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ORIGINAL ARTICLE

Effects of 18-month low-magnitude high-frequency vibration on fall rate and fracture risks in 710 community elderly—a cluster-randomized controlled trial

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Abstract

Summary This study is a prospective cluster-randomized controlled clinical trial involving 710 elderly subjects to investigate the long-term effects of low-magnitude high-frequency vibration (LMHFV) on fall and fracture rates, muscle performance, and bone quality. The results confirmed that LMHFV is effective in reducing fall incidence and enhancing muscle performance in the elderly.

Introduction Falls are direct causes of fragility fracture in the elderly. LMHFV has been shown to improve muscle function and bone quality. This study is to investigate the efficacy of LMHFV in preventing fall and fractures among the elderly in the community.

Methods A cluster-randomized controlled trial was conducted with 710 postmenopausal females over 60 years. A total of 364 participants received daily 20 min LMHFV (35 Hz, 0.3 g), 5 days/week for 18 months; 346 participants served as control. Fall or fracture rate was taken as the primary outcome. Also, quadriceps muscle strength, balancing abilities, bone mineral density (BMD), and quality of life (QoL) assessments were done at 0, 9, and 18 months.

Results With an average of 66.0 % compliance in the vibration group, 18.6 % of 334 vibration group subjects reported fall or fracture incidences compared with 28.7 % of 327 in the control (adjusted HR=0.56, $p=0.001$). The fracture rate of vibration and control groups were 1.1 and 2.3 % respectively ($p=0.171$). Significant improvements were found in reaction time, movement velocity, and maximum excursion of balancing ability assessment, and also the quadriceps muscle strength ($p<0.001$). No significant differences were found in the overall change of BMD. Minimal adverse effects were documented.

Conclusion LMHFV is effective in fall prevention with improved muscle strength and balancing ability in the elderly. We recommend its use in the community as an effective fall prevention program and to decrease related injuries.

Keywords Clinical trial · Fracture prevention · Fracture risk assessment · Low-magnitude high-frequency vibration · Osteoporosis

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Introduction

Fragility fracture is one of the most prominent medico-social problems among the elderly in the community. Most fractures result from a combination of poor balance, falls, and deteriorating bone strength. Resistance training exercise is effective in improving lower extremity strength in the elderly [1], although this is only beneficial to those with good compliance with exercise programs. Fall prevention education is a common and significant way to increase the awareness of fall and fracture prevention among the elderly but not specific to biological risk factors [2]. An intervention to improve muscle function, movement coordination, bone mass, and hence reducing the risk of fracture is needed.

Vibration treatment has been demonstrated to have multiple effects on muscle strength [3], postural control [4, 5], balancing ability [6, 7], new bone formation [5, 8, 9], and circulation [10]. We also previously studied the effects of low-magnitude high-frequency vibration (LMHFV) on the healing of normal and osteopenic fractures [11, 12], bone remodeling [13] in animal models, on limits of stability in elderly women [6], and prolonged bed rest in humans [14]. Effects of vibration treatment on incidence of falls were reported in previous studies [9, 15], but the sample size and statistical power were insufficient to confirm its effect in preventing falls. However, a recent clinical trial showed discrepant results with no benefits on bone quality from vibration treatment [15]. There is a need to further investigate the potential effects of long-term, whole body vibration treatment on fall and fracture prevention among postmenopausal women.

In this study, we hypothesized that LMHFV improves the muscle performance and bone mass in the community elderly, thus reducing fall and fracture rates. A prospective cluster-randomized controlled single-blinded clinical trial involving 710 subjects was conducted to investigate the long-term effects of LMHFV on fall and fracture rates in the community elderly. The multiple effects on muscle and bone were also evaluated.

Methods

Design overview

This study was a cluster-randomized, single-blinded, controlled trial to investigate the effects of 18 months of LMHFV on fall and fracture rates. The study protocol was approved by the Joint Chinese University of Hong Kong—New Territories East Cluster Clinical Research Ethics Committee (Ref. no.: CRE-2008.067-T) and complied with the Declaration of Helsinki. This study was registered in ClinicalTrials.gov: NCT00973167.

Setting and participants

Our research staff recruited subjects through poster announcements and talks in 24 elderly community centers located in different regions in Hong Kong. Only elderly centers with standardized settings (sharing the same scope of service, operating hours, manpower, and target groups) and regulated by the Social Welfare Department of Hong Kong SAR Government were invited to join this study. Healthy females aged 60 years or above, independent and active in the community were eligible. We excluded anyone: (1) who was taking any medications or had medical conditions which affected metabolism of the musculoskeletal system, e.g., bisphosphonates, (2) who participated in supervised regular exercise for twice a week or more, (3) with pacemaker in situ, (4) with malignancy, or (5) with a history of smoking or excessive alcohol use (more than seven drinks per week). Preliminary screening was done by telephone interview, followed by baseline assessment for eligible subjects at the Prince of Wales Hospital, The Chinese University of Hong Kong. All subjects gave written consent.

Randomization and interventions

Center-based simple randomization by envelop drawing was performed by an independent research staff to avoid: (1) control subjects from using vibration platform located in the centers and (2) interaction between subjects from the two groups. Control group subjects remained in their habitual life style and participated in the normal interest group activities (e.g., card games, drama) organized by the community centers. Elderly enrolled in the vibration group, in addition to the normal activities in the centers, received LMHFV by standing upright without knee bending on a specially designed vibration platform that provided vertical synchronous vibration at 35 Hz, 0.3 g (peak-to-peak magnitude), displacement of <0.1 mm, 20 min/day, 5 days/week for 18 months [14]. Safety issues and operative procedures of LMHFV were instructed by research staff, and on-site validation and calibration of the platforms were done monthly by a technician. Outcome assessments for both groups were performed at baseline 0-month, 9-month, and 18-month time points for all subjects by the same group of research workers from the authors' institute. Staff from the community centers was not involved in any assessment. Outcome assessors and the statistician were blinded to group allocation, and participants were reminded not to tell the assessors of their group allocation. Research staff who enrolled clusters, took consent before randomization, and assigned interventions to clusters were not involved in outcome assessment. Blinding the subjects for 18 months was not possible because the vibration signal from the treatment platform could easily be felt and for this reason, placebo is rare in most vibration clinical trials [16].

Allocation sequence of centers was concealed until vibration intervention was assigned.

Outcomes and follow-up

The primary outcome is a composite occurrence of fall or fracture. Subjects were required to self-report their fall and fracture incidences on a fall and fracture calendar which had to be returned at every follow-up visit, where calendar-reporting has been well proven to be reliable for fall studies [17, 18]. On the calendar, subjects recorded the day of fall or fracture and a short description of each incident. The information provided was used to identify whether the reported incident met the definition of a fall, which refers to resting on the ground, floor, or lower level unintentionally [19]. Fall records were collected through telephone interview from subjects who declined to attend follow-up visit. Fractures and other injuries were confirmed with clinical information including radiographs obtained from the electronic patient record (EPR) of the Hong Kong Hospital Authority [20].

The usage of LMHFV was recorded by a built-in data logger in the vibration platform with the date, time, duration of each session, and user ID. The user ID was specific to each user, and a radio-frequency identification card was used to trigger the vibration when the subject stands on the vibration platform. The compliance rate was defined as the number of sessions that the subjects attended over the total number of available sessions across the study period.

Balancing ability was assessed with the limits of stability test using the Basic Balance Master System (NeuroCom International Inc, OR, USA). Subjects were instructed to stand barefoot on the force plate and control the location of their center-of-gravity cursor by swaying and weight-shifting of her body to eight different target directions without falling or moving their feet [6]. The measured parameters of limits of stability test included reaction time (second), directional control (%), movement velocity (degrees/s), endpoint excursion (%), and maximum excursion (%). The short-term coefficient of variation percentage is 3.92 %.

Quadriceps muscle strength was measured by instructing the subjects to perform an active extension of the knee joint in a sitting position with both feet free from the ground, and the hip and knee joint flexed at 90°. The peak isometric forces of the knee extension were measured by a dynamometer attached at the malleoli level. Measurements were repeated thrice in each lower limb, and the maximum force was used for analysis [21]. The short-term coefficient of variation percentage is 3.39 %.

Areal bone mineral density (BMD, g/cm^2) was measured at the hip of the nondominant leg and lumbar spine (L1 to L4) by dual energy x-ray absorptiometry (Delphi W, Hologic, Waltham, MA, USA). For consistency, one certified bone densitometry technologist performed all measurements. Calibration of DXA machine was done using bone phantom every day, which gave an acceptable precision error of 1.31 % for total hip and 0.72 % for spine [22].

The health-related quality of life was assessed with the validated Chinese version of the 36-Item Short-Form Health Survey (SF-36) [23]. The physical component summary, mental component summary, and total score of the SF-36 were analyzed. All scores range from 0 to 100 with higher scores indicating better quality of life.

Statistical analysis

With the cluster-randomization design of this study, sample size calculations were inflated to accommodate for the clustering effect [24]. The local annual fracture and fall rates in the elderly women were estimated to be 8 % [25] and 18–20 % [26], respectively. Assuming a 40 % reduction of fall rate in the vibration group based on our previous findings [6], given an average cluster size (subjects recruited in each center) of 30, an intracluster correlation coefficient of 0.005 [27] and an anticipated dropout rate of 15 %, a total sample size required for this study was 704 (352 per study group) with 24 centers, having statistical power of 0.8 and alpha of 0.05.

One-way analysis of variance was used to estimate the intracluser correlation coefficient to obtain estimates of the inflation factor for comparison with planned sample size. The primary outcomes were analyzed according to the intention-to-treat principle to compare the fall or fracture rates between the two groups. Cox regression and the robust calculation method of the variance-covariance matrix [28] were used in the primary outcomes analysis, with cluster-randomization taken into account. We also used Poisson regression to allow for clustering of falls by the same subject during the study period, with random effects to allow for clustering by center, to compare the rate ratio between the groups. When the Poisson model was not a good fit, the negative binomial was performed. Differences of secondary outcomes from baseline to the 18-month follow-up were compared between groups using cluster-adjusted t test [28]. Bone mineral density change between high compliance (over 80 %) vibration group and control group were further compared with cluster-adjusted t test analysis. Bonferroni adjustment was performed for multiple comparisons. A linear mixed models (a two-level random intercept model) was used to evaluate further the effectiveness of the intervention in improving the secondary outcomes [29]. We included random cluster effects (which implied that observations on the same cluster were correlated) and fixed effects associated with treatment, while adjusting for baseline covariates (i.e., age and BMI) [30]. All statistical analyses were conducted using SPSS version 16.0 (SPSS Inc, Chicago, IL, USA) and STATA version 8.0 (StataCorp, College Station, TX, USA). Significance level was set at $p<0.05$ (two-sided).

Adverse event management and termination

An information card with our contacts and trial details was provided to every subject after written consent was obtained. All subjects were instructed to contact us and report any health problems or suspected adverse events to us. All complaints or complications from the subjects with regard to the LMHFV were documented. Also, at baseline and follow-up assessments, clinicians performed a list of physical examination and updated the health status of the subjects (e.g., deterioration of preexisting medical problems, newly diagnosed problems). Any reported adverse effects potentially attributed to the vibration were assessed and followed up by the responsible clinicians. LMHFV was stopped immediately if the reported event was considered to be related.

Results

Baseline characteristics

A total of 1,026 subjects were screened for eligibility from September 2009 to November 2010, and 710 subjects were recruited into the study (Fig. 1): 364 subjects in the vibration group and 346 subjects in control group. They received follow-up assessments from June 2010 to April 2012. Baseline data were shown in Table 1. The mean age was 73 years and mean body mass index was 24.1. Eighty-six percent of the subjects walked unaided, and all subjects were able to access the elderly community center independently. An average of 3.3 vibration sessions per week was recorded in the vibration group giving an average of 66 % compliance of vibration in the study period. All subjects were included into fracture rate analysis; 280 vibration group subjects and 316 control subjects attended follow-up visits and included into secondary outcomes analysis (Fig. 1).

Primary outcome

The 334 vibration group subjects and 327 control subjects reported their fall records. Sixty-two (18.6 % of 334) subjects in the vibration group reported falls or fractures compared with 94 (28.7 % of 327) in the control group (Table 2 and 3). The adjusted hazard ratio of falls or fractures in the vibration group was 0.56 (95%CI, 0.40–0.78, $p=0.001$) compared with control. The incidence rate of falls was significantly lower in the vibration group, with 46 % lower fall incidence rate when compared with the control group (adjusted incidence rate ratio=0.54, 95%CI 0.37–0.78, $p=0.001$). In the control group, 6.4 % subjects had repeated falls (two or more fall incidences during the study period) reported compared with 2.1 % in the vibration group. The rate of fracture (all resulted from falls) in the vibration and control group were 1.1 and 2.31 %, respectively, but not statistically different (adjusted HR=0.42, 95%CI, 0.12–1.45, $p=0.171$).

Secondary outcomes

The changes in secondary outcomes from baseline to 9 months and 18 months in the two groups were shown in Table 4 and Supplementary Table 1. From the results of cluster-adjusted analysis, at 18 months, the vibration group had shown significant improvement on the quadriceps muscle strength, with mean between-group difference of 2.46 kg in the dominant leg (95%CI, 1.70–3.22, $p<0.001$) and 2.43 kg in the nondominant leg (95%CI, 1.59–3.27, $p<0.001$). The significances remained unchanged after adjustment for covariates with linear mixed model.

Balancing ability in the vibration group significantly improved compared with the control group. From baseline to 18 months, improvement in reaction time was found in the vibration group with mean between-group difference of −0.38 s (95%CI,−0.55to−0.21, $p<0.001$). Significant improvements were noted in movement velocity and maximum point excursion, with mean between-group difference of 0.94 °/s (95%CI, 0.63–1.26, $p<0.001$) and 10.72 percentage points (95%CI, 7.05–14.39, $p<0.001$). No significant difference of directional control was observed between groups. Adjustment for covariates by linear mixed model reproduced all significant different observations in balancing ability.

At 9 months, the vibration group had a trend of better SF-36 mental health component and total score with a mean between-group difference of 2.84 (95%CI, 0.06–5.62, $p=0.046$) and 3.02 (95%CI, 0.05–5.99, $p=0.047$), respectively. However, it was not statistically significant after Bonferroni adjustment. The change of physical health component score, mental health component score, and total score from baseline to 18 months favored the vibration group, though the intergroup differences were not statistically significant.

For lumbar spine BMD, the mean change in the vibration group was 0.08 % compared with−0.64 % in the control group at 18 months (mean between-group difference=0.72 %, 95%CI,−0.12 to 1.56, $p=0.089$). A trend of increasing spine BMD in the vibration group was found from 9 months to 18 months, with a mean between-group difference of 0.82 % (95%CI, 0.12 to 1.52, $p=0.023$), although not statistically significant after Bonferroni adjustment. Subjects in both vibration and control groups had decrease in hip BMD at 18 months. The mean change of total hip BMD in the vibration group was−1.86 % compared with−1.89 % in the control group. When the vibration group with high compliance (≥80 %) was compared with the control, BMD of hip and spine showed a positive trend in the vibration group compared with the control (mean between-group difference=1.43 % for femoral neck, 1.12 % for spine) yet not statistically significant after Bonferroni adjustment (Supplementary Table 2).

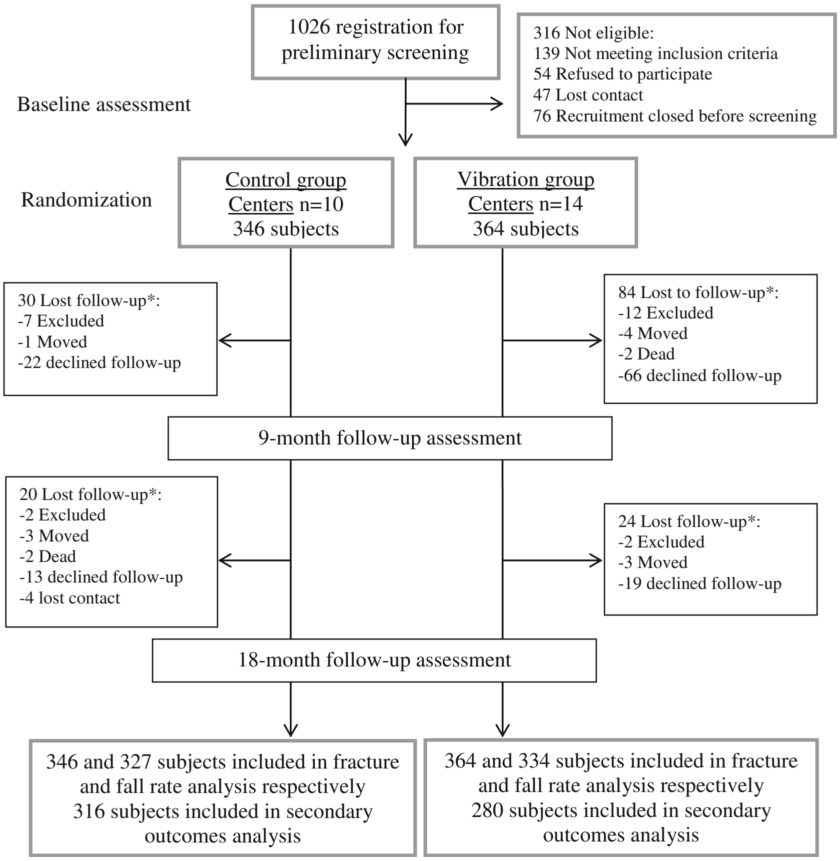

Fig. 1 Recruitment and allocation of centers and elderly to the study groups. *In both control and vibration groups, most subjects lost to follow-up because they were not interested in the study or unwilling to visit the hospital for assessment. In the vibration group, most subjects drop-out from the study because: (1) they had moved to districts which were distant from the cluster centers, (2) found too time-consuming and demanding to receive vibration daily, or (3) had difficulties arranging time to visit vibration center in designated time (i.e., office hour). There were a number of participants who reported the use of bisphosphonates, strontium ranelate, or steroids during the study period and had to be excluded

Adverse effects

During the 18-month study period, no serious adverse events were noted to associate with the vibration intervention. Lower-limb pain was reported in nine vibration subjects and seven control subjects. Among the vibration subjects, three reported pain within first month of commencement of LMHFV and the other subjects reported pain after 3–17 months of LMHFV. Five subjects in the vibration group reported dizziness: two were within the first month of commencement of LMHFV; three felt dizzy after 6–18 months of LMHFV. One control subject reported dizziness. Other adverse events (Supplementary Table 3) experienced by subjects included back pain in four vibration subjects and three control subjects, depression in four control subjects, and newly confirmed or worsening hypertension in eight vibration subjects and fifteen control subjects.

Discussion

The most direct cause of fragility fractures is fall in the presence of poor bone quality in the elderly; therefore, it would be logical to consider an intervention that can decrease the risk of fall and/or improve bone quality to prevent fractures. An intervention which can achieve both of these would be most ideal, especially if this can be carried out in the community. LMHFV is a biophysical stimulation to the whole body with documented positive effects on muscle function but discrepant results in bone [3–9, 15, 16, 31]. Its effect in fall prevention has not been confirmed in large scale clinical trials. The theoretical basis for the application of this stimulation to prevent falls has been confirmed in this study. The fall or fracture rate was significantly lower in the vibration group (adjusted HR=0.56, 95 % CI 0.40 to 0.78, p=0.001) (Table 2) as compared with the control group. This beneficial effect was evident as early as 9 months after the commencement of LMHFV, and the effects were sustained for up to 18 months. When the incidence of falls is further analyzed within the study period (Table 3), it is obvious that the number of subjects with repeated falls is much lower in the vibration group (2.1 %:6.4 %). This may imply that the protective effect from falls is effective as long as LMHFV continues. The incidence rate of repeated falls in the control group (6.4 %) is comparable to the results of a local cohort study which reported 6.5 % of women had multiple falls [32]. Not only do falls lead to physical injuries like fractures and soft tissue injury, they may also result in increased fear of falling and self-perceived restriction in physical activity in the elderly with detrimental effects on their quality of life. Altogether,

Table 1 Baseline characteristics of study subjects

Characteristic[a]	Vibration group (n=364)	Control group (n=346)	Vibration group (n=280, included for secondary outcome analysis)	Control group (n=316, included for secondary outcome analysis)
Age (years)	74.5 (7.1)	71.3 (7.2)	74.2 (7.0)	71.0 (7.0)
Height (cm)	150.9 (5.9)	151.7 (5.8)	150.9 (5.8)	151.7 (5.9)
Body mass index[b] (kg/m^2)	24.1 (3.6)	24.0 (3.7)	24.1 (3.6)	24.0 (3.7)
Age of menopause (years)	49.4 (4.8)	49.4 (4.5)	49.5 (5.0)	49.5 (4.5)
Walk with aids	52 (14 %)	50 (14 %)	42 (15 %)	47 (15 %)
Disease—no. of subjects				
Hypertension	192 (53 %)	167 (48 %)	151 (54 %)	155 (49 %)
Diabetes	53 (15 %)	50 (14 %)	45 (16 %)	47 (15 %)
Muscle strength[c] (kg)				
Dominant leg	7.1 (2.7)	8.2 (2.8)	7.1 (2.6)	8.2 (2.8)
Nondominant leg	7.8 (2.5)	7.1 (2.6)	6.6 (2.7)	7.8 (2.8)
Balancing ability				
Reaction time (s)	1.0 (0.4)	0.9 (0.3)	1.1 (0.4)	0.87 (0.3)
Movement velocity (°/s)	2.5 (1.4)	2.7 (1.1)	2.5 (1.5)	2.8 (1.1)
Endpoint excursion (%)	56.4 (12.9)	58.6 (13.6)	56.7 (13.1)	58.8 (13.8)
Maximum point excursion (%)	70.2 (13.0)	73.1 (13.9)	70.5 (13.0)	73.3 (14.1)
Directional control (%)	69.3 (10.3)	66.9 (11.3)	69.7 (10.1)	67.1 (11.4)
SF-36				
Physical health component	63.3 (20.7)	62.1 (19.9)	63.4 (20.6)	61.8 (20.1)
Mental health component	78.5 (16.4)	77.8 (16.2)	78.5 (16.0)	77.4 (16.2)
Total	72.3 (17.2)	71.6 (16.6)	72.5 (17.1)	71.2 (16.7)
Bone mineral density (g/cm^2)				
Total hip	0.70 (0.12)	0.73 (0.12)	0.71 (0.12)	0.73 (0.12)
Total spine	0.78 (0.15)	0.78 (0.16)	0.78 (0.15)	0.78 (0.16)
T-score				
Total hip	−1.72 (1.15)	−1.51 (1.15)	−1.67 (1.13)	−1.49 (1.16)
Total spine	−2.01 (1.45)	−1.99 (1.54)	−2.00 (1.41)	−1.97 (1.56)

[a] Values above are mean (SD)

[b] The body mass index was body weight (in kilogram) divided by the square of height (in meter)

[c] Leg dominance was determined by asking the subject which leg she would use to kick a ball placed in front of her [36]

these will further increase the risk of recurrent falls and results in a vicious cycle, so prevention of the "first fall" is critical. In Slatkovska et al study [15], the fall rate of 30 Hz vibration group was around 50 % lower than the 90 Hz control groups. Although the sample size was small (a total of 202 in three groups) and the difference in fall rates was not statistically

Table 2 Fall or fracture incidences and each component reported by vibration group and control group during 18-month study period

	Vibration group	Control group	Intracluster correlation coefficient	Crude HR (95 % CI)	p value	Adjusted HR[a] (95 % CI)	p value
Fall or fracture—no. of subjects (%)[b]	62 (18.6)	94 (28.7)	0.018	0.59 (0.43, 0.81)	0.001	0.56 (0.40, 0.78)	0.001
Fracture—no. of subjects (%)[c]	4 (1.1)	8 (2.3)	0.000	0.47 (0.14, 1.57)	0.22	0.42 (0.12, 1.45)	0.17

HR hazard ratio, *CI* confidence interval

[a] Adjusted for age and body mass index

[b] 334 vibration and 327 control group subjects returned fall calendar or reported their fall record in telephone interview

[c] All fractures were resulted in fall incidence, and all recruited subjects (364 in vibration and 346 in control group) were included into the fracture rate analysis

Table 3 Total number of falls during the study period (18 months)

Total no. of falls—no. of subjects (%)[a]	Vibration group (n=334)[b]	Control group (n=327)[b]
0	272 (81.4)	233 (71.3)
1	55 (16.5)	73 (22.3)
2	6 (1.8)	14 (4.3)
3	1 (0.3)	7 (2.1)

[a] Incidence rate ratio (95 % CI), *P* value 0.57 (0.41, 0.81), 0.002. Incidence rate ratio adjusted for age and body mass index (95 % CI), *P* value 0.54 (0.37, 0.78), 0.001

[b] 334 vibration and 327 control group subjects returned their fall calendar or reported their fall record in telephone interview

significant, Slatkovska et al suggested the frequency of vibration stimulation is critical in preventing fall incidence. In a study by von Stengel et al [9], a 53 % lower fall incidence was observed in the vibration training group when compared with the control. However, the primary outcome of the study was bone mineral density and the statistical power was low to confirm its effect in preventing falls. The reduction of fall rate in combined vibration and exercise group (TGV) and conventional exercise training group (TG) were also compared in this study. The fall rate was markedly lower in both TGV and TG though only significant in the TGV, and showing the implementation of vibration intervention had further reduced the fall incidence rate by 17 %. Together with our results, this may suggest that vibration intervention benefits both the elderly with or without routine exercise training. In our study, the reduction of fall rate is further supported by the significant positive effects on muscle strength, coordinated movements, and excursions (Table 4). In previous studies with elderly women, 15–16 % improvement of knee extensor and dynamic muscle strengths were observed after a 6-month whole body vibration [5, 31]. In this study, increase of 22.5 and 19.7 % quadriceps strengths were recorded in the dominant and non-dominant legs of the vibration group after an 18-month intervention. The difference in magnitude of improvement in the two studies suggests that the positive effect on muscle strength may be accumulative and sustainable in the untrained elderly as long as the treatment continues to up to 18 months. The results of the limit of stability test for balancing ability assessment shows significant improvement in movement velocity and excursion in vibration subjects, implying they had better control of muscle coordination for balancing, and less fear of falling (self-restriction of speed and movement), and these results are substantiated by previous studies [3–6]. However, the mechanism of how vibration enhances muscle function is not well understood. A recent study demonstrated the preservation of muscle power 1 year after the cessation of whole body vibration intervention, and neurological adaptation rather than muscle volume gain may explain the long residual effect of whole body vibration on muscle performance [33]. Also, growing evidence indicates that whole body vibration elicits tonic vibration reflex which involves Ia afferents of muscle spindles and facilitates the reflex action of the motion units [34, 35]. Prolonged LMHFV provides mechanical vibration signal to actively stimulate the muscle, which may enhance the muscle power and balancing ability with lower recruitment thresholds and increase the firing rate of motor units. Decline of balancing ability and muscle strength in the control group were also observed. Subjects in our study were relatively old (averaged 73±7 years) and some of them walked with aids. Sarcopenia was reported to accelerate in those over 70 years, together with lower basal quadriceps strength of Chinese compared with other ethnic groups, these may explain the marked functional deterioration.

The effect on BMD on the hip and spine within the vibration group, though the differences were statistically insignificant compared with the control group, did show a positive trend in later phase (9 to 18 months). The percentage of fracture with those who fell in the vibration group was 6.5 % while that in the control group was 8.5 % (Table 2), but the low incidence rate of fractures resulted in low statistical power to confirm the effect of fracture prevention. When the data are compared with the group with higher compliance rate (≥80 %) of vibration (Supplementary Table 2), relative benefit of 1.43 and 1.12 % were found in the BMD changes in the femoral neck and spine (p=0.02 and 0.048, respectively) in 9–18 months, despite not statistically significant after Bonferroni adjustment. These findings show that the effects of LMHFV on muscle are much more pronounced and needs a much shorter duration of stimulation. The osseous effects may need longer stimulation of at least 9 months, with more frequent intervention (i.e., more than four vibration sessions every week). The BMD results are comparable to a previous study which demonstrated the benefits of 1-year low-magnitude high-frequency vibration (30 Hz, 0.2 g) on bone mineral density of postmenopausal women (average age 57 years, 0.94 and 2.05 % relative benefit in the spine and femoral neck) [8]. Contrasting result on BMD was also reported showing no benefit to bone density and structure after vibration treatment [15, 16]. The differences in sample size, calcium and vitamin D supplements, baseline BMD, body mass, ethnic group, and duration of intervention may partly explain the discrepant results observed in different trials. Only a limited number of trials studied the effect of low-magnitude vertical vibration without integrated exercise training, and most of them performed multiple comparisons in small subgroups; therefore, it is difficult to compare and have conclusive results.

In the authors' institute, LMHFV has been applied to study fracture healing in animal models. From these studies, it has confirmed the acceleration of normal and osteoporotic fracture healing [11, 12] and enhanced bone remodeling [13] with

Table 4 Difference in secondary outcomes between vibration and control groups (cluster-adjusted 2 sample *t* test analysis)

	Cluster-adjusted mean (95 % CI) (vibration group)	Cluster-adjusted mean (95 % CI) (control group)	Cluster-adjusted difference between groups (V-C) (95 % CI)	*p* value[a]	Intracluster correlation coefficient
Muscle strength: dominant leg (kg)					
18-month-baseline	1.61 (1.10, 2.12)	−0.85 (−1.48, −0.22)	2.46 (1.70, 3.22)	<0.001*	0.095
9-month-baseline	1.35 (0.82, 1.87)	−0.74 (−1.40, −0.07)	2.08 (1.29, 2.87)	<0.001*	0.125
Nondominant leg					
18-month-baseline	1.54 (0.99, 2.10)	−0.89 (−1.59, −0.19)	2.43 (1.59, 3.27)	<0.001*	0.110
9-month-baseline	1.33 (0.80, 1.86)	−0.72 (−1.40, −0.05)	2.06 (1.25, 2.86)	<0.001*	0.134
SF-36[b]					
Physical score					
18-month-baseline	2.17 (−0.50, 4.84)	0.94 (−2.00, 3.89)	1.22 (−2.50, 4.95)	0.50	0.020
9-month-baseline	3.75 (1.30, 6.21)	1.13 (−1.60, 3.87)	2.62 (−0.83, 6.07)	0.129	0.017
Mental score					
18-month-baseline	3.04 (0.43, 5.65)	2.57 (−0.45, 5.58)	0.48 (−3.26, 4.21)	0.80	0.034
9-month-baseline	4.15 (2.14, 6.15)	1.31 (−0.88, 3.50)	2.84 (0.06, 5.62)	0.046	0.013
Total score					
18-month-baseline	2.45 (0.01, 4.90)	1.62 (−1.18, 4.43)	0.83 (−2.66, 4.32)	0.63	0.032
9-month-baseline	3.85 (1.75, 5.94)	0.83 (−1.55, 3.21)	3.02 (0.05, 5.99)	0.047	0.023
Bone mineral density					
Total hip (% change)					
18-month-baseline	−1.86 (−2.35, −1.38)	−1.89 (−2.43, −1.36)	0.03 (−0.65, 0.71)	0.925	0.020
9-month-baseline	−0.95 (−1.24, −0.65)	−1.04 (−1.34, −0.74)	0.10 (−0.30, 0.49)	0.619	0.0003
18–9 months	−0.91 (−1.36, −0.46)	−0.87 (−1.38, −0.36)	−0.04 (−0.67, 0.60)	0.910	0.028
Total spine (% change)					
18-month-baseline	0.08 (−0.51, 0.68)	−0.64 (−1.31, 0.04)	0.72 (−0.12, 1.56)	0.089	0.028
9-month-baseline	−0.24 (−0.59, 0.12)	−0.26 (−0.62, 0.09)	0.03 (−0.44, 0.50)	0.907	0.0000
18–9 months	0.46 (−0.05, 0.96)	−0.36 (−0.91, 0.18)	0.82 (0.12, 1.52)	0.023	0.016
Balancing ability					
Reaction time (s)[c]					
18-month-baseline	−0.25 (−0.36, −0.14)	0.13 (−0.01, 0.27)	−0.38 (−0.55, −0.21)	<0.001*	0.155
9-month-baseline	−0.25 (−0.35, −0.15)	0.15 (0.03, 0.28)	−0.40 (−0.55, −0.25)	<0.001*	0.115
Movement velocity (°/s)[d]					
18-month-baseline	0.93 (0.71, 1.15)	−0.01 (−0.27, 0.25)	0.94 (0.63, 1.26)	<0.001*	0.052
9-month-baseline	0.69 (0.49, 0.88)	−0.05 (−0.29, 0.18)	0.74 (0.45, 1.03)	<0.001*	0.050
Endpoint excursion (%)					
18-month-baseline	6.15 (3.45, 8.86)	−1.74 (−4.87, 1.40)	7.89 (4.02, 11.76)	<0.001*	0.054
9-month-baseline	4.54 (2.47, 6.61)	−2.56 (−4.96, −0.17)	7.10 (4.14, 10.07)	<0.001*	0.032
Maximum excursion (%)[e]					
18-month-baseline	7.95 (5.38, 10.52)	−2.78 (−5.75, 0.19)	10.72 (7.05, 14.39)	<0.001*	0.052
9-month-baseline	5.29 (3.11, 7.48)	−4.72 (−7.33, −2.11)	10.02 (6.83, 13.21)	<0.001*	0.049
Directional control (%)[f]					
18-month-baseline	−0.36 (−2.34, 1.63)	−0.81 (−3.07, 1.46)	0.45 (−2.36, 3.27)	0.74	0.043
9-month-baseline	−1.57 (−3.52, 0.38)	−1.53 (−3.83, 0.76)	−0.04 (−2.86, 2.78)	0.98	0.040

V vibration, *C* control, *CI* confidence interval

[a] From the cluster-adjusted *t* test. Using a Bonferroni-adjusted critical *p* value of 0.025 (*n*=2 comparisons) or 0.017 (*n*=3 comparisons) for the analyses presented in Table 4, the significance test results would not change. Asterisk marks significant difference (*$p<0.025$, $n=2$ comparisons; *$p<0.017$, $n=3$ comparisons)

[b] The SF-36 questionnaire is a validated measure of general health status which covers thirty six items in eight domain scores: physical functioning, role-physical, bodily pain, general health perceptions, vitality, social functioning, role-emotional, and mental health

[c] Reaction time is the time (seconds) taken between the appearance of signal to move and the initiation of subject's movement toward the target

[d] Movement velocity (degrees per second) is the average speed of the COG traveled

[e] Maximum excursion (%) is the largest distance traveled by the COG toward the target during the trial period

[f] Directional control (%) refers to the accuracy of movement toward the target, by comparing the intended movement with the extraneous movement

LMHFV. The differences with the findings from previous studies on fracture healing may be due to the much higher metabolic activities during fracture healing. The relatively slower response of the bony tissue to LMHFV in normal osseous tissue may invite further exploration using different parameters of stimulations.

In the quality of life assessment, the vibration group had shown a trend of improved SF-36 mental health component and total score in 9 months (Table 2) despite not statistically significant after Bonferroni adjustment. The change of quality of life was observed as early as 9 months after treatment, when most of the benefits on muscle performance were observed, and thus may positively affect their functional and social activities.

The compliance for the vibration is good and vibration was well accepted by most elderly with minimal adverse effects (Supplementary Table 3), with an average compliance rate at 66 %. This showed that the vibration at a frequency of 3–4 times per week is effective. In this study, vibration treatment was provided in a community-center setting but not delivered to individuals for home-use. It is understandable that vibration treatment provided by community-center setting is less convenient to users, but is very effective in lowering the cost of treatment as each vibration platform can serve more than 10 subjects each day. Lowering the cost is critical to encourage the introduction of vibration treatment to elderly care. And the overall treatment compliance of this study is satisfactory considering the long study period of 18 months (63 % of the vibration subjects had >60 % compliance) while a previous study showed that 72 % of subjects were at least 60 % compliant in a 1-year home-use vibration treatment setting [8]. Besides the prevention of fall and fracture [9], LMHFV can be another form of biophysical stimulation as an adjunct to regular exercise and is specially indicated in the elderly who may not be able to do regular weight bearing exercise. In most of the previous studies of whole body vibration in older women [5, 3], high-magnitude (>1 g) and side-alternating vibration was adopted and subjects were required to perform knee extensor exercises on the vibration treatment platform. Also, it was common to combine whole body vibration with exercise training program and the treatment protocols were varying (ranged 3–20 min/day, 3–7 day/week, 3–12 months) [3–9]. However, performing intensive exercise on vibration platform is physically demanding and restricted to those who have good balancing ability and physical functions, as fall and fracture are most commonly seen in the elderly with poor balancing ability and muscle strength. We focused on studying the benefits of vibration treatment alone which is more applicable and safer to most elderly. Previous studies also demonstrated that both whole body vibration treatment and resistance training can provide significant and comparable benefits in muscle performance in terms of postural control, muscle strength, and jump height [3, 5]. In this study, low-magnitude (0.3 g) vibration of 20 min/day was adopted considering the generalizability in frail elderly and potential application on postfracture patients, and comparable positive effect on muscle strength was found.

This study was made possible with the participation of 24 community centers. This is unique in Hong Kong where people live in a very compact community in different housing estates. In almost every housing estate, there is an elderly day center managed either by the government or nongovernment organizations (NGOs) where the elderly participate in different daily programs and activities. With our specially designed vibration platforms with automatic programing and data logger, this allowed accurate compliance rate recording and attendance records. The citywide Clinical Management System (CMS) [20] from the Hong Kong Hospital Authority also provided accurate information on fractures and other related injuries in our study population. The ideal design of the study would have been an individual randomized double-blinded one. However, blinding the subjects continuously for 18 months is difficult if not impossible because the vibration, though in low magnitude, can easily be felt. From an organizational point of view, as the requirement of daily vibration of 20 min, it would be most efficient to have the elderly grouped together in centers where vibration platforms were housed and closely monitored by the center staff during vibration sessions. The low incidence rate of fracture resulted in a low power to detect effects on fracture prevention although the fracture rate was considerably lower in the vibration group (adjusted HR=0.42). Difference in the dropout rates of the two groups was due to the demands for daily vibration intervention in the centers, while the control group remained as participants in the regular program in the community centers. The overall dropout rate of our 18-month study (16 %) is comparable with most 6–12-month vibration interventional studies (13–23 %) [16].

The study was done with fixed vibration parameters (35 Hz and 0.3 g). Variation of these parameters may give different effects on muscle or bony tissue. The study duration was confined to 18 months as previous studies indicated the positive effects can be observed within 3–6 months [6]. The cumulative effects of subjecting one to a longer period of vibration and the sustainability of the beneficial effects after stopping vibration remain to be explored in further studies. It would be interesting to see whether the effects will be sustained after cessation of vibration, and it is our plan to assess the cohorts again 1 year after this study.

In conclusion, this is the first study to show the beneficial effects of LMHFV in the prevention of falls among the elderly in the community. The LMHFV is well accepted with negligible adverse effects. This noninvasive intervention should be promoted in the community as an effective fall prevention program and to decrease fall-related injuries.

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Conflicts of interest None.

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