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Effects of whole-body vibration training on balance and ankle awareness in stroke survivors

Submission date
22/07/2024

Recruitment status
No longer recruiting

Registration date
29/07/2024

Overall study status
Completed

Last Edited
02/10/2024

Condition category
Musculoskeletal Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[X] Individual participant data

Plain English summary of protocol
Background and study aims
Although whole-body vibration (WBV) training is acknowledged for its benefits in enhancing motor functions across several neurological disorders, its precise influence on ankle joint proprioception (the body's ability to sense movement, action, and location) and balance in stroke patients is still not well understood. This research seeks to assess the impact of WBV training on ankle joint proprioception and balance in stroke patients, thereby filling this important research void.

Who can participate?
Patients aged ≥30 years old after their first-episode stroke, defined as individuals with no prior stroke events.

What does the study involve?
Thirty-five stroke patients will be randomly assigned to either the WBV group (n = 17) or a control group (n = 18) using a random number table method. The control group will receive daily general rehabilitation for four weeks, while the WBV group will receive an additional 30 minutes of WBV training each day with the Trunsan S110 Vibration Training System. Assessments will be conducted at baseline and after four weeks of intervention, using various scales and tests for ankle joint proprioception and balance.

What are the possible benefits and risks of participating?
The possible benefit of the WBV training is to help restore ankle joint proprioception and balance in stroke patients. No serious or other adverse events are expected during the follow-up of studies.

Where is the study run from?
The Rehabilitation Medicine Department, the First Affiliated Hospital of the University of Science and Technology of China

When is the study starting and how long is it expected to run for?
February 2020 to May 2022

Who is funding the study?
This research was funded by a grant from Anhui Province Twelfth Five-Year Clinical Medicine Key Specialty (Grant No. ZD125_0013), Key Technologies R&D Program of Anhui Province (Grant No. 202004h07020017), and the Fundamental Research Funds for the Central Universities (Grant No. WK9110000134).

Who is the main contact?
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Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Funder grant numbers: ZD125_0013, 202004h07020017, WK9110000134

Study information

Scientific Title
Impact of whole-body vibration training on ankle joint proprioception and balance in stroke patients: A prospective cohort study

Study objectives
Whole-body vibration (WBV) training will significantly improve both balance and proprioceptive abilities

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 03/04/2022, Ethics Committee of the First Affiliated Hospital of the University of Science and Technology of China (17 Lujiang Road, Luyang District, Hefei, Anhui Province, 230001, China; +86 0551-62282931; ahslyyllwyh@163.com), ref: XJS2020-1-5 (NK)

Study design
Single-center prospective cohort study

Primary study design
Observational

Study type(s)
Efficacy

Health condition(s) or problem(s) studied
Restoration of ankle joint proprioception and balance in stroke patients

Interventions
Thirty-five stroke patients will be randomly assigned to either the (whole body vibration) WBV group (n = 17) or a control group (n = 18) using a random number table method. The control group will receive daily general rehabilitation for four weeks, while the WBV group will receive an additional 30 minutes of WBV training each day with the Trunsan S110 Vibration Training System. Blinded outcome assessments will be conducted at baseline and post-treatment, using the Berg balance scale (BBS), functional reach test (FRT), Romberg test length (RTL) and area (RTA), and completion rates of ankle joint dorsiflexion-plantar flexion (DP) and inversion-eversion (IE) tests. Follow-up assessments will be performed after four weeks of intervention.

Data will be analyzed using SPSS 26.0 (SPSS, Inc., Chicago, IL). The measurement data will be expressed as mean ± standard deviation (SD). Upon confirming the homogeneity of variances, independent samples t-tests will be used for inter-group analyses, while paired-sample t-tests will be employed for intra-group comparisons. For data sets not following the normal distribution, Mann-Whitney U tests and Wilcoxon signed-rank tests will be employed. A correlation analysis will be performed to explore the correlation between DP (times) and IE (times). Moreover, multiple linear regressions will be conducted to explore the existence of confounders. A P-value of less than 0.05 will be deemed indicative of statistical significance.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Measured using the TecnoBody PROKIN System (PK252) at baseline and after four weeks of intervention:
1. Balance measured using the Romberg test length (RTL).
2. Stability measured using the Romberg test area (RTA).
3. Ankle joint flexibility measured using the completion rates of ankle joint dorsiflexion-plantar flexion (DP).
4. Foot stability measured using the inversion-eversion (IE) tests.

Key secondary outcome(s))
Assessed at baseline and after four weeks of intervention:
1. Aspects of balance, such as sitting to standing and standing on one foot, measured using the

Berg balance scale (BBS) score
2. Maximum reach distance beyond arm's length in a standing position measured using the functional reach test (FRT)

Completion date
20/05/2022

Eligibility

Key inclusion criteria
1. Eligible participants (≥30 years of age) were first-episode stroke patients, defined as individuals with no prior stroke events
2. Stroke diagnosis was confirmed through CT or MRI, with characteristic imaging features: low attenuation in ischemic strokes or high/mixed-intensity signals in hemorrhagic strokes, accompanied by hemiplegia
3. Participants had stable vital signs (heart rate: 60–100 bpm; blood pressure: 90/60 to 120/80 mmHg; respiration: 16–26 breaths per minute; temperature: 36.5–37.3 °C) and cognitive function (mini-mental state examination (MMSE) score > 27)
4. Additionally, they were required to maintain an independent standing balance

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
30 years

Upper age limit
100 years

Sex
All

Total final enrolment
58

Key exclusion criteria
1. Severe complications such as major neurological deficits or severe aphasia that could impede study involvement
2. Severe cardiovascular conditions posing significant health risks, including hypertension (systolic ≥ 180 mmHg or diastolic ≥ 120 mmHg), heart failure with an ejection fraction < 35%, symptomatic coronary artery disease, and severe valvular heart disease, following the American College of Cardiology and American Heart Association guidelines
3. Advanced bone and joint diseases affecting participation, such as severe osteoarthritis, rheumatoid arthritis, recent or unhealed fractures, or significant post-surgical limitations

4. Recent lower extremity venous thrombosis, defined as episodes within the last six months, which could be aggravated by study activities
5. Cognitive impairments severe enough to interfere with understanding instructions or providing informed consent, like advanced dementia or significant intellectual disability, regardless of MMSE scores

Date of first enrolment
01/03/2020

Date of final enrolment
15/05/2022

Locations

Countries of recruitment
China

Study participating centre
The First Affiliated Hospital of the University of Science and Technology of China
17 Lujiang Road, Luyang District, Division of Life Sciences and Medicine
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Sponsor information

Organisation
University of Science and Technology of China

ROR
https://ror.org/04c4dkn09

Funder(s)

Funder type
Not defined

Funder Name
Anhui Province Twelfth Five-Year Clinical Medicine Key Specialty

Funder Name
Key Technologies Research and Development Program of Anhui Province

Alternative Name(s)
Key Technologies R & D Program of Anhui Province

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
China

Funder Name
Fundamental Research Funds for the Central Universities

Alternative Name(s)
Fundamental Research Funds for the Central Universities of China, Fundamental Research Fund for the Central Universities

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
China

Results and Publications

Individual participant data (IPD) sharing plan
The type of data that will be shared:
Data for analysis in Microsoft Word (.xlsx). (see outputs table)

Timing for availability:
Immediately after publication

Whether consent from participants was required and obtained:
Yes, consent was obtained from participants (Informed Consent Form in Chinese).

Comments on data anonymization:
All data will be anonymized to ensure participant privacy.

Any ethical or legal restrictions:
Data sharing will be in compliance with ethical guidelines and institutional policies.

Any additional comments:
The datasets generated during and/or analysed during the current study will be available upon request from Jingsong Mu, jsmu@ustc.edu.cn

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/10/2024	02/10/2024	Yes	No
Dataset			29/07/2024	No	No
Participant information sheet			29/07/2024	No	Yes