

# Effects of a low-frequency sound wave therapy programme on functional capacity, blood circulation and bone metabolism in frail old men and women

**A Zheng, R Sakari, SM Cheng and A Hietikko** Department of Health Sciences, **P Moilanen and J Timonen** Department of Physics, University of Jyväskylä, Jyväskylä, **KM Fagerlund** Department of Cell Biology and Anatomy, University of Turku, Turku, **M Kärkkäinen** Department of Health Sciences, University of Jyväskylä, **M Alén** Department of Medical Rehabilitation, Oulu University Hospital and Institute of Health Sciences, University of Oulu, Oulu and **S Cheng** Department of Health Sciences, University of Jyväskylä, Jyväskylä, and Department of Orthopaedics and Traumatology, Kuopio University Hospital, Kuopio, Finland

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**Objective:** To evaluate the effects of a low-frequency sound wave therapy programme on functional capacity, blood circulation and bone metabolism of the frail elderly.

**Design:** Single-blind, randomized, controlled trial.

**Setting:** Two senior service centres.

**Subjects:** Forty-nine volunteers (14 males and 35 females) aged 62–93 years with up to 12 diagnosed diseases were allocated in either the intervention group ( $n=30$ ) or control group ( $n=19$ ).

**Intervention:** The intervention group underwent sound wave therapy, 3–5 times a week for 30 minutes per session over a period of 6 months. The control group received no intervention.

**Main measurements:** Blood pressure, functional capacity, mobility, bone density, biochemical markers, isometric muscle strength, balance, and skin surface temperature.

**Results:** Compared with the control group, the intervention group's mobility and the amount of self-reported kilometres walked per week increased by 3 km ( $P<0.05$ ), while levels of cholesterol (4.97 (0.72) to 4.52 (0.65) mmol/L,  $P=0.019$ ), low-density lipoprotein (2.82 (0.72) to 2.45 (0.61) mmol/L,  $P=0.022$ ), bone markers of total osteocalcin (11.0 (6.5) to 10.3 (5.9) ng/mL,  $P=0.048$ ) and tartrate-resistant acid phosphatase isoform 5b (2.50 (1.0) to 2.41 (1.1) IU/L,  $P=0.021$ ) decreased. The average skin surface temperature was significantly higher during active sessions at the end of the intervention than in the beginning ( $P=0.004$ ). No change was found during placebo sessions.

**Conclusions:** Low-frequency sound wave therapy may have the potential to promote well-being of frail elderly subjects via improved functional capacity, especially in subjects who are too frail to undertake exercise.

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Address for correspondence: Professor Sulin Cheng,  
Department of Health Sciences, University of Jyväskylä,  
PO Box 35, 40014 Jyväskylä, Finland.  
e-mail: sulin.cheng@sport.jyu.fi

## Introduction

Globally, it is predicted that the proportion of elderly people in the population will exceed by 2047 the proportion of children for the first time in human history.<sup>1</sup> Such changes in the population structure provide both opportunities and challenges to health care systems. Many improvements to the well-being of aged people have been made in recent decades. Especially in developed countries, efforts towards enhancement of living standards and provision of appropriate services and activities have improved the functional capacity of the elderly (e.g. in Finland<sup>2</sup>).

Ageing reduces muscle strength and balance, leading to problems in the activities of daily living and increasing risk of falling and fractures.<sup>3</sup> Exercise, strength training and balance training have proved to be effective and useful ways of maintaining or improving muscle strength and balance in the elderly.<sup>4-6</sup> Unfortunately, it can be difficult to apply such approaches in frail or disabled old people. Therefore, it is necessary to explore alternative, more widely applicable methods for maintaining and improving at least some aspects of functional capacity and well-being in frail elderly subjects.

It has been suggested that whole body mechanical vibration produces an adaptive response similar to that of conventional exercise.<sup>7,8</sup> There are indications of positive effects from whole body vibration in different types of subjects, including the elderly,<sup>9,10</sup> people with multiple sclerosis,<sup>7</sup> athletes<sup>11</sup> and immobilized patients.<sup>12</sup> Low-frequency sound waves are similar in their physical nature to mechanical vibration. The use of low-frequency sound waves could be a useful approach for very old and disabled individuals because participation does not require good functional ability. A device using low-frequency sound waves has been approved by the Food and Drug Administration in the USA, and three medical claims have been allowed: that it improves blood circulation, reduces pain and relaxes muscles where applied. However, the mechanisms of interaction with the body are not clear. We hypothesize that low-frequency sound waves penetrate deep into tissues from the skin surface to bones, and affect blood circulation, and potentially muscle and bone

metabolism. Consequently, such an intervention could lead to improved functional capacity such as better postural balance, greater isometric muscle strength, walking ability, and daily functioning in the elderly. To test this hypothesis, we studied a group of frail elderly people in a randomized controlled trial, and assessed the physiological effect of the intervention with low-frequency sound waves.

## Materials and methods

The investigation was performed as a single blind study for the researchers. All the data collection was done by a study nurse and research assistants from the Department of Health Sciences, University of Jyväskylä. Participants were randomized after their eligibility had been determined at the screening (see Subjects section). Then assignments were generated by a computer program in blocks of randomly varying size. Study group assignments were placed in double sealed envelopes and recorded in a log. The investigators were unblinded at the conclusion of the trial. In addition, all the biomarker and hormone measurements were performed blind and assessed randomly with respect to the time the sample was taken and assigned intervention group. The project was approved by the ethical committee of the Central Finland health care district.

## Subjects

The study subjects were recruited from two senior service centres. The residents and service users of the centres, as well as other older persons living near the centres were informed about the study in two briefings. The eligibility of the volunteers was checked by a nurse, who consulted a doctor when necessary. Exclusion criteria were (1) age less than 60 years, (2) impaired mental status that prevented giving informed consent, (3) history of severe or progressive disease or any illness that might confound the results of the study or pose additional risks to the subject, and (4) diseases or posttraumatic disorders that would inhibit participation in tests (e.g. inability to stand without assistance). In addition, pacemaker

patients were excluded from the intervention group. Finally, the subjects consisted of 49 men ( $n=14$ ) and women ( $n=35$ ) aged 62–93 years who gave their informed consent. Fifteen of the subjects lived independently in the community, 16 in sheltered housing, and 18 in residential homes. Their medical information for the preceding year was checked from the patient records of the local health centre. On average, each subject had six chronic diseases (range 0–12) and used nine different prescription drugs (range 0–22). Seventy-two per cent of them used walking aids indoors and 55% outdoors, most often walkers and canes. One subject used a wheelchair but also a walker for shorter distances.

Due to the small sample size and great variation within subjects, the allocation was done in groups stratified for sex, age, self-reported mobility and use of medication that affects bone. The intervention group was constituted larger than the control group to ensure that the possibility of a high drop-out rate would not impede the study. There were two couples in the study. One couple was in the intervention group and the spouse was not allocated in the same intervention session. Many of the old and frail subjects were expected to have natural changes in their health status over six months and the intervention required continuous commitment several times a week. The subjects were then randomly allocated to either the intervention group ( $n=30$ ) or control group ( $n=19$ ).

### **Intervention programme**

Subjects who were assigned into the intervention group underwent a supervised programme by a study nurse. The subjects sat on the chair 3–5 times a week, for 30 minutes per session over a period of six months. In each session, the study nurse guided the subject to sit on the sound wave therapy chair, operated the programme (see below), and followed through the whole intervention process. The study nurse also performed all the measurements of blood pressure before and after each 30-minute intervention as well as the temperature measurements (see below). Once a month the subjects sat in the chair in the usual way for 30 minutes, but the loudspeakers were not connected (placebo sessions).

The low-frequency sound wave device used was the 'Physioacoustic Sound Wave Therapy System' (Next Wave Ltd, Finland) which comprises a reclining chair housing six speakers and a computer. The computer creates and controls low-frequency sinusoidal sound waves within a range of 27–113 Hz, which are broadcast through the speakers locating under lower limbs, hips and back. The sixth loudspeaker under the neck was not used. The computer-controlled programmes used in this study were progressive in terms of rhythms and frequencies. During the entire intervention, nine different combinations of the rhythms and frequencies were used.

The control group members were instructed to continue their daily routines and not to change their physical activity levels.

### **Questionnaires**

A questionnaire administered by interview was used to evaluate each participant's daily functioning as well as their health history. The health history including diseases and medications was checked and verified from medical records. Activities of daily living were assessed with nine basic activities of daily living questions, nine instrumental activities of daily living questions and five mobility questions with scoring as follows: 0=no difficulties, 1=slight difficulties, 2=major difficulties, 3=needs assistance and 4=not able. The 'basic activities of daily living score' was the sum of the scores for the following tasks: eating, washing up, toileting, transferring in and out of bed, dressing, walking indoors, walking outdoors, climbing stairs and cutting toe nails. The 'instrumental activities of daily living score' comprised the tasks of taking care of one's own medication, using telephone, cooking, doing light household tasks, handling finances, laundry, cleaning, using public transportation, and shopping. The 'mobility score' included the tasks of getting up from a chair without using hands, squatting down and getting up, picking up an item from floor, walking at least 2 km and climbing stairs without resting at least one flight. After the intervention, the subjects in the intervention group were also asked for their positive and negative experiences about the chair sessions.

### **Anthropometric measurements**

Participants were weighed with light clothes and without shoes. Weight was determined within 0.1 kg for each subject using a calibrated electronic scale. Height was determined using a fixed wall-scale measuring device to the nearest 0.1 cm.

### **Blood pressure**

All subjects sat quietly for 5 minutes before the measurement was taken. Blood pressure was assessed each time the subject returned to the laboratory for measurements. In addition, the intervention group subjects had their blood pressure taken each time they sat on the treatment chair before it was activated and immediately after 30 minutes of treatment. Measurement of blood pressure was done using a standard automatic sphygmomanometer with cuffs matched to arm size and positioned at cardiac level (inferior margin of sternum).

### **Bioimpedance assessments for body composition**

Whole body fat mass, percentage of fat mass and fat free mass was measured using a commercial electrical impedance device (In Body Composition Analyzer, Biospace Co., Ltd, Korea). The precision of the repeated measurements expressed as coefficient of variation (CV) was, on average, 0.6% for percentage of fat mass.

### **Peripheral quantitative computed tomography (PQCT) assessments**

Volumetric bone mineral density of the left tibia shaft and muscle cross-sectional area were measured in the lower leg using peripheral quantitative computed tomography with a pixel size of 0.59 mm (pQCT, XCT 2000, Stratec Medizintechnik, GmbH, Pforzheim, Germany). The CV between two consecutive measurements with repositioning varied between <3% for the muscle cross-sectional area and <1% for volumetric bone mineral density.

### **Assessments of biochemical markers, hormones and bone turnover**

Blood samples were taken in the morning between 7:30 and 9:00 after an overnight fast.

Serum samples were stored at  $-70^{\circ}\text{C}$  until analyzed. Serum cholesterol, triglycerides, high-density lipoprotein, low-density lipoprotein and very-low-density lipoprotein were assessed by Konelab.

The level of serum total osteocalcin, a marker of bone turnover, was measured using an in-house immunofluorometric assay.<sup>13</sup> The inter- and intra-assay coefficients of variations of the assay were <8% and <5%, respectively. Serum tartrate-resistant acid phosphatase 5b, a marker of bone resorption, was assessed using an in-house immunoassay.<sup>14</sup> The intra- and inter-assay coefficients of variation were 2.7% and 24.5%, respectively.

### **Assessment of isometric muscle strength and balance**

Maximum isometric strength of the hand grip, elbow flexors and leg extensors were measured in a dynamometer chair (Metitur, Finland). The left side extremity was measured unless medical reasons dictated otherwise, in which case the right side extremity was used. The subject sat in the chair in an erect position with the left knee 60 degrees flexed. The ankle was attached to a strain gauge with a Velcro strap. Three trials were recorded and the best record was used as the final result, adjusted for body weight (Newton/kg). The measurement procedures have been described in detail elsewhere.<sup>15</sup>

The standing balance of the participants was measured on a force platform (Metitur, Finland).<sup>16</sup> The subject tried to stand as still as possible for 30 seconds with eyes open, feet comfortably apart. The anteroposterior and mediolateral speed (mm/s) of the movement of the centre of pressure was measured and adjusted for the subject's height. The best of the two trials was used as the final result.

### **Skin surface temperature**

To examine whether the low-frequency sound wave intervention was able to affect blood circulation of skeletal muscles, we measured surface temperature of the gastrocnemius muscle during the 30-minute session. Surface muscle temperature from the left shank was measured by a thermistor

with probes (TrendReader 8 data logger, MicroDAQ.com, Ltd., Contoocook, USA). The probes were placed on the skin surface of lateral and medial parts of the gastrocnemius muscle. The temperature was measured during the sessions. The results were compared with those of the placebo sessions carried out once a month so that during an ordinary session the loudspeakers were not connected to the computer. The temperature averaged over 10 minutes in the middle of the 30-minute session was used as the final result to ensure the results were reliable. The surface muscle temperature was compared between placebo sessions and treatment sessions, carried out on consecutive days in the beginning of the study and near the end of the six months' intervention.

### Statistical analysis

All data were checked for normality using Shapiro-Wilk's *W*-test in SPSS 15.0 for Windows. The effects of the interventions were assessed using an analysis of variance (ANOVA) for repeated measures (group, time and group by time interaction). The level of statistical significance chosen was  $P < 0.05$ . An intention-to-treat analysis was performed to compare the intervention group with the control group. In addition to the intention-to-treat analysis, efficacy or active treatment analyses were done so that those who did not complete the intervention were excluded. Exclusion criterion from the efficacy analyses was participating in less than 80% of all sessions.

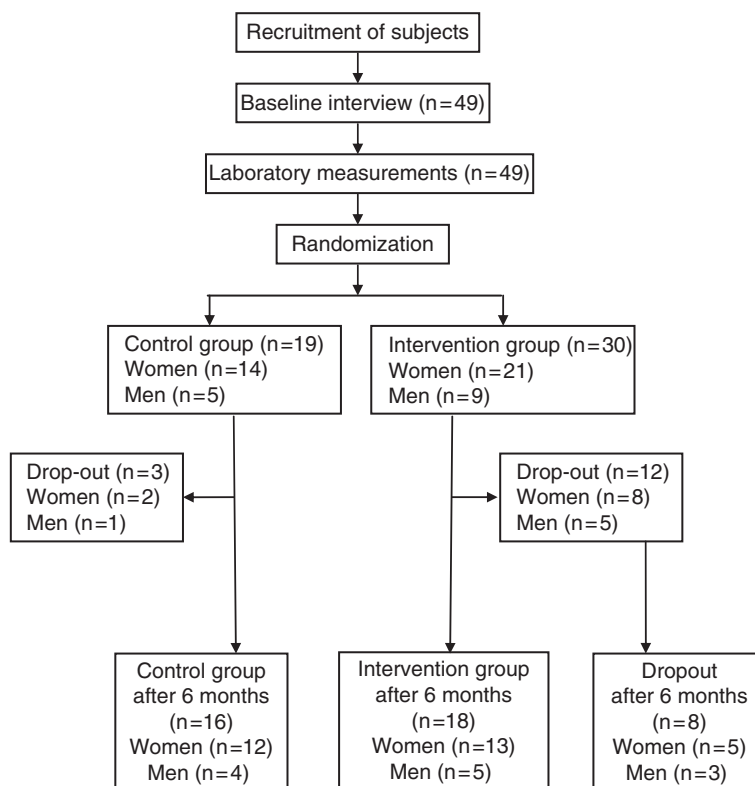
### Results

There were no statistically significant differences between the intervention group and the control group in the number of diseases or medication used at the baseline. Over the course of the study, a total of 15 subjects dropped out, 3 from the control group and 12 from the intervention group (Figure 1). Reasons for drop-out were back pain ( $n=2$ ), cardiac arrhythmias ( $n=3$ ), foot pain ( $n=2$ ), high blood pressure ( $n=2$ ), difficulties in breathing ( $n=1$ ), participating too burdensome ( $n=4$ ) and transport problems as the partner stopped going to the sessions ( $n=1$ ) (Figure 1).

Of the 18 subjects in the intervention group who completed six months of intervention, 16 (89%) reported that they felt pleasant or very pleasant sitting in the chair. Two of them (11%) felt neither pleasant nor unpleasant. Furthermore, 5 subjects (28%) experienced tiredness and 4 (22%) felt refreshed immediately after the sessions. After the intervention, 8 subjects (44%) reported positive effects in their daily life that they connected to the chair sessions (e.g. disappearance of overnight foot pain, feet feeling lighter, feeling refreshed, better daily functioning, decreased blood pressure and increased social interaction). Four subjects (22%) reported that the intervention had not obviously affected their daily life. Five subjects (28%) reported negative effects, which concerned mostly the difficulties and restrictions in planning weekly routines because of the sessions. One person reported excessive tiredness which prevented certain exercise activities.

No significant effect of the intervention was found in weight, body mass index, waistline, fat, systolic and diastolic blood pressure, chair stand time, maximal isometric knee extension strength or grip strength, muscle cross-sectional area, balance, 10 m walking speed, nor the scores of basic activities of daily living or instrumental activities of daily living when comparing the intervention and the control groups (Table 1). The difficulties according to the mobility score decreased in the intervention group, but not in the control group (the group by time interaction was statistically significant  $P < 0.05$ ). The number of kilometres walked per week was slightly increased in the intervention group (from 11.8 (10.1) to 14.5 (12.5) among those who completed the intervention) and decreased in the control group (from 14.1 (9.5) to 9.9 (7.2), group by time interaction  $P < 0.05$ ).

After the intervention, the levels of total cholesterol were lowest in the intervention group (4.47 (0.10 SE) mmol/L) compared with the control group (4.90 (0.11) mmol/L) and the drop-out group (4.65 (0.14) mmol/L) after controlling for the baseline value (Table 1, Figure 2a). The level of low-density lipoprotein was also decreased significantly more in the intervention group (2.37 (0.09) mmol/L) compared with the control group (2.65 (0.92) mmol/L) and the drop-out group (2.52 (0.12) mmol/L) after controlling for the baseline value (Table 1, Figure 2b). No significant



**Figure 1** Flowchart of subjects in this study.

group by time interaction was found in triglycerides, high-density lipoprotein and very-low-density lipoprotein (Table 1).

The blood pressure decreased significantly in each session during the entire intervention. On average the systolic pressure decreased by 12 mmHg (9.2%), and the diastolic pressure by 2.9 mmHg, (4%) (Figure 3). The decrease in blood pressure was seen after placebo sessions as well.

The average surface temperatures over the gastrocnemius muscle were increased from 33.5 (SE 0.28) to 34.2 (0.29) at the end of the chair sessions intervention than in the beginning ( $P=0.004$ , Figure 4). No change was recorded during placebo sessions when the loudspeakers were not connected.

We found that the concentration of total osteocalcin decreased from 11.0 (6.5) ng/mL to 10.3 (5.9) ng/mL in the intervention group but increased from 7.23 (3.2) ng/mL to 9.06 (4.5) ng/mL in the

control group. Controlling for the baseline differences, the serum total osteocalcin level in the intervention group decreased significantly with time, in contrast to the control group (Figure 5, left panel). The activity of a bone resorption marker, tartrate-resistant acid phosphatase 5b also decreased from 2.50 (1.0) IU/L to 2.41 (1.1) IU/L in the intervention group and increased from 2.20 (0.7) IU/L to 2.54 (1.0) IU/L in the control group. However, no significant change was found in bone mineral density of the tibia (Table 1).

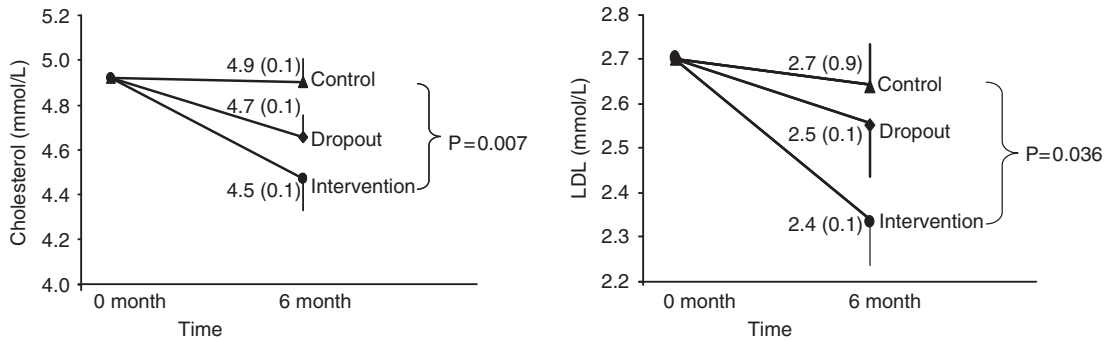
## Discussion

In the present study, we found some evidence that participation in a low-frequency sound wave therapy programme can improve both functional capacity and well-being in terms of mobility,

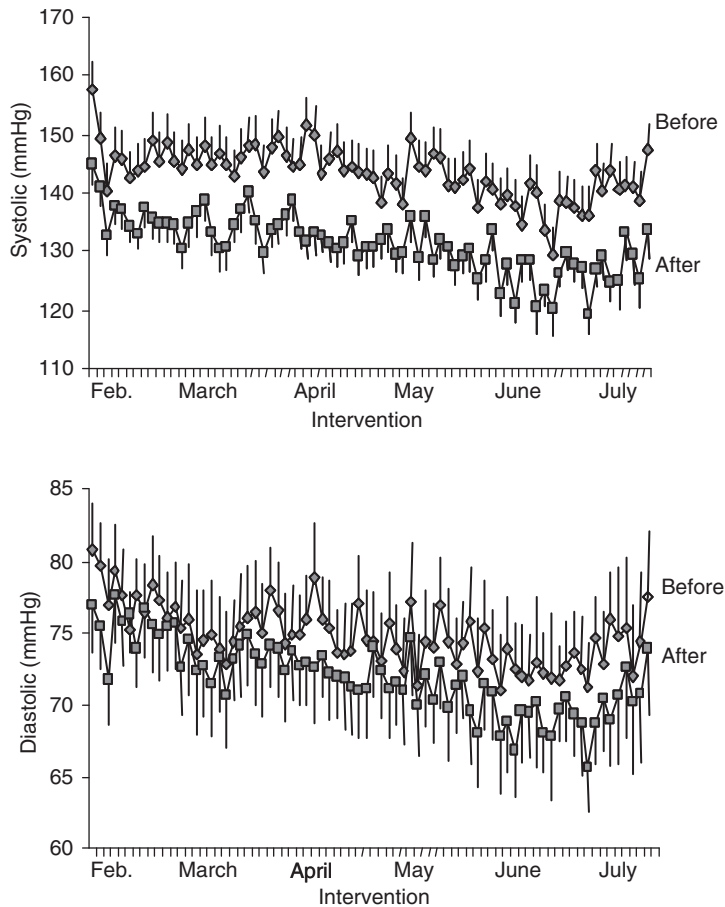
**Table 1** Functional capacity measurements at baseline and after six months and the significance of group, time and group × time interaction in control group and intervention group (intention-to-treat analysis and efficacy analysis including only those who satisfactorily completed the intervention programme)

	Control group (n = 12–16)				Intervention group							
	Efficacy analysis (n = 16–18)				Intention-to-treat analysis (n = 23–29)							
	Baseline	6 months	Baseline	6 months	Group P-value	Time P-value	Group × time P-value	Baseline	6 months	Group P-value	Time P-value	Group × time P-value
Weight (kg)	72.3 (11.6)	70.7 (10.6)	71.9 (11.4)	71.2 (11.1)	0.992	0.004	0.277	72.3 (11.2)	71.5 (11.6)	0.924	0.002	0.233
BMI <sup>a</sup>	27.9 (4.3)	27.4 (4.2)	28.4 (4.0)	27.9 (3.8)	0.728	0.002	0.745	28.3 (3.8)	27.9 (3.9)	0.729	0.003	0.459
Waistline (cm)	90.9 (13.6)	89.9 (12.4)	89.8 (8.9)	90.2 (8.7)	0.928	0.638	0.303	91.2 (10.5)	91.1 (10.2)	0.841	0.371	0.424
Fat %	36.7 (8.6)	34.5 <sup>b</sup> (8.5)	37.4 (9.1)	35.8 <sup>b</sup> (10.4)	0.830	<0.001	0.535	37.6 (8.1)	36.3 <sup>c</sup> (9.5)	0.756	0.001	0.375
BP Systolic (mmHg)	154.8 (22.1)	146.6 (23.5)	155.0 (21.0)	143.4 (18.8)	0.826	0.007	0.623	151.0 (22.1)	141.2 (19.9)	0.481	0.008	0.801
BP Diastolic (mmHg)	77.5 (12.8)	76.6 (12.9)	76.2 (12.9)	74.1 (11.1)	0.649	0.377	0.704	76.0 (11.9)	74.2 (10.3)	0.594	0.384	0.752
Chair stand time (s)	12.2 (5.1)	12.4 (4.4)	13.3 (3.5)	13.5 (3.1)	0.460	0.622	0.969	13.8 (3.5)	13.7 (4.1)	0.316	0.998	0.670
Walking speed (m/s)	1.6 (0.6)	1.7 (0.5)	1.5 (0.5)	1.5 (0.5)	0.398	0.025	0.934	1.4 (0.5)	1.5 (0.5)	0.352	0.019	0.843
PADL score	2.4 (3.1)	2.8 (4.5)	4.7 (5.8)	5.3 (6.0)	0.157	0.297	0.734	6.3 (6.5)	6.2 (6.4)	0.039	0.746	0.612
IADL score	2.5 (4.3)	3.1 (5.9)	6.7 (8.7)	7.3 (8.4)	0.093	0.033	0.093	8.6 (10.0)	9.2 (10.0)	0.026	0.143	0.996
Mobility score	4.0 (4.6)	4.4 (5.3)	6.4 (5.8)	5.1 (5.8)	0.406	0.279	0.042	7.5 (6.5)	6.3 (6.4)	0.148	0.301	0.034
Self-reported kilometres walked/week	14.1 (9.5)	9.9 (7.2)	11.8 (10.1)	14.5 (12.5)	0.711	0.622	0.031	10.8 (10.5)	11.9 (12.1)	0.825	0.214	0.041
Muscle CSA (mm <sup>2</sup> )	7089 (1034)	6995 (1041)	6746 (1326)	6659 (1256)	0.016	0.992	0.614	6685 (1399)	6599 (1371)	0.013	0.903	0.549
vBMD <sub>tibia</sub> (g/cm <sup>3</sup> )	597 (128)	605 (123)	617 (112)	605 (91)	0.803	0.846	0.224	604 (103)	597 (90)	0.986	0.962	0.282
Balance: antero-posterior speed (m/s)	7.5 (3.4)	8.2 (7.0)	8.5 (6.6)	8.6 (6.7)	0.754	0.518	0.642	8.9 (6.6)	9.2 (7.4)	0.591	0.351	0.732
Balance: mediolateral speed (m/s)	3.8 (1.8)	4.3 (3.3)	4.1 (3.3)	4.1 (2.9)	0.982	0.375	0.388	4.5 (3.4)	4.5 (3.3)	0.652	0.371	0.349
Grip strength (N)	257 (87)	261 <sup>d</sup> (84)	231 (87)	234 <sup>b</sup> (107)	0.516	0.740	0.992	228 (102)	237 <sup>e</sup> (111)	0.520	0.516	0.787
Knee extension strength (N/kg)	4.8 (1.1)	5.4 <sup>f</sup> (1.6)	3.7 (1.2)	4.2 <sup>g</sup> (1.2)	0.052	0.004	0.744	3.6 (1.2)	4.0 <sup>h</sup> (1.2)	0.018	0.001	0.646
Cholesterol (mmol/L)	4.99 (0.94)	4.95 (0.82)	4.97 (0.72)	4.52 (0.65)	0.389	0.006	0.019	4.88 (0.72)	4.51 (0.63)	0.235	0.011	0.039
Triglycerides (mmol/L)	1.54 (1.04)	1.65 (1.33)	1.12 (0.35)	1.07 (0.43)	0.096	0.620	0.137	1.21 (0.38)	1.18 (0.43)	0.114	0.385	0.165
HDL (mmol/L)	1.70 (0.53)	1.63 (0.47)	1.64 (0.52)	1.59 (0.50)	0.788	0.108	0.750	1.57 (0.49)	1.51 (0.46)	0.420	0.066	0.817
LDL (mmol/L)	2.59 (0.81)	2.57 (0.68)	2.82 (0.72)	2.45 (0.61)	0.833	0.010	0.022	2.77 (0.65)	2.46 (0.56)	0.886	0.020	0.043
VLDL (mmol/L)	0.70 (0.47)	0.75 (0.60)	0.51 (0.16)	0.48 (0.20)	0.096	0.620	0.137	0.55 (0.17)	0.54 (0.20)	0.114	0.385	0.165
Osteocalcin (ng/mL)	7.23 (3.22)	9.06 (4.54)	11.0 (6.50)	10.3 (5.86)	0.144	0.367	0.048	10.5 (5.8)	9.96 (5.3)	0.177	0.216	0.036
TRACP 5b (U/L)	2.20 (0.72)	2.54 (1.01)	2.50 (1.00)	2.41 (1.07)	0.779	0.179	0.021	2.34 (0.93)	2.26 (0.97)	0.820	0.099	0.009

<sup>a</sup>n = 6; <sup>b</sup>n = 11; <sup>c</sup>n = 14; <sup>d</sup>n = 9; <sup>e</sup>n = 15; <sup>f</sup>n = 8; <sup>g</sup>n = 13; <sup>h</sup>n = 18. BMI, body mass index; BP, blood pressure; PADL, physical activities of daily living; IADL, instrumental activities of daily living; HDL, high-density lipoprotein; LDL, low-density lipoprotein; VLDL, very low-density lipoprotein; TRACP, tartrate-resistant acid phosphatase isoform 5b.



**Figure 2** Comparison of the changes of total cholesterol and low-density lipoprotein (LDL) in different groups. The values are the estimated mean and standard error adjusted for baseline differences and *P*-values are between intervention and control groups (ANCOVA).

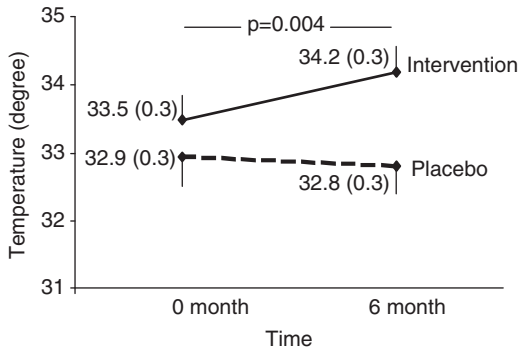


**Figure 3** Change of blood pressure during each session in entire intervention. The dotted lines represent average values, and the error lines indicate the standard error.



reduced serum cholesterol, and decelerated bone turnover of elderly subjects living in different levels of senior housing (community, sheltered housing and residential home).

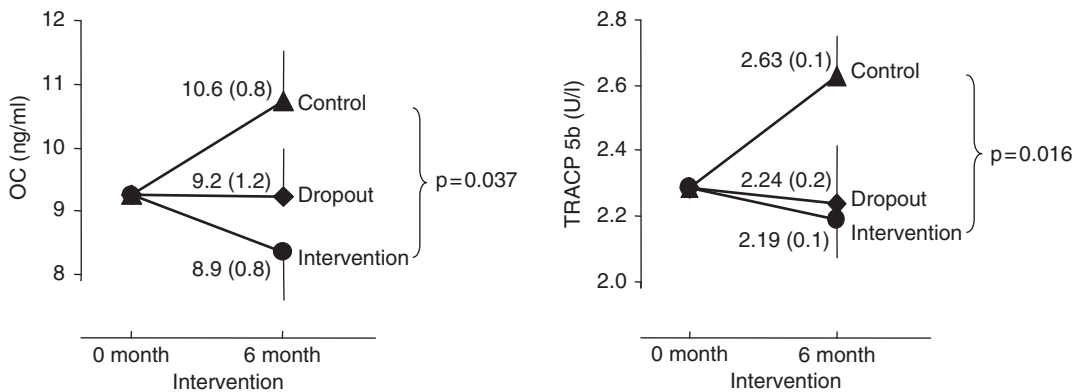
The first positive impact for the intervention group was that most (89%) of the subjects enjoyed sitting in the chair and thus the acceptance of the intervention was good. Placing the chairs at the senior service centre made the treatment accessible both for the residents of the residential home and for all the people who lived independently, but were used to visiting the centre and using its services. The positive effects caused by increased social activity among those who participated in the intervention cannot be separated from the total effects of the programme, as shown in some other's studies.<sup>3,4</sup>



**Figure 4** The changes of surface temperatures of gastrocnemius muscle (mean and standard error).

In Finland, older people are usually able to walk outdoors more frequently during the summer as the weather is warmer and the roads are not slippery. However, in the present study, the control group did not increase their outdoor walking even though the study lasted until the end of summer. On the other hand, the subjects in the intervention group increased their outdoor walking and their mobility difficulties decreased. This implies that participation in a sound wave therapy programme may increase general functional capacity and the physical activity level in these fragile elderly subjects. However, the underlying mechanisms behind these improvements are not clear. The increased outdoor walking and decreased mobility difficulties could be partly explained by some physiological mechanisms, for example, better blood flow in the lower extremities due to the intervention, or by psychological mechanisms due to the increased social activity during the sessions.

Earlier studies have reported increased muscle strength and balance after physical exercise programmes among old people, but often these programmes failed to show any improvement in self-reported disability or daily mobility.<sup>17,18</sup> Hettinger reported that the application of low-frequency vibration (50 Hz, 10 g) for 2–5 h daily could increase muscle cross-section and reduce the fat content of muscle tissue.<sup>19</sup> Recently, several studies have demonstrated that whole body vibration can significantly enhance skeletal muscle strength and may prevent or possibly reverse



**Figure 5** Comparison of the changes of bone biomarkers of total osteocalcin (OC) and tartrate-resistant acid phosphatase isoform 5b (TRACP 5b) in different groups. The values are the estimated mean and standard error adjusted for baseline differences and *P*-values are between intervention and control groups (ANCOVA).

age-related sarcopenia.<sup>11,20,21</sup> In the present study, where the intervention consisted of regular sound wave therapy sessions, the results found were the opposite to the ones described above as positive changes could be seen only in mobility but not in the muscular level or balance of the subjects.

It is well recognized that high serum cholesterol and low-density lipoprotein (LDL) are risk factors associated with cardiovascular diseases, which is a leading cause of death in the elderly in industrialized societies.<sup>22</sup> One of the strategies to prevent cardiovascular diseases in the elderly is to reduce serum lipid as well as the 'bad' lipoprotein, LDL.<sup>23</sup> Aerobic exercise has been recommended as a therapeutic lifestyle for improving lipid and lipoprotein levels in adults.<sup>24</sup> However, intense exercise is not appropriate for all old, frail persons due to their illness and weakness. It is difficult to explain the reason for the lowered cholesterol levels found in the intervention group in the present study. Although the mechanisms behind these changes have not been determined, they may have some similarity to those associated with physical exercise. The significant change found in the intervention group may be linked to changes in blood circulation, indicated by the changes in muscle temperature during the treatment sessions. This finding is in accordance with previous studies showing that short-term increase in skin temperature is linked to increase in blood volume and plasma volume<sup>25</sup> and that regular exercise increases the blood volume.<sup>26</sup>

In the present study we observed that both the systolic and the diastolic pressures were significantly decreased at the end of each session. We assume that it might be because the vibration increased peripheral blood flow, leading to a reduction in peripheral resistance. Indeed, it has been reported that low-frequency (26 Hz) whole body vibration is capable of increasing blood volume and speed of blood flow in quadriceps and gastrocnemius muscles in healthy adult men.<sup>26</sup> The elevated surface temperature of the gastrocnemius muscle found in the intervention group at the end of the study provides further indirect evidence of improvement of the local blood circulation. Taken together, these results indicate that sound wave therapy may have positive effects on local metabolism in these elderly subjects and they thereby improve their physical condition.

However, the intervention produced a transient decrease in blood pressure at the time of therapy, but did not show a systematic effect on blood pressure compared with control subjects over the duration of the study. The transient effect was also present in the placebo case when the subjects sat in the chair but the sound waves were deactivated. Hence the transient lowering of blood pressure is likely to be a psychological effect associated with the relaxing feeling of being in the chair. The absence of a systematic effect on blood pressure may be influenced by the fact that most of the participants have a history of high blood pressure and of medication to control this.

Osteoporosis is characterized by decreased bone mass and skeletal microarchitectural deterioration, which together increase susceptibility to fracture.<sup>27,28</sup> It has been predicted that this preventable but not incurable disease will constantly increase worldwide due to population ageing.<sup>29,30</sup> The major cause of osteoporosis in the elderly is sex hormone deficiency, which leads to increasing bone turnover.<sup>31,32</sup> Regular physical exercise may help to maintain, even increase, bone mass density in the elderly<sup>33,34</sup> but such exercise is hard to achieve for elderly subjects with disabilities. Recently, mechanical vibration has been demonstrated to have potential for prevention and possibly treatment of osteoporosis induced by oestrogen deficiency, both in animal models<sup>35</sup> and in postmenopausal women.<sup>36</sup> In this current study, no change in bone mineral density was observed due to the relatively short (six months) intervention. On the other hand, two sensitive biomarkers of bone turnover, total osteocalcin and tartrate-resistant acid phosphatase 5b, decreased significantly after a six-month intervention, which suggests that the intervention may have acted so as to slow down bone turnover, and hence possibly reduce bone loss in the longer term.

When interpreting our results one must keep in mind that the study sample size is relatively small. But this did not prevent us from observing the significant differences between the intervention and the control group. It is possible that our results were biased by the high drop-out rate. If subjects who responded poorly to the intervention or were otherwise less healthy were those in the intervention group who dropped out, then this could explain much of the observed findings.

To investigate this we compared the subjects who dropped out with those who remained in the intervention and control groups in terms of the measured variables, number of the diseases and medications at the baseline (data not shown). No significant differences were found. Therefore, our results are not likely to be due to a bias associated with those subjects who failed to complete the study. In addition, the study was a supervised intervention, thus it is not possible to separate the social effect from that of the true therapeutic effect. This is a common problem in all such supervised intervention programmes.<sup>5-9</sup> The effects found by using the low-frequency sound wave therapy programme have some similarities to the effects of exercise. However, one must realize that the sound wave therapy cannot replace exercise even it has similar effects. Active lifestyles are essential if people are to stay fit and healthy.

#### Clinical messages

- Low-frequency sound wave therapy may help increase mobility in frail elderly people.
- It may also reduce serum cholesterol and bone turnover.

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