

A study protocol for a randomized controlled trial evaluating vibration therapy as an intervention for postural training and fall prevention after distal radius fracture in elderly patients

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Study protocol

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Abstract

Background: Fractures of the distal radius are one of the most common osteoporotic fractures in elderly men and women. These fractures are a particular health concern amongst the elderly, who are at risk of fragility fractures, and are associated with long-term functional impairment, pain and a variety of complications. This is a sentinel event as these fractures are associated with 2 to 4 times increased risk of subsequent hip fractures in elderly patients. This is an important concept as it is well established that these patients have an increased risk of falling. Fall prevention is therefore crucial to decrease further morbidity and mortality. The purpose of this study is to investigate the effect of low-magnitude high frequency vibration (LMHFV) on postural stability and prevention of falls in elderly patients post distal radius fracture.

Methods: This is a prospective single-blinded randomized controlled trial. 200 patients will be recruited consecutively with consent, and randomized to either LMHFV (n=100) or control group (n=100). The primary outcome is postural stability measured by the static and dynamic ability of patients to maintain center of balance on the Biodex Balance System SD. Secondary outcomes are the occurrence of fall, the health-related quality of life (SF-36), Timed Up and Go (TUG) test for basic mobility skills, compliance and adverse events. Outcome assessments for both groups will be performed at baseline 0 months, 6 weeks, 3 months and 6 months time-points.

Discussion: Previous studies have stressed the importance of reducing falls in distal radius fracture elderly patients, and an effective intervention is crucial. Numerous studies have proven vibration therapy to be effective in improving balancing ability in normal patients. No previous study has applied the device for fracture patients. Our study will be going to translate LMHFV to fracture patients to improve postural stability and prevent recurrent falls. Positive results would provide a large impact in the prevention of secondary fractures and save healthcare costs.

Background

Fractures of the distal radius are one of the most common osteoporotic fracture in elderly men and women (1–3) and accounts for approximately 18% of all fractures in the elderly (4). Currently, there is approximately a 3:1 female to male ratio (2). These fractures are a particular health concern amongst the elderly, who are at risk of fragility fractures, and are associated with long-term functional impairment, pain and a variety of complications. Current medical costs for distal radius fractures are estimated to exceed USD 535 million each year and projected to rise as the incidence increases (5, 6).

The occurrence of distal radius fractures is well known to be a sentinel event as these fractures are associated with 2 to 4 times increased risk of subsequent hip fractures in elderly patients (7–9). This is an important concept as it is well established that these patients have an increased risk of falling (8). Fall prevention is therefore crucial to decrease further morbidity and mortality. Studies have shown a significantly increased degree of postural sway in patients with distal radius fractures, in both

anteroposterior and lateral directions, which is strongly characterized in older patients for recurrent falls, which is related to lower limb strength (10). Another strong association with fragility fractures is sarcopenia, which has loss in muscle mass and strength leading to postural instability and falls (11). Recent evidence has shown that the prevalence of sarcopenia reaches up to 95% in male and 64% in female patients after an osteoporotic fracture (12). Instability of these patients have also been validated with the use of objective measurements from computerized instruments (9).

Despite on-going studies on distal radius fractures, the latest Cochrane systematic review shows a lack of evidence on the effectiveness of current rehabilitation interventions (13). The American Academy of Orthopaedic Surgeons (AAOS) position statement also recommends patients with fragility fractures to undergo evaluation of osteoporosis and treatment to prevent future fractures (9). Notably, there are no recommendations on the role of balance training or physical conditioning currently. Consequently, the evaluation and treatment of fall risks have been largely overlooked (14). Further research that target rehabilitation and treat postural instability after distal radius fracture to reduce fall rates are therefore warranted.

Low-magnitude high-frequency vibration (LMHFV) is a biophysical intervention that provides non-invasive, systemic mechanical stimulation and has been shown to improve muscle strength and balancing abilities in healthy, independent and active elderly women in our previous study (15, 16). The device has been proven to act as a form of physical exercise as muscle activity is induced during vibration (16, 17). Numerous other studies have reported whole body vibration to have positive effects on blood circulation in lower extremities and enhanced muscle performance in the elderly (18, 19). The use of this device has not yet been established in fracture patients but has great potential as a rehabilitation tool. This is the first study to translate LMHFV to distal radius fracture patients, which are high-risk patients prone to falls and would potentially be more cost-effective.

We hypothesize that LMHFV will improve postural stability and decreases fall rates. As current rehabilitation interventions lack effectiveness, the objective of this study is to investigate the effect of LMHFV on postural stability and recurrent falls in elderly patients post distal radius fracture.

Methods

Study Design and setting

This study is a randomized, single-blinded controlled clinical trial to evaluate the effect of LMHFV (VH-001, V-health Limited, Hong Kong) on postural stability in elderly patients with distal radius fracture. Patients are recruited from the Prince of Wales Hospital, The Chinese University of Hong Kong.

Inclusion criteria

The inclusion criteria are as follows:

- Aged 60 or above
- Fracture distal radius after 6 weeks to 3 months
- Injury was due to unintentional fall

Exclusion criteria

The exclusion criteria are as follows:

- Medical condition causing balance disturbance e.g. vertigo
- Participated in supervised regular exercise or physiotherapy for twice a week or more
- Activities of Daily Living (ADL) dependent
- Malignancy
- Medications or conditions that affect metabolism of the musculoskeletal system e.g. hyperthyroidism.

Sample size

The primary outcome of this study is postural stability. Based on our previous clinical study of LMHFV on balancing ability in normal community elderly (15), we detected 7.89 mean difference in endpoint excursion (key parameter of balancing ability) between two groups after treatment. A sample size of 85 in each group will have 80% power to detect a significant difference using two-sided independent t-test with a 0.05 significance level (PASS 11.0, NCSS, LLC, Utah, USA). Our previous clinical trial also showed a satisfactory compliance rate of LMHFV (averaged 66%) and approximately 15% dropout rate (15). Taking account of the dropout, we further increase the sample size to $n = 100$ for each arm (total $n = 200$).

Recruitment

Eligible patients will be recruited from specialist out-patient clinics or clinical wards consecutively with written consent in the Prince of Wales Hospital, Hong Kong, base on inclusion and exclusion criteria. Patient demographics on age, gender, education level, ethnicity, occupation, body mass index, smoking or drinking habits will be recorded. Medical history will also be confirmed and recorded from the Clinical Management System (CMS), Hospital Authority, which is the central electronic database for public hospitals in Hong Kong (15). Before signing the consent form, each patient will be explained the objectives, benefits and risks of the study, their rights and responsibility, as well as privacy and

confidentiality. An information sheet will be distributed and all patients are encouraged to ask questions at anytime.

Randomization and blinding

A total of 200 patients will be enrolled. Randomization to either control or LMHFV group (n = 100 per group) will be performed by envelope drawing of computer-generated random numbers (20) and will be performed by an independent research staff. The random number list is kept strictly confidential and the researchers will not have access to the list. The outcome assessor and statistician will be blinded to the group allocation. The central technical staff in our Orthopaedics and Traumatology Department will perform all measurements. The participants will be reminded not to tell the assessor of their allocation. Blinding the patients is not feasible because the vibration signal from the platform is easily felt and placebo is rare in vibration clinical trials (15).

Interventions

Each patient in the LMHFV group will undergo vibration in community centers. We have an established network with LMHFV platforms set up at community centers in several locations in Hong Kong (15, 21). The patient will stand upright without knee bending on a specially designed vibration platform that provides vertical synchronous vibration at 35Hz, 0.3g (peak to peak magnitude), displacement of <0.1mm, 20 min/day, at least 3 days/week (18) for 6 months. The research staff will instruct the safety issues and operative procedures. Each patient in the control group will remain in their habitual life style and no vibration machine is used.

Outcome and outcome assessments

Outcome assessments for both groups will be performed at baseline 0 months, 6 weeks, 3 months and 6 months time-points. The primary outcome is the postural stability. To assess the postural stability, the Biodex Balance System SD (Biodex Medical Systems Inc, Shirley, NY) is used to measure the static and dynamic ability of the patients to maintain the center of balance. The score generated by the machine assesses the deviation from the center via an Overall Stability Index (OSI), Anterior/Posterior Stability Index (APSI) and Medial/Lateral Stability Index (MLSI), which have been shown to be a reliable tool for objective assessment of postural stability in several studies for elderly patients (16, 22).

Secondary outcome includes the occurrence of falls. To assess the occurrence of fall, patients are required to self-report these events via a fall calendar, which has to be returned at every follow-up visit. Calendar reporting has been well proven to be reliable for fall studies(23, 24). Other secondary outcomes are quality of life, compliance and adverse events. The health-related quality of life with a validated Chinese Version of the 36-Item Short-Form Health Survey (SF-36) will be assessed. The physical

component, mental component and total score will be analysed. All scores range from 0 to 100 with a higher score indicating better quality of life. In addition, the Timed Up and Go test (TUG) will be used to test the basic mobility skills, which is a useful predictor of risk of falls.

Additionally, patients will be phone contacted once every 2 weeks to record for any problems in the study.

Safety and Compliance Assessment

A smart card is given to each participant to record and count compliance to the LMHFV device. Any adverse events or problems during the study is recorded by the independent staff. Any participant may quit the study anytime for any reason, and will be asked in whether they wish for follow-up according to the trial schedule.

Data Collection and Management

The research assistant will be trained to ensure accuracy of outcome assessments and data collection. The ethics committee will oversee any issues disturbing quality of research and corresponding measures will be taken if necessary. Patients are free to withdraw from the study at any time without giving any reasons, and their medical care or legal rights will not be affected. The study will comply with good clinical practice guideline according to the International Council for Harmonisation. Each patient will be assigned an identification code. The patient identification code list and database will be safeguarded.

Data Analysis Plan

Data in this study will be analysed according to the intention-to-treat principle. All results will be expressed in mean \pm SD (parametric data). Normality test will be performed to determine the normal distribution of data. Analysis of variance tests were used to compare means for continuous variables. Chi-square tests to compare proportions for categorical variables. The statistical analysis will be performed using SPSS 20.0 (IBM, NY, USA). Significant level is set at $p < 0.05$ (2-tailed).

Discussion

Previous studies have stressed the importance in reducing risk of falls after distal radius fractures in elderly patients due to postural instability (25–27). A prospective, longitudinal cohort study had shown overall functional status and deterioration of mobility for these patients, and future fracture risk increased significantly 1 year after fracture (27). With the aging population, prevention of imminent fracture risk, i.e. secondary fractures within 2 years, for distal radius fracture patients are crucial to decrease mortality and health care costs (28).

Numerous studies have proven the effect of vibration therapy in preventing falls and fracture, and improving balancing ability in normal elderly (29, 30). Our previous randomized controlled trial with 710 healthy, active and independent postmenopausal women over 60 years old had shown LMHFV to have significant improvements in reducing falls, reaction time, movement velocity, and maximum excursion of balancing ability assessment and also quadriceps muscle strength (15). Our case-control study also showed that at 1-year post-intervention of LMHFV for the patients, the benefits were retained (16).

The use of Biodex Balancing System SD (BBS) provides an objective measurement on the postural stability and balancing ability for our patients. Several studies have used the device and have been proven to be reliable and valid for clinical studies (22, 31–36)

The enrollment of this trial began on November 2018 and completion is expected to take 24 months. The results from this trial would change clinical practice, as currently there are no validated interventions addressing the problem of postural stability for distal radius fracture patients. We speculate that positive results would allow the incorporation of LMHFV into multidisciplinary rehabilitation programs to improve the healthcare for our patients in the future.

Trial Status

At the time of manuscript submission, the trial is still currently recruiting patients.

Trial Registration

[ClinicalTrials.gov](https://clinicaltrials.gov), NCT03380884. Registered on 21 December 2017,
<https://clinicaltrials.gov/ct2/show/NCT03380884>.

List Of Abbreviations

***ADL*: Activities of Daily Living**

***AHNH*: Alice Ho Miu Ling Nethersole Hospital**

***APSI*: Anterior/Posterior Stability Index**

***BBS*: Biodex Balancing System SD**

***CMS*: Clinical Management System**

***LMHFV*: Low Magnitude High Frequency Vibration**

***LOS*: limits of stability index**

***MLSI*: Medial/Lateral Stability Index**

***NDH*: North District Hospital**

***OSI*: Overall Stability Index**

***PEMF*: Pulsed electromagnetic field**

***PWH*: Prince of Wales Hospital**

***TUG*: Timed Up and Go Test**

Declaration

Ethics approval and consent to participate has been obtained (The Joint CUHK-NTEC Clinical Research Committee approved the study (Ref: 2018.415))

Consent for publication: Not applicable

Availability of data and materials: Not applicable

Competing interests: The authors declare that they have no competing interests

Authors' contributions: RMY Wong, SKH Chow and WH Cheung contributed to study conception, design and drafting the manuscript. RMY Wong, N Tang, CY Tso WKR Ng contributed to patient recruitment. WT Ho and CSE Chui contributed to acquisition of data.

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Figures

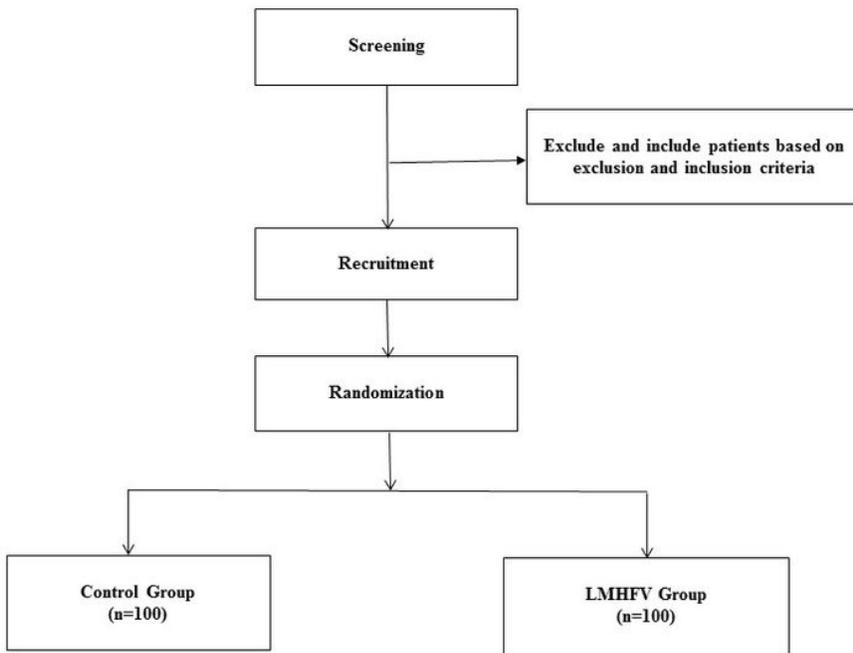


Figure 1

Recruitment of study subjects

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