

Long-Term Effects of 6-Weeks Whole-Body Vibration on Balance Recovery and Activities of Daily Living in the Postacute Phase of Stroke

A Randomized, Controlled Trial

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Background and Purpose—The long-term effects of 6-weeks whole-body vibration, as a novel method of somatosensory stimulation, on postural control and activities of daily living were compared with those of 6 weeks of exercise therapy on music of the same intensity in the postacute phase of stroke.

Methods—Fifty-three patients with moderate to severe functional disabilities were randomized within 6 weeks poststroke and within 3 days after admission to a rehabilitation center to either whole-body vibration or exercise therapy on music in addition to a regular inpatient rehabilitation program. The whole-body vibration group received 4×45-second stimulation on the Galileo 900 (30-Hz frontal plane oscillations of 3-mm amplitude) for 5 days per week during 6 weeks. The exercise therapy on music group received the same amount of exercise therapy on music. Outcome variables included the Berg Balance Scale, Trunk Control Test, Rivermead Mobility Index, Barthel Index, Functional Ambulation Categories, Motricity Index, and somatosensory threshold at 0, 6, and 12 weeks follow up.

Results—At baseline, both groups were comparable in terms of prognostic factors and outcome measures. Both at 6 and 12 weeks follow up, no clinically relevant or statistical differences in outcome were observed between the groups. No side effects were reported.

Conclusions—Daily sessions of whole-body vibration during 6 weeks are not more effective in terms of recovery of balance and activities of daily living than the same amount of exercise therapy on music in the postacute phase of stroke. (*Stroke*. 2006;37:2331-2335.)

Key Words: cerebrovascular accident ■ postural balance ■ proprioception ■ vibration

Several studies have claimed beneficial effects of somatosensory stimulation (SSS) in patients with stroke in terms of balance, motor performance, and activities of daily living. These studies described both short-term (<1 hour) and long-term (>6 weeks) results of SSS in different phases poststroke.¹⁻⁴ However, well-controlled randomized, controlled trials^{5,6} and reviews^{7,8} did not show clear evidence of beneficial effects of transcutaneous electrical nerve stimulation or acupuncture on balance in patients with stroke. Yet, these recent insights do not preclude beneficial effects of other forms of SSS in (post)acute stroke rehabilitation.

A relatively novel form of SSS that shows considerable promises for the rehabilitation of stroke patients is whole-body vibration (WBV). To underscore this notion, four important considerations can be given. First, WBV is a deeper way of sensory stimulation compared with the more

superficial modes such as acupuncture and transcutaneous electrical nerve stimulation, targeting the Ia and II afferents of (large) muscle groups.^{9,10} Second, WBV provides bilateral stimulation, which may induce plastic changes in both hemispheres after stroke.¹¹ Third, WBV induces sensory stimulation of foot-sole afferents as well, which afferents are well known to play an important role in postural control.¹² Lastly, WBV research in general has shown promising results in various domains of sports and geriatric medicine.^{13,14} In addition, there is preliminary evidence for short-term effects (<1 hour) of WBV on postural stability in patients with chronic stroke.¹⁵

Therefore, the purpose of this study was to investigate whether WBV, added to regular rehabilitation, has beneficial effects on balance control and activities of daily living in patients with subacute stroke. We also tested whether such

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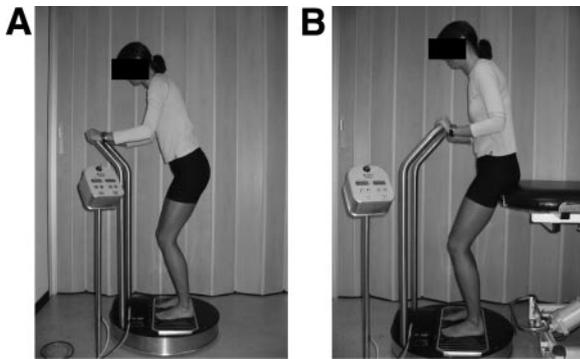


Figure 1. A, Standing posture of the subjects (FAC score=3 to 5) on the Galileo 900 vibration platform. B, Standing posture of the subjects (FAC score=0 to 2) on the Galileo 900 vibration platform. The buttocks are supported with a height-adjustable bench.

functional benefits coincide with improvements of strength and somatosensation.

Methods

Subjects

All patients with a first supratentorial stroke, confirmed by computed tomography or magnetic resonance imaging scan, admitted to one of three rehabilitation centers in The Netherlands (St. Maartenskliniek, Nijmegen; Groot Klimmendaal, Arnhem; Tolbrug, Den Bosch) between May 2003 and February 2005, were eligible. Inclusion criteria were (1) a poststroke interval less than 6 weeks and (2) moderate or severe balance impairments defined as a score less than 40 on the Berg Balance Scale.¹⁶ Exclusion criteria were (1) nonstroke-related sensory or motor impairments, (2) use of medication that could interfere with postural control, (3) concomitant cognitive problems that impaired the ability to follow simple verbal instructions, and (4) contraindications for WBV such as pregnancy, recent fractures, gallbladder or kidney stones, malignancies, and cardiac pacemaker. After receiving verbal and written information, all subjects gave their written informed consent to participate in the study. The regional medical-ethical committee approved the study.

Intervention

All patients were treated with either WBV or exercise therapy on music (ETM) on each working day during 6 weeks of their admission in the rehabilitation center. Both treatments consisted of four sessions of 45 seconds stimulation interrupted by a 1-minute break between each session. In this way, a total of 120 treatment sessions were given per patient. By selecting this specific intensity of WBV, all patients received a strong stimulation of their proprioceptive afferents¹⁰ (in particular Ia and II afferents), whereas muscular fatigue was prevented.¹⁷ ETM of this intensity was considered a “sham” treatment.

WBV was provided through a commercially available device.* This apparatus consists of a moveable rectangular platform built within a circular ground surface on which a support bar is mounted at the front. The platform makes fast oscillating movements around a sagittal axis in the middle. Subjects were required to stand on the platform with their feet at an equal and standardized distance from the axis of rotation so that the **vibration amplitude was ≈ 3 mm**. The frequency was set at its **maximum of 30 Hz**. Patients who could stand independently (Functional Ambulation Categories [FAC]=3 to 5) were instructed to adopt a “squat” position with slight flexion at the hips, knees, and ankle joints to damp the vibrations approximately at the pelvic level. They were allowed to hold the support bar (see Figure 1A). Patients who could not yet stand independently (FAC=0 to 2) were supported at their buttocks by a height-adjustable bench

with their knees and hips in 45° flexion while holding onto the support bar as well (see Figure 1B). An experienced physical therapist supervised all the WBV administrations.

During the ETM, patients were instructed to adopt the same standing position as during the WBV. The whole program consisted of regular exercises for the trunk, arm, and leg muscles interrupted by periods of relaxation. ETM was given either individually or in small groups of two to three patients and was supervised by an experienced physical therapist as well. To standardize ETM between the participating rehabilitation centers, five different compact discs were recorded, one for each day of the week, to guide the exercises so that patients in different centers received the same type of treatment.

Before the onset of the study, all treating physical therapists received specific instructions on both interventions to ensure uniformity in the treatment procedures. They were also instructed *not* to communicate with the patients about the possible goals of or rationale for either treatment. In addition to the WBV or ETM treatments, all patients participated in an individualized treatment program consisting of at least five 30-minute individual sessions of physical therapy, five 60-minute group sessions of physical therapy, and three 30-minute individual sessions of occupational therapy augmented with speech and language therapy and psychologic treatment if necessary.

Procedure

This study was a 2-armed randomized, controlled trial with blinding of patients and assessors with respect to the nature of therapy. With the use of opaque closed envelopes and stratified by center, included patients were randomized into blocks of 4 to either WBV or ETM by an independent collaborator within 3 days after admission. At baseline, before patient allocation, patient characteristics and outcome measures were assessed (t_0). After 6 weeks of WBV or ETM treatment (t_1), as well as after 6 weeks follow up (t_2), the outcome measures were repeated.

All assessments were done by 3 independent, experienced physical therapists, who were not working in the stroke unit of the participating rehabilitation centers, who were blind with regard to treatment allocations and who had no contact with any of the patients during the study. Patients were instructed not to discuss their treatment with these assessors. Each assessor received the same practical instructions. All assessments took place in one rehabilitation center (St. Maartenskliniek).

At baseline, the following patient characteristics were registered: Motricity Index,¹⁸ Modified Ashworth Scale,¹⁹ somatosensory threshold of the affected leg, and the presence of hemineglect. The somatosensory threshold was determined by investigating the pressure sensitivity at the tip of the hallux using 5 calibrated monofilaments (2.83, 3.61, 4.31, 4.56, and 6.65). To determine the presence of neglect, we used a computerized visual reaction-time task. Patients had to respond as quickly as possible to visual stimuli at different locations in both visual hemifields by pressing a button with their nonparetic hand. A bias in the mean reaction time between the left and right visual hemifield greater than 34% indicated the presence of neglect.

Outcome Measures

The Berg Balance Scale was selected as the primary outcome measure.¹⁶ Secondary outcome variables were the Barthel Index,²⁰ Trunk Control Test,²¹ Rivermead Mobility Index,²² and FAC.²² The Motricity Index and somatosensory threshold of the affected leg were also regarded as secondary outcome measures. Possible adverse reactions during or 30 minutes after the treatment sessions were registered as well.

To assess the subjective experience and the success of blinding, patients were asked two questions 1 week after t_2 : “Do you think that the extra therapy (WBV or ETM) you received had a positive effect on your rehabilitation?” and “Which of the two extra therapies do you think is most beneficial?”

*Galileo 900, Galileo 2000, Enschede, The Netherlands.

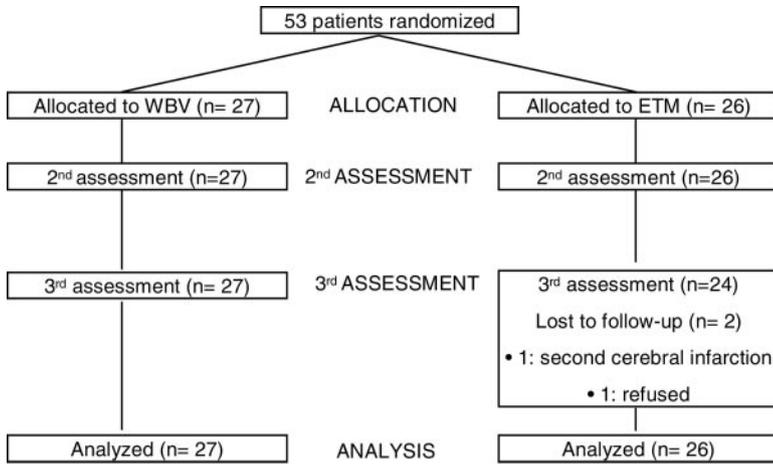


Figure 2. Flow chart of the participants.

Statistical Analysis

The independent samples *t* test and χ^2 test were used to compare both groups at baseline. A 2-way analysis of variance (group×time) was used to assess the effects of treatment depending on group allocation. We performed an intention-to-treat analysis by carrying the last value forward in the case of missing values at the third assessment. All tests were applied 2-sided with a critical α level of $P<0.05$.

Results

Fifty-three patients were allocated to either the WBV group (n=27) or the ETM group (n=26). All subjects participated in both the first (t_0) and second (t_1) assessment. In one patient, the

WBV was stopped prematurely because of severe shoulder pain, although these complaints could not be directly related to the WBV. At t_2 , two patients of the ETM group were lost to follow up: one as a result of a second cerebral infarction and one as a result of refusal to further participate (see Figure 2).

At baseline, the WBV and ETM groups were comparable (Table 1), except for the type of stroke; the WBV group consisted of fewer patients with cerebral infarction (59%) than the ETM group (85%) (Table 1). During the intervention period, both groups received a similar amount of rehabilitation treatment (Table 2).

TABLE 1. Patient Characteristics

	WBV (n=27)	ETM (n=26)	
Male	16 (59%)	14 (54%)	NS*
Age (years)	59.7±12.3	62.6±7.6	NS†
Type of stroke			
Ischemic	16 (59%)	22 (85%)	$P<0.05^*$
Hemorrhagic	11 (41%)	4 (15%)	
Location of stroke			
Left hemisphere	14 (52%)	11 (42%)	NS*
Right hemisphere	13 (48%)	15 (58%)	
Time post stroke (days)	38.9±9.2	34.2±11.1	NS†
Neglect: present	8 (30%)	13 (50%)	NS*
Motricity Index (0 to 100)	47.4±28.7	50.6±28.4	NS†
Modified Ashworth Scale (0 to 5)			
Knee flexion (median/range)	0 (0 to 3)	0 (0 to 2)	NS*
Knee extension (median/range)	0 (0 to 4)	0 (0 to 2)	NS*
Ankle dorsiflexion (median/range)	1 (0 to 4)	1 (0 to 4)	NS*
Ankle plantar flexion (median/range)	0 (0 to 2)	0 (0 to 1)	NS*
Somatosensory threshold			
Affected side (median/range)	4.56 (2.83 to 6.65)	6.65 (3.61 to 6.65)	NS*
Berg Balance Scale (0 to 56) (mean±SD)	23.9±14.8	23.7±18.6	NS†
Barthel Index (0 to 20) (mean±SD)	10.3±3.1	9.9±3.7	NS†
Trunk Control Test (0 to 100) (mean±SD)	75±25.9	69.5±24.0	NS†
Rivermead Mobility Index (0 to 15) (mean±SD)	5.3±2.9	5.2±3.2	NS†
Functional Ambulation Categories (0 to 5) (median/range)	1 (0 to 4)	1 (0 to 4)	NS*

* χ^2 test; †independent samples *t* test. NS indicates not significant.

TABLE 2. Therapies (mean hours)

	WBV (n=27)	ETM (n=26)	
Physical therapy	149.6±58.3	118.0±59.6	NS*
Occupational therapy	44.9±20.1	41.9±26.6	NS*
Speech therapy	10.9±12.0	17.2±18.4	NS*
Intervention	26.2±3.9	26.7±1.93	NS*

*Independent samples *t* test.
NS indicates not significant.

Table 3 shows the values of all outcome measures with their standard deviations. Both groups showed a main effect of time on the Berg Balance Scale score ($F[2,50]=56.67, P<0.01$) as well as the Barthel Index ($F[2,50]=97.12, P<0.01$), Rivermead Mobility Index ($F[2,50]=76.20, P<0.01$), Trunk Control Test ($F[2,50]=11.83, P<0.01$), FAC score ($F[2,50]=76.48, P<0.01$), Motricity Index ($F[2,50]=26.85, P<0.01$), and somatosensory threshold ($F[2,50]=3.92, P<0.05$). Table 3 clearly shows that improvements were most pronounced during the intervention period, but patients continued to improve during the follow-up period. There were no group×time interactions, indicating similar recovery profiles for both treatment groups.

One week after the follow-up period (t_2), 38 of the 51 patients (75%) who participated in the third assessment responded to the questionnaire (18 of the WBV group and 20 of the ETM group). Most patients (74%) were positive or very positive about their treatment. Whereas 72% of the patients in the WBV group believed that WBV was the favorable treatment, 55% of the ETM group believed ETM to be most favorable. No adverse reactions occurred during or directly after treatment in either group.

Discussion

The aim of this study was to examine the long-term effects of repeated WBV on balance and activities of daily living in postacute stroke patients compared with the effects of ETM. No group differences in functional improvement on any of the selected outcome measures were observed, although the WBV group received on average a little (but insignificantly) more rehabilitation treatment than the ETM group. In addition, no group differences in muscle strength and somatosensation were found. Hence, the results of this study do not support the a priori hypothesis that repeated WBV in the

postacute phase of stroke would be beneficial and a valuable addition to regular rehabilitation interventions.

In the past, several randomized, controlled trials have reported beneficial effects of additional SSS (eg, electroacupuncture) on balance recovery after stroke compared with regular rehabilitation.¹⁻⁴ In all the randomized, controlled trials reporting positive group differences, however, the control group only received conventional rehabilitation without any type of sham or control intervention. As a result, all patients were well aware of group allocation, and it is likely that large differences in the number of patient contacts, in the amount of professional attention, and subsequent expectations occurred. In the present study, the control group received a sham intervention (ETM) with an equal amount of contact time and attention by the same physical therapists. In this way, potential bias by differences in the amount of attention by the physical therapists was prevented in the trial. In addition, the selected sham intervention was quite successful in terms of subjective experience and believed efficacy, based on the results from the questionnaires, which indicates reasonably effective patient blinding. The negative results found in the present study are in accordance with other randomized, controlled trials that used sham interventions and did not find evidence of beneficial effects of SSS in patients with stroke either.^{5,6} The beneficial effects of SSS found in some studies may thus (at least partly) be explained by nonspecific mechanisms.

Sze et al and Zhang et al^{7,8} both performed a meta-analysis of the effects of acupuncture after stroke. They reported poor quality of the randomized, controlled trials reviewed, resulting in possible type I errors, still leaving uncertainty about the efficacy of acupuncture. In addition, the limited number of negative trials included in this meta-analysis seemed to indicate publication bias, because negative trials may not have been published. In negative trials, a potential type II error should always be considered as a result of lack of statistical power.^{5,6} As for the present study, such a type II error seems unlikely, because all outcome measures showed not even a trend toward a group difference in recovery profiles. It is, nevertheless, possible that the selected outcome measures were not sensitive enough to detect certain (small) group differences. On the other hand, one might argue the clinical relevance of any group difference obtained with an alternative outcome when there are at the same time no

TABLE 3. Outcomes for the First, Second, and Third Assessment

Outcome Measure	First Assessment		Second Assessment		Third Assessment	
	WBV	ETM	WBV	ETM	WBV	ETM
Berg Balance Scale (mean±SD)	23.9±14.8	23.7±18.6	40.6±12.8	41.1±14.3	44.3±10.9	44.9±11.9
Barthel Index (mean±SD)	10.3±3.1	9.9±3.7	15.3±3.9	14.9±3.9	17.1±3.6	16.9±3.6
Trunk Control Test (mean±SD)	75.0±25.9	69.5±24.0	80.5±21.6	79.8±21.3	86.2±17.4	83.7±18.5
Rivermead Mobility Index (mean±SD)	5.3±2.9	5.2±3.2	8.7±3.6	8.8±4.0	10.8±3.9	10.4±3.5
Functional Ambulation Categories (median/range)	1 (0 to 4)	1 (0 to 4)	3 (0 to 5)	3 (0 to 5)	4 (1 to 5)	4 (1 to 5)
Motricity Index (mean±SD)	47.4±28.7	50.1±28.3	59.8±25.0	61.2±25.4	65.7±22.9	66.7±25.9
Somatosensory Threshold (median/range)	4.56 (2.83 to 6.65)	6.65 (3.61 to 6.65)	4.56 (3.61 to 6.65)	6.65 (3.61 to 6.65)	4.31 (2.83 to 6.65)	4.31 (2.83 to 6.65)

effects on well-established clinical measures such as the Berg Balance Scale, Rivermead Mobility Index, Barthel Index, and the FAC.

Another possible explanation for the absence of group differences in this study may be that both interventions were equally beneficial. This possibility, however, seems unlikely because of 2 reasons. First, the observed improvements on the primary outcome measure (Berg Balance Scale) were comparable with the functional improvements found in longitudinal observational studies.^{23,24} Second, the exercises on music in the control group were given during a relatively short period and did not essentially differ from the regular training during individual and group sessions.

Lastly, it is possible that the selected intensity and duration of WBV were still too low to induce lasting changes in the somatosensory pathways or sensorimotor cortices. Yet, we selected an intensity and duration comparable with previous research in healthy subjects and nursing home residents reporting beneficial effects of WBV.^{13,14} We judged a stronger than this selected intensity in a first study of patients with stroke as unwarranted, particularly because it has been shown that WBV induces early muscle fatigue compared with regular muscle exercises. Even in healthy subjects, muscle fatigue already occurs after a few minutes of stimulation.¹⁷

Conclusion

To our knowledge, this is the first randomized, controlled trial that addresses the long-term effects of WBV on the recovery of balance and activities of daily living in the postacute phase of stroke. Although this treatment was well tolerated and appreciated by most patients, it appeared that daily sessions of WBV during 6 weeks are no more effective in terms of recovery of balance and activities of daily living than the same amount of ETM.

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Disclosures

None.

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