ISRCTN20398227 https://doi.org/10.1186/ISRCTN20398227

The effects of whole body vibration on balance and physical performance in the older people with chronic stroke

Submission date
19/06/2018

Recruitment status
No longer recruiting

Registration date
03/08/2018

Overall study status
Completed

Last Edited
01/05/2019

Condition category
Nervous System Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Chronic stroke is common in elderly people throughout the world. Aging causes a loss of posture control and balance that can affect daily activities. Older people would be expected to have more difficulties in physical ability following a stroke than younger stroke patients. Some research suggests that whole body vibration (WBV) training can improve balance when standing on one leg, ability to stand up from a chair and walking speed. Other studies have shown no positive effects of WBV training on balance and mobility. This study aims to investigate the effect of WBV training on balance and physical performance in elderly people who have had a stroke. The study also aims to investigate which frequency of WBV has the best effects.

Who can participate?
People aged 65 years or above with chronic stroke who are being treated in the Department of Rehabilitation of Wuhan Brain Hospital (General Hospital of the Yangtze River Shipping) . The stroke must have happened at least 6 months before the study. The person must be able to stand independently with or without aids for at least 2 minutes and walk independently with or without aids for at least 10 meters.

What does the study involve?
WBV training will be held at the Department of Rehabilitation of Wuhan Brain Hospital (General Hospital of the Yangtze River Shipping). All training sessions will be supervised by a physical therapist and will be implemented at 5 days/week for 2 weeks. Each training session consists of 360 seconds (4 bouts of 90 seconds). 1 minute of rest will be given between training sessions to avoid over-exertion of the participants. No warm-up exercises will be given before WBV training. The frequencies of the low-frequency group and high-frequency group will be 13 Hz and 26 Hz, respectively. Participants will be asked to place their foot in the same place on the WBV machine each time. During training, the participants will stand barefoot with knee angle of 80° on the platform of the WBV machine (GalileoDelta A, Novotech, Germany). A manual goniometer will be used to measure the knee joint angle before and after each training session. All participants will also receive the conventional rehabilitation program at 5 days/week for 2 weeks. The conventional rehabilitation program comprises physical therapy (PT) - exercises focusing on

muscle-stretching, relaxation, and body perception, occupational therapy (OT) and acupuncture. In the conventional rehabilitation program, each therapy will last 30 minutes. Meanwhile, we will advise the participants to keep their lifestyle and physical activities as usual during the study period. The treatments will be assessed using tests of balance and mobility, including the five-repetition sit-to-stand test (5STS), the 10-meter walking test (10MWT), the timed-up-and-go test (TUG) and the Berg Balance Scale (BBS). These assessments will be conducted before the treatment starts and 2 weeks later, after the treatment has been completed, by the same researcher, who will not know which treatment group each person was in.

What are the possible benefits and risks of participating?
Participants will gain WBV training as additional therapy, which might improve their physical performance. WBV training is free for all participants. The control group will receive WBV training after the study. All participants will receive the usual rehabilitation therapy as well.

Where is the study run from?
This study is being run by Wuhan Polytechnic University and will take place in Wuhan Brain Hospital (General Hospital of the Yangtze River Shipping).

When is the study starting and how long is it expected to run for?
October 2017 to December 2019

Who is funding the study?
Hubei Province Education Office

Who is the main contact?
Ning Wei, Nicole.weining@whpu.edu.cn

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

L20170010

Study information

Scientific Title
The effects of whole body vibration on balance and physical performance in the older people with chronic stroke: A randomized controlled trial

Study objectives
1. Whole body vibration (WBV) training programme is effective for improving balance and physical performance in elderly subjects with chronic stroke
2. Different frequencies would affect balance and physical performance in elderly subjects with chronic stroke.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Current ethics approval as of 01/05/2019:
Human Ethics Review Board of Wuhan Brain Hospital (General Hospital of the Yangtze River Shipping), 26/03/2018, L20180010

Previous ethics approval:
Human Ethics Review Board of Wuhan Brain Hospital (General Hospital of the Yangtze River Shipping), 26/03/2018, L20170010

Study design
Randomised parallel-group study

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Chronic stroke

Interventions
Hospital in-patients aged 65 years or above with ischemic or hemorrhagic stroke in Department of Rehabilitation of Wuhan Brain Hospital (General Hospital of the Yangtze River Shipping) will

be invited to a screening process. Eligible participants will be recruited and randomly assigned into three groups (Low-frequency group (LFG), high-frequency group (HFG) and control group (CG)) by a computer program (Research Randomizer Form www.randomizer.org). WBV training will be held at Department of Rehabilitation of Wuhan Brain Hospital (General Hospital of the Yangtze River Shipping). All training sessions will be supervised by a physical therapist and implemented at 5 days/week for 2 weeks. Each training session consists of 360 seconds (4 bouts of 90 seconds). One minute of rest will be given between training sessions to avoid over-exertion of the participants. No warm-up exercises will be given before WBV training.
The frequencies of low-frequency group and high-frequency group will be 13 Hz and 26 Hz, respectively. Participants will be asked to place their foot at the standard distance from the axis of rotation to have the same peak-to-peak amplitude. During training, the participants will stand barefoot with knee angle of 80° on the platform of WBV machine (GalileoDelta A, Novotech, Germany). A manual goniometer will be used to monitor the knee joint angle before and after each training session.
All participants will receive a conventional rehabilitation program at 5 days/week for 2 weeks. The conventional rehabilitation program comprises physical therapy (PT) exercises focusing on muscle-stretching, relaxation, and body perception), occupational therapy (OT) and acupuncture. In the conventional rehabilitation program, each therapy will last 30 minutes. Meanwhile, we will advise the participants to keep their lifestyle and physical activities as usual during the study period.

Intervention Type
Device

Phase
Not Specified

Primary outcome measure
Physical ability assessed using five-repetition sit-to-stand test (5STS), 10-m walking test (10MWT) and timed-up-and-go test (TUG) at baseline and post-intervention (2 week) by the same researcher, who will be blinded to the intervention

Secondary outcome measures
Berg Balance Scale (BBS)

Overall study start date
19/10/2017

Completion date
30/12/2019

Eligibility

Key inclusion criteria
1. Hospital in-patient at Department of Rehabilitation of Wuhan Brain Hospital (General Hospital of the Yangtze River Shipping)
2. Aged 65 years or above
3. Ischemic or hemorrhagic stroke with stroke onset at least 6 months before the study
4. Able to stand independently with or without aids for at least 2 minutes
5. Able to walk independently with or without aids at least 10 m

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
51

Key exclusion criteria
1. Metal implant
2. Severe heart problem
3. Neuro-degenerative diseases
4. Peripheral vascular disease
5. Vestibular disorders
6. Cognitive impairment
7. Severe osteoporosis with fractures within 1 year prior to the study

Date of first enrolment
08/08/2018

Date of final enrolment
01/07/2019

Locations

Countries of recruitment
China

Study participating centre
Wuhan Brain Hospital (General Hospital of the Yangtze River Shipping)
Wuhan
China
430010

Sponsor information

Organisation
Wuhan Polytechnic University

Sponsor details

Wuhan Polytechnic University, DongXi District, Wuhan, Hubei Province
Wuhan
China
430023

Sponsor type
University/education

ROR
https://ror.org/05w0e5j23

Funder(s)

Funder type
Not defined

Funder Name
Hubei Province Education Office

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
30/12/2021

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during this study will be included in the subsequent results publication.

IPD sharing plan summary
Available on request