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# Virtual reality-based robotic training for lower limb rehabilitation in stroke patients with Hemiplegia: A pilot study

Lijing Chen [a,b,1], Huanzhi Zhu [a,c,1], Jing Wang [d], Rongrong Lu [e], Jing Tian [e], Bei Wu [f], Jing Chu [a,**], Juan Li [b,g,*]

[a] Naval Medical University, School of Nursing, Shanghai, PR China
[b] Department of Nursing Huashan Hospital Fudan University, Shanghai, PR China
[c] Department of Anesthesiology, The 924th Hospital of Joint Logistics Support Force of Chinese People's Liberation Army, Guilin, Guangxi, 541000, PR China
[d] College of Health and Human Services, University of New Hampshire, Durham, NH, USA
[e] Department of Rehabilitation Huashan Hospital Fudan University, Shanghai, PR China
[f] Rory Meyers College of Nursing, New York University, NY, NY, USA
[g] National Medical Center for Neurological Disorders, Shanghai, PR China

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ABSTRACT

*Background:* More than half of stroke survivors suffer from movement disorders after receiving routine rehabilitation treatment. Evidence suggests that virtual reality (VR)-based robotic training for lower limb rehabilitation is a promising approach for improving motor function recovery.
*Methods:* A pilot open-label randomized controlled trial was conducted to explore the feasibility and preliminary effects of VR-based robotic training for lower limb rehabilitation in stroke patients with hemiplegia. We enrolled 42 stroke patients with hemiplegia, 21 received VR-based robotic training for lower limb rehabilitation and conventional rehabilitation treatment as the intervention, and 21 only received conventional rehabilitation treatment as the control.
*Results:* Forty participants completed the trial. We found a statistically significant difference in lower limb motor function scores from baseline to week 4 between the intervention and control group (mean difference (MD): 6.5 vs 3.3, $p<0.001$). At week 4, participants in the intervention group demonstrated significant enhancements in balancing function, walking ability, activities of daily living, and quality of life ($p<0.05$). However, the intervention group did not show a significant improvement in global cognitive function compared to the control group (MD: 3.8 vs 3.7, $p = 0.873$). No adverse events were observed during the trial.
*Conclusion:* The VR-based robotic training for lower limb rehabilitation showed promise in improving motor function, activities of daily living, and quality of life in stroke patients with hemiplegia. These preliminary findings support the feasibility of this approach and highlight the need for large-scale studies to validate its effectiveness.

## 1. Introduction

Stroke is a leading cerebrovascular disease with high morbidity, high disability rate, high mortality and high recurrence rate. The Global Burden of Disease Study 2021 (GBD 2021) reports that stroke is the second leading cause of death worldwide, following ischemic heart disease, and remains the primary contributor to long-term disability globally [1,2]. Effective rehabilitation is critical for post-stroke recovery, yet stroke rehabilitation presents significant physiological and psychological challenges for patients, caregivers, and healthcare providers [3]. These challenges underscore a critical gap in current practice, the need for innovative, patient-centered solutions that enhance neuroplasticity, sustain motivation, and reduce clinical burden.

Virtual reality (VR) and robotic-assisted therapy have emerged as

* Correspondence author at. Department of Nursing Huashan Hospital Fudan University, No.521Huashan Road, Jing'an District, Shanghai, 200400, PR China.
** Correspondence author at. Naval Medical University, School of Nursing, No. 800 Xiangyin Road, Yangpu District, Shanghai, PR China.
*E-mail addresses:* zwz2399082@foxmail.com (H. Zhu), jing.wang1@unh.edu (J. Wang), bei.wu@nyu.edu (B. Wu), chujing1999@smmu.edu.cn, 2539371351@qq.com (J. Chu), lijuan_fd@fudan.edu.cn (J. Li).

[1] Lijing Chen & Huanzhi Zhu contributed equally to this work and should be considered co-first authors.

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promising technologies to address these gaps. VR systems leverage immersive environments and real-time biofeedback capabilities, mitigate training monotony to transform repetitive tasks into gamified, goal-directed activities (e.g., simulating daily living scenarios), which can promote cortical reorganization through reward-motivated learning [4]. When combined with robotic devices that provide precisely calibrated assistance/resistance, this hybrid approach enables data-driven personalization while alleviating therapists' manual labor burdens [5].

Lower limb rehabilitation robots grounded in motor relearning theory offer precise biomechanical assistance, enabling high-intensity training while reducing therapist labor [6]. The robots also record relevant data during training, allowing therapists to analyze and objectively evaluate patient progress, thereby guiding subsequent rehabilitation treatment plans [7]. Currently, while lower limb rehabilitation robots cannot replace therapists, they offer a new training method that, when combined with other rehabilitation techniques, can enhance the effectiveness of rehabilitation for stroke patients with hemiplegia. A number of randomized controlled trials [8,9] and a meta-analysis [10] show that the robotic training for lower limb rehabilitation combined with VR technology can significantly improve the walking function, balance ability and nerve remodeling effect of stroke patients [11–13]. Current evidence supports the use of robot-assisted therapy to improve motor function in stroke patients as an additional therapeutic intervention combined with traditional rehabilitation treatments. In recent years, many researchers have focused on the application of VR in the rehabilitation of stroke patients [14,15]. However, there is little research on the safety of robotic rehabilitation using fully immersive VR games, and existing research mostly uses non immersive or semi-immersive VR (such as virtual supermarket scene training).

The purpose of this pilot study was to evaluate the effectiveness and safety of VR-based lower limb rehabilitation robot on improving lower limb motor function, cognitive function, activities of daily living and quality of life in stroke patients with hemiplegia.

## 2. Methods

### 2.1. Study design

This pilot study was an assessor-blinded, two-arm randomized controlled trial, conducted at a tertiary teaching hospital in Shanghai, China, from November 2022 to June 2023. This study was conducted as per the Declaration of Helsinki (revised in 2013), and was approved by the Institutional Review Board (IRB) of Huashan Hospital, Fudan University (No. 2019–459). All participants provided written informed consent before the enrollment. This study was registered with the Chinese Clinical Trial Registry (ChiCTR2200055871).

### 2.2. Participants

Stroke patients with hemiplegia admitted to the rehabilitation department were recruited. Inclusion criteria included (1) aged $\geq$18 years, (2) diagnosed with stroke confirmed by CT or MRI, (3)first-time stroke, after 48–72 hours of stable condition, with a disease duration$\leq$6 months,(4)unilateral limb paralysis, with the lower limb Brunnstrom stage $\geq$ III on the hemiplegic side. Patients were excluded if they had: (1) speech and language impairment, or hearing or visual impairments that may interfere with assessment and rehabilitation training,(2)a diagnosis of dementia by neurologists and documented in medical records prior to the onset of stroke, (3) neurological or other medical diseases affecting central nervous system function (such as multiple epilepsy, traumatic brain injury, and organic brain lesions),(4) severe heart, lung, liver, or kidney diseases that preclude rehabilitation treatment, (5) lower limb osteoarthritis/osteodystrophy, joint replacement, fractures, or other bone disorders.

### 2.3. Randomization and blinding

Trained research assistants recruited eligible patients, explained the study, and obtained written informed consent. Participants were randomly assigned into the VR-based robotic training vs control group in a 1:1 ratio. The random number table was generated using SAS 9.4 software and stored in a secure, electronic database with restricted access. After participants met the inclusion and exclusion criteria and completed the baseline assessment, independent research coordinators accessed the electronic system to obtain the grouping information, ensuring that the researchers responsible for recruitment and intervention were blinded to the allocation sequence. Participants were sequentially selected for their corresponding treatment plan according to their order of entry into the group, without skipping any numbers. The regimen number remained constant throughout the trial. Rehabilitation nurses documented the patients' conditions post-training and recorded these details on the training log. After four weeks of intervention, assessments were conducted by rehabilitation nurses who were not involved in the intervention or aware of the randomized grouping.

### 2.4. Interventions

#### 2.4.1. Control group

In the control group, each participant received routine rehabilitation treatment and nursing care, which was guided and accompanied by rehabilitation therapists and rehabilitation nurses lasting 5 days per week for 4 weeks. Routine rehabilitation therapy included physical therapy and occupational therapy, and routine rehabilitation nursing included health education, physical exercise, daily life activities, psychological care, and dietary guidance.

#### 2.4.2. Intervention group

Participants in the intervention group underwent VR-based robotic training in addition of conventional rehabilitation therapy and nursing care (same as that in control group). This was administered for 5 days per week over 4 weeks. The VR-based robotic training program included VR-based walking training, sitting-standing training, balance training, and game training in VR scenarios.

The training content of the lower limb rehabilitation robot based on VR involves a comprehensive rehabilitation training program that combines fully immersive VR with pelvic weight loss exercises. This training was primarily conducted by rehabilitation therapists and nurses, ensuring individualized intervention for each patient. The intervention frequency was set at one 30-minute session per day, five times a week, over a period of four weeks. The main components of the VR-based lower limb rehabilitation robot training included walking training, sitting-standing training, balance training, and game-based training. The intelligent lower limb rehabilitation robot IREGO, developed by Shanghai Jinya Robot Science and Technology Co., Ltd., was used in this trial. The robot can complete walking training, gait analysis, balance training/evaluation, sitting/standing training/evaluation, virtual scene training, game training and so on in indoor, outdoor and other venues. With 5 G communication, VR and other modules, it can meet more than 80% of the lower limb rehabilitation training needs. The instruments and equipment of VR system include: a VR head-mounted display (HMD), two hand-held controllers and a positioning system. This technology is totally immersive VR technology. The model of VR-HMD is HTC Vive Pro 2, and the resolution of one eye can reach 2448 $\times$ 2448, with a refresh rate of 120 Hz and a viewing angle of 120. A detailed description of the training scheme is provided in Table 1, Fig. 1 and Fig. 2.

***Weight loss walking training:*** Includes three modes: assistance, resistance, and following with the aim of reducing weight.

***Balance Training:*** Focuses on improving balance capabilities.

***Sitting-Standing Training:*** Involves both active and passive sit-to-stand exercises.

**Table 1**
Training scheme for virtual reality-based robotic training.

| Training content | Training tasks and VR scenes | Time |
|---|---|---|
| Walking training | Walking task: The patient follows the system's voice prompts and walks forward on the straight track of the circular track with the assistance of the lower limb rehabilitation robot. There are three training modes to choose from: assist, resistance, and follow. The assist mode can adjust the assist force from 0 to 10 Newtons, the resistance mode can adjust the resistance force from 0 to 10 Newtons, and the following mode can adjust the speed quickly, moderately, and slowly.<br>In VR scenes, patients can hear pleasant music, see the forest environment, flowers, trees, animals, high mountains and flowing water, blue sky and white clouds, and other scenery. During the walking process, one passes through grasslands, single plank bridges, pebble floors, and uphill and downhill slopes. | 6 min |
| Break | | 2 min |
| Balance training | 1. Capture Butterfly Task: When the patient reaches the bend of the circular track, they use the pelvic weight loss system and complete the training task by sensing the pelvic safety belt while standing. In the VR scene, butterflies of different colors can be seen flying towards the patient from different heights and directions. The patient needs to use a nearby capture net to capture the butterflies and continue walking forward after capturing all the butterflies.<br>2. Fishing task: When reaching the bend of the circular track, the patient stands and uses their healthy hand to hold the controller as a virtual reality scene hand. In the VR scene, the patient sees a lake and fish swimming back and forth. There is a fishing rod on the surface of the lake, which needs to be picked up by hand and observed by the float. If the float sinks, the patient lifts the rod by hand and continues to move forward after catching the fish.<br>The system can provide multiple balance measurement methods: left foot, right foot, parallel foot, and forward leaning limit, comprehensively achieving balance measurement and training; The pelvic training trajectory system provides random trajectories and various motion trajectories - circular, triangular, 8-shaped, random, etc. | 6 min |
| Break | | 2 min |
| Sitting and standing training | Sitting and standing training: The task is completed through the system prompt sound. When the patient reaches the position of the stone seat, they need to complete the sitting and standing action, pause briefly after each sitting, and then stand up. In the VR scene, a stone seat appears on the track, and the height of the seat is adjusted in advance according to the patient's functional level. The patient needs to sit completely on the seat and stand up, completing sitting and standing training as many times as possible within the specified time.<br>The weight reduction system during standing achieves adjustable dynamic weight reduction of 0–50 kg through force feedback technology. | 6 min |
| Break | | 2 min |
| Game training | There are four types of game tasks: space puzzle (pattern matching), groundhog, parkour cat (obstacle avoidance 1, horizontal direction), and woof angel (obstacle avoidance 2, vertical direction). This task selects different game tasks based on the patient's interests and hobbies. In VR scenes, patients can see different scenes and complete training tasks by using a pelvic weight loss system and sensing the pelvic safety belt while standing. | 6 min |

Note: Training intensity: divided into three modes, simple, general, and difficult, adjusted according to the patient's functional level. Training duration: 30 min in total; Training frequency: 5 times a week, lasting for 4 weeks; VR scenes: dreamy forest, space walk; training location: rehabilitation hall, circular training area.

Intervention method: medical staff use this equipment to provide one-on-one intervention for patients in the above four modules.

***Game Training:*** Comprises four games—Universe Puzzle (pattern matching), Whack-a-Mole, Cool Running Cat (obstacle avoidance in the horizontal direction), and Wangwang Angel (obstacle avoidance in the vertical direction).

***VR Scenes training:*** Includes Dream Forest and Spacewalk environments.

Each task's difficulty level is categorized into simple, moderate, and difficult modes to accommodate various patient needs. The level of task difficulty is selected based on the patient's function level.

### 2.5. *Quality control*

A rehabilitation medical team in the stroke rehabilitation ward consisted of rehabilitation physicians, rehabilitation therapists, rehabilitation nurses, and charge nurses. All team members underwent unified training to ensure consistent standards, intervention methods, and approaches. Researchers understood and monitored the patient's training progress and disease condition to ensure the safe and gradual development of a rehabilitation plan. Researchers maintained effective communication with patients and their caregivers, timely explained rehabilitation training plans and precautions during the trial.

### 2.6. *Outcomes measures*

The primary outcome of interest was motor function of lower limbs measured by the Fugl-Meyer Assessment of Lower Extremity (FMA-LE). FMA-LE is a widely used scale for assessment of motor function after stroke. The scale is recognized as a gold standard and is recommended both for clinical use and research worldwide [16]. Secondary outcomes included balancing function, walking ability, global cognitive function, activities of daily living and quality of life, i.e. BBS, FAC, MoCA and SS-QoL-12 scores. Table 2 presents the outcomes and the instruments used in the trial. The assessment data were collected at two distinct time points: baseline at admission (V0) and 4 weeks post-intervention (V1).

Assessment of safety: The number of adverse events recorded includes a range of symptoms including dizziness, falls, and psychological distress and other discomfort during the trial.

### 2.7. *Statistical analysis*

In this study, the post-intervention scores reported in the literature were utilized to estimate the sample size. Previous studies [11] indicated that the Fugl-Meyer lower limb motor function scores (primary outcome) after intervention were (22.5 $\pm$ 3.3) and (17.7 $\pm$ 3.3) for the two groups, respectively. The study considered a power value of 90% and an alpha level of 0.05 (two-tailed). Consequently, a minimum of 24 participants needed to be recruited: 12 in each group. Considering a 30% dropout rate, a minimum of 34 participants would need to be recruited. To account for potential bias in data used for sample size calculation, the number was rounded to 40 (20 in each group).

Descriptive statistics were used to summarize baseline and clinical characteristics in the overall sample and by group. Baseline characteristics of patients were reported as mean and standard deviation (SD) or median (interquartile) for continuous variables, and as frequency (proportion) for categorical variables. Between-group differences at the 4-weeks endpoint, the significant level was set at $p < 0.05$. All analyses were conducted using IBM SPSS Statistics for Windows, version 27.0 (IBM Corp., Armonk, N.Y., USA).

## 3. Results

Forty-five patients with stroke hemiplegia who met the criteria were initially screened. Of these, 3 refused to participate, leaving 42 patients

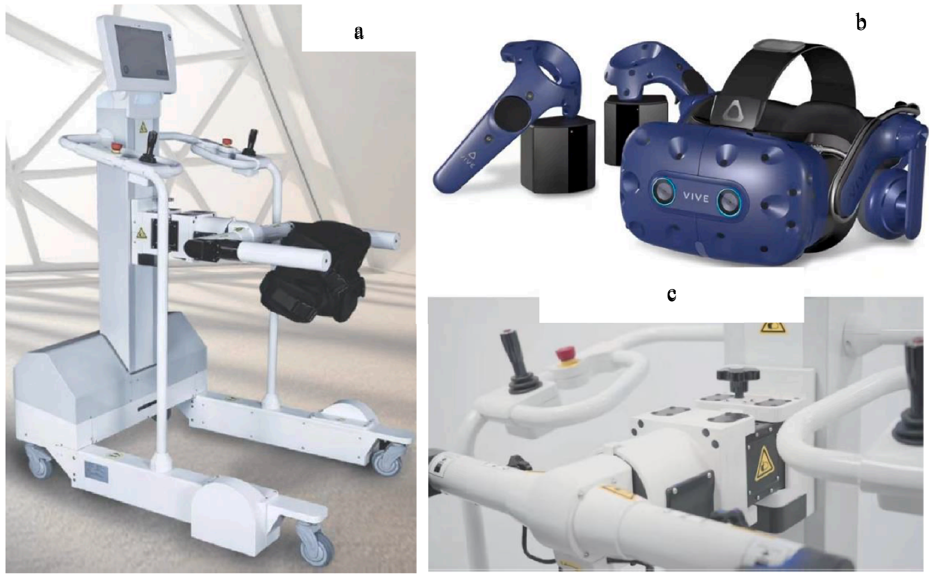


**Fig. 1.** Instruments and equipment of virtual reality-based robotic training.
(a)Lower limb rehabilitation robot; (b)Instruments and equipment for VR system; (c)Full degree of freedom pelvic supporting mechanism

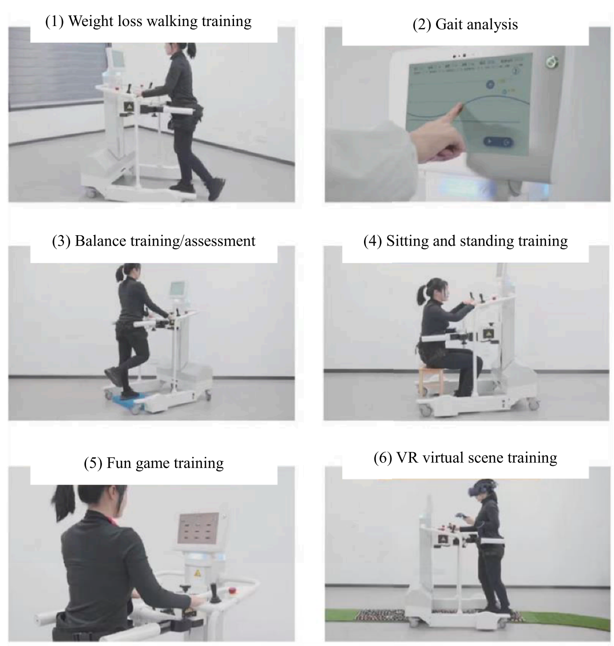


**Fig. 2.** Components of virtual reality-based robotic training.
(1) Weight loss walking training;(2) Gait analysis; (3) Balance training/assessment; (4) Sitting-standing training; (5) Fun game training; (6) VR scene training

who signed the informed consent form and were subsequently randomized into two groups, each comprising 21 patients. Two patients dropped out from each group, resulting in 20 patients per group and a total of 40 participants completed all the collection visits pre- and post-intervention (Fig. 3).

### 3.1. Baseline characteristics

The average age was 55.3 (SD 12.5) years in the 40 participants. About one-fourth of the participants were women ($n = 11$, 27.5%), and a minority of participants ($n = 14$, 35.0%) lived in urban area. The average years of education of the participants was 10.7 (SD 3.1) years, and 62.5% of the participants ($n = 25$) were employed before their stroke onset. No significant differences were observed across all socio-demographic and clinical characteristics between participants in the intervention and control group (Table 3).

As shown in Table 4, there were no significant between-group differences in FMA-LE scores, BBS, FAC, MoCA and SS-QoL-12 scores at baseline.

### 3.2. Preliminary effect of the virtual reality-based robotic training

Compared with pre-intervention, the intervention group participants (mean difference=6.5, 95% CI: 5.6 to 7.3, $p < 0.001$) and control group participants (mean difference=3.3, 95% CI: 2.7 to 4.0, $p < 0.001$) showed statistically significant improvement in lower limb motor

**Table 2**
Outcomes and instruments used in this study.

| Outcomes | Instruments | Description of the instruments |
|---|---|---|
| Motor function of lower limbs | Fugl-Meyer Assessment lower extremity (FMA-LE) | The FMA-LE, designed in Europe in 1980, is the earliest internationally utilized scale for assessing motor function in stroke patients. Its widespread application in clinical and scientific research is attributable to its quantitative nature. The scale encompasses items evaluating motor function, balance, sensation, range of motion, and pain, specifically focusing on lower limb movement levels. It comprises 7 major categories and 17 subcategories, employing a 3-point scoring system (0–2) for each subcategory, with a maximum total score of 34 points. A higher score indicates superior lower limb motor function [16]. |
| Balancing function | Berg Balance Scale (BBS) | BBS is commonly used to assess the balance function of stroke patients. It primarily evaluates static sitting balance, dynamic standing balance, and coordination in balance function. The scale comprises 14 items, ranging from easy to difficult, utilizing a five-level scoring system from "0 to 4," with a maximum total score of 56. A higher score indicates stronger balance ability, whereas a lower score or a score of 40 suggests an increased risk of falling. BBS is widely applied to stroke patients, exhibiting a Cronbach's α coefficient of 0.92–0.98, thereby demonstrating good internal reliability and concurrent validity in this population [32]. |
| Walking ability | Functional ambulation category scale (FAC) | FAC is divided into six grades based on the level of external assistance required by patients when walking, with scores ranging from 0 to 5. A higher score indicates better walking ability. A score of 0 denotes that the patient cannot walk or requires the help of two or more people to walk. Conversely, a score of 5 signifies that the patient can walk independently without any external assistance. FAC has excellent reliability, good validity, and good responsiveness in patients with hemiplegia after stroke [33]. |
| Global cognitive function | Montreal Cognitive Assessment (MoCA) version 8.1 | The MoCA covers eight cognitive domains: memory, attention, visual-spatial abilities, executive functions, language, calculation, temporal orientation and spatial orientation. The score of MoCA ranges from 0 to 30 With higher scores indicating better cognitive function. The optimal cutoff points of MoCA for detecting cognitive impairment were 26/27 (sensitivity 96.1% and specificity 75.6%) [34]. The Cronbach's α coefficient for the MoCA scale in this study was 0.858, and the test-retest reliability was 0.983. |
| Activities of daily living | Barthel Index (BI) | BI is used to evaluate the ability of daily living. BI, designed by Mahoney and Barthel in the mid-1950s, is the most widely used scale of activities of daily living in the world with good reliability and validity. It is mainly based on the actual performance of patients in daily living, not on the possibility ability of patients. It consists of 10 items, and the score is graded from 0 to 15, with a total score of 100. The higher the score, the higher the ability of daily living. The Chinese version of BI has good retest reliability and inter-rater reliability, with Cronbach'sα value of 0.916, which has structural validity and predictive validity and is widely used in the assessment of stroke patients [35]. |
| Quality of life | short version of the Stroke-Specific Quality of Life Scale (SS-QoL-12) | The SS-QoL-12, developed by Chen et al. [36] at the Hong Kong Institute of Education, is a self-assessment tool specifically designed for stroke patients. It comprises 12 items, each rated on a five-point Likert scale ranging from "1″ (completely agree) to "5" (completely disagree), yielding a total score out of 60 points. A higher score indicates a better health status. |

function after the intervention. Compared with that of the control group, the lower limb motor function in the intervention group had statistically significantly greater improvements at post-intervention with respect to baseline ($p < 0.001$). The intervention group demonstrated significantly greater improvements in almost all the secondary outcomes at post-intervention, except global cognitive function when compared with the control group (Table 4). The effect sizes as estimated by Cohen's d ranged from 0.7 to 2.1, indicating that the effects of the intervention on motor function and quality of life were large.

Compared to the control group, the intervention group had statistically significantly greater improvement in balancing function at post-intervention (mean difference = 17.6, 95 % CI: 5.5 to 10.5, $p < 0.001$). The intervention group also demonstrated significantly greater improvement in walking ability (median difference = 1.5, 95 % CI: 0.1 to 0.8, $p = 0.042$). The effects of the intervention on different aspects of motor function were generally medium to large. Compared to the control group, the intervention group had statistically significant increased scores in activities of daily living (mean difference = 20.8, 95 % CI: 18.4 to 23.1, $p < 0.001$) and quality of life (mean difference = 5.2, 95 % CI: 0.9 to 3.1, $p < 0.001$) from pre-intervention to post-intervention with large effect sizes. After intervention, the MoCA scores in the intervention group (mean difference = 3.8, 95 % CI: 2.8 to 4.8, $p < 0.001$) and the control group (mean difference = 3.7, 95 % CI: 2.9 to 4.5, $p < 0.001$) increased with respect to baseline, showing that both groups had improvement in global cognitive function after intervention. However, the differences between pre-post intervention changes of MoCA in two groups were not statistically significant ($p = 0.873$).

No adverse events (e.g., dizziness, falls, or psychological distress and other discomfort) happened in the intervention group and control group during this trial.

## 4. Discussion

This pilot study evaluated the effectiveness and safety of the

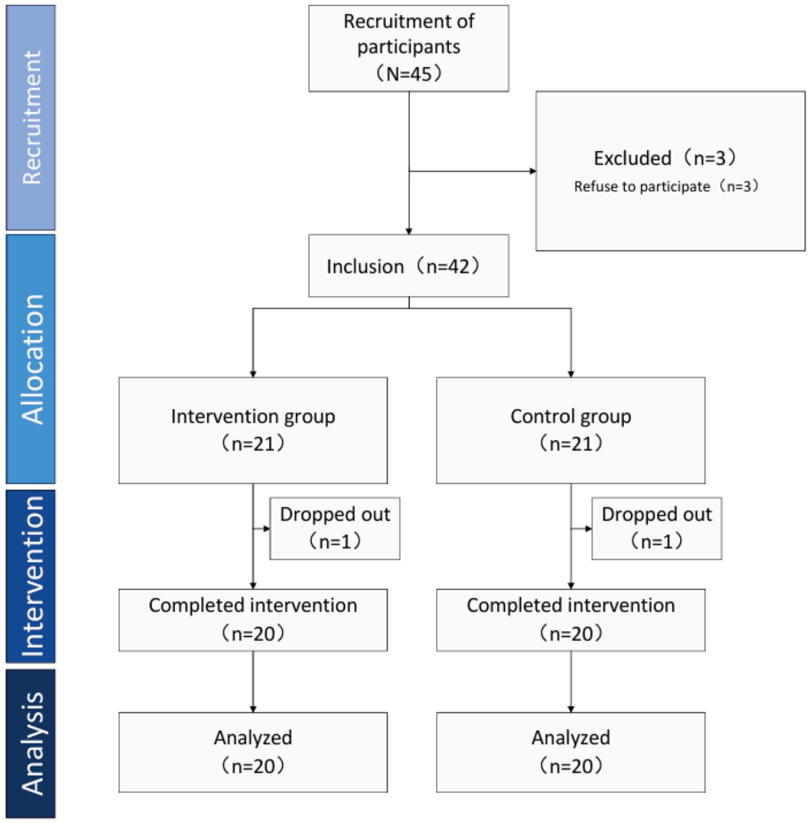


**Fig. 3.** Flowchart of participants.

**Table 3**
Sociodemographic and clinical characteristics of participants.

| Variables | Total (*n* = 40) | Intervention (*n* = 20) | Control (*n* = 20) | *P* value |
|---|---|---|---|---|
| Age, year, mean (SD) (Minimum, Maximum) | 55.3 (12.5) (21~76) | 52.8 (11.5) (27~70) | 57.8 (13.1) (21~76) | 0.204 |
| Female, n (%) | 11(27.5) | 6 (30.0) | 5 (25.0) | 0.723 |
| Han ethnicity, n (%) | 38 (95.0) | 19 (95.0) | 19 (95.0) | |
| Urban Residence, n (%) | 14 (35.0) | 8 (40.0) | 6 (30.0) | 0.507 |
| Years of education (year), mean (SD) | 10.7 (3.1) | 11.6 (3.3) | 9.8(2.7) | 0.059 |
| Currently employed, n (%) | 25 (62.5) | 15 (75.0) | 10 (50.0) | 0.102 |
| Married, n (%) | 33 (82.5) | 17 (85.0) | 16 (80.0) | 0.972 |
| Smoking, n (%) | 5 (12.5) | 2 (10.0) | 3 (15.0) | 0.948 |
| Drinking, n (%) | 5 (12.5) | 1 (5.0) | 4 (20.0) | 0.342 |
| Stroke type, n (%) | | | | |
| Ischemic stroke | 18 (45.0) | 8 (40.0) | 10 (50.0) | 0.525 |
| Hemorrhagic stroke | 22 (55.0) | 12 (60.0) | 10 (50.0) | |
| Hemiplegia, n (%) | | | | |
| Left hemiplegia, n (%) | 15 (37.5) | 7 (35.0) | 8 (40.0) | 0.744 |
| Right hemiplegia, n (%) | 25 (62.5) | 13 (65.0) | 12 (60.0) | |
| Time of onset, month, median (IQR) | 2.5 (1.3) | 2.9 (1.3) | 2.2 (1.2) | 0.107 |
| Dysphagia n (%) | 13 (32.5) | 6 (30.0) | 7 (35.0) | 0.736 |
| Speech and language impairment, n (%) | 25 (62.5) | 11 (55.0) | 14 (70.0) | 0.327 |
| BMI, mean (SD) | 23.8 (2.5) | 23.3 (2.4) | 24.3 (2.4) | 0.207 |

Abbreviation: IQR: interquartile range, SD: standard deviation.
Note: P values presented were based on chi-squared test for categorical variables, *t*-test and Mann-Whitney U test for continuous variable.

application of VR-based robotic training in stroke patients with hemiplegia. Preliminary data suggested that such multimodal training may support neural plasticity in stroke patients. Additionally, the intervention appeared to improve patient motivation and adherence, with observed trends toward enhanced motor function (e.g., motor function of lower limb, balancing function and walking ability), activities of daily living and quality of life in post-intervention assessments. Furthermore, VR-based robotic training in stroke patients with hemiplegia was feasible. The interventions were feasible to deliver and acceptable to participants without adverse events.

VR-based robotic training showed a positive impact on stroke patients with hemiplegia. These outcomes, measured by FMA-LE, BBS, and FAC showed an improvement in motor function in both intervention group and control group after intervention. However, the motor function in intervention group had greater improvement than that in the control group. This study aligns with previous findings [17,18]. In these two RCTs involving 128 patients with cerebrovascular disease, VR rehabilitation significantly improved motor function and daily living abilities compared to traditional methods. The intervention groups which received VR rehabilitation exhibited enhanced FMA scores, BI, improved the step length difference, increased walking speed, and higher FAC scores after treatment. In recent years, substantial advancements have been made in the development and application of rehabilitation robot technologies within healthcare. These technologies include end effectors and exoskeleton devices used for sports rehabilitation, with one notable application being the improvement of gait function in stroke patients. Zhao's study [19] showed that, stroke patients undergoing robot assisted training with Lokohelp system for 30 min per day, five days per week for 12 weeks combined with conventional rehabilitation, showed more significant improvement in the balance coordination than those stroke patients undergoing conventional rehabilitation. A meta-analysis [20] based on 14 studies involving 106 participants showed a statistically significant improvement in the Berg Balance Scale scores for patients with chronic stroke following VR intervention compared to usual care. Another meta-analysis [21] pooled data from 52 studies, demonstrating that robot-assisted rehabilitation combined with VR was the most effective in improving balance. Lower

**Table 4**
Within and between T test results for study measures, testing the change in mean scores for control and intervention.

| Scale | Pre-intervention mean score and p value | | | Post-intervention mean score | | Pre-post diff. average score | | p value within groups | | p value between groups | Effect size |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | Intervention | Control | p value | Intervention | Control | Intervention | Control | Intervention | Control | | |
| Motor function of lower limbs ↑better | 19.1 (4.1) | 18.9 (5.1) | 0.892 | 25.5 (3.1) | 22.2 (4.2) | 6.5 (1.7) | 3.3 (1.4) | <0.001 | <0.001 | <0.001 | 2.0 [a] |
| Balancing function ↑better | 23.3 (10.3) | 23.5 (9.7) | 0.937 | 40.9 (8.8) | 33.1 (10.9) | 17.6 (3.4) | 9.6 (4.4) | <0.001 | <0.001 | <0.001 | 2.1 [a] |
| Walking ability[#] ↑better | 1.0 (1.0, 2.0) | 1.0 (1.0,2.0) | 0.480 | 2.0 (2.0, 4.0) | 2.0 (2.0, 3.0) | 1.5 (1.0, 2.0) | 1.0 (1.0, 1.5) | <0.001 | <0.001 | 0.042 | 0.8[b] |
| Global cognitive function ↑better | 17.9 (6.9) | 17.7 (4.3) | 0.913 | 21.7 (5.8) | 21.4 (4.8) | 3.8 (2.2) | 3.7 (1.7) | <0.001 | <0.001 | 0.873 | 0.1 [a] |
| Activities of daily living ↑better | 49.0 (13.3) | 49.8 (16.5) | 0.875 | 69.8 (12.1) | 62.8 (14.8) | 20.8 (4.9) | 13.0 (5.5) | <0.001 | <0.001 | <0.001 | 1.5 [a] |
| Quality of life ↑better | 33.3 (3.7) | 34.4 (4.1) | 0.377 | 38.5 (3.5) | 37.6 (3.3) | 5.2 (1.6) | 3.2 (1.7) | <0.001 | <0.001 | <0.001 | 1.2 [a] |

Paired sample $N = 40$, intervention $n = 20$, control $n = 20$.
Note. [#] denotes categorical variable, with the statistical description presented as Median (Interquartile Range).
[a] indicates T test, and.
[b] indicates Mann-Whitney U test. For the *t*-test, effect size is given by Cohen's d. For the Mann-Whitney test, effect size is given by the rank biserial correlation.

limb muscle weakness is one of the limiting factors for functional recovery in stroke hemiplegic patients. The resulting posture asymmetry and body imbalance greatly affect their balance ability. It also causes difficulty in walking ability by reducing lower limb functional movement [22]. Mirelman A et al. [23]and Bonnyaud C et al. [24] found that rehabilitation robot assisted gait training is a highly effective method for restoring asymmetric walking ability caused by muscle weakness. In addition, study has shown that robot assisted rehabilitation training can effectively alter balance ability, thereby improving walking function in stroke patients [25]. This is consistent with the results of this study. Secondly, VR allows patients to train without spatial limitations, enhancing their actual experience by creating VR, lower limb robots, and balance boards, enabling them to obtain stronger visual information [26]. Therefore, by increasing patient participation and real-time feedback, the rehabilitation effect of patients can be improved. The combination of VR and robot training not only increases patients' motivation to participate, but also increases the support stage on the affected side, improves stability, and thus increases the speed at which patients can quickly start walking [27].

Our research findings suggested that global cognitive function improved significantly after the intervention compared with that before intervention (within-group comparison), however, between-group differences in changes of global cognitive function before and after intervention were not significant. This may be due to the small sample size and the short duration of the intervention. The results of the present study are consistent with those of Akinci et al. [28] in global cognitive function. A systematic review and meta-analysis [29] showed that VR-based cognitive interventions among stroke patients led to significant improvements in global cognitive function, executive function, and memory, however, no significant effect on attention, visuospatial and language.

Our research findings also suggested that compared with traditional rehabilitation therapy and nursing care, lower limb rehabilitation robot training based on VR showed more improvements in activities of daily living and quality of life. The results of this study are consistent with those of previous studies. Akinci's study [28] showed that, robot-assisted gait training with Lokomat and VR in subacute stroke patients could improve patients' self-reported quality of life and daily activities compared to conventional physical therapy. The incremental effect on cognitive function is not obvious, which may be due to the rapid recovery of cognition, or the limited cognitive test failed to find the change of cognitive function. In the randomized controlled trial of Manuli et al. [30], the training combined with VR technology and rehabilitation robot have significantly improved quality of life. Stroke patients' quality of life declines and their happiness declines due to various reasons such as diseases and dysfunction. The results of this study are realistic, and the rehabilitation training of VR technology combined with lower limb rehabilitation robot can alleviate various adverse effects of stroke patients due to diseases and improve their quality of life, which is consistent with the research results of Zhang E [31]. This may be because when carrying out intelligent rehabilitation training, patients have the opportunity to do activities that they can't exercise in their daily life, help patients feel happy and fulfilled that they can't get in real life, reduce the psychological gap between patients before and after illness, and thus improve their quality of life.

While this study demonstrates the feasibility and preliminary efficacy of VR-robotic training, its scalability in clinical settings requires careful consideration. First, spatial and environmental constraints arise from the need for specialized tracking systems and circular pathways inherent to VR-based lower limb training. Such setups require ample, quiet space to minimize distractions and ensure immersive scenarios, escalating infrastructural demands. Second, the necessity for continuous one-on-one supervision during VR-robotic sessions, due to patients' motor impairments and virtual environment risks, coupled with real-time adjustments to exercise parameters (e.g., intensity, mode) based on ongoing functional assessments, mandates dedicated clinical staff, further increasing operational costs. Third, the complexity of synchronizing robotic devices with VR interfaces necessitates meticulous maintenance; high-frequency usage in scaled deployments could incur significant repair and calibration expenses, exacerbating long-term sustainability concerns. Finally, economic barriers persist as most robotic rehabilitation programs remain out-of-pocket expenses, while stroke rehabilitation's protracted nature imposes substantial financial strain on patients. Future research should prioritize cost-benefit analyses to quantify the health economic impact of VR-robotic interventions, informing resource allocation and policy decisions for stroke care.

This study had certain limitations. First, single center design and relatively small sample size may limit the power of the evidence. Future research should conduct multi center large sample intervention studies on training programs to improve sample representativeness and generalizability of research results. Second, the intervention time is relatively short, only 4 weeks, and no follow-up was conducted on the patients after 4 weeks of intervention, making it impossible to predict the long-term impact of the training program on the patients. In the future trials, the intervention time should be extended, and long-term follow-up should be conducted on stroke patients after intervention to explore the long-term impact of training programs on stroke patients. Third, due to the inherent characteristics of the intervention, implementing a double-blind design was unfeasible, introducing potential performance bias risks. To mitigate these biases, the research team has implemented several measures including standardized training for all intervention personnel and establishment of uniform operating procedures. Forth, there was an inconsistency in the duration of intervention between the intervention group and the control group, which may affect the results. Future trials should balance intervention dosage between groups, and use a "conventional treatment + placebo intervention" design for further validation.

## 5. Conclusion

This study combines the advantages of immersive VR and lower limb rehabilitation robots for rehabilitation training of stroke patients with hemiplegia, contributing preliminary clinical evidence for this novel rehabilitation treatment approach. Our pilot findings suggest that VR-based robotic training may offer potential benefits compared to conventional rehabilitation, particularly in areas such as lower limb motor function, balance function, walking ability, activities of daily living, and quality of life. However, non-significant trends were observed in cognitive function (e.g., MoCA). Given the small sample size and short-term of this study, these observations should be interpreted as supporting the feasibility and promise of the intervention rather than its definitive effectiveness. Further research with larger cohorts and longer-term assessments is needed to establish robust clinical evidence for this integrated rehabilitation strategy.


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## Data sharing statement

The raw data supporting the conclusions of this manuscript will be made available by the authors, without undue reservation, to any qualified researcher.

## Statement of ethics

This study was approved by the Institutional Review Board (IRB) of Huashan Hospital Fudan University [2019–459]. All participants provided written informed consent.

## CRediT authorship contribution statement

**Lijing Chen:** Writing – original draft, Investigation, Conceptualization. **Huanzhi Zhu:** Writing – review & editing, Methodology, Investigation, Conceptualization. **Jing Wang:** Writing – review & editing, Conceptualization. **Rongrong Lu:** Investigation. **Jing Tian:** Investigation. **Bei Wu:** Writing – review & editing, Conceptualization. **Jing Chu:** Writing – review & editing, Project administration, Conceptualization. **Juan Li:** Writing – original draft, Project administration, Funding acquisition, Formal analysis, Conceptualization.

## Declaration of competing interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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