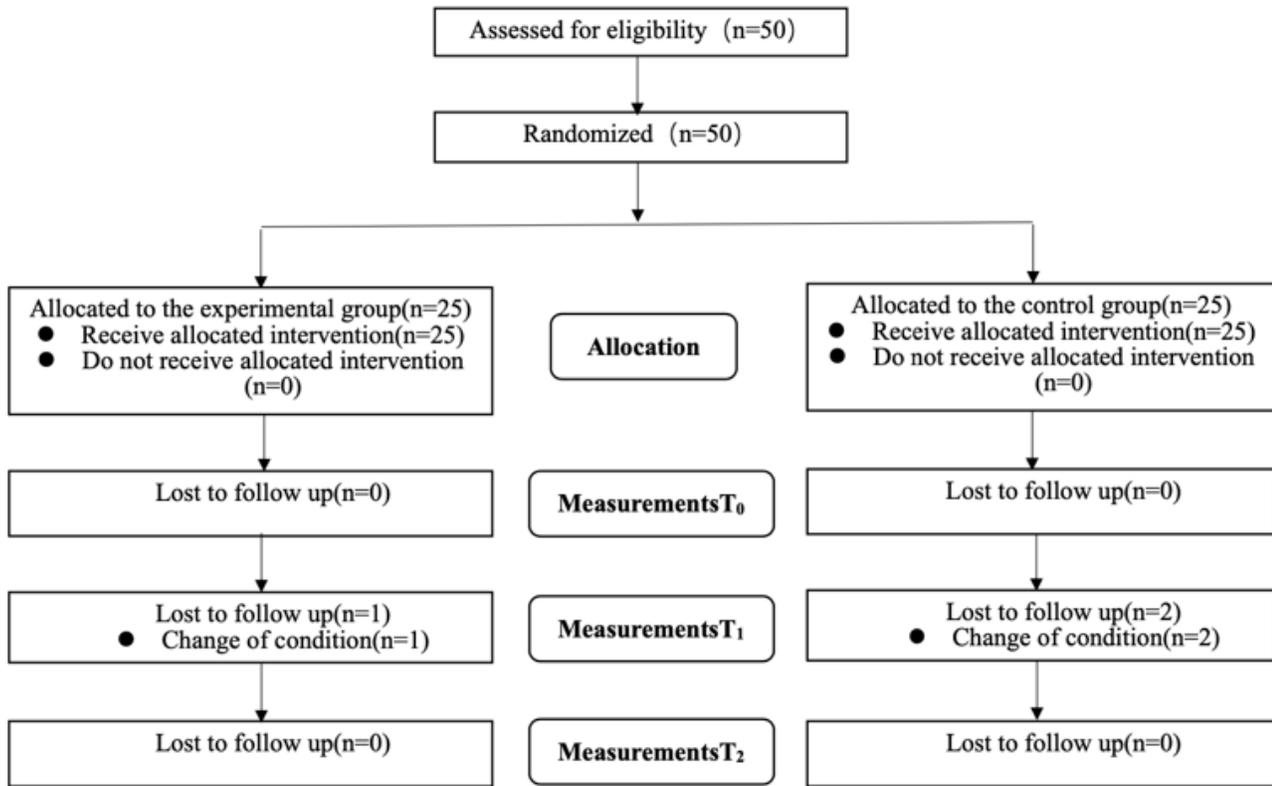


Figure 4

Power calculation



**Figure 5**

Flowchart T0: baseline; T1:4 weeks from baseline; T2: 4 weeks after completion of the intervention.

## Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- [Appendix.docx](#)