

Vibration treatment in cerebral palsy: A randomized controlled pilot study

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Abstract

In this 6-month trial, twenty children with cerebral palsy (age 6.2 to 12.3 years; 6 girls) were randomized to either continue their school physiotherapy program unchanged or to receive 9 minutes of side-alternating whole-body vibration (WBV; Vibraflex Home Edition II[®], Orthometrix Inc) per school day in addition to their school physiotherapy program. Patients who had received vibration therapy increased the average walking speed in the 10 m walk test by a median of 0.18 ms⁻¹ (from a baseline of 0.47 ms⁻¹), whereas there was no change in the control group (P=0.03 for the group difference in walking speed change). No significant group differences were detected for changes in areal bone mineral density (aBMD) at the lumbar spine, but at the distal femoral diaphysis aBMD increased in controls and decreased in the WBV group (P=0.03 for the group difference in aBMD change). About 1% of the WBV treatment sessions were interrupted because the child complained of fatigue or pain. In conclusion, the WBV protocol used in this study appears to be safe in children with cerebral palsy and may improve mobility function but we did not detect a positive treatment effect on bone.

Keywords: Bone Mineral Density, Cerebral Palsy, Children, Mobility, Vibration

Cerebral palsy (CP) is the most common cause of severe physical disability in childhood¹. In the US about 500,000 individuals are estimated to have CP, which in 2002 resulted in an estimated cost of care of \$8.6 billion¹. The large majority of children with CP have difficulty in walking. Improving the ability to walk or perform other functional activities are often the primary therapeutic goals for children with CP¹. Adaptive measures that try to compensate for reduced mobility consume a large proportion of the costs related to CP². Measures that improve mobility in children with CP therefore potentially could result in substantial savings for health care systems.

One factor contributing to impaired walking ability is muscle weakness³. Muscle weakness in turn is commonly associated with abnormal bone development, leading to increased susceptibility to fractures⁴. A recent task force of experts in the

field of CP identified the prevention and treatment of secondary conditions such as muscle weakness and bone fragility as critical areas of future research on CP⁵.

Muscle strengthening thus might be useful for improving both motor function and bone development in children with CP. A method for muscle strengthening that is increasingly used in a variety of clinical situations is whole-body vibration (WBV)⁶⁻⁸. Some studies have also found that WBV can increase bone mineral density (BMD)⁷. WBV is practiced on a vibrating platform on which the user is standing in a static position or moving in dynamic movements.

We conducted a randomized controlled pilot trial of 6 months duration to evaluate the effects of WBV treatment in children with CP. The main hypothesis was that the treatment would improve motor function in these patients. The secondary hypotheses were that WBV would lead to an increase in walking speed and in areal BMD at the distal femur and lumbar spine.

The authors have no conflict of interest.

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Edited by: J. Rittweger
Accepted 25 January 2010

Subjects and methods

Subjects

The participants of this study were recruited among the students of a primary school for children with special needs (Ecole Victor-Doré, Montreal). Children of either sex were eligible for

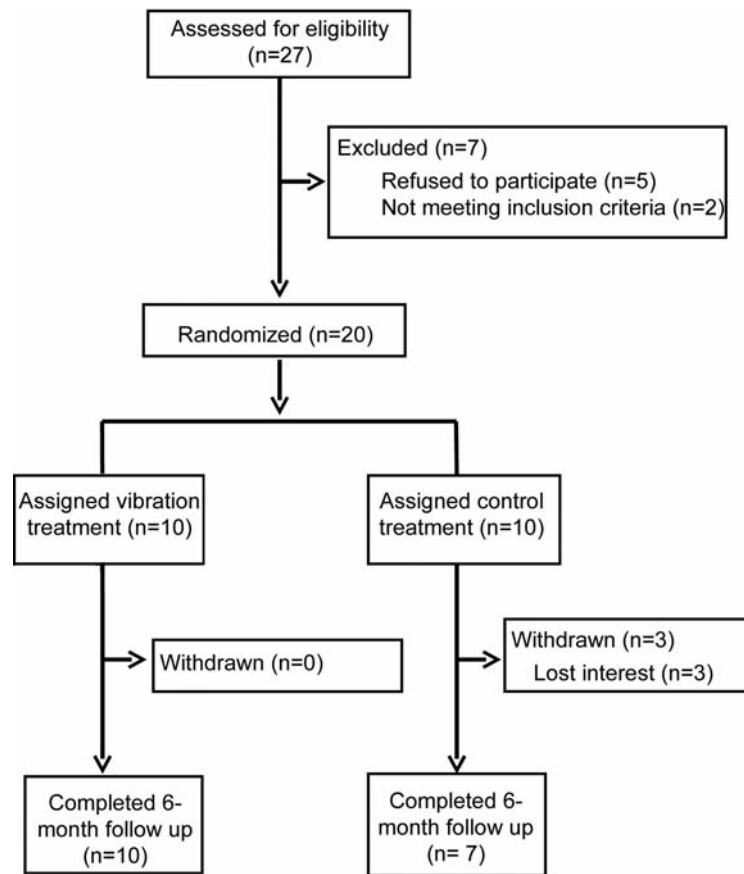


Figure 1. Study population.

the study if they were between 5.0 years and 12.9 years old at entry into the study, had a diagnosis of CP, and were functioning at Gross Motor Function Classification System (GMFCS) Levels II, III or IV. Patients were ineligible for study participation if they had a history of recent surgery or unhealed fractures, of acute inflammatory processes in the lower extremities or acute thrombosis. Of the 27 children who were assessed for eligibility, 5 declined to participate and 2 did not meet entrance requirements for the study (Figure 1). Thus 20 children (age 6.2 to 12.3 years; 14 boys, 6 girls) were randomized.

The study was approved by the Institutional Review Boards of McGill University and Hôpital Sainte-Justine, both in Montreal, Canada. Informed consent was obtained from the legal guardians and/or patients. Assent was obtained from children 7 years or older.

Randomization

Patients were randomized in equal number to either continue the regular physiotherapy program administered by their school or to receive vibration therapy in addition to the physiotherapy program offered by the school. The randomization was stratified according to GMFCS level to ensure similar functional levels in both study groups. Following the baseline evaluation of

each child, a closed envelope was randomly selected that contained the child's group allocation. The treatment allocation was disclosed to the child and the parents immediately after the baseline evaluation. Blinding of study participants and therapists is not possible with the WBV system used in this study, as the vibration produced by the device is easily observable.

Treatment protocol

All patients continued to receive physiotherapy according to the program established at their school, regardless of treatment allocation. The physiotherapy program offered by the school was individualized according to the needs of each child and comprised one to two therapeutic sessions per week. The patients randomized to receive vibration treatment in addition received one WBV session at the participants' school on each school day (usually 5 days per week) during school hours.

The WBV treatment was administered in one-on-one sessions by one of two fully trained physiotherapists. These two study physiotherapists were instructed in WBV therapy by one of the investigators (J.R., a physiotherapist with 30 years experience). Adherence to study treatment procedures was ensured through regular interaction between this investigator and the study physiotherapists.

For the WBV treatment, a commercially available WBV device was used (Vibraflex Home Edition II[®], Orthometrix Inc, White Plains, NY. Outside of North America, the brand name Galileo Basic[®] is used for this equipment). This device has a motorized board that produces side-to-side alternating vertical sinusoidal vibrations around a fulcrum in the mid-section of the plate.

The frequency of the vibrations can be selected by the user. The patient stands on the board with both feet. The feet are placed at an equal distance from the center of the board. The peak-to-peak displacement to which the feet are exposed increases with the distance of the feet from the center line of the vibrating board. Three positions are indicated on the vibrating board, marked as '1', '2' and '3', which correspond to peak-to-peak displacements of 2 mm, 4 mm and 6 mm.

The treatment schedule was adapted from published observational studies that had used the same WBV system as the present study to treat children with neuromuscular diseases and bone fragility disorders⁹⁻¹⁰. Each WBV session consisted of the following schedule: (3 minutes of WBV) - (3 minutes rest) - (3 minutes of WBV) - (3 minutes rest) - (3 minutes of WBV). Thus, one treatment session corresponded to 9 minutes of exposure to WBV.

The study physiotherapist documented the vibration settings used for each treatment session as well as other clinical observations made during the vibration sessions. The physiotherapist was instructed to terminate the session if the child complained of fatigue or pain.

In order to get acquainted with WBV treatment and to evaluate the child's capacity to be vertical on the plate, all patients performed the first treatment sessions using a vibration platform attached to the base of a tilt table. The identical set-up has previously been described as 'Cologne Standing and Walking Trainer System Galileo'⁹⁻¹⁰. The patient was positioned on the tilt table with the feet touching the vibration plate. The patients wore shoes during the WBV sessions to have a more stable position on the vibration plate. The patient was initially attached to the tilt table with two straps, one at the level of the pelvis and the other on the level of the knees. The initial tilt angle was set to 35 degrees. The goal for the subsequent sessions was to increase the angle of the tilt table and to eventually perform the WBV without a tilt table, using a WBV device placed on the ground. A walker was used to provide support for patients who could not stand on the vibration plate unsupported. The speed of the progress towards this goal depended on the child's ability to maintain an upright posture under the conditions of WBV.

The first treatment sessions were performed using a vibration frequency of 12 Hz, with the middle toe of each foot placed 5.5 cm from the neutral axis of the vibration plate (indicated as position '1' on the WBV device). The peak acceleration exerted by vibration increases with the frequency and the amplitude of the vibration. Therefore, higher frequency and higher amplitude are likely to elicit higher musculoskeletal force in the user of the WBV device. The goal was to increase the vibration frequency to 18 Hz and the peak-to-peak displacement to 4 mm (as determined for the middle toe of each foot). These target settings correspond to a peak acceleration of approximately 2.6 g and were based on our previous experience from a small ob-

servational study which indicated that these settings are usually well tolerated by children with CP¹¹. The protocol foresaw to increase the WBV frequency in steps of 0.5 Hz every two treatment sessions until the target frequency of 18 Hz was attained. The actual speed of the increase in WBV frequency depended on the child's tolerability of the vibration. The frequency was increased only if the child felt comfortable with the setting. Once the frequency of 18 Hz was reached, the feet were gradually placed wider apart until they were vertically below the hip joint. Thus, the middle toe of each foot was eventually placed between 8 cm and 11 cm from the neutral axis of the vibration plate, depending on the width of the child's pelvis.

Whether using the tilt table or the ground-based WBV system, the patients flexed their knees and hips between 10 and 45 degrees (to prevent the vibration from extending up to the head). Guided by the study physiotherapist, the patients shifted their weight from side to side or increased and decreased the knee and hip angle. Other exercises included weight shift with rotation of the trunk, and alternate flexion and extension of knees. Postural correction was encouraged through visual feedback (by performing the treatment in front of a mirror) and through the therapist's verbal cueing.

Treatment adherence was calculated as the ratio between the total time of WBV treatment received and the time of WBV exposure scheduled as per study protocol.

Assessments

Study visits at the Shriners Hospital occurred before and after the 6-month WBV treatment period. Each visit included physical examination and anthropometric measures. Height was measured with a Harpenden stadiometer.

The primary efficacy variable was the change in gross motor function during the study interval as assessed by the D and E domains of the 88 item Gross Motor Function Measure (GMFM). The GMFM is a widely used measure of gross motor function with good reliability and validity in children with CP¹². Function in different domains is expressed on a scale from 0 to 100, a higher number corresponding to better function. The GMFM D domain reflects standing function, the E domain provides information on walking running and jumping. The assessments were performed by one of the investigators (J.R.) who at the time of the second evaluation was unblinded as to treatment allocation.

Secondary efficacy variables were the change in self-selected walking speed as assessed by the 10 m walk test and the change in areal BMD of the lumbar spine and distal femur during the study interval. The 10 m walk test was performed twice at each occasion and the fastest time was recorded.

Bone densitometry was performed by dual-energy x-ray absorptiometry (QDR Discovery; Hologic Inc., Waltham, MA, USA) at baseline and after the 6-month study interval. A quality-control program using a phantom was conducted on each study day before measurements were performed. Areal BMD of the lumbar spine (L1 to L4) was measured in the antero-posterior direction. Areal BMD at the distal femur was determined as described by Henderson et al¹³. Briefly, a lateral scan

	N	Control Group	N	WBV Group	P
Sex (m/f)		6/4		8/2	
GMFCS group (II/III/IV)		1/4/5		1/5/4	
Age (years)	10	8.1 (7.3; 10.6)	10	8.3 (6.6; 9.6)	0.63
Height (cm)	10	121 (110; 132)	10	118 (109; 131)	0.74
Weight (kg)	10	22.3 (17.3; 26.0)	10	21.8 (16.7; 25.1)	0.85
GMFM88					
D domain	10	16.7 (5.1; 43.9)	10	9.0 (0.0; 26.3)	0.35
E domain	10	11.8 (0.0; 23.2)	10	2.1 (0.0; 13.2)	0.25
10 m Walk Test (speed, m/s)	10	0.74 (0.39; 0.93)	8	0.47 (0.14; 0.82)	0.32
Lumbar Spine areal BMD (g/cm ²)	10	0.46 (0.40; 0.52)	10	0.49 (0.40; 0.52)	0.97
Distal Femur Region 1 areal BMD (g/cm ²)	9	0.60 (0.52; 0.73)	8	0.60 (0.46; 0.65)	0.68
Distal Femur Region 2 areal BMD (g/cm ²)	9	0.67 (0.60; 0.85)	8	0.69 (0.62; 0.81)	0.91
Distal Femur Region 3 areal BMD (g/cm ²)	9	0.86 (0.77; 0.96)	8	0.86 (0.81; 0.95)	1.0

Results for sex and GMFCS Level are expressed as N. For the other variables results are given as median (interquartile range). P values were determined by using the Mann-Whitney U-test.

Table 1. Baseline characteristics of the study population.

	GMFCS Level	Total exposure to WBV (min)	Adherence (%)	Sessions in vertical position (%)	Sessions at frequency of 18 Hz (%)
Patient 1	III	891	94	88	78
Patient 2	III	887	91	84	61
Patient 3	III	864	89	94	86
Patient 4	IV	840	84	60	78
Patient 5	IV	914	82	0	45
Patient 6	II	731	78	90	98
Patient 7	III	900	83	34	76
Patient 8	IV	747	78	0	88
Patient 9	IV	774	83	0	81
Patient 10	III	882	84	86	74

Table 2. Characteristics of WBV treatment in each patient randomized to WBV therapy.

of the left distal femur region was obtained and areal BMD was determined separately for three rectangular scan regions, representing metaphyseal bone (Region 1), the transition zone from the metaphysis to the diaphysis (Region 2), and diaphyseal bone (Region 3). The distal femur scan could not be obtained in two patients of the WBV group and in one patient of the control group, because they were not able to maintain the required position long enough for the scan to be completed.

Statistical analysis

This pilot study aimed at generating data that could be used for estimating the required size of the study population in subsequent studies. Therefore, no power analysis was undertaken for the present study.

All comparisons between treatment groups were based on an as-observed analysis. For group comparisons of continuous variables, U-tests were used, as many results were not normally distributed. Frequencies of discrete variables were compared using the chi square test. All tests were two-tailed. P values below 0.05 were considered significant. Calculations were performed using PASW Statistics software version 17.0 for Windows (SPSS, Inc., Chicago, IL, USA).

Results

Twenty patients were randomized (Figure 1). Baseline characteristics of the vibration and control groups were similar (Table 1). None of the patients in the vibration group discon-

	N	Control Group	N	WBV Group	P
Height (cm)	7	3.3 (1.2; 5.7)	10	1.5 (1.4; 4.5)	0.67
Weight (kg)	7	0.5 (0.3; 1.0)	10	0.6 (0.4; 1.2)	0.67
GMFM					
D domain	7	0.0 (0.0; 5.1)	9	2.5 (0.0; 5.2)	0.54
E domain	7	1.4 (0.0; 4.2)	9	4.2 (2.8; 9.7)	0.14
10 m Walk Test (speed, m/s)	7	0.0 (-0.25; 0.15)	9	0.18 (0.08; 0.66)	0.03
Lumbar Spine areal BMD (mg/cm ²)	7	0.010 (0.001; 0.055)	10	0.013 (0.005; 0.022)	0.89
Distal Femur Region 1 areal BMD (mg/cm ²)	6	-0.046 (-0.107; 0.003)	8	0.032 (0.003; 0.099)	0.11
Distal Femur Region 2 areal BMD (mg/cm ²)	6	0.020 (-0.017; 0.042)	8	-0.002 (-0.041; 0.024)	0.41
Distal Femur Region 3 areal BMD (mg/cm ²)	6	0.034 (-0.019; 0.041)	8	-0.026 (-0.073; -0.015)	0.03
<i>Results are expressed as median (interquartile range). P values were determined by using the Mann-Whitney U-test.</i>					

Table 3. Changes during the 6-month study period.

tinued the study prematurely, but three of the patients in the control group did not return to the second assessment visit (Figure 1). Two of the patients and their families had lost interest in the study. A third patient of the control group was excluded because her parents had purchased the vibration equipment and the patient received WBV at home.

Patients randomized to vibration treatment received between 82 and 103 WBV sessions. Most patients enjoyed WBV and did not consider it to be a difficult workout. The most frequent subjective complaint, made by three boys, was that the WBV sessions were ‘sometimes boring’. The total time of vibration exposure ranged from 731 minutes to 915 minutes, corresponding to an adherence rate of 78% to 94% (Table 2). The main reasons for missed WBV treatments were organizational (such as scheduling difficulties) and missed school days (mostly due to illnesses, such as respiratory infections).

As described in the Methods section, all patients were introduced to WBV by using the tilt table-based WBV system. Seven patients were able to progress to the floor-based WBV system after 6 to 66 (median: 13) treatment sessions (Table 2). Three boys at GMFCS Level IV could not maintain a stable vertical position on the floor-based vibration plate even with the help of a walker and therefore were treated with the tilt table-based system throughout the treatment interval. However, in the course of the study it was possible to increase the tilt angle to between 70 and 80 degrees in these three patients.

Changes during the 6-month study interval were compared between the 10 patients who received WBV and the 7 control patients who could be assessed twice (Table 3). No significant group differences were found for the changes in GMFM. However, patients who had received vibration therapy increased the average walking speed in the 10 m walk test by a median of 0.18 m/s (corresponding to an increase in speed of 38% compared to the median baseline result), whereas there was no change in the control group. This difference between groups was statistically significant (Table 3).

No significant group differences were detected for changes in areal BMD at the lumbar spine. At the distal femur, areal

BMD in Region 1 (metaphysis) tended to decrease in controls and to increase in the WBV group, whereas in Region 3 (diaphysis) a significant group difference was found suggestive of a reduction in areal BMD in the WBV group.

Regarding safety, no serious adverse events related to vibration therapy were observed. Redness of the feet or ankle area was noted in 8 patients during the first few treatment sessions. Of the 937 WBV treatment sessions administered to all patients combined, 6 (0.6%) were interrupted because the child complained of fatigue. Another 5 (0.5%) treatment sessions were interrupted because the child complained of pain (stomach ache on 3 occasions; headache and back pain on one occasion each).

Discussion

In the present study we observed that WBV was feasible and appeared to be safe in children with CP. Six months of WBV therapy had some effect on mobility. However, we did not observe a positive influence of the treatment on areal BMD at the lumbar spine and areal BMD seemed to decrease somewhat in the cortical region of the femoral diaphysis.

WBV was well tolerated by all patients. The most consistent adverse event was redness of the feet or ankle area, which was observed in 80% of patients after the first treatment sessions and which is a well-known reaction to WBV^{8,14}. Less than 1% of the treatment sessions were discontinued due to pain, and it was not clear that these episodes of pain were caused by WBV.

WBV was introduced in a gradual fashion. Initially a tilt table was used in all participants and the vibration was performed at low frequency and small amplitude. All of these factors diminish the force that is transmitted from the vibration platform to the body. The subsequent increase in load was made dependent on the patient’s capacity to verticalize and to tolerate the treatment. Although one might argue that this lack of standardization in WBV settings makes the results hard to compare with other studies, it could also be maintained that our treatment protocol was standardized according to the clin-

ically most relevant factor, namely the patients' capacity to tolerate the treatment. In any case, we believe that such a patient-centered approach is necessary to minimize adverse events and to ensure treatment adherence.

With regard to efficacy measures, a statistical power analysis was not undertaken in this pilot study, as there was no prior information on the expected effect of WBV in children with CP. The changes in the main outcome parameters, the GMFMD and E domains (which reflect standing as well as walking, running and jumping), did not differ significantly between the control and the treatment groups.

In a secondary measure of mobility function, the average speed during a 10 m walk test, the change in the WBV group was significantly larger than in the control group. The WBV group experienced a median increase in walking speed that corresponded to a 38% improvement compared to the median baseline result, whereas the median walking speed did not change in the control group.

Although these results suggest some effect of WBV therapy on muscle function, we did not find a positive effect of the treatment on areal BMD. The only significant difference was observed at the distal femoral diaphysis, where the observed changes in areal BMD were the opposite of the initial study hypothesis, namely a decrease in the treatment group and an increase in the control group. The reason for the decrease in areal BMD at this cortical bone site is unclear at present. A possible explanation is that mechanical stimulation increases intracortical bone remodeling and thereby cortical porosity. For example, runners have a lower cortical bone density in their tibia than sedentary controls¹⁵. It is possible that a similar mechanism is at play during WBV. However, it must be acknowledged that distal femur densitometry is not always technically easy to perform in a CP population, due to difficulties with positioning and movement artifacts. Our findings therefore require confirmation in larger studies.

With regard to the lack of a detectable positive bone response to WBV, it is possible that the gain in mobility function was not sufficient to elicit a bone adaptation. It is also possible that skeletal changes occurred in ways that are not reflected by areal BMD, such as a redistribution of mineral within the bones. Such changes might be detectable by techniques such as peripheral quantitative computed tomography. It was attempted to use this method in the present study, but unfortunately the measurement was not possible in most patients as movement artifacts due to spasticity interfered with scan acquisition (data not shown).

This study has a number of limitations. Most importantly, this was a pilot study that was designed to generate data for future studies and was not powered to provide definite proof of efficacy and safety. The 30% drop out rate in the control group further decreased the likelihood of finding statistically significant group differences. Second, although the control group continued to follow the physiotherapy treatment provided by their school, the treatment group received more professional attention, as they underwent additional WBV sessions during school days. This may have favored results in the WBV group. In future studies it may therefore be preferable to perform a 'control treatment' in

the control group, such as performing the exercises on the platform while the vibration is turned off. This might also help to motivate control patients and their families to continue the study after the baseline visit and thus lead to a lower drop-out rate.

In conclusion, the present WBV protocol to treat children with CP appears to be safe and may improve mobility function. We did not detect a positive treatment effect on bone. These pilot data should inform the design of larger studies that examine the efficacy and safety of WBV in children with CP.

Acknowledgements

We are indebted to Tina Del Duca (Hôpital Sainte-Justine, Montreal), Josée Ouimet (Ecole Victor-Doré, Montreal) and the department of physiotherapy at Ecole Victor-Doré for their help in the execution of the study. We thank Kathleen Montpetit for her contribution to patient evaluation, as well as Andrea Poupart and Nancy Cyr for organizational support. F.R. is a Chercheur-Boursier Clinicien of the Fonds de la Recherche en Santé du Québec. This study was supported by a grant from the Shriners of North America.

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