Skilling up for training: a feasibility study investigating acute effects of stochastic resonance whole-body vibration on postural control of older adults

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Abstract

The present pilot study investigated the feasibility of applying a single bout stochastic resonance whole-body vibration in deconditioned elderly individuals and the effects on static and dynamic balance and reaction time. We report the results of a non-blinded randomized control trial with a pre-test/post-test design. Twenty elderly individuals were randomized into either single bout stochastic resonance whole-body vibration (SR-WBV) (n=10, frequency 5 Hz, Noise 4) or control (n=10). SR-WBV received 5 sets of 1 min stochastic whole-body vibration (5 Hz, Noise 4: vibration with a randomly varying frequency, 1=low, 4=high) with 1 min rest in between. The control group rested for 10 min without any intervention. Functional reach test (FRT), semi-tandem stand (STS), Expanded Timed Get Up-and-Go Test (ETGUG), single task- (ST) and dual task walking time (DT), chair rising (CR), and foot (RTF) and hand reaction time (RTH) were measured before and after the intervention. Within- and between group differences were analyzed using repeated measures. In order to assess the meaningfulness of pre-training to post-training changes, the effect size (ES) was calculated according to Cohen's *d*. All participants in the study accepted and adhered to the WBV session and performed scheduled follow-up measurements. There were no adverse events. Change values for dynamic balance showed a strong trend towards improvement for FRT of about 4.5% (ES=0.52, P=0.161). Change values for RTF (5.9%; ES=0.55; P =0.169) showed a trend towards improvement in the SR-WBV only. The results suggest that stochastic resonance WBV is both safe and well accepted by elderly individuals in assisted living institutions, and might have beneficial effects on balance in these adults. Further research is warranted to determine whether this device might be of use in the *skilling-up* phase of an exercise program when training is initiated in strongly deconditioned and/or frail elderly. The new training protocol is expected to allow for safe *skilling-up* training of deconditioned older adults in assisted living institutions.

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Introduction

The balance abilities of the elderly become increasingly limited due to normal or pathological ageing.[1] These age-related limitations in balance abilities may be explained by changes in muscle mass, decreased reflex activity, mobility impairments, or loss of somatosensory sensors. These limitations are also the result of an impairment of central processing, a deficit of motor response functions and a reduction in the functioning of the vestibular and visual systems.[2] This implies that an observable limitation in balance abilities in the clinical setting is most probably multifactorial. These limitations are, furthermore, most likely associated with risk of injury or risk of falls.[3,4] Fall-related injuries, such as hip fractures, are considerable problems in the elderly, as they often lead to sustained disability. A sedentary lifestyle in older people increases the risk of falling, whereas physically active older people have a clearly reduced risk, especially of falls with injuries.[5] These findings indicate that ways should be found to encourage elderly individuals to become more physically active.

It can be expected that an improvement in balance abilities through better postural control may lead to a decrease in risk of falling. Therefore, preventive programs are needed in order to reduce disability, reduce the costs of health care, and to improve the quality of life of elderly individuals. It is well known that exercise programs can be effective for fall prevention in elderly individuals.[6,7] What seems to be lacking from this line of research is an appreciation of what exercises are best suited and most effective for specific subpopulations of elderly individuals, *e.g.* for people who have marked physical limitations because of frailty who want to start a training program. These populations are advised to first enter a *skilling-up* phase before more traditional forms of training exercises are implemented.[4] The question of what kinds of exercises are appropriate for *skilling-up* , however, needs to be answered.[8] In consideration of this, trainers may prescribe balance exercises more effectively to frail and deconditioned elderly individuals with different physical activity backgrounds that have impairments in static and dynamic balance skills.

Sensorimotor and exercise training are traditional intervention methods in the field of physical therapy. Recently, whole body vibration techniques have been introduced as a new methodology for balance training. Although there is much variation in protocol design, the results of this form of training, as summarized in a recent systematic review, are encouraging in the sense that WBV may be a viable alternative to exercise training in improving balance and functional mobility among sedentary and frail elderly individuals.[9] To date, there has been little research into the effect of WBV in general, and stochastic resonance WBV[10] in particular, on postural control in the elderly. No randomized control studies have been carried out into stochastic resonance WBV.[11] Furthermore, those WBV studies that were performed in the past mainly focused on elderly individuals under the age of 75 years.[11] Since no study has applied stochastic resonance

WBV in an intervention for elderly individuals, there is some uncertainty about the dose levels needed, the range of possible treatments and their effects.

Modern exercise equipment may not always be suitable for elderly individuals who might be concerned about the intensity of training sessions and may express a preference for more traditional therapy approaches.[12] Furthermore, the effect on humans of exposure to whole body vibration is believed to cause, under certain conditions, a range of problems.[13] Therefore, new treatments usually have to go through a series of phases to test whether they are feasible, safe and effective.[14] In this context, a pilot study to assess the feasibility of applying stochastic resonance WBV in an elderly population is justified. The findings of such a study can be useful in carrying out a larger scale main phase III study.[14]

The aim of this pilot study was to perform a phase II trial according to the model for complex interventions advocated by the British Medical Research Council[15] to test the effects of stochastic resonance WBV in sedentary elderly individuals. Our intervention targeted individuals who were living in a senior citizens' hostel who are likely to have deconditioning due to a sedentary life style.[16] This pilot study aimed to: i) develop a WBV intervention based on principles of exercise physiology and to deliver it to the individuals living in the hostel; ii) evaluate the feasibility of the intervention process, and the ability to recruit and retain elderly individuals for such an intervention; and iii) assess the acute effects of the intervention.

Materials and Methods

The study involved two randomized groups in a pre-test/post-test design with no blinding of the participants or assessors to the contents of the SR-WBV training.

Twenty elderly individuals (10 male and 10 female) living in a residential care setting took part in the study (Table 1). They were recruited through an oral request and a local newspaper article between November 2009 and January 2010.

Participants were included if they were aged older than 65 years, were able to stand without aids, were classified as being lightly dependent on nursing care (BESA classification level 0, 1, 2,[17] lived in the Bern Canton and had a score over 22 in the Mini-Mental Status Examination (MMSE). Exclusion criteria were: visual disturbances, lower or upper limb prostheses, acute joint diseases, acute thrombosis, acute fractures, acute infections, acute tissue damage, or acute surgical scars.

Randomization procedure was carried out by an independent research assistant with Microsoft Excel 2010. The participants were stratified by sex and allocated to either an intervention (receiving SR-WBV) or a control group (receiving no intervention), using a computer-generated sequence.

The treatment protocol was explained to the participants one week prior to data collection. The study protocol was approved by the local Ethics Committee of the Bern Canton (n. 228/09) and was registered under Clinical Trial.gov: NCT01045746. All participants gave written informed consent.

Criteria for success

The criteria for success, an important part of a pilot study,[14] were based on the primary feasibility objective and focused on recruitment, attrition and adherence to the stochastic resonance WBV exercise. Values for these parameters were compared with median rates in fall prevention interventions in institutional settings for clinical trials.[18] Recruitment of a third of the residents who were eligible for the training session, a 15% attrition rate, and 80% adherence to the WBV session were considered acceptable.

For recruitment, data for the total sampling frame (both those approached and not approached) for inclusion in the trials were taken to assess generalizability to all elderly individuals within the facility. We measured the inclusion rate, *i.e.* the proportion of participants invited to participate who then enrolled in the study, and distinguished between those who refused, who did not respond or who volunteered but did not meet the study inclusion criteria.

For attrition, we measured the number of participants lost at final follow up.

For adherence to the intervention we recorded engagement with the intervention, *e.g.* compliance with all 5 consecutive times of 1 min SR-WBV with a 1 min rest in between the sets.

Secondary outcome measurements

Semi-tandem stand (STS) was measured using a multi-component force platform (Kistler, Typ 9286BA, Winterthur, Switzerland). The participants were instructed to perform a semi-tandem stand (STS) for 20 sec on the force platform. They were positioned by placing their right foot in the right upper quadrant and the left foot in the left lower quadrant of a custom built calibre that was removed after positioning. The arms were in a neutral position at their side. The participants had to look straight ahead and fix their gaze on a green marker positioned at eye-level at a distance of 3 meters. Anterior-posterior (AP) and medial-lateral (ML) sway during the STS was measured. The test was repeated twice with a rest of 1 min in between.

The functional reach test (FRT) was used for measuring dynamic balance.[19] This is a validated clinical measure for balance.[20] The FRT has been associated with an increased risk of falls and frailty in the elderly who are unable to reach more than 15 cm.[19] Five measures were recorded on each side and a mean score from three out of five was calculated.

Chair rising (CR) was used as a performance measurement of upper leg strength and was performed on a multi-component force platform (Kistler, Typ 9286BA, Winterthur, Switzerland). Participants were required to rise from a chair as quickly as possible, to immediately recover balance and to stand upright for 20 sec. For standing, the participants were instructed to look straight ahead and to fix their gaze on a marker positioned at eye-level at a distance of 3 meters. The subjects held their arms crossed over their chest during the whole testing procedure. Vertical ground reaction forces (VGRF) during chair rising were measured before and after intervention. Variables used were chair rising time (CRT) and time to stabilization (TTS) normalized to body weight.[21] The test was repeated twice with a rest of 1 min in between.

The Expanded Timed Get Up-and-Go (ETGUG) was used to measure dynamic balance. The ETGUG[22] has good reliability for experienced raters and acceptable internal consistency. For the current study, the ETGUG was repeated twice.

Table 1. A summary description of the demographic variables of the groups.

	SR-WBV (n=10)	Control (n=10)	P
Age (years)	80.2±6.8	77.4±7.1	0.406
Height (cm)	167,1±6.8	172.9±9.4	0.173
Weight	74. 4±2.8	75.2±11.5	1.0
Gender female/male	5/5	5/5	1.0
BMI (Kg/m^2)	26.8.±.4	25±1.8	0.199
Falls Efficacy Scale-International (FES-I)	19.6±7.3	17.4±4.2	0.330
Amount of individuals using walking aids (%)	10% (wheeled walker)	10% (wheeled walker)	1.0

BMI, body mass index; SR-WBV, stochastic resonance whole-body vibration.

Walking was assessed with different cognitive tasks[23] in single and dual task test conditions. For the single task condition (ST), the participants were instructed to walk a distance of 20 meters at their self-selected walking speed. For the dual task condition (DT), the participants had to count backwards from the number 250 in steps of 7 while walking the same distance at their self-selected walking speed. Total walking times were measured using a digital hand stopwatch (Timex: Ironmen Triathlon, Middlebury, CL, USA). The test was repeated twice.

Reaction time (RT) was measured from the hand (RTH) and feet (RTF) as these measures represent important systems involved in the maintenance of postural stability.[24] A finger and a foot push-button were used as the response to a random light stimulus. The seated participants placed their dominant hand on a table as well as their dominant foot in front of the push-button. The system measured the elapsed time from the release of the light stimulus to the moment the button was pressed. Participants performed 5 practice and 10 experimental trials. The best attempt of the 10 trials was recorded.

SR-WBV intervention

The participants in the SR-WBV group were exposed to SR-WBV (Setting: 5 Hz, Noise 4) using a Zeptor med® vibration device (Frei Swiss AG, Zürich, Switzerland). While standing on the platform of the vibration device, participants had to maintain an upright standing position with slightly flexed hip, knee and ankle joints. The treatment protocol consisted of 5 times of 1 min SR-WBV with a 1 min rest in between the sets. The participants in the control group were tested twice with a 10-minute break between tests.

Immediately following the vibration-treatment and the resting period, post-tests were carried out using the same protocol as for the pre-tests.

Statistical analyses

Descriptive statistics (Mann-Whitney U test) were used to assess baseline characteristics between SR-WBV and the control group. Within- and between-group differences on STS (AP, ML), FRT, CRT, TTS, ETGUG, ST, DT, RTH and RTF were analyzed using repeated measures (ANOVA).[25] P<0.05 was considered significant. All values are presented as means±standard deviations (SD) as well as 95% confidence intervals. The mean differences between pre-test /post-test variables were calculated. The magnitude of difference between conditions was evaluated using Cohen's *d* effect size (ES), where values below 0.20 were considered trivial, 0.20-0.50 small, 0.50-0.80 moderate and over 0.80 large effects.[26] All analyses were conducted using SPSS software version 18.0 (SPSS Inc., Chicago, IL, USA). The G*Power 3 program was used for the *post hoc* calculation of power (www.psycho.uni-duesseldorf.de/abteilungen/aap/gpower3/). The CONSORT 2010 guidelines regarding randomized trials (www.consort-statement.org) and recommendations of items to include when reporting a pilot study[14] were followed to present the results of the study.

Results

Feasibility and safety; recruitment, attrition and adherence

The facility had a total of 100 residents from which staff representatives estimated that 65 fulfilled eligibility criteria. Two information sessions were held and attended by 45 residents. Twenty-three residents were not eligible and were excluded. Twenty-two residents were eligible to participate based on the inclusion-exclusion criteria and were invited to participate. Of these, 20 individuals agreed to take part in the study. This resulted in a recruitment rate of 31% for the total sample frame. The inclusion rate (22 invited to participate; 20 enrolled) was 91%. One person declined to participate and one person had other reasons not to participate.

All elderly individuals participated at follow-up measurements; a 0% attrition rate. For adherence to the intervention, we had 100% compliance with all 5 consecutive times of 1 min SR-WBV with a 1 min rest in between the sets. The flow of participants through the study per training group is shown in Figure 1.

The participants were willing to be randomized. Neither subjective nor objective side-effects related to the intervention used were reported (Figure 1). Socio-demographic and anthropometric characteristics of the two groups are summarized in Table 1. At baseline and after intervention, no statistically significant differences (P<0.05) were found between groups.

Table 2 shows the effect of SR-WBV on the secondary outcomes between both groups. No significant difference was found for STS. A significant difference was found only for RTF ($F_{1,18}$=9.277; P=0.007). Within-group analysis shows no significant differences between results on primary and secondary outcome measures (data not shown).

Discussion

The aim of the current study was to: i) develop a WBV intervention based on principles of exercise physiology and to deliver it to the individuals living in the hostel; ii) evaluate the feasibility of the intervention process and the ability to recruit and retain elderly individuals' participation; and iii) assess the acute effects of the intervention.

We demonstrated the feasibility of acquiring acceptable recruitment, attrition and adherence rates for elderly individuals in an assisted living facility randomized to the experimental WBV training arm. Our target of about a third recruitment rate for the total sample frame was only just met. Those individuals who responded and attended an information session showed a large inclusion rate. These

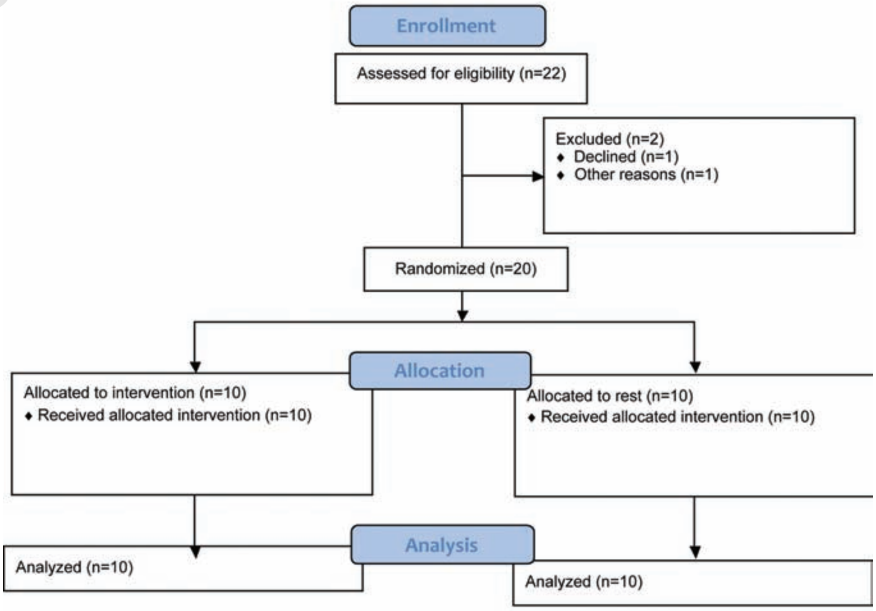

Figure 1. CONSORT diagram for the trial.

findings indicate the importance of information sessions for elderly individuals where questions and concerns about new interventions can be discussed.

Compliance with the WBV intervention and retesting was excellent. All the 20 elderly individuals who were initially included completed the training and retest data were obtained from all of them. This is far more than the rate that could have been expected. It should be noted, however, that the mean compliance rate that was previously determined for several studies summarized in a systematic review[18] mainly focused on studies carried out over far longer time periods. Our data should, therefore, be replicated in another study in which the intervention is applied during several training sessions over several weeks. It can be expected that, because of such a longitudinal design in an institutional setting, less favorable compliance and retention rates are to be expected. Our findings warrant, however, follow-up studies based on these first results.

Safety and acceptance are critical features of the program and we applied strict exclusion criteria for this small cohort, particularly as it was a pilot study. It is hoped that the criteria can be relaxed in time as experience is gained.

Neither the elderly individuals of the SR-WBV nor those who were acting as controls showed improvements or tendencies towards improvement in any of the outcome parameters within a round of 5 consecutive 1-minute single SR-WBV training sessions. Kawanabe and colleagues[6] indicated that acute effects of WBV training in the elderly may be expected after a 2-month study period.

Summarizing the findings and limitations of this study, it becomes clear that results only provide first estimates for the chosen outcome measures. We implemented a strict study design to control threats to validity. Should the protocol continue to be successful, we envisage stochastic resonance WBV will be undertaken as a *skilling-up* exercise in frail deconditioned older people. Before this, further formal evaluation of potential risks and outcome is required in longitudinal studies. A next step would be to replicate the findings in a new exercise group of frail elderly individuals as an additional control procedure.[17] We are, therefore, undertaking an RCT to rigorously compare the WBV protocol with the current standard of usual care. The data collected allow for calculation of the sample size needed for a larger study. The FRT test, for example, showed that there was no difference in baseline means and the effect size of the intervention was moderate at 0.52. To avoid a type I or type II error in a future study, we need, based on our observed values for the FRT (with post-training values of SR-WBV=30.13±8.02; control=33.3±8.02) an estimated sample size of 120 participants for a 2-group RCT-design.

Table 2. Between-groups results for static and dynamic balance and reaction time.

	SR-WBV group mean±SD	Control group mean±SD	P [95% CI] ES
STS ML (mm)			
pre	31.67±9.3	38.70±12.3	0.207
post	34.79±11.1	40.60±14.2	[26-47.2]
			0.092
STS AP(mm)			
pre	27.02±9.5	35.7±15	0.86
post	27.92±5.7	39.5±18.7	[19.39-64.11]
			0.163
FRT (cm)			
pre	27.78±8.6	31.89±6.8	0.299
post	29.02±8.1	32.36±8.0	[26.6-33.9]
			0.06
CR (s)			
pre	1.40±0.19	1.36±0.20	0.858
post	1.35±0.17	1.35±0.17	[1.26-1.51]
			0.002
TTS (s)			
pre	0.48±0.32	0.48±0.29	0.610
post	0.37±0.17	0.47±0.28	[0.28-0.62]
			0.017
ETGUG 0-2 m (s)			
pre	3.38±0.8	2.97±0.8	0.173
post	3.46±1.3	3.03±0.8	[2.8-3.6]
			0.60
ETGUG 2-8 m (s)			
pre	5.40±2.24	4.12±0.95	0.147
post	5.19±2.24	4.19±0.81	[3.9-5.5]
			0.113
ETGUG turn (s)			
pre	3.74±1.45	3.29±0.95	0.378
post	3.62±1.34	3.15±0.74	[2.9-4]
			0.43
ETGUG 12-18 m (s)			
pre	5.27±2.01	4.01±0.95	0.97
post	5.08±2.02	3.93±0.84	[3.8-5.3]
			0.145
ETGUG 18-20 m (s)			
pre	2.33±0.78	2.15±0.69	0.280
post	2.38±0.81	1.93±0.39	[1.9-2.5]
			0.64
ST (s)			
pre	17.33±6.52	15.06±3.87	0.638
post	16.17±6.28	15.20±4.04	[13.8-18.6]
			0.13
DT (s)			
pre	21.01±9.38	17.89±4.81	0.442
post	19.13±8.84	17.26±4.16	[15.5-22.2]
			0.33
RTH (s)			
pre	0.307±0.08	0.250±0.04	0.096
post	0.312±0.07	0.276±0.06	[0.259-0.314]
			0.146
RTF (s)			
pre	0.359±0.07	0.271±0.04	0.07
post	0.343±0.06	0.296±0.05	[0.294-0.341]
			0.40

Values are in mean (±SD) for each intervention. P after pre and post intervention were computed using a Wilcoxon's signed rank test for SR (n=10) and CT (n=10). Effect size (ES) computed with G*Power 3. 95% CI=95% confidence interval. SR-WBV, stochastic resonance whole-body vibration; STS, semi-tandem stand; FRT, functional reach test; ETGUG, Expanded Timed Get Up-and-Go Test; CR, chair rising; ST, single task walking time; DT, and dual task walking time; RTF, RTH, foot and hand reaction time; TTS, time to stabilization. *Statistically significant (P≤0.05) after pre and post intervention

This would result in 80% power at α-level 0.05 and is based on the assumption that the standard deviation of the response variable is 8.02. The sample size would be approximately 106 participants when the foot reaction time is taken as the primary outcome. With this in mind, the relationship between WBV research and its effect on postural control in frail elderly individuals requires further exploration. Translating the results from postural control experiments with non-frail elderly to therapeutic interventions should, therefore, be managed with caution until the appropriate studies with clinically relevant population outcomes have been conducted. In frail elderly individuals, the FRT will be around 15 cm.[27] This implies that the possible range for improvements due to training will be much larger, and this in turn will affect the sample size needed to obtain sufficient power in a future study design.

The lack of blinding of both participants and assessors is a major limitation of this pilot study and this approach should be taken into consideration in future phase III trials. It should be possible to offer a *sham* vibration procedure that is able to successfully blind the participants. This would overcome many of the potential placebo effects. Likewise, it seems possible to blind future assessors to the intervention.

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