

Effects of innovative hip-knee-ankle interlimb coordinated robot training on ambulation, cardiopulmonary function, depression, and fall confidence in acute hemiplegia

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Abstract.

BACKGROUND: While Walkbot-assisted locomotor training (WLT) provided ample evidence on balance and gait improvements, the therapeutic effects on cardiopulmonary and psychological elements as well as fall confidence are unknown in stroke survivors.

OBJECTIVE: The present study aimed to compare the effects of Walkbot locomotor training (WLT) with conventional locomotor training (CLT) on balance and gait, cardiopulmonary and psychological functions and fall confidence in acute hemiparetic stroke.

METHODS: Fourteen patients with acute hemiparetic stroke were randomized into either the WLT (60 min physical therapy + 30 min Walkbot-assisted gait training) or CLT (60 min physical therapy + 30 min gait training) groups, 7 days/week over 2 weeks. Clinical outcomes included the Berg Balance Scale (BBS), Functional Ambulation Category (FAC), heart rate (HR), Borg Rating of Perceived Exertion (BRPE), Beck Depression Inventory-II (BDI-II), and the activities-specific balance confidence (ABC) scale. The analysis of covariance (ANCOVA) was conducted at $P < 0.05$.

RESULTS: ANCOVA showed that WLT showed superior effects, compared to CLT, on FAC, HR, BRPE, BDI-II, and ABC scale ($P < 0.05$), but not on BBS ($P = 0.061$).

CONCLUSIONS: Our results provide novel, promising clinical evidence that WLT improved balance and gait function as well as cardiopulmonary and psychological functions, and fall confidence in acute stroke survivors who were unable to ambulate independently.

Keywords: Neurorehabilitation, stroke, hemiplegia, robot-assisted gait training, Walkbot, cardiopulmonary function, psychological function

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1. Introduction

Acute stroke survivors suffer from altered sensorimotor (balance and gait), cardiopulmonary (endurance) and psychological (depression) functions, which are often associated with high risk of fall (Go et al., 2014). Depending on the location and severity of the brain lesion, acute stroke survivors are initially unable to maintain balance (Tyson et al., 2006) or to ambulate independently due to sensorimotor impairments (muscle weakness, spasticity, proprioceptive deficit, lack of coordination, and muscle imbalance) (Smania et al., 2008). These impairments have been implicated with cardiopulmonary (poor endurance, dyspnea) (Tang et al., 2009) and psychological (depression) (Carson et al., 2009) health in stroke patients. To mitigate the multi-system impairments, recent systemic review of neurorehabilitation evidence reported that robotic gait training can provide promising benefits for balance and locomotor recovery primarily (Kim et al., 2015; Mayr et al., 2007; Schwartz et al., 2009) in subacute to chronic stroke patients when integrated into conventional physical therapy (Park et al., 2018). However, there is a dearth of evidence in the current literature about effects of robotic gait training on cardiopulmonary (Chang et al., 2012) and psychological (Calabro et al., 2014) functions as well as confidence in balance and gait performance in various ambulatory activities without falling in acute hemiparetic stroke (Bang et al., 2016).

Recently, we developed an innovative hip-knee-ankle interlimb coordinated robot training system (Walkbot locomotor training, WLT; P&S Mechanics, Seoul, Republic of Korea), which is designed to provide accurate proprioceptive, kinematic, and kinetic guidance, as well as variable error practice and high-intensity, repetitive, task-specific, and interactive exercises of the paretic lower limb (Park et al., 2018; Kim et al., 2013; Park et al., 2019). Compared with current exoskeletal robot-assisted gait training systems, the WLT system can quantitatively assess kinematics, kinetics, and stiffness during treadmill walking; this information is utilized for sensorimotor feedback (visual, sound) during locomotor training. Furthermore, ankle-knee-hip joint actuators facilitate ankle dorsiflexion, which prevents foot drop and associated asymmetrical circumduction or hip hiking gait, thereby enabling safe ambulation with minimal risk of falling.

Earlier patient mobilization using a robot-assisted gait training system is believed to be beneficial for locomotor recovery (Winstein et al., 2016), while it concurrently enhances cardiopulmonary endurance (Chang et al., 2012; Stoller et al., 2015) and psychological motivation to participate in the rehabilitation process (Calabro et al., 2015). However, whether WLT improves cardiopulmonary fitness function, according to the American College of Sports Medicine (ACSM) training intensity guidelines, or prevents psychological deterioration, has not been investigated in acute stroke survivors (Winstein et al., 2016). Therefore, the specific aim of the present randomized control trial was to examine the effects of WLT and conventional locomotor training (CLT) on balance, gait, cardiopulmonary function (heart rate [HR], endurance), psychological (depression) health, and confidence of fall risk in survivors of acute hemiparetic stroke. Primary outcome measures included balance, gait, and fall confidence whereas the secondary outcome measures entailed cardiopulmonary function (HR, endurance) and psychological (depression) health. We hypothesized that WLT would produce greater changes in the balance, gait performance score and reduce risk of fall confidence variables than CLT in the acute hemiparetic patient.

2. Materials and methods

2.1. Participants

A convenience sample of 14 acute hemiparetic stroke survivors (mean age = 72.8 ± 9.9 ; 5 women) was recruited among inpatients at the rehabilitation hospital center. The experimental study protocol was approved by the local Institutional Review Board. Informed consent was obtained from all participants prior to their participation. The number of participants was determined for a moderate effect size and a power of 0.80 based on a pilot study and power analysis.¹⁶ The inclusion criteria were as follows: (1) survivors of acute cortical/subcortical ischemic stroke (2-weeks post-stroke onset), (2) age between 18 and 99 years, (3) first clinical stroke presentation or prior stroke with no residual deficits affecting ambulation, (4) ability to follow a two-step command, (5) Fugl-Meyer sensory score >2 , (6) suitability for gait training as assessed clinically (ability to ambulate at least one step with a

device/assistance), (7) height: 132–200 cm, (8) hip-knee joint length: 33–48 cm, and (9) knee joint – foot length, 33–48 cm. The exclusion criteria were (1) cerebellar/brainstem stroke survivor, (2) body weight >135 kg, (3) uncontrolled hypertension (stage 2) with blood pressure >160/100 mmHg, (4) cardiopulmonary impairments affecting the ambulation test, (5) integumentary impairment, such as skin breakdown or bedsores around the suspension belt loading area, (6) significant and persistent mental illness, (7) lower extremity fixed contracture or deformity, (8) bone instability (non-consolidated fractures, unstable spinal column, or severe osteoporosis requiring treatment with bisphosphonates), (9) other neurodegenerative disorders (amyotrophic lateral sclerosis, Parkinson's disease), (10) Modified Ashworth Scale >3 in the affected leg, (11) significant pain and sensory deficit, and (13) aphasia and dysarthria sufficient to prevent the ability to communicate discomfort.

2.2. Experimental procedure

A procedural checklist was followed to ensure consistent experimental protocols and that all instruments were calibrated daily, prior to data acquisition. Within the first week after admission, all stroke inpatients were randomized with the coin flipping method into one of the two groups (WLT or CLT), prior to the first outcome measurements. Primary outcome measures included balance, gait, and fall confidence whereas the secondary outcome measures entailed cardiopulmonary function (heart rate [HR], endurance) and psychological (depression) health. All tests were consistently implemented and all participants completed a demographic and health questionnaire.

2.3. Balance and gait function

BBS was used to examine performance-oriented balance. The test comprises a set of 14 simple balance-related tasks, ranging from standing up from a sitting position, to standing on one foot. The degree of success in achieving each task was given a score between 0 (unable to perform) to 4 (able to perform independently) and all scores were summed up to obtain the final score (Berg et al., 1989). FAC was used to assess patient's functional ambulation ability, scored from 0 (inability to walk) to 5 (independent ambulation) (Holden et al., 1984).

2.4. Cardiopulmonary function

6 MWT was performed along a flat, straight, 40 m track with a hard surface. Each patient was allowed to stop and rest, as necessary, within the allotted 6-minute time. At the end of the task, the walk distance was measured. Throughout the test, patient's HR was continuously recorded with a portable monitor (Gruet et al., 2010). BRPE is a quantitative measure of perceived exertion used to assess training intensity; patients reported their perceived level of exertion on a numerical scale, ranging from 6 (no exertion) to 20 (maximal exertion), following the 6 MWT (Borg et al., 1982). BRPE is an indirect method for the estimation of cardiopulmonary fitness endurance (Chang et al., 2012).

2.5. Psychometric measurement

BDI-II was used to measure symptoms of depression (hopelessness and irritability), cognition (guilt or feelings of punishment), and physical symptoms (fatigue, weight loss, and lack of interest in sex). The tool contains 21 questions, with each item being scored from 0 (symptoms absent) to 3 (severe symptoms). A total score of 0–13 indicated minimal depression; 14–19, mild depression; 20–28, moderate depression; and 29–63, severe depression (Beck et al., 1996).

2.6. Balance and performance in various ambulatory activities without falling

The ABC scale was used to estimate balance and performance in various ambulatory activities without falling. The ABC scale is composed of 16 items, each scored from 0 (no confidence) to 100 (completely confident) (Powell et al., 1995). Reliability and validity of the outcome measurement tests have been previously established (Godi et al., 2013; Guerra-Balic et al., 2015; Holden et al., 1986; Lee et al., 2017; Mehrholz et al., 2007; Milot et al., 2019; Schepens et al., 2010).

2.7. The Client Satisfaction Questionnaire

Client Satisfaction Questionnaire-8 (CSQ-8) was used to assess client satisfaction with Walkbot treatment. CSQ-8 is an 8-item, easily scored and administered measurement designed to measure

client satisfaction with services. The items for CSQ-8 were selected on the basis of rating of a number of items by mental health professionals that could be related to client satisfaction and by subsequent factor analysis. CSQ-8 is unidimensional, yielding a homogeneous estimate of general satisfaction with services. CSQ-8 is easily calculated by summing the individual item scores to produce scores ranging from 8 to 32, with high scores indicating greater satisfaction. This information was only collected from the participants in the WLT group.

2.8. Intervention

Both groups received 30 additional minutes of therapy every day, 7 days/week for 2 weeks. The CLT group received the usual inpatient care, including at least one 60 min physical therapy session per day, and an additional 30 min standard physical therapy session focused on pre-gait and/or gait training activities. The WLT group received the usual inpatient therapy, including at least one 60 min physical therapy session and an additional 30 min WLT session. The standardization of CLT included that physical therapist stands facing the subject with the subject holding the hands of the physical therapist. The physical therapist then walked backward, facilitating a reciprocating arm swing of the patient and offering enough support through the patient's arms to maintain balance and gait training (Behrman et al., 2000). The WLT system was activated anthropometric data, including height, weight, foot size, thigh length, shank length, and ankle height, were measured and entered into the participant database. These data were then used to automatically adjust the length of the exoskeleton legs and the optimal gait cycle, according to each individual participant's condition. Each participant then used a suspension vest secured with elastic straps, which was connected to the harness mounted on the counterweight system. Depending on the participant's initial clinical conditions (e.g., pain, muscle weakness, spasticity, tolerance, fatigue, or endurance), approximately 40–60% (adjustable range, 0–100%) of the total body weight was sustained at the first session and then gradually decreased in 5–10% increments per session. Stride length was initially adjusted at 1.0–1.6 m/cycle and walking velocity started at 1.00–1.20 km/h and gradually increased by 0.1 km/h every 5 min, as tolerated to 2.40–2.60 km/h (maximally adjustable to 3.00 km/h). The guidance force mode in the WLT system was used to accurately increase active engagement during

the robot-assisted gait retraining. As the participant's walking ability improved from the initial target level (e.g., 40 Nm), the Walkbot system interactively adjusted the walking speed and resistive torque parameters while attempting to minimize the kinematic trajectory errors. The assistance guidance force was systematically reduced from 100% (passive mode) to 0% (active mode), where the system compensated for the weight, resistance, and inertia in accomplishing symmetrical, optimal gait patterns, as it is capable of applying such a differential mode to the more affected (hemiparetic) leg. Furthermore, realtime audiovisual biofeedback concerning gait kinematics (joint angles), kinetics forces (active, resistive torque, stiffness) on the ankle, knee, and hip interlimb joint movement as well as on the center of the pressure from the force plate mounted on the treadmill. During and after each session, participants were provided with constant verbal encouragement using the knowledge from the results derived from the realtime kinematic and kinetic data. A subcortical locomotor relearning strategy (subconscious, implicit learning) was reinforced by means of asking the participant to kick the ball presented in front of the hemiparetic foot, rather than consciously making an accurate step (Navarro et al., 2018). Heart rate was monitored to maintain the target HR ($220 - \text{Age}$) below 55–85% and BRPE (<11–13), which was in line with American Heart Association (AHA)/American Stroke Association (ASA) guidelines (Billinger et al., 2014). Additionally, blood pressure was closely monitored during WLT to avoid cardiac overload, and rest between training sessions was provided to minimize fatigue when necessary (Park et al., 2018; Kim et al., 2013; Park et al., 2019).

2.9. Statistical analysis

Results were expressed as means and standard deviations. An analysis of covariance (ANCOVA) was used for between-group comparisons because the baseline (pretest) primary and secondary outcome measure data were statistically different between groups. A power analysis, using G-Power software, was conducted to assess the minimum sample size requirement, based on a prior pilot study. Based on our previous study, the sample size was determined as 30 based on effect size (Eta squared, $\eta^2 = 1.02$) and power ($1 - \beta = 0.8$) on FAC and BBS [9]. Based on our previous study, the sample size was determined as 14–20 based on effect size (Eta squared, $\eta^2 = 0.283$ –0.45) and power

($1-\beta = 0.70-0.90$) on FAC, BBS. Additionally, minimal clinical important difference (MCID) was determined to estimate clinical meaningfulness and revealed that all outcome variables were clinically relevant in between-group and within-group changes except for the within-group HR variable (Tables 2–5). All continuous variables were analyzed, using the Kolmogorov-Smirnov test, assuming a normal distribution. ANCOVA tests were used to determine intervention-related changes in FAC, BBS, cardiopulmonary function, HR, BRPE, BDI-II, and the fall risk measurements (ABC scale). SPSS for Windows (version 25.0, SPSS, Chicago, IL, USA) was used to conduct statistical analyses. An alpha was set to 0.05. Data were adjusted for imputative outliers and missing data. In addition, the effect size in real values was used to allow judgement of the magnitude of

the differences and the practical significance of these variables between the two groups.

3. Results

All participants who successfully completed the pre-test, intervention (14 sessions), and post-test were included in the analysis. Table 1 summarizes the demographic and clinical characteristics of participating patients. Chi-squared did not show any significant differences in the baseline demographic or clinical characteristics data between the two groups.

3.1. Clinical outcome and gait comparison

ANCOVA analysis did not show significant changes in the BBS score between the WLT and CLT

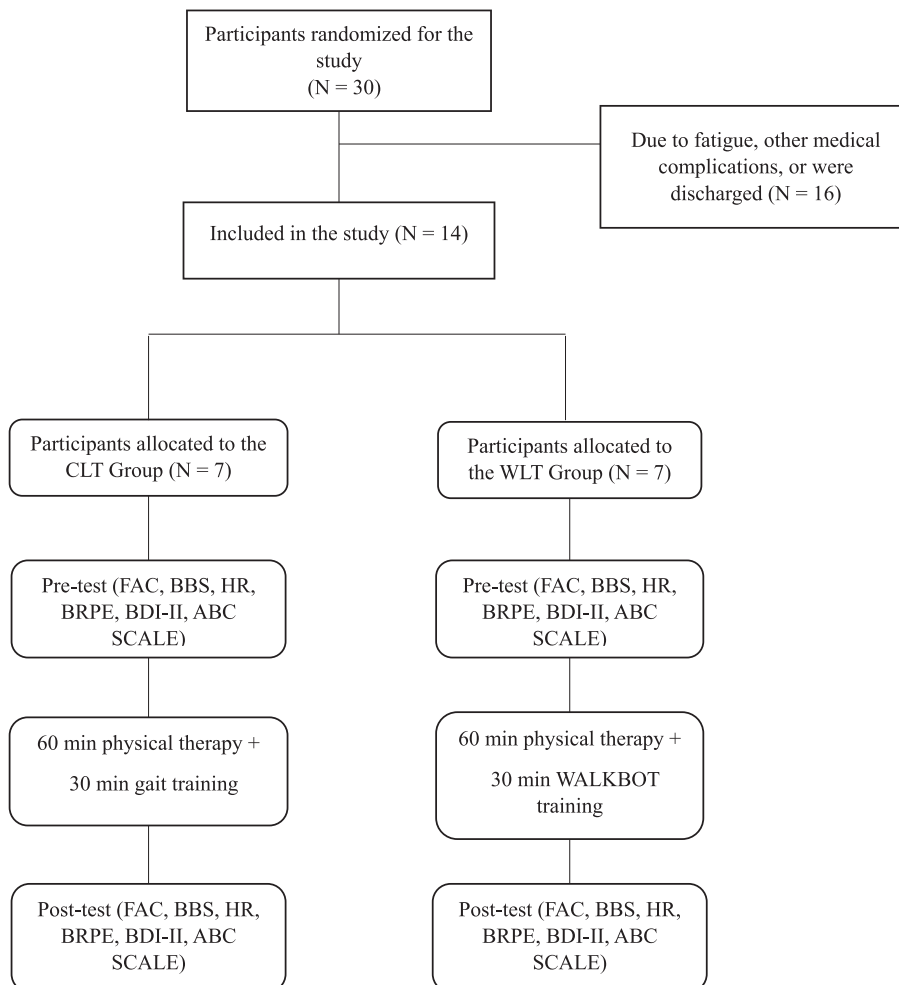


Fig. 1. Flowchart of the study.

Table 1
Demographic and clinical characteristics of the participating patients (N = 14)

Characteristics	CLT (n = 7)	WLT (n = 7)	P-value
Age (years)	69.86	76.29	0.691
Sex			
Male (%)	4 (58)	6 (75)	0.234
Female (%)	3 (42)	2 (25)	
Type of stroke			
Ischemic (%)	7 (100)	7 (100)	-
Side of hemiplegia			
Left (%)	4 (58)	4 (58)	-
Right (%)	3 (42)	3 (52)	

CLT, conventional locomotor training; WLT, Walkbot locomotor training.

groups ($P=0.061$). However, our effect size analysis indicated a medium effect (Eta squared, $\eta^2=0.283$), suggesting greater static and dynamic balance after WLT than after CLT. The FAC score change was significantly greater for the WLT group than for the CLT group ($P=0.030$), signifying better ambulation recovery after WLT than after CLT (Table 2).

3.2. Cardiopulmonary function

There were significantly greater increases in HR ($P=0.009$) and BRPE ($P=0.009$) scores in the WLT group than in the CLT group, representing improved cardiopulmonary endurance following WLT for participants who suffered from stroke (Table 3).

3.3. Psychological functions

ANCOVA showed significantly greater decreases in BDI-II scores in the WLT group than in the CLT

group ($P=0.046$), indicating that depression became less common and less severe after WLT than after CLT (Table 4).

3.4. Balance and performance in various ambulatory activities without falling

ANCOVA showed greater increases in the ABC values in the WLT group than in the CLT group ($P=0.049$), suggesting a greater increase in participants' confidence in their balance and performance in various ambulatory activities without falling after WLT than after CLT (Table 5).

3.5. The Client Satisfaction Questionnaire

The Client Satisfaction Questionnaire showed high scores of 27.62 out of a possible 32 points (86%), indicating that participants were satisfied with WLT. A narrative report is summarized in Table 6.

4. Discussion

The present randomized control trial is the first clinical study to highlight the superior, positive effects of WLT, when integrated with conventional physical therapy, compared to CLT alone, on balance and gait tests, cardiopulmonary function, depression, and self-confidence in balance and performance in various ambulatory activities without falling in participants with acute hemiparetic stroke. Consistent with our hypothesis, the WLT group showed a significantly greater improvement, compared to

Table 2
Berg Balance Scale (BBS) and Functional Ambulation Category (FAC)

	CLT (n = 7)			WLT (n = 7)			P-value	Effect size
	Pre-test	Post-test	Mean Change, MCID	Pre-test	Post-test	Mean Change, MCID		
BBS	24.86 ± 8.32	34.71 ± 9.86	9.85 [‡] >4.73	25.43 ± 5.00	42.86 ± 7.38	17.43 [‡] >4.77	0.061	0.283
FAC	2.14 ± 0.69	3.29 ± 0.76	1.15 [‡] >0.35	2.71 ± 1.25	4.43 ± 0.98	1.72 [‡] >0.25	0.030*	0.359

* ANCOVA test was significant at $P<0.05$. Data are expressed as mean ± standard deviation. CLT, conventional locomotor training; WLT, Walkbot locomotor training; ANCOVA, analysis of covariance; BBS, Berg Balance Scale; FAC, Functional Ambulation Category; [‡]Change in Minimal Clinical Important Difference (MCID) is significant.

Table 3
Heart rate (HR) and Borg Rating of Perceived Exertion (BRPE)

	CLT (n = 7)			WLT (n = 7)			P-value	Effect size
	Pre-test	Post-test	Mean Change, MCID	Pre-test	Post-test	Mean Change, MCID		
HR	84.57 ± 6.53	84.29 ± 2.93	-0.28 <2.56	91.14 ± 14.05	96.00 ± 12.95	4.86 [‡] >1.46	0.009*	0.475
BRPE	14.57 ± 1.40	13.43 ± 0.53	1.14 [‡] >0.61	15.14 ± 2.12	12.00 ± 1.83	3.14 [‡] >0.68	0.009*	0.479

*ANCOVA test was significant at $P<0.05$. Data are expressed as mean ± standard deviation. CLT, conventional locomotor training; WLT, Walkbot locomotor training; ANCOVA, analysis of covariance; HR, heart rate; BRPE, Borg Rating of Perceived Exertion; [‡]Change in Minimal Clinical Important Difference (MCID) is significant.

Table 4
Beck Depression Inventory-II (BDI-II)

BDI-II	CLT (<i>n</i> = 7)			WLT (<i>n</i> = 7)			<i>P</i> -value	Effect size
	Pre-test	Post-test	Mean Change, MCID	Pre-test	Post-test	Mean Change, MCID		
	8.71 ± 5.38	9.86 ± 9.89	1.15 < 3.05	8.86 ± 3.93	4.14 ± 2.41	4.72 [‡] > 1.41	0.046*	0.315

*ANCOVA test was significant at $P < 0.05$. Data are expressed as mean ± standard deviation. CLT, conventional locomotor training; WLT, Walkbot locomotor training; ANCOVA, analysis of covariance; BDI-II, Beck Depression Inventory-II; [‡]Change in Minimal Clinical Important Difference (MCID) is significant.

Table 5
Activities-specific balance confidence (ABC) scale

ABC scale	CLT (<i>n</i> = 7)			WLT (<i>n</i> = 7)			<i>P</i> -value	Effect size
	Pre-test	Post-test	Mean Change, MCID	Pre-test	Post-test	Mean Change, MCID		
	511.43 ± 385.20	685.71 ± 546.62	174.28 [‡] > 140.41	482.14 ± 344.70	1068.86 ± 251.32	586.72 [‡] > 196.00	0.049*	0.308

*ANCOVA test was significant at $P < 0.05$. Data are expressed as mean ± standard deviation. CLT, conventional locomotor training; WLT, Walkbot locomotor training; ANCOVA, analysis of covariance; ABC scale, activities-specific balance confidence; [‡]Change in Minimal Clinical Important Difference is significant.

Table 6
Participant Satisfaction Questionnaire

Selective comments from participants in the WLT group.	
Participant A	"I found program very helpful to my PT problems. Extra time helped a great deal. I feel I can do things now because of the extra time."
Participant B	"It was a sturdy (good) experience. I would talk to people about it and tell about the good experience."
Participant C	"I didn't know what to expect and was scared when I came here but everyone has made this an amazing experience ("Walkbot") and helped me heal."
Participant D	"The PT (including 'Walkbot') ... here all exceptional. I cannot say enough for the extraordinary care that I have received."
Participant E	"Train one person instead of training multiple people to use the robot."

the CLT group, in several outcomes including balance, gait, and performance in various ambulatory activities without falling, cardiopulmonary function (HR, BRPE), and depression. Most importantly, cardiopulmonary function (HR, BRPE) and psychiatric depression data demonstrated that robot-assisted locomotor training contributed to clinically meaningful improvements in cardiopulmonary fitness endurance and reduced the characteristic attitudes and symptoms of depression in acute to subacute phase of stroke rehabilitation.

Clinical balance and gait analyses revealed more significant enhancements in BBS (between-group mean difference = 28.92%) and FAC (mean difference = 9.73%) in the WLT group compared to the CLT group. This finding is consistent with previous robotic locomotor retraining in patients recovering from hemiparetic stroke, which also showed greater BBS improvements (Hornby et al., 2008; Dundar et al., 2014) and FAC (Schwartz et al., 2009; Scherr et al., 2013). Additional MCID analysis demonstrated clinical meaningfulness in within-group (FAC 1.15,

1.72; BBS 9.85, 17.43) changes. Similarly, other Walkbot studies have shown that functional recovery in gait, balance, mobility, and daily living activities were enhanced after WLT in patients with subacute hemiparetic stroke (Park et al., 2018; Kim et al., 2013; Park et al., 2019). A possible underlying mechanism for such positive improvement is that robotic gait training provides an ample number of repetitions (1800–3600 steps), with accurate proprioception inputs on the hip, knee, and ankle joints, which may result in neuroplasticity and associated functional motor recovery (Park et al., 2018; Kim et al., 2013; Park et al., 2019). Clinical cardiopulmonary function analyses demonstrated significant decreases in HR (mean difference = 5.00%) and BRPE (mean difference = 57.50%) in the WLT group (post-HR = 96.00; BRPE = 12.00), as opposed to the CLT group (post-HR = 84.29; post-BRPE = 13.43). Interestingly, the WLT group showed a 5% increase in HR whereas the CLT group failed to show any meaningful change after the intervention, suggesting that the Walkbot intervention was substantially challenging the car-

diopulmonary fitness level. Further, MCID analysis showed clinical relevance in within-group (HR 4.86; BRPE 1.14, 3.14) changes but failed to achieve clinical significance in HR within the CLT group, corroborating previous robotic locomotor retraining results in patients with hemiparetic stroke (Hornby et al., 2008; Milot et al., 2019). In fact, Scherr and colleagues reported in their cohort study with 2,560 individuals that BRPE was strongly correlated with heart rate ($r=0.74$, $p<0.001$), indicating that both BRPE and HR provide important guidelines for exercise intensity in individuals with cardiopulmonary impairments (Scherr et al., 2013). Furthermore, Chang and colleagues demonstrated that the average aerobic measurements of patients with subacute hemiparetic stroke, before training, were 54%–72% lower compared to healthy, age-matched adults, indicating compromised or deteriorated cardiopulmonary function in these patients (Chang et al., 2012). However, as much as 12.8% cardiopulmonary function was improved after robot-assisted training of participants who were not initially ambulatory-independent. These findings clearly suggest that robotic gait training is beneficial for non-ambulatory stroke survivors and that such training increased cardiopulmonary fitness and endurance capacity in patients with compromised cardiopulmonary conditions (hypertension, dyspnea, fatigue). Moreover, such cardiopulmonary fitness capacity may help to prevent further cardiovascular deterioration and associated recurrent stroke (Park et al., 2018). Considering the emphasis on cardiopulmonary fitness in the recommendation from AHA/ASA on stroke rehabilitation (Guerra et al., 2015), this result supports the promising role of robot-assisted gait training in improving cardiovascular fitness in stroke survivors. Currently, cardiopulmonary rehabilitation for stroke patients is not reimbursed by the Center for Medicare and Medicaid Services, although the majority of the risk factors are common between stroke survivors and individuals with coronary heart disease.

Psychiatric depression analysis revealed more significant reduction in BDI-II scores (mean difference, 78.91%) in the WLT group than in the CLT group. MCID confirmed clinical meaningfulness in within-group (4.72) changes, but failed to achieve clinical significance in BDI-II within the CLT group. The BDI-II values for both CLT and WLT are below 13. The BDI-II indicates that a total score of 0–13 is considered in the minimal range, which implies a normal to mild mood disturbance. Thus, since both

groups had scores that remained below 13 on the BDI-II regardless of intervention, it does not seem that these changes would really be clinically meaningful, as they do not indicate mood disorder in the participants enrolled in this study. To date, the absence of studies regarding robotic training-induced effects on depression and falls in acute stroke rehabilitation makes comparisons with the present data impossible. Nevertheless, robotic assisted treadmill gait training was previously shown to be effective for reducing depression in chronic patients with hemiparetic stroke (Calabro et al., 2014). In the present robot-assisted training, WLT may have facilitated motivation and active engagement while also decreasing depression and anxiety associated with the risk of falling (Danielle et al., 2014).

Similarly, ABC scale analysis demonstrated that the WLT group had significantly increased confidence in their balance and performance in various ambulatory activities without falling compared to the CLT group (mean difference = 87.62%). MCID showed clinically relevant within-group (174.28, 586.72) changes. Recent ABC evidence demonstrated high sensitivity (86.36%) and specificity (87.38%) area under the curve, and positive and negative odds ratios, 0.91 ($P<0.001$), indicating good discrimination ability between fallers and non-fallers and predictive validity for future falls (Moiz et al., 2017). A possible underlying mechanism for these superior effects is that robotic gait training provides safe and accurate kinematic and kinetic control of the ankle-knee-hip joint segment and variable motor learning modes (e.g., random speeds, kinematic angles, impedances, and forces) to maximize participant's active participation [9, 14, 15]. In fact, the Walkbot is capable of producing variable random control modes that facilitate active locomotor training and motor relearning with a built-in safety control system embedded in the suspension, actuator control sensors, and external emergency switches (Park et al., 2018, 2019; Kim et al., 2013). Nonetheless, actual fall data were not determined in the present study, which warrants further investigation to ascertain that such actual falls are reduced in WLT compared to CLT. Additionally, the results from the Participant Satisfaction Questionnaire support that the Walkbot-assisted gait training was safe, enjoyable, and helpful; the majority of participants wished to continue the robot-assisted gait training.

A couple of limitations of the current research should be considered in future investigations. One

of the main limitations is that although we extensively measured clinical balance, gait, depression, and balance confidence, the underpinning mechanism for neuroplasticity changes was not investigated due to the lack of quantitative measuring equipment available for assessing neuroplasticity. Future studies should develop advanced imaging tools for measuring robotic training-induced neuroplasticity changes during and after robotic gait training in participants with hemiparetic stroke. Another limitation is that although the present results are promising, they should be interpreted carefully when attempting to extrapolate the current findings to clinical practice and to the management of stroke participant rehabilitation due to the small sample size. The initial sample size was proposed to be 30 participants while accounting for 25% attrition rate. However, due to the complicated nature of acute stroke participants, only 14 participants (46% out of 30) who successfully completed the pre-test, intervention, and post-test were included in the final data analysis. The remaining participants were unable to participate or complete the test due to fatigue, other medical complications, or were discharged. Nevertheless, our effect size analyses, combined with the accumulated results of robot-assisted gait training in participants with hemiparetic stroke indicate that Walkbot use consistently demonstrated the advantageous effects of WLT on gait, balance, cardiopulmonary function, depression, and fall confidence. Additionally, further clinical research is warranted to investigate possible multifactorial interventions for cardiopulmonary function, depression and fall prevention in participants with acute hemiparetic stroke.

5. Conclusion

This clinical research study demonstrated that WLT is more effective than CLT alone at improving balance, gait, cardiopulmonary function, depression, and balance and performance in various ambulatory activities without falling in participants recovering from hemiparetic stroke. The present results provide clinical evidence-based insights into the utilization of robot-assisted locomotor training with conventional neurorehabilitation, to maximize recovery of balance and gait as well as cardiopulmonary and psychological functions at an early stage of stroke neurorehabilitation in acute stroke survivors who were unable to ambulate independently.

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Conflict of interest

None to report.

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