ORIGINAL ARTICLE

A Primary Care—Based Randomized Controlled Trial of 12-Week Whole-Body Vibration for Balance Improvement in Type 2 Diabetes Mellitus

Jesús del Pozo-Cruz, PhD,[a] Rosa M. Alfonso-Rosa, MSc,[a] José Luis Ugia, PhD,[b]
Joseph G. McVeigh, PhD,[c] Borja del Pozo-Cruz, PhD,[a] Borja Sañudo, PhD[a]

From the [a]Department of Physical Education and Sport, University of Seville, Seville, Spain; [b]6 Wunderkinder GmbH, Berlin, Germany; and [c]Centre for Health and Rehabilitation Technologies, School of Health Sciences, University of Ulster, Jordanstown, Northern Ireland.

Abstract

Objective: To determine whether a 12-week whole-body vibration (WBV) training program improved balance in participants with type 2 diabetes mellitus (T2DM).

Design: Randomized controlled trial.

Setting: Primary health care setting.

Participants: Participants with T2DM (N=50).

Interventions: Participants were randomly allocated to either a WBV group (n=25), which performed a 12-week WBV-based exercise program on an oscillating platform (12−16Hz−4mm; 3 sessions/wk), or a usual-care control group (n=25).

Main Outcome Measures: Clinical and sociodemographic variables were recorded at baseline. Static balance and dynamic balance were also assessed at baseline by measuring postural sway (measurement of center of pressure [COP] excursions in the anteroposterior and mediolateral directions) using a Wii Balance Board and the Timed Up and Go test.

Results: Significant between-group differences in COP excursions with participants' eyes closed were found with their feet apart and feet together. In addition, participants in the WBV group exhibited significantly lower COP excursions with their eyes closed after the intervention, while participants in the control group experienced a nonsignificant deterioration in COP excursions (ie, greater excursion) with their eyes open (mediolateral axis). There was no significant difference in the Timed Up and Go test values postintervention.

Conclusions: WBV provides a safe and well-tolerated approach to improve balance in participants with T2DM. These findings may have important implications for falls prevention in those with T2DM in the primary health care setting.

Archives of Physical Medicine and Rehabilitation 2013;94:2112-8

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Type 2 diabetes mellitus (T2DM) represents a major health burden on society and individuals. The characteristic feature of T2DM is impaired insulin secretion, and the condition has numerous primary and secondary effects on the body, including microvascular and macrovascular complications.[1] Individuals with T2DM frequently complain of feeling dizzy and unstable and often exhibit impairments in balance, sensory capacity, and gait, with the consequent increased risk of falling.[2,3] Adults with T2DM are almost 15 times more likely

to fall during gait and have an odds ratio of 2.0 for having mobility limitations as compared with those without diabetes,[4] with the chance of falling even greater for older individuals.[2]

It has been suggested that the motor control problems displayed by people with T2DM are associated not only with peripheral sensory impairment[5] but also with specific clinical findings such as reduced muscle strength,[6] impaired vision,[7] or impaired vestibular system function.[8] It has also been suggested that T2DM affects dynamic balance control, with those with T2DM displaying significantly more sway than that seen in healthy control subjects while standing on a balance platform.[9] It is suggested that decreased balance in T2DM may result from altered somatosensory inputs to the central nervous system.

Disturbances in postural control were reported to be a precursor to falls in those with diabetes[10]; loss of balance control is therefore a key concern for this population.[11] Consequently, there is a need to develop ways to intervene with these high-risk individuals to minimize the risk of future falls.[10]

There is evidence that exercise is effective for lowering the risk of falls in the elderly and that the consequent reduction in the incidence of fall-related injuries reduces health care costs.[12] Exercise interventions can improve balance and gait in T2DM[2,13]; however, loss of confidence or fear of falling often leads to decreased physical activity, which may cause a further decline in postural stability. It is also noted that most of those with T2DM are unable to engage with high-intensity exercise regimens[14] because of their compromised exercise tolerance.[15]

Whole-body vibration (WBV) is a new type of physical exercise intervention that consists of performing static and dynamic exercises on a vibrating platform. In recent years, it has been suggested that WBV may be a useful intervention to address some of the adverse motor effects commonly seen in T2DM.[16] Although the exact mechanism of action of WBV is yet to be conclusively determined, some authors have suggested that the improvement in balance and functional mobility attributable to WBV[12,16-19] could be ascribed to any of a number of factors, for example, an enhancement in neuromuscular performance due to improved muscle reflex,[16,20] or neurogenic adaptation due to better synchronization of motor unit activation in response to the vibrations, or increased muscle spindle activation.[21] These mechanisms are also responsible for an automatic postural response and therefore may be important to address in T2DM.[22]

Despite the reported positive effects of WBV,[23] the effect of WBV training on neuromotor function in older adults remains controversial[24] and only a few well-performed studies have described the effects of balance training on patients with T2DM.[2,13] The assessment of standing balance normally requires expensive and complex systems that are not easily available in primary care settings,[25] and the results are not consistent across studies.[26] Consequently, the aim of the current study was to assess the effectiveness of a primary care–based, 12-week WBV training program on balance in participants with T2DM.

Methods

Sample size calculation

Sample size was estimated following the recommendations of McCrum-Gardner[27] using PS software.[a] On the basis of the recent work of Liao et al,[28] who used the Timed Up and Go (TUG) test in the assessment of balance, sample size was calculated on the basis of a mean difference of 1.34 ± 1.5 seconds between the 2 groups; this gives a sample size of 21 per group. Allowing for an attrition rate of approximately 20% gives a total sample size of 50, providing 80% power at the 95% significance level.

List of abbreviations:

COP	center of pressure
T2DM	type 2 diabetes mellitus
TUG	Timed Up and Go
WBB	Wii Balance Board
WBV	whole-body vibration

Participants

Participants in the study were recruited via health care staff from a primary care center in Seville, Spain. To achieve our sample, 57 volunteers were screened and completed detailed medical history questionnaires and underwent a medical examination to determine eligibility. Eligible participants had to have T2DM confirmed by a primary care provider using the American Diabetes Association diagnostic criteria. The T2DM diagnosis was based on one of these abnormalities: glycated hemoglobin $\geq 6.5\%$; or fasting plasma glucose $\geq 126 mg/dL$ (7.0mmol/L); or 2-hour plasma glucose $\geq 200 mg/dL$ (11.1mmol/L) during an (75-g) oral glucose tolerance test; or random plasma glucose $\geq 200 mg/dL$ (11.1mmol/L). Exclusion criteria included a history of or evidence of advanced cardiovascular, renal, or hepatic diseases, diabetic retinopathy, nephropathy or neuropathy, insulin use, and orthopedic or other limitations that may interfere with participants' ability to exercise safely. Participants with a glycated hemoglobin level of >10% were also omitted. Participants receiving physical therapy were also excluded to avoid possible interactions with the present trial. Seven patients were excluded (cardiovascular diseases, n=2; musculoskeletal diseases, n=5), and the 50 participants who fulfilled the inclusion/exclusion criteria were randomly allocated to either a WBV group (n=25) or a usual-care control group (n=25). Randomization was undertaken by a member of the research team not directly involved in the recruitment or assessment of patients using a computer-generated random allocation data processing program and a 1:1 ratio (intervention/control). All participants provided informed consent before their participation in this study, and the study was approved by the institutional ethics committee of the University of Seville and conducted in accordance with the Declaration of Helsinki (2008).

Demographic and clinical data

At baseline, sociodemographic (ie, age and sex) and clinical variables (ie, years since diagnoses, T2DM-related medications, blood pressure, and heart rate) were recorded. Participants' weight, height, and waist and hip circumference were also measured, allowing for the calculation of body mass index (kg/m^2), the percentage of body fat, and waist-to-hip ratio.

Outcome measures

The primary outcome of interest was balance, as measured by changes in the TUG test values and postural sway. Postural sway was recorded using the Wii Balance Board (WBB),[b] and balance/mobility/muscle function were assessed using the TUG test.[29]

Balance assessment
The WBB system (sampling rate 100Hz) was connected wirelessly with a Bluetooth adapter[c] to a laptop, and raw data were stored and processed using custom-written software (Labview 8.5).[d] Data were filtered using a 256-order low-pass linear-phase filter (cutoff frequency 8Hz) with a Hamming window. The device was tested for validity and reliability, with results showing good to excellent center of pressure (COP) path length test-retest reliability within device (intraclass correlation coefficient=.66–.94) and between device (intraclass correlation coefficient=.77–.89) when comparing the WBB and force platform data.[30]

Participants were asked to stand motionless on the WBB for 30 seconds, and each trial was repeated 3 times with participants' eyes open and another 3 times with participants' eyes closed (Romberg test), with 45 seconds of rest between trials. The protocol was repeated with feet approximately shoulder width apart and with feet together. During each trial, participants were instructed to keep their hands placed on their hips and to remain as still as possible for the duration of the trial. The chosen outcome measures were COP excursions in the anteroposterior and mediolateral directions measured in millimeters. It appears that the minimal important clinical difference in COP excursion has not yet been established; however, Lafond et al[31] reported that a significant difference in COP excursion between people with diabetic neuropathy and healthy older volunteers was apparent, with a difference of 1.61mm in COP excursion in a 10-second test.

TUG test

For the TUG test, participants were requested to stand up from a chair, walk 3 meters as quickly and safely as possible, cross a marked line on the floor, turn around, and then walk back and sit down on the chair. The chair was adjusted according to individual height and was fixed to the wall. The time taken to complete the test was recorded. The minimal important clinical difference of the TUG test has been reported to be 0.8, 1.4, and 1.2 seconds on the basis of 3 different assessment methods.[32] The figure used in the sample size calculation as reported by Liao et al[28] is at the higher end of the minimal important clinical difference, and any reported differences should therefore be clinically meaningful. All outcomes were assessed at baseline and after the 12-week study period; the outcome assessor was blind to group allocation throughout.

Intervention

The intervention group received a program of WBV followed by exercises, 3 sessions/wk for 12 weeks.

Whole-body vibration

Before testing, all subjects participated in a familiarization session to acquaint them with the WBV and the proposed exercises. Participants in the WBV group undertook a 12-week WBV-based program on a side-altering platform (Phyisio Wave 700)[e] comprising 3 sessions/wk, 1 day off between sessions. The intensity of vibration ($\approx 1-2g$) was chosen on the basis of previously published literature, where improvements in mediolateral postural control were demonstrated using side-alternating vibration with frequencies between 12.6 and 26Hz.[33,34] It has also been reported that higher frequencies have resulted in nonsignificant outcomes.[35,36] It was therefore decided to start WBV in the lower range frequencies (12Hz) and progress to 14Hz for the second month and 16Hz for the last month; a further consideration in selecting the frequency was patient safety. Peak-to-peak displacement of 4mm was maintained during the whole program. Participants in the WBV group adopted an isometric squat position during all exposures, with their feet shoulder width apart and knees flexed at 100° during the 30-second vibration.

Exercises

Following the WBV, participants were asked to perform 8 exercises on the vibration platform. These exercises were lunge, step up and down, squat, calf raises, left and right pivot, shoulder abduction with elastic bands, shoulder abduction with elastic bands while squatting, and arm swinging with elastic bands. Exercises were performed with slow movements at a rate of 2 seconds for both the concentric and eccentric phases. For the first month, the duration of each exercise was 30 seconds, with a recovery time of 30 seconds between exercises. For the second and third months, the duration of exercises was increased to 45 seconds and 60 seconds, respectively, with a maintained recovery time of 30 seconds. To ensure maximum comfort, avoid injuries, and try to standardize vibration transmission, participants were asked to wear the same sports footwear during all exercise and vibration sessions. To ensure that exercise intensity was progressed safely throughout the program, on the first day of each exercise intensity increase, a preexercise, postexercise, and post−48-hour fasting blood glucose control test was performed in each patient.

Control group

During the 12-week study period, participants in the usual-care control group had no additional intervention but continued with their normal daily activities, which did not include any form of structured physical exercise.

Statistical analysis

The distribution of data was examined by using the Kolmogorov-Smirnov test. After confirming a normal distribution of the data, between-group comparisons at baseline were performed using the Student t test for independent samples for continuous variables or the chi-square test for categorical variables. A 1-way analysis of variance with time as the factor was used to test for within-group changes. Because physical disability may occur more frequently in people with diabetes of longer duration,[37] differences between groups over time (ie, before and after treatment) were determined using a 2×2 analysis of covariance (Group×Time), using time since diagnosis of T2DM as a covariate. The results are presented as means ± SD and 95% confidence intervals. Effect sizes were presented using Cohen's d, where $d=0.2$ was considered to be a "small" effect size, $d=0.5$ represented a "medium" effect size, and $d=0.8$ represented a "large" effect size.[38] All tests were performed using SPSS, version 17.0.[f] The significance level was set at $P \leq .05$ for all tests performed.

Results

The CONSORT flowchart (fig 1) shows that 6 participants from the intervention group and 5 participants from the control group dropped out of the study; data from the remaining 39 participants were therefore included in the analysis. The primary reason for dropout was lack of time. As shown in table 1, there were no statistically significant differences between groups for demographic characteristics at baseline. It appears that groups were balanced in terms of the severity of T2DM because there was no significant difference between the groups for those taking between 8 and 10 T2DM-related drugs.

Table 2 demonstrates the effects of the intervention on the participants' balance. Participants in the WBV group exhibited significantly lower COP excursions with their closed eyes (positive changes) after the intervention. Significant between-group differences in COP excursions (with closed eyes) were also
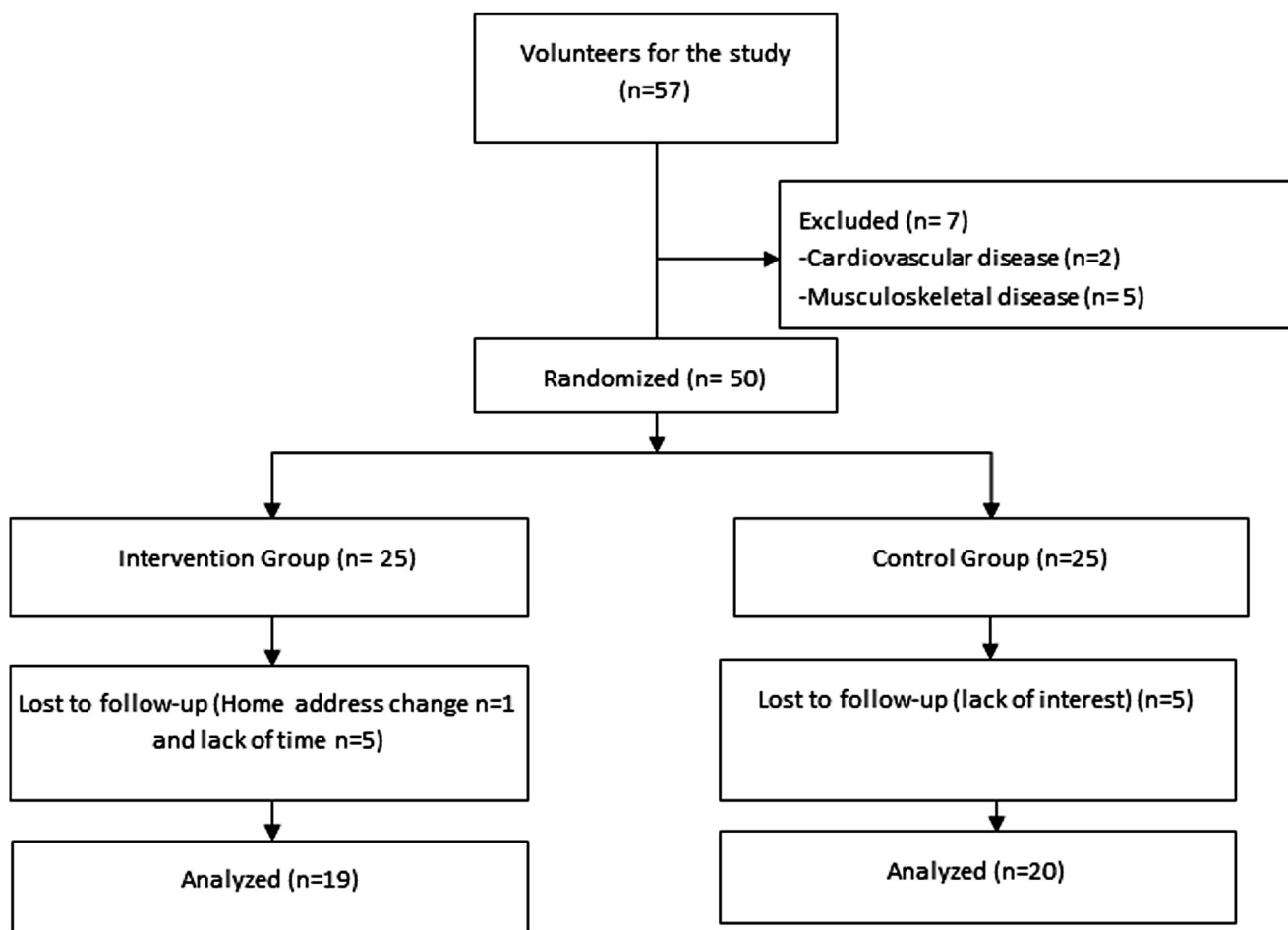
Fig 1 CONSORT flowchart.

found when participants had their feet apart and their feet together, in favor of the WBV group; this improvement represented a large treatment effect ($d=0.5$). Over the course of the study, there were no significant within-group changes in COP excursion for participants in the control group, although there was a nonsignificant change in COP excursion of 13%, which may indicate some deterioration in balance for the control group.

For the TUG test, as shown in figure 2, there was no statistical difference between the groups at baseline, although the between-group difference in change scores from baseline showed a positive effect of the intervention (mean [95% confidence interval] $=-0.44$ [-1.27 to 0.38]). While not significant, this change represents a medium effect size ($d=.578$, $P=.273$) and participants in the WBV group improved >6% in their mobility and muscle function.

Discussion

To our knowledge, this is the first randomized controlled trial to test whether a 12-week intervention based on WBV training, carried out in a primary health care setting, can improve balance in participants with T2DM. The most important finding of this investigation was that participants in the WBV group demonstrated significant improvements in balance with their eyes closed; these improvements were present when participants had their feet apart and had their feet together. Participants in the control group experienced a nonsignificant increase in the COP excursion (therefore a decrease in balance) with their feet together and their eyes closed.

Table 1 Characteristics of participants in the study (N=39)

Variables	Control Group (n=20)	WBV Group (n=19)	P
Socioeconomic variables			
Age (y)	66.80±10.83	71.60±8.54	.752
Sex: Female (%)	50	45	
Body composition			
BMI (kg/m²)	31.55±5.41	30.61±6.8	.641
WHR	0.92±0.85	0.92±0.09	.893
Body fat (%)	36.02±10.17	35.88±10.02	.964
Clinical variables			
Years since diagnosis	8.37±8.00	10.11±7.29	.492
T2DM-related drugs	2.10±1.58	2.12±1.62	.961
Systolic blood pressure (mmHg)	149.70±17.00	149.15±21.90	.933
Diastolic blood pressure (mmHg)	71.07±12.97	67.36±8.26	.323

NOTE. Values are mean ± SD unless otherwise indicated.
Abbreviations: BMI, body mass index; WHR, waist-to-hip ratio.

Table 2 Effects of a 12-week WBV intervention on body balance in older adults with T2DM (N=39)

	Control Group (n=20)			WBV Group (n=19)				Between-group difference (95% CI)
	Pretest	Postest	P*	Pretest	Postest	P*	P[†]	
Feet apart								
COP_OE_G	31.85±7.48	38.80±11.34	.072	33.51±13.93	35.06±11.86	.714	.217	5.40 (−1.17 to 11.98)
COP_OE_ML	16.29±5.42	17.55±4.43	.438	15.69±3.92	15.36±3.85	.793	.221	−1.53 (−4.51 to 1.32)
COP_OE_AP	29.37±11.59	35.82±11.44	.124	28.62±9.63	32.87±10.06	.192	.573	4.31 (−1.21 to 9.80)
COP_CE_G	53.24±20.61	59.58±26.42	.416	46.36±11.61	46.24±12.43	.975	.010[‡]	−6.45 (−12.41 to 0.49)
COP_CE_ML	18.07±5.12	19.24±5.38	.496	18.15±6.48	18.01±5.40	.938	.321	−1.32 (−2.10 to 4.75)
COP_CE_AP	41.31±10.83	45.47±12.79	.314	42.98±13.09	43.85±15.85	.863	.246	3.29 (−5.18 to 11.77)
Feet together								
COP_OE_G	56.54±18.82	61.24±15.01	.432	59.61±26.90	61.11±15.45	.838	.772	3.23 (−10.95 to 17.42)
COP_OE_ML	36.29±9.52	41.94±8.80	.067	34.17±10.81	39.96±12.80	.250	.934	0.14 (−8.43 to 8.72)
COP_OE_AP	37.18±13.80	43.62±16.50	.256	40.01±15.77	43.22±13.09	.498	.551	3.23 (−7.64 to 14.10)
COP_CE_G	87.29±34.07	90.35±21.23	.805	95.20±20.04	82.25±15.59	.050[‡]	.029[‡]	−15.99 (−29.78 to −2.49)
COP_CE_ML	52.56±21.66	56.69±28.72	.645	60.87±13.88	62.33±17.13	.774	.586	2.37 (−7.58 to 12.31)
COP_CE_AP	61.62±24.96	62.30±27.82	.937	62.82±13.99	61.68±15.81	.816	.588	−1.81 (−7.92 to 11.55)

NOTE. Values are mean ± SD. COP is reported in centimeters.
Abbreviations: ANCOVA, analysis of covariance; ANOVA, analysis of variance; AP, anteroposterior axis; CE, closed eyes; CI, confidence interval; G, general; ML, mediolateral axis; OE, open eyes.
C: Statistically significant differences (P<.05) achieved between groups at posttreatment moment by using the Student t test for independent measurement.
* P value from 1-way ANOVA (time factor).
† P value from 2×2 (Group×Time) ANCOVA with repeated measurements for the time factor adjusted by years since T2DM diagnosis.
‡ Indicates variables with significant values.

Patients with diabetes are less stable than age-matched controls, mainly in the mediolateral direction[31]; our finding for the control group supports this. Patients in the control group showed greater postural sway (worse stability) with their feet together in the mediolateral axis (13% greater COP excursion). In the current study, following training, the WBV group demonstrated improvements in balance, which support previous studies based on physical exercise in this population.[2] After the intervention period, participants who exercised with WBV improved postural balance by 13.60% with their eyes closed (feet together). There were significant differences between groups when the assessment was carried out with the participants' eyes closed, which is consistent with the results described by Bonnet et al,[5] who suggested that patients with T2DM may lack peripheral-central communication and have disturbances in vestibular signaling.[8]
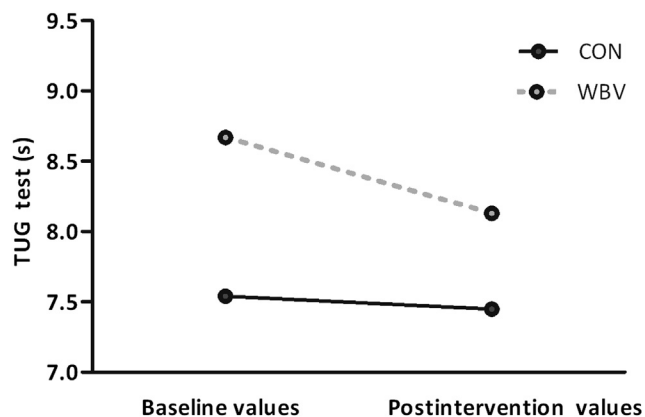
Fig 2 Effects of the 12-week intervention in the TUG test.

One possible explanation for these results is that improvements following WBV can be attributed to vibration-induced sensory stimulation that activates muscle spindles, which is thought to enhance propioception.[39] These mechanisms are also the primary sensory inputs for automatic postural response.[22] Another explanation for the decreased COP motion in the WBV group may be a consequence of the increased body stiffness reported after vibration.[40] Sensory receptors that modulate muscle stiffness detect the vibration through reflex muscular activity and attempt to dampen the vibratory waves.[40] It is also important to note that WBV was combined with an exercise intervention in this study to examine the relative contribution to the benefits demonstrated; future studies should compare "exercise with WBV" to "exercise alone" in patients with T2DM.

To our knowledge, this is the first study conducted to assess the effect of a 12-week WBV training on balance in participants with T2DM. There is evidence that WBV is effective in improving balance in older populations.[16-20] However, different WBV settings can lead to different results. In our study, we applied WBV at an intensity of 12 to 16Hz (peak-to-peak displacement of 4mm) for a duration of 8 to 16 minutes, 3 times/wk, for 3 months. A similar training program, although with a slightly greater frequency (20Hz), showed a significant enhancement in stability with respect to movement velocity, maximum point excursion, and directional control.[16] Similarly, Bruyere et al[20] assessed the effects of 6 weeks of WBV training in the older population. The training sessions consisted of 4 sets of 1 minute (10−26Hz—3−7mm), with 90 seconds of rest, 3 times/wk. The authors used a vertical vibrating platform and also reported improvements in body balance (Tinetti test). These findings are contrary to those of Bautmans et al[18] who investigated the feasibility of a 6-week WBV program (35−40Hz—2mm) in institutionalized older people, who performed 6 exercises 3 times/wk (with the same type of platform), and demonstrated that participants in the WBV group maintained their

baseline level of balance (as measured by the Tinetti test). Van Nes et al[17] also reported no significant effects of a 6-week WBV program on balance and activities of daily living for patients in the subacute phase of stroke. It seems that the different protocols used, patient type, and disability level may all affect the response to WBV treatment. It may be the case that greater benefits of WBV on muscle performance and stability might be obtained after longer or more intensive training programs. However, as previously suggested,[12] the WBV intensity in the current study was set taking into account the ability of the patient population to tolerate the intervention because we wanted to assess the feasibility of the program. In setting the intensity and frequency, we perhaps erred on the side of caution and set the parameters low.

Previous studies support the effectiveness and feasibility of using WBV to enhance muscle performance and balance.[41] The findings of the present study demonstrated that in the TUG test participants in the WBV group improved their mobility and muscle function by 6%. Our results are consistent (although slightly lower) with those reported by Bautmans et al[18] but are greater than the results reported by Bruyere et al.[20] One possible explanation for the differences between the current study and that reported previously may be in the use of the TUG test. In the current study, participants were instructed to "walk as quickly and safely as possible" rather than "walk at their regular pace" (the usual instructions) when performing the TUG test. This modification to the TUG test may be the reason why we did not find a significant difference in the TUG test results between groups.

The muscular benefits of WBV could be explained in part by the effects on muscular performance. It seems that greater frequencies lead to greater muscle activation and gains in strength.[40] Volpato et al[6] reported that reduced muscle strength is common in those with T2DM and may compromise their stability; thus, the results of the present study may have clinical importance, particularly with respect to improvements in balance. Despite the positive effects on the TUG test, the group differences were not significant, which may indicate that WBV improvements are due to a remodeling of the central balance control circuits rather than strength gains.[41]

A novel aspect of this study was that we tested balance by means of the WBB in a primary care context. Although this device was previously shown to produce reliable and valid results,[30] we demonstrated that it can easily be adopted for T2DM exercise-based management interventions in primary care. Authors such as Najafi et al[11] highlighted the need for a convenient, cost-effective tool to identify individuals with postural instability and who are at risk for falls. Traditionally, force platforms were considered the criterion standard measure of balance[42] and laboratory-based and clinical assessments of balance were based on both force platform and posturography analysis.[43] However, because of their complex setup and their cost, the use of force platform and posturography analysis in the clinical setting is not always feasible.[30] In the current study, we have demonstrated that the WBB (portable and easy to configure) could provide practitioners with important information to monitor and reduce the risk of falling in those with T2DM.

Study limitations

This study had a number of limitations: first, the study sample was determined using the TUG test and it may have been the case that the study was not sufficiently powered to detect all changes in COP excursion due to the intervention; hence, type II errors cannot be completely discounted. Future studies, examining COP excursions, could perhaps use data from the current study in sample size calculations. Second, instructions given to patients when using the TUG test deviated slightly from the standard instructions and this may have impacted the results obtained from this test; this highlights the importance of strictly adhering to guidelines when implementing validated outcome measures.

Conclusions

From the results it may be assumed that WBV is a safe and well-tolerated strategy to improve balance in participants with T2DM. The findings have important implications for falls prevention in patients with T2DM in primary health care, and health care professionals should consider this therapeutic device in monitoring changes in postural sway and balance over time in patients with T2DM.

Suppliers

a. PS software. Available from: http://biostat.mc.vanderbilt.edu/wiki/Main/PowerSampleSize.
b. Wii Balance Board; Nintendo Company, Ltd, 11−1 Kamitoba−hokotate−cho, Minami−ku, Kyoto 601−8501, Japan.
c. Bluetooth adaptor; Belkin International, Inc, 12045 E Waterfront Dr, Playa Vista, CA 90094.
d. Labview 8.5; National Instruments, 11500 N MoPac Expwy, Austin, TX 78759−3504..
e. Phyisio Wave 700; Globus, Globus Italia Srl, Via Vittorio Veneto 52, 31013−Codognè (TV), Italy.
f. SPSS, version 17.0; SPSS, Inc, 233 S Wacker Dr, 11th Fl, Chicago, IL 60606.

Keyword

Corresponding author

Borja Sañudo, PhD, Department of Physical Education and Sport, University of Seville, Pirotécnia s/n, N-41013 Seville, Spain. E-mail address: bsancor@us.es.

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