Environmental-Perturbation Balance Training Improves Functional Outcomes in Patients with Subacute Stroke: A Prospective Randomized Controlled Trial

NCT Number: Not yet assigned

Document Date: 19 May 2026

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1. Abstract

Objective: This study aims to design a prospective, assessor-blinded, randomized controlled trial to evaluate the efficacy of environmental-perturbation balance training (E-PBT) on the functional prognosis of patients with subacute stroke.

Methods: This trial will enroll 148 patients with first-ever or recurrent stroke. Rehabilitation will commence once the patient's condition stabilizes, as indicated by stable vital signs and no further progression of neurological deficits. Participants will be randomly assigned (1:1) to the experimental group (E-PBT) or the control group (conventional rehabilitation), receiving 5 sessions per week for 8 weeks.

Outcomes: The primary outcome will be the binary modified Rankin Scale (mRS) score at 90 days post-stroke, categorized as favorable (0–3 points) versus poor (4–6 points). Secondary outcomes at 90 days will include: (1) shift analysis of mRS scores; (2) Modified Barthel Index (MBI); (3) mini-Balance Evaluation System Test (miniBESTest); (4) Overall Stability Index (OSI); (5) Scale for Contraversive Pushing (SCP); (6) Trunk Impairment Scale (TIS); (7) Timed Up and Go Test (TUG); (8) 6-Minute Walk Test (6MWT); and (9) Fugl-Meyer Assessment for Lower Extremity.

Discussion: This study uniquely integrates the core principle of perturbation training with structured environmental challenges. By employing stable, controllable environmental disturbances instead of unpredictable physical perturbations, it aims to enhance safety and compliance in subacute stroke patients, promote the transfer of balance gains to real-world contexts, and ultimately improve overall functional prognosis.

Conclusion: This protocol offers a safe, low-cost, and easily scalable therapeutic strategy for subacute stroke rehabilitation. Its effectiveness will be rigorously evaluated through this randomized controlled trial.

Key words: Stroke; Subacute stage; Functional prognosis; Environment-perturbation balance training; Randomized controlled trial; Modified Rankin Scale

2. Background

Stroke has a persistently high incidence worldwide and is the second leading cause of disability and death, imposing a heavy burden on society and the economy[1]。Compared with stroke-free individuals of the same age group, stroke patients have a significantly higher risk of falls[2]. Falls not only cause direct physical injuries such as fractures and craniocerebral trauma, but also induce a fear of falling again, which often prompts patients to actively reduce their daily activities and social participation, ultimately severely impairing their quality of life and social reintegration. Therefore, how to effectively improve balance function and prevent falls after stroke remains a core challenge that urgently needs to be addressed in the field of neurological rehabilitation. Perturbation-based balance training (PBT) is an intervention that can effectively improve balance function and specifically enhance reactive balance control in stroke patients[3, 4]. By repeatedly exposing to controlled postural perturbations, it enables patients to practice and refine their control of balance reactions, thereby improving reactive stability and fall-resistance skills[5].

PBT has been shown to be effective in improving balance and stability both immediately[4, 6] and over the long term[7], as well as in reducing fall rates. The beneficial effects of PBT on post-stroke balance function can be attributed to multilevel plastic changes in the central nervous system. Through repeated exposure to controlled postural perturbations, the central nervous system is forced to continuously optimize motor strategy, shifting postural control from rigid, inefficient patterns to more economical and precise ones. Furthermore, repetitive perturbation training has been found to increase activation in the prefrontal and parietal cortices, suggesting that perturbation training not only strengthens subcortical automatic postural reflex pathways but also recruits higher-order cortical networks[8, 9]. Despite the promising clinical prospects of PBT, existing studies still have several critical limitations that hinder its clinical translation and widespread adoption. First, in terms of evidence quality, the level of evidence supporting the improvement of balance function by PBT has been rated as "very low", mainly due to risks of bias in the included studies and imprecision caused by small sample sizes, which undermine confidence in the effect

estimates[3]。In the randomized controlled trial designed by Mansfield et al., although intended to provide high-quality evidence, the final results showed that PBT did not reduce fall rates in stroke patients[10]. The insufficient sample size, combined with underreporting of falls due to reliance on patient self-report, may account for the negative findings. Moreover, previous RCTs have enrolled only community-dwelling individuals who were able to stand independently for more than 30 seconds, with a median Berg Balance Scale score of 50 (out of a maximum of 56 points)[4]. This may limit the generalizability of the findings to stroke patients with poorer functional status and potentially higher fall risk. Furthermore, although subgroup analyses have suggested that patients in the subacute phase may derive greater benefits (SMD = 0.83), dedicated studies specifically targeting this critical recovery period remain scarce[3]. From a clinical implementation perspective, PBT typically requires the direct application of unpredictable pushes, pulls, or rapid platform movements to patients[5]. For subacute stroke patients who are in the early stage of recovery and have severely compromised balance confidence, such interventions can be psychologically demanding and fear-provoking, potentially leading to avoidance behaviors or poor engagement. Moreover, given the compromised neuromuscular control commonly seen in stroke patients, the relatively intense perturbations pose higher safety risks, which further limits their widespread clinical application.

Therefore, we innovatively propose an "environment-perturbation balance training (E-PBT)" intervention, which delivers stable, graded environmental perturbations to keep the challenges within the manageable range. This approach can significantly reduce fear, align with the psychological characteristics of subacute stroke patients, and improve training engagement and safety, thereby filling the current research gap that has insufficiently addressed subacute patients and those with moderate-to-low functional levels. By altering the size and angle of the support surface, this training heightens patients' alertness and psychological adaptability, prompting them to actively integrate sensory information and adjust motor strategies. In turn, this can more effectively reshape internal model of balance control and facilitate genuine

neuroadaptive learning in the brain. Moreover, this training more closely mimics real-life fall scenarios, with the aim of directly cultivating the proactive postural control and strategic decision-making abilities required in daily living.

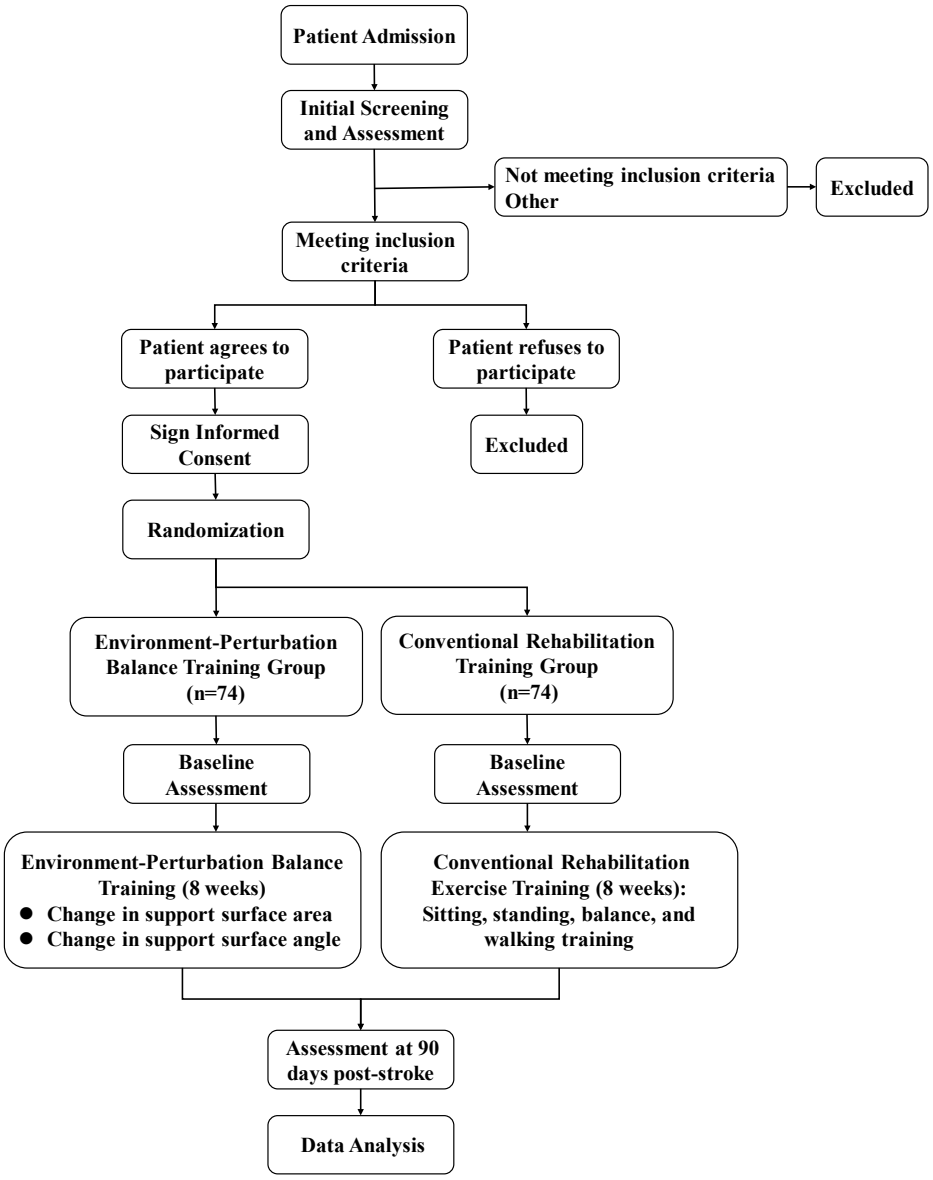
This study aims to systematically evaluate the efficacy of this E-PBT intervention on functional recovery in patients during the subacute stage of stroke through a prospective randomized controlled trial, and to explore its potential effects on balance ability, activities of daily living, and overall functional outcomes, thereby providing a more effective and clinically translatable new strategy for post-stroke rehabilitation.

3. Methods

3.1 Ethics approval

This study protocol has been submitted to and approved by the Ethics Committee of Shenyang First People's Hospital (2026SYKYPZ42). All procedures will be conducted in accordance with the principles of the Declaration of Helsinki. All participants will receive comprehensive information about the study prior to enrollment and will be required to provide written informed consent.

3.2 Flow chart



3.3 Inclusion criteria

(1) Diagnosed with stroke according to the International Symposium on Cerebral Vascular Disease criteria, with definite confirmation by imaging modalities such as computed tomography (CT) or magnetic resonance imaging (MRI).

(2) First-ever or recurrent cerebral hemorrhage or cerebral infarction. According to the Guidelines for the Early Management of Patients with Acute Ischemic Stroke: A Guideline for Healthcare Professionals from the American Heart Association/American Stroke Association[11] and the Chinese Guidelines for Early Rehabilitation of Stroke[12], rehabilitation can be initiated once the patient's condition is stable (vital signs are stable and no further progression of symptoms

and signs).

(3) Total NIHSS score between 5 and 20 (inclusive) prior to randomization, with a lower limb motor score ≥2.

(4) Presence of balance dysfunction, with a miniBESTest total score ≤12.

(5) Good compliance with rehabilitation therapy and no contraindications to active training.

(6) Age between 18 and 85 years.

(7) The subject or their legal representative is able and willing to provide written informed consent.

3.4 Exclusion criteria

(1) History of prior cerebral hemorrhage or cerebral infarction with residual significant limb dysfunction.

(2) Severe cognitive impairment or sensory aphasia that precludes communication and cooperation with treatment.

(3) Concomitant severe cardiopulmonary, hepatic, or renal insufficiency, or other serious medical diseases.

(4) Presence of neurological or musculoskeletal disorders affecting balance function prior to stroke onset.

(5) Uncontrolled severe hypertension or diabetes mellitus.

(6) Active bleeding or deep vein thrombosis.

(7) Current participation in another clinical trial or rehabilitation program that may affect the results of this study.

(8) Any other condition that may interfere with the outcomes of this study.

(9) History of limb amputation affecting bilateral coordination or independent walking ability.

(10) Pregnancy.

3.5 Participant recruitment

Participants will be recruited from the Neuro-Intelligent Rehabilitation Center of Shenyang First People's Hospital and the First Department of Rehabilitation, Staff Central Hospital of China Railway 19th Bureau Group Co., Ltd. Upon patient

admission, research staff will first screen the medical records regarding the current admission and medical history. Once potential participants are identified, the study details will be explained to them. After obtaining informed consent from those who agree to participate, they will be enrolled and subsequently randomly assigned to groups.

3.6 Baseline assessment

Table 1 lists the participant data to be collected. Baseline data will be collected by trained research staff who will not be involved in the intervention process for the participants.

Table 1：Baseline data of the subjects

	All	Experimental group	Control group
general information			
Age (year)			
Sex			
Weight (kg)			
Height (cm)			
Time from stroke onset to randomization (day)			
Educational level Primary school Junior high school Senior high school College or above			
Employment status Employed Retired Unemployed Student Not employed			
Marital status Married Single Divorced Widowed			
Lifestyle and behavioral risk factors			
Smoking history Never smoker Current smoker Former smoker (quit			

≥6 months ago)			
Alcohol consumption history Never drinker Occasional drinker Regular drinker (⩾2 times per week)			
Physical activity level Sedentary Regularly active			
Dietary habits Usual diet High-salt / high-fat / high-sugar diet Vegetarian diet			
Medical history			
Diabetes mellitus			
Hypertension			
Obesity			
Dyslipidemia			
Coronary heart disease / Angina pectoris			
Atrial fibrillation			
Previous stroke			
Previous myocardial infarction			
Heart failure			
Peripheral arterial disease			
Chronic kidney disease			
Sleep apnea			
Migraine			
Medication history			
Antiplatelet agents			
Anticoagulants			
Antihypertensives			
Antidiabetic agents			
Lipid-lowering agents			

Antiarrhythmic agents			
Baseline stroke severity and functional status			
NIHSS score			
Pre-stroke mRS score			
miniBESTest			
Trunk Impairment Scale (TIS)			
Scale for Contraversive Pushing (SCP)			
Clinical subtype and imaging characteristics			
Stroke type Ischemic Hemorrhagic Subarachnoid hemorrhage Cerebral venous sinus thrombosis			
Lesion location Brainstem Cerebellum Corticospinal tract Basal ganglia Cortex Multiple lesions			

3.7 Standardization procedures

To ensure a high level of standardization and reproducibility, the following quality control measures will be implemented. First, a detailed Standard Operating Procedures (SOP) manual will be developed, and all participating therapists will receive unified training and certification. Second, all assessments will be conducted in the same quiet, spacious, and consistently lit assessment room. The brand, model, and placement of all equipment will be fixed and clearly marked. Detailed standardized assessment protocols will be developed for each assessment tool, including standardized wording for patient instructions, standardized demonstration of movements, permitted encouragement, and prohibited cues. All assessors, who will be blinded to group allocation, will undergo centralized training on the assessment procedures.

3.8 Randomization procedure

First, a computer-generated random number sequence will be used to allocate eligible participants in a 1:1 ratio to either the environmental-perturbation balance training group (experimental group) or the conventional rehabilitation training group (control group). The randomization process will be performed by an independent researcher

who will not be involved in participant recruitment, intervention delivery, or outcome assessment. After randomization, baseline data will be measured by an independent evaluator. Subsequently, the physical therapists will be informed of the participants' group assignments. Blinding of the physical therapists is not feasible due to the distinct nature of the interventions. Upon completion of the intervention, outcome assessments will be conducted by independent assessors who will be blinded to group allocation. Finally, after the follow-up and outcome assessments of all participants have been completed, the data will be finalized and subjected to quality checks. Unblinding will then be performed by an independent statistician, who will conduct the statistical analyses.

3.9 Intervention

3.9.1 E-PBT

Participants in the experimental group will receive environmental-perturbation balance training, at a frequency of 5 sessions per week for 8 weeks (±1 week). The core principle of this training is to deliver standardized, controllable environmental perturbations tailored to the patient's functional level. All perturbations will be administered under safe conditions, following a stepwise "challenge–adapt–rechallenge" progression principle, with the aim of maximizing the patient's active postural control strategies and neuromuscular adaptation, thereby improving balance function and ultimately facilitating the patient's return to home and community life. Each training session will be structured as follows: 30 minutes in total, consisting of a warm-up, environmental-perturbation balance training, and a cool-down period.

3.9.2 Conventional rehabilitation training

Participants in the control group will receive conventional rehabilitation training at a frequency of 5 sessions per week for 8 weeks (±1 week), based on the principles of neuro-developmental therapy (NDT) and motor relearning programme (MRP). The training will include static and dynamic sitting and standing balance, weight shifting, single-leg stance, weight-bearing exercises, core stabilization training, straight-line walking on firm, level ground, and step up and down exercises. Each session will be structured as follows: 30 minutes in total, consisting of a warm-up, conventional rehabilitation training, and a cool-down period.

3.9.3 Other rehabilitation interventions

Participants in both the experimental and control groups will receive other rehabilitation

interventions as clinically indicated, including occupational therapy, speech therapy, swallowing function training, aerobic training, physical modality therapy, acupuncture, and rehabilitation nursing care.

3.10 Outcomes

All assessments will be conducted at 90 days (±7 days) post-stroke by the same assessor.

3.10.1 Primary outcome

The primary outcome of this study is the improvement in neurological functional outcome at 90 days post-stroke, as measured by the modified Rankin Scale (mRS). The mRS is a 7-level ordinal scale ranging from 0 to 6, with higher scores indicating greater disability. For clinical interpretability and statistical analysis, the mRS will be dichotomized as follows: a favorable outcome is defined as an mRS score of ≤ 3 (indicating the ability to walk independently or with minimal assistance), and an unfavorable outcome is defined as an mRS score of ≥ 4 (indicating inability to walk independently and requiring assistance in daily activities). At 90 days (±7 days) after stroke, the mRS score will be assessed by trained evaluators who are blinded to group allocation, through face-to-face interviews or telephone follow-ups. The primary comparison will be the difference in the proportion of favorable outcomes (i.e., mRS $\leq$ 3) between the two groups.

3.10.2 Secondary outcome

3.10.2.1 Shift analysis of the modified Rankin Scale (mRS)

In contrast to the primary binary outcome, the shift analysis will be able to capture the treatment effect of E-PBT on the functional prognosis of post-stroke patients more sensitively, by avoiding information loss associated with the use of a fixed dichotomization threshold.

3.10.2.2 Assessment of activities of daily living

Activities of daily living will be assessed using the Modified Barthel Index (MBI), which consists of 10 items with a total score ranging from 0 to 100. Higher scores indicate greater independence in daily living. The assessment will be administered through a structured interview to capture the patient's actual performance during the preceding week.

3.10.2.3 Assessment of balance function assessment

a) mini-BESTest: Balance function will be assessed using the mini-Balance Evaluation Systems Test (mini-BESTest), which consists of 14 items with a total score ranging from 0 to 28. Higher scores indicate better dynamic balance ability. This scale has been demonstrated to have good responsiveness to changes in balance function in stroke patients.
b) Overall Stability Index (OSI): The Overall Stability Index will be measured using the balance function training and assessment system (XY-PH-V) to quantify the displacement of the center of pressure (COP) during static standing. A lower OSI value indicates better postural control ability. Since the majority of participants are unable to stand independently at baseline, this outcome will only be collected after the completion of the intervention.

3.10.2.4 Assessment of trunk function

a) Trunk Impairment Scale (TIS): Trunk function will be assessed using the Trunk Impairment Scale (TIS), which consists of three subscales: static sitting balance, dynamic sitting balance, and coordination. The total score ranges from 0 to 23, with higher scores indicating better trunk control.
b) Scale for Contraversive Pushing (SCP): The presence of pusher syndrome will be evaluated using the Scale for Contraversive Pushing (SCP). The SCP comprises the following three items: (1) asymmetry of posture, (2) abduction or extension of the non-paretic limb, and (3) resistance to passive correction of posture. Pusher syndrome is considered to be present when the score for each of the three SCP items is > 0.

3.10.2.5 Assessment of walking ability

Since the majority of participants are unable to stand independently at baseline, walking ability will only be assessed after the completion of the intervention.

a) Timed Up and Go Test (TUG): The TUG will record the time (in seconds) required for the participant to rise from a chair, walk 3 meters, turn around, return, and sit down again. Shorter times indicate better mobility. The use of assistive devices is permitted during the test, but physical assistance from others is not allowed.

b) 6-Minute Walk Test (6MWT): The 6MWT will record the total distance (in meters) that the participant can walk as far as possible within 6 minutes. If the test is terminated early due to fatigue or safety concerns, the actual distance walked and the reason for termination will be recorded.

3.10.2.6 Motor function assessment

Lower extremity motor function will be assessed using the Fugl-Meyer Assessment for Lower Extremity (FMA-LE). The scale consists of 17 items, with a total score ranging from 0 to 34. Higher scores indicate better lower limb motor function.

3.11 Statistical analysis

For the primary outcome, the modified Rankin Scale (mRS) score at 90 days post-stroke will be dichotomized into favorable outcome (mRS 0–3) and unfavorable outcome (mRS 4–6). A binary logistic regression model will be used, with group assignment (experimental vs. control) as the primary independent variable, adjusting for baseline mRS score, age, and stroke type, to calculate the odds ratio (OR) and its 95% CI.

For the secondary outcome of mRS shift analysis, the mRS score at 90 days post-stroke will be treated as an ordinal dependent variable, with treatment group as the primary independent variable. An ordinal logistic regression model will be used to calculate the common odds ratio and its 95% CI, and the model goodness-of-fit will be reported.

For the other continuous secondary outcomes, including the Modified Barthel Index (MBI), mini-BESTest, Trunk Impairment Scale (TIS), Scale for Contraversive Pushing (SCP), Overall Stability Index (OSI), Timed Up and Go Test (TUG), 6-Minute Walk Test (6MWT), and Fugl-Meyer Assessment for Lower Extremity (FMA-LE), the Shapiro-Wilk test will be used to assess whether the data follow a normal distribution. Normally distributed data will be analyzed using independent-samples t-test, while non-normally distributed data will be analyzed using non-parametric tests.

3.12 Sample size

This study is a prospective randomized controlled trial, with the primary outcome being favorable functional outcome at 90 days post-stroke, defined as a modified Rankin Scale (mRS) score of 0–3 (i.e., able to walk independently or with minimal assistance). Based on the results of a prospective cohort study conducted in Queensland, Australia,

the rate of favorable mRS outcomes at 90-day follow-up among patients receiving conventional inpatient rehabilitation was approximately 70%[13]. This rate was used as the expected favorable outcome rate for the control group. The experimental group will receive environmental-perturbation balance training, and it is anticipated that this will increase the favorable outcome rate to 90%. With a two-sided significance level of $\alpha = 0.05$, a power of $1 - \beta = 0.80$, and a 1:1 allocation ratio between the two groups, the sample size will be calculated using the formula for comparison of two independent proportions:

$$n = \frac{(Z_{\alpha/2} + Z_{\beta})^2 \times [P_0(1 - P_0) + P_1(1 - P_1)]}{(P_1 - P_0)^2}$$

The calculated sample size was 59 participants per group. Accounting for an anticipated dropout or loss to follow-up rate of approximately 20%, we plan to recruit at least 74 participants per group, totaling 148 participants across both groups. This sample size will provide sufficient statistical power for the comparison of the primary outcome between the two groups.

3.13 Adverse event monitoring and reporting

A priority of this study is to ensure the safety of all participants during the training process and to systematically document any adverse reactions that may be related to the intervention. An adverse event (AE) is defined as any untoward medical occurrence in a participant during the study period, which does not necessarily have a causal relationship with the intervention. AEs include, but are not limited to: falls, musculoskeletal pain (e.g., shoulder pain, low back pain), dizziness, palpitations, and excessive fatigue. A serious adverse event (SAE) is defined as any event that results in death, is life-threatening, requires hospitalization or prolongation of existing hospitalization, or leads to persistent or significant disability/incapacity. Any SAE must be reported immediately upon occurrence.

During the intervention period, therapists will inquire about and document any discomfort experienced by participants after each training session. All adverse events, regardless of whether they are considered related to the study, will be recorded in detail

in a unified Adverse Event Record Form, including the nature of the event, time of onset, severity, duration, actions taken, and outcome. The principal investigator will review the adverse event records on a weekly basis.

In the event of an adverse event, the therapist will immediately suspend the training, assess the participant's condition, and provide appropriate management (e.g., rest, adjustment of the training protocol). Depending on the severity, a decision will be made as to whether to temporarily suspend or withdraw the participant from the study. In the case of a serious adverse event, it must be reported to the Ethics Committee and the Data and Safety Monitoring Board within 24 hours, and the intervention for the affected participant will be suspended until safety has been reassessed and confirmed.

4. Disscussion

This study innovatively proposes a training approach for improving walking ability in patients during the subacute stage of stroke—environmental-perturbation balance training (E-PBT). Through systematic, progressive environmental perturbations, E-PBT can enhance patients' reactive postural control and sensory integration capabilities, thereby driving adaptive reorganization of the central nervous system. Compared with conventional perturbation-based balance training, E-PBT shifts the focus of intervention from unpredictable physical pushes and pulls to stable, controllable environmental challenges. This approach is designed to reduce fear and safety risks in patients during the early stage of recovery, while more closely mimicking real-life fall scenarios, thus making it safely applicable to patients who are in the critical recovery window but have not yet achieved higher functional levels. The potential mechanisms of action of this study encompass three levels: at the functional level, repeated environmental perturbations can optimize the efficiency of automatic postural responses, as reflected by a reduction in excessive stepping steps and improved response speed following perturbations; at the neural level, diverse sensory challenges can promote activation of the prefrontal and parietal cortices and enhance the connectivity efficiency of sensorimotor networks; and at the psychological level, controllable progressive challenges can improve patients' balance confidence and break the vicious "fear-avoidance" cycle.

This study employs a prospective, assessor-blinded randomized controlled design and adheres to the CONSORT guidelines. Nevertheless, several limitations should be acknowledged. First, due to the nature of the rehabilitation interventions, blinding of patients and therapists is not feasible, which may introduce expectation bias. However, we have minimized detection bias through assessor blinding and standardized assessment procedures. Second, the primary outcome measure, the mRS as a binary variable, may not be sufficiently sensitive to capture improvements in the specific domain of balance function. To address this, we have included multiple secondary outcomes, including the mRS shift analysis, as complementary measures. Finally, the intervention duration is limited to 8 weeks, and the follow-up period extends to 90 days post-stroke; therefore, the long-term effects of the intervention warrant further investigation.

5. Conclusion

This study provides a safe, low-cost, and easily scalable rehabilitation approach for clinical practice. The required training equipment is readily available in rehabilitation facilities at various levels, and therapists can master the progressive difficulty adjustment method after a brief training period. If the efficacy and safety of E-PBT are validated in this study, this protocol could be incorporated into routine clinical pathways as a standardized intervention for post-stroke balance rehabilitation, with clear potential for widespread dissemination and significant public health implications.

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Environmental-Perturbation Balance Training Improves Functional Outcomes in Patients with Subacute Stroke: A Prospective Randomized Controlled Trial

Informed Consent Form

Research Institution: Neur-Intelligent Rehabilitation Center of Shenyang First People's Hospital

Principal Investigator: Wang Hong

Version number: V2.0

Version date: June 25, 2026

Informed Consent Form

The clinical study described in this Informed Consent Form is initiated by Shenyang First People's Hospital, entitled “Environmental-Perturbation Balance Training to Improve Functional Outcomes in Patients with Subacute Stroke: A Prospective Randomized Controlled Trial.” As the research team, we will provide you with a detailed introduction to this study. Your participation is entirely voluntary. This document contains information required by applicable regulations, and to safeguard the rights and welfare of study participants, it has been reviewed and approved by the Ethics Committee of Shenyang First People's Hospital.

1. Why is this study being conducted?

Background

Stroke has a relatively high incidence worldwide and is the second leading cause of disability and death, imposing a heavy burden on society and the economy. Compared with people of the same age who have not had a stroke, stroke patients have a higher risk of falling. Falls not only lead to direct injuries such as fractures and craniocerebral injuries, but more importantly, they can trigger a fear of falling again in patients, and this fear often prompts patients to actively reduce daily activities and social participation, ultimately seriously impairing quality of life and the ability to return to society. Therefore, how to effectively improve balance function and prevent falls after stroke has always been a core issue that urgently needs to be resolved in the field of neurological rehabilitation.

In stroke patients, perturbation-based balance training (PBT) is an intervention that can effectively improve patients' balance function and specifically strengthen their reactive balance control ability. By allowing participants to repeatedly experience controlled postural perturbations, it enables them to practice and improve their control of balance reactions, thereby enhancing patients' reactive stability and fall-resistance skills. PBT has been proven to be effective in both immediate and long-term improvement of balance and stability, as well as in reducing fall rates. Although PBT demonstrates clear prospects for clinical application, existing studies still have several

key limitations that constrain its clinical translation and implementation, including low level of evidence leading to insufficient confidence in effect estimates, research results being unable to be extrapolated to stroke populations with poorer function and potentially higher fall risk, and the direct application of unpredictable pushes, pulls, or rapid support-surface movements to patients in the early recovery phase with severely insufficient balance confidence—which imposes high psychological stress and strong fear, potentially leading to avoidance or low participation, among others.

Therefore, this study innovatively proposes "environment-perturbation balance training (E-PBT)," which designs stable, graded environmental perturbations to control challenges within the range that patients can "cope with." This can significantly reduce fear, conform to the psychological characteristics of subacute patients, improve training participation and safety, and thereby fill the gap in current research on insufficient attention to subacute and middle-to-low function populations.

Objective

This study aims to systematically verify the improvement effects of this E-PBT on function in patients with subacute stroke through a prospective randomized controlled trial, and to explore its potential impact on balance ability, activities of daily living, and long-term functional outcomes, so as to provide a new strategy that is more effective and has clinical translational value for post-stroke rehabilitation.

2. How many people will participate in this study?

It is expected that approximately 148 eligible patients with subacute stroke will be recruited from multiple centers to participate in this study.

3, Which people will be selected to participate in this study?

(8) Diagnosed with stroke according to the International Symposium on Cerebral Vascular Disease criteria, with definite confirmation by imaging modalities such as computed tomography (CT) or magnetic resonance imaging (MRI).

(9) First-ever or recurrent cerebral hemorrhage or cerebral infarction. According to the Guidelines for the Early Management of Patients with Acute Ischemic Stroke: A Guideline for Healthcare Professionals from the American Heart

Association/American Stroke Association[11] and the Chinese Guidelines for Early Rehabilitation of Stroke[12], rehabilitation can be initiated once the patient's condition is stable (vital signs are stable and no further progression of symptoms and signs).

(10) Total NIHSS score between 5 and 20 (inclusive) prior to randomization, with a lower limb motor score ≥2.

(11) Presence of balance dysfunction, with a miniBESTest total score ≤12.

(12) Good compliance with rehabilitation therapy and no contraindications to active training.

(13) Age between 18 and 85 years.

(14) The subject or their legal representative is able and willing to provide written informed consent.

4. Which people are not suitable to participate in this study?

(1) History of prior cerebral hemorrhage or cerebral infarction with residual significant limb dysfunction.

(2) Severe cognitive impairment or sensory aphasia that precludes communication and cooperation with treatment.

(3) Concomitant severe cardiopulmonary, hepatic, or renal insufficiency, or other serious medical diseases.

(4) Presence of neurological or musculoskeletal disorders affecting balance function prior to stroke onset.

(5) Uncontrolled severe hypertension or diabetes mellitus.

(6) Active bleeding or deep vein thrombosis.

(7) Current participation in another clinical trial or rehabilitation program that may affect the results of this study.

(8) Any other condition that may interfere with the outcomes of this study.

(9) History of limb amputation affecting bilateral coordination or independent walking ability.

(10) Pregnancy.

5. How long will this study last?

The entire study cycle is expected to be 18 months, and the time for each subject to participate in the study is 8 weeks. You may voluntarily withdraw from the study at any time, and this will not affect your subsequent normal treatment and rights and interests.

6. How is this study conducted?

If you agree to participate in this study, the investigators will perform a baseline assessment on you, including: demographic information, medical history, medication use, physical examination, balance function tests, motor function assessment, walking ability assessment, activities of daily living assessment, etc.

Randomization: All participants will be randomly assigned by computer, and you will have a 50% chance of being assigned to the experimental group (environment-perturbation-based balance training group) and a 50% chance of being assigned to the control group (conventional rehabilitation training group). The grouping status will be informed to your investigators in advance during the training period, but you and the assessors will not be informed of the grouping, which is for the purpose of more objective evaluation of the results.

Intervention

Experimental group: Patients in the experimental group will receive environmental-perturbation balance training for 8 weeks (±1 week), five times per week. The core of this training lies in applying standardized, controllable environmental perturbations to patients according to their different functional levels. All perturbations, under the premise of ensuring safety, follow the stepwise progression principle of "challenge-adaptation-rechallenge," aiming to maximize the stimulation of patients' active postural control strategies and neuromuscular adaptation, thereby improving patients' balance function and ultimately achieving the purpose of patients' return to family and society. The training structure for the intervention group is: each training session lasts 30 minutes, including warm-up, environmental perturbation balance training, and relaxation.

Control group: The control group will receive conventional sitting, standing, balance,

and walking training based on neurodevelopmental therapy and motor relearning theory for 8 weeks (±1 week), five times per week, including static or dynamic sitting and standing balance, weight shifting, single-leg standing, weight-bearing, core training, straight-line walking on flat hard ground, stepping up and down stairs, and other exercises. Its training structure is: each training session lasts 30 minutes, including warm-up, conventional motor training, and relaxation.

Other rehabilitation: Subjects in both the experimental group and the control group will receive rehabilitation treatments such as occupational therapy, physical modality therapy, acupuncture, and rehabilitation nursing according to patients' clinical needs.

Assessment nodes

Baseline (at enrollment): collection of basic information and clinical information, physical examination, mRS score, NIHSS score, miniBESTest score, etc.

Follow-up period (at 90 days from onset): telephone or outpatient follow-up, assessment of activities of daily living, motor function, balance function, trunk function, walking function, etc.

Data and Sample Collection

This study does not involve the collection of biological samples such as blood; only clinical assessment data and kinematic parameters during the training process will be collected (if recording is needed, prior consent will be obtained). All data will be strictly confidential and will only be used for scientific research analysis.

7. What obligations do I need to comply with to participate in the study?

(1) Truthfully report health status

During the study period, participants need to promptly and truthfully inform the investigators of any changes in health status, including but not limited to discomfort, falls, disease recurrence, new symptoms, etc.

(2) Attend training and assessment on time

Participants need to cooperate in completing all prescribed training sessions, assessment tests, and subsequent follow-up work in accordance with the requirements of the study protocol. If unable to attend on time, they should inform the investigators in advance.

(3) Accept randomization and follow the intervention protocol

Participants need to accept random assignment to either the experimental group or the control group, and strictly adhere to the training protocol of their assigned group for intervention, and may not change or choose training methods on their own.

(4) Not participate in other interventional rehabilitation studies

During the study period, without the consent of the investigators, participants may not simultaneously participate in other interventional rehabilitation studies or clinical trials.

(5) Comply with safety instructions and promptly report discomfort

During the training process, participants need to follow the instructions of the investigators and complete the movements as required. If feeling unwell (such as dizziness, pain, excessive fatigue, etc.), they should immediately inform the investigators.

(6) Properly withdraw from the study

If a participant decides to withdraw from the study, they should inform the investigators as early as possible, and cooperate in completing the necessary safety assessment and withdrawal procedures before withdrawal.

(7) Confidentiality obligations

Participants may not obtain, copy, or disclose others' information or research data in the study without authorization. Personal information obtained during the research process will be kept confidential in accordance with the law.

(8) Cooperate with the investigators' decision to terminate participation

If the investigators determine that continued participation may cause obvious harm to the participant, or if the participant repeatedly fails to comply with the study requirements, the investigators have the right to terminate the participant's study participation. The participant should cooperate in completing the safety assessment prior to termination.

(9) Timely update contact information and notify of absences

Participants need to provide accurate contact information and promptly inform the investigators when their information changes. If unable to attend a training session or

assessment for any reason, they should request leave in advance and explain the reason.

8. What are the costs involved in participating in this study?

Costs you need to bear: The standardized rehabilitation treatment and examinations, as well as drug therapy, that are required due to your condition. If you concurrently have other diseases or experience changes in condition and require treatment and examinations, as well as costs for switching to other treatments due to ineffective treatment, etc.

Costs you do not need to bear: All study-related assessments, rehabilitation guidance programs, and online assessments and follow-up are all free of charge.

9. What are the benefits of participating in this study for the treatment of my disease?

You may directly benefit from the training, or you may not. If you are assigned to the experimental group, you may obtain better improvement in balance function and walking ability than conventional training. Even if you are assigned to the control group, you can still receive standard conventional balance training. Regardless of the group assignment, the knowledge gained from this study will contribute to the rehabilitation of more stroke patients in the future.

10. Do I have other treatment options?

You may choose not to participate in this study, receive conventional rehabilitation treatment, or choose other rehabilitation institutions or training methods. Please discuss the most suitable option for you with your doctor.

11. What are the possible risks of participating in this study?

Training-related risks

The environmental perturbations provided by environmental-perturbation balance training only change the direction and angle of the support surface. As far as current clinical practice and known literature are concerned, this balance training content, compared with conventional training, does not increase additional training risks.

Ineffective risks

Any rehabilitation training may have the possibility of poor effect or ineffectiveness,

and your condition may still progress due to the natural course of the disease or concurrent other problems.

In addition, for the protection of your core rights and interests, we promise that:

(1) The entire training process will be supervised one-on-one by experienced rehabilitation therapists;

(2) An individualized risk assessment will be conducted before training, and the perturbation intensity and difficulty will be adjusted according to the level that the patient can tolerate;

(3) The training area will be equipped with protective equipment such as handrails, non-slip mats, and protection belts;

(4) If you feel excessive fatigue or discomfort during the training, you may terminate the training at any time.

12. Can I voluntarily choose to participate in the study and withdraw from the study midway?

Yes. Whether to participate in this study is entirely voluntary. You may withdraw at any time without giving any reason, and this will not affect your subsequent medical treatment or your relationship with your doctor.

If you decide to withdraw, please inform the investigators in advance. If you only stop training but do not declare withdrawal, we will still contact you to complete the follow-up assessment (if you agree), in order to ensure data integrity, but you have the right to refuse.

13. What will happen if there is new information related to the study?

If during the study new information that may affect your willingness to continue participation appears (such as new risk findings), we will inform you in a timely manner and discuss with you whether to continue participation.

14. How will participating in this study affect my life?

You need to undergo regular assessments and follow-up work according to the study plan. This may take up your time and energy, and may require family accompaniment. Please carefully consider this in light of your own situation and family support conditions.

During the study period, you should avoid participating in other interventional rehabilitation clinical studies.

15. Will my personal information be kept confidential?

We will strictly keep your personal information and medical records confidential. The research results may be published in medical journals or presented at academic conferences, but your name or any information that could identify you will never appear. The Ethics Committee, regulatory authorities, or the study sponsor have the right to access the original data to verify the research process, provided that your privacy is protected, and all relevant personnel are obligated to maintain confidentiality. We will make every effort to protect the privacy of your personal medical information to the extent permitted by law.

16. Related Inquiries

For study-related questions: please contact the investigators _____, phone _____, address_____.

For subject rights issues or complaints: please contact the Ethics Committee of Shenyang First People's Hospital, phone 024-31956272, email synkll@163.com.

Subject Consent Statement

I agree to participate in Environmental-Perturbation Balance Training Improves Functional Outcomes in Patients with Subacute Stroke: A Prospective Randomized Controlled Trial.

By signing here, it means:

1 have read and understood this Informed Consent Form, and the investigators have fully explained the study content to me.

2 I have had the opportunity to ask questions, and all questions have been answered to my satisfaction.

3 I have had sufficient time to consider whether to participate.

4 I voluntarily agree to participate in this study.

5 I agree that study-related personnel and regulatory authorities may review my medical and personal information when necessary, but it must be strictly kept confidential.

6 I agree □ disagree □ (please mark √ in the box) to allow my anonymized data to be used for subsequent related research (subject to Ethics Committee approval).

Subject Signature: _____ Date: _____

Print Name of Subject: _____ Phone Number: _____

Signature of Legal Representative (if applicable): _____ Relationship to Subject: _____ Date: _____

Signature of Impartial Witness (if applicable): _____ Date: _____

Print Name of Witness: _____ Phone Number: _____

Investigator Signature: _____ Date: _____

Print Name of Investigator: _____ Phone Number: _____