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Effects of a 12-wk whole-body vibration based intervention to improve type 2 diabetes

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ABSTRACT

Objective: To test the feasibility, safety and effectiveness of a 12-wk whole body vibration (WBV) intervention on glycemic control, lipid-related cardiovascular risk factors and functional capacity among type 2 diabetes mellitus (T2DM) patients in a primary care context.

Methods: Fifty non-insulin dependent T2DM patients were randomized 1:1 to an intervention group that, in addition to standard care, received a 12-wk WBV intervention, and a control group receiving only standard care (from February 2012 through May 2012). Outcomes, including glycated hemoglobin (HbA1c), fasting blood glucose, lipid-related cardiovascular risk factors (i.e., cholesterol, triglycerides, lipoproteins, LDL/HDL and atherogenic index) and functional capacity were measured at baseline and after the 12-wk intervention.

Results: After intervention, there was a reduction in HbA1c and fasting blood glucose when compared to the control group, with a mean difference in change scores between groups of -0.55% (95% CI -0.15 to -0.76) and -33.95 mm/dl (95% CI -51.38 to -3.47), respectively. Similarly, most lipid-related cardiovascular risk factors (i.e., cholesterol, triglycerides and atherogenic index) were also reduced ($p < 0.05$).

Conclusion: A 12-wk WBV intervention in a primary care context is feasible, safe and effective in improving glycemic profile, lipid-related cardiovascular risk factors and functional capacity among T2DM patients.

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1. Introduction

Type 2 diabetes mellitus (T2DM) is a prevalent and costly chronic metabolic disorder characterized by hyperglycemia and insufficiency of secretion or action of endogenous insulin [1]. Likewise, T2DM is an independent risk factor for vascular diseases and also is frequently associated with other cardiovascular diseases [2]. Therefore, the major causes of morbidity and mortality among T2DM patients are cardiovascular diseases [3]. Consequently, it is necessary to address both T2DM outcomes (i.e., glycated hemoglobin (HbA1c) and fasting blood glucose) and modifiable cardiovascular disease risk factors (e.g., dyslipidemia or blood pressure) for a complete therapeutic approach among this population.

Along with nutrition, exercise has long been recognized as a cornerstone for T2DM management in both primary and secondary prevention. Although there are no definitive conclusions, results from different meta-analyses [4–6] show that aerobic exercise or resistance training reduce HbA1c, fasting blood glucose, dyslipidemia or blood pressure when compared with standard care. Nonetheless, greater achievements seem to be reached by combining both modes of exercise. Moreover, better functional capacity is associated with better outcomes among diabetic patients [7].

Whole-body vibration (WBV) training is a relatively new form of exercise that has been shown to be effective in healthy subjects [8] and individuals with a range of medical disorders [8]. Moreover, WBV training has been shown to be useful among frail individuals who were previously physically untrained [9,10], as most diabetics patients are, and because WBV training takes less time than other kinds of exercise such aerobic or resistance training, this method could be a very good alternative to exercising in clinical contexts. Unfortunately, the effects of WBV training have seldom been investigated among T2DM patients. Existing studies [11–13] have yielded inconsistent results and no studies have been conducted to test the effects of WBV training on cardiovascular risk factors among T2DM patients. We therefore conducted a randomized

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controlled trial to contribute to the ongoing discussion on the effectiveness of WBV training for T2DM management in a clinical context. The aim of this study was 2-fold: (1) to test the feasibility, safety and effectiveness of this intervention on glycemic control, dyslipidemia and functional capacity among T2DM patients in a primary care context and (2) to quantify the possible relationship between functional capacity and glycemic control among participants receiving the WBV intervention.

2. Methods

2.1. Study design and participants

A single-blind (researchers) randomized controlled trial was conducted from February 2012 through May 2012. The study was approved by the research ethics committee of the University of Seville and conducted in accordance with the Declaration of Helsinki, as revised in Edinburgh, 2008. All participants signed an informed consent form prior to participation in the study. Participants in the study were recruited via health care staff from a primary care center in Seville, Spain. The inclusion criteria were T2DM diagnosis and a level of exercise less than advised by the American Diabetes Association (i.e., 150 min/week of moderate-intensity aerobic physical activity) [14]. Potential participants were excluded if they had a baseline value for fasting blood glucose >250 mg/dl or HbA1c >10%, diagnosed cardiovascular or mental disease, a diabetes-related complication including nephropathy, or retinopathy unrepaired hernia, or any other functional impairment that would preclude safe participation in a WBV-based training program. Out of 57 initial volunteers, 50 fulfilled the inclusion/exclusion criteria and were allocated (randomization was undertaken by a member of the research team not directly involved in the recruitment or assessment of patients) to one of the two study groups using a computer generated random allocation data processing program and a 1:1 ratio (intervention:control).

2.2. Experimental

Participants in both the intervention and control groups had access to the usual care (consisting on outpatient visit for the control of the diabetes-related parameters and on giving advices to improve it) and were asked not to change their nutritional or exercise habits during the 12-wk period. Participants in the intervention group participated in a 12-week WBV-based program on an oscillating or side-alternating vibration device (i.e. two simultaneous movements, one vertical and one horizontal platform) (Physio Wave 700, Globus, Italy) consisting of three sessions per week with at least one day between sessions. Description of the WBV intervention is provided in Table 2. Each exercise session was performed with a frequency of 12 Hz for the first month, 14 Hz for the second month and 16 Hz for the last month. Peak to peak displacement of 4 mm was maintained during the entire program. Participants adopted an isometric squat position during all exposures, with knees flexed at 100° for 30 s. After that, participants were asked to perform 8 exercises (lunge, step up and down, squat, calf raises, left and right pivot, shoulder abduction with elastic bands, shoulder abduction with elastic bands while squatting, arm swinging with elastic bands) with slow movements at a rate of 3 s for both concentric and eccentric phases. For the first month, the duration of exercises was 30 s with a recovery time of 30 s between exercises. For the second and third month, the duration of exercises was increased to 45 s and 60 s, respectively, while maintaining the 30 s recovery time. To ensure a correct and safe increase in intensity throughout the program, non-fasted blood glucose tests were performed on each participant during the first day of each increase

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

Variables	Control group (n = 20)	Intervention group (n = 19)	p
Socio-economic variables			
Age (years)	66.80 (10.83)	71.60 (8.54)	0.752
Gender (% females)	50	45	
Marital status			
Married (%)	60	60	0.154
Unmarried (%)	0	15	
Separated/divorced/widowed (%)	40	25	
Income/month			
<USD 1544 (%)	60	50	0.203
USD 1544–2315 (%)	35	25	
>USD 2315 (%)	5	25	
Body composition			
BMI (kg/m ²)	31.55 (5.41)	30.61 (6.8)	0.641
WHR	0.92 (0.85)	0.92 (0.09)	0.893
Body fat (%)	36.02 (10.17)	35.88 (10.02)	0.964
Clinical variables			
Years since diagnoses	8.37 (8.00)	10.11 (7.29)	0.492
T2DM-related drugs	2.10 (1.58)	2.12 (1.62)	0.961
Systolic blood pressure (mmHg)	149 (17.0)	149 (21.9)	0.933
Diastolic blood pressure (mmHg)	71 (12.9)	67 (8.2)	0.323
Heart rate (ppm)	77 (12.0)	75 (10.7)	0.601

Values are mean (SD) unless otherwise indicated; BMI, body mass index; WHR, waist to hip ratio; p, p value from Student's-t for independent measurement or Chi square analysis.

in intensity including pre-exercise, post-exercise and post 48 h tests.

2.3. Outcome measures

Socio-demographic variables (i.e. age, gender, marital status and income) as well as clinical predictor variables (i.e. years since diagnosis, T2DM-related drugs, blood pressure and heart rate) were recorded. Weight, height, and waist and hip circumference were measured to calculate body-mass index (BMI; kg/m²) and waist to hip ratio. Body-fat percentage was also estimated using an impedance analyzer (Bodystat © 1500, Bodystat Ltd, Douglas, Isle of Man, UK) according to the manufacturer's instructions. Outcome measurements were assessed at baseline and after the 12-wk study period.

2.3.1. HbA1c, fasting blood glucose and lipid-related cardiovascular risk factors

HbA1c (%), fasting blood glucose (mg/dl) and lipid-related cardiovascular risk factors (i.e. cholesterol, triglycerides, high density lipoprotein (HDL) and low density lipoprotein (LDL)) were assessed as part of regular care and performed by a diagnostic center in Seville, Spain. Derived from the lipid assay, LDL/HDL and atherogenic index were calculated for cardiovascular risk assessment purposes [15].

2.3.2. Functional capacity

To assess functional capacity, a test battery consisting of three assessments was used [16]. Motor agility and mobility were assessed by the Timed Up and Go (TUG) test. The participant had to stand up from a chair, walk 2.44 m to and around a cone, and return to the chair in the shortest possible time. The best time of two trials (1-min rest period between each trial) was recorded. To assess cardiovascular fitness, the Six Minute Walking Test (T6MW) was used. Participants were instructed to walk as far as they could at a fast, comfortable pace in 6 min. The maximum distance (m)

Table 2
Description of the training protocol.

Weeks	Sessions/wk	Time per exercise (s)	Number of WBV exercises	Frequency (Hz)/ Amplitude (mm)	Rest period (s)	WBV total time (s)
1–2	3	30	8	12/4	30	480
3–4	3	30	8	12/4	30	480
5–6	3	45	8	14/4	30	720
7–8	3	45	8	14/4	30	720
9–10	3	60	8	16/4	30	960
11–12	3	60	8	16/4	30	960

walked was recorded as the score of the test. Participants were discouraged from talking during the test and were notified of each passing minute. The 30-s Sit-to-Stand (30-s-STST) test was used to assess lower body strength. Participants were instructed to perform the task starting and finishing in the seated position. Participants were allowed a practice trial before the beginning of the test. The number of times within 30 s that the participant could raise to a full stand from a seated position with back straight and feet flat on the floor “as quickly as possible” without pushing off with the arms was counted.

2.4. Sample size

We anticipated that a 0.57% reduction in the primary outcome for the study (HbA1c) was a clinically important change on the basis of a meta-analysis of exercise in T2DM patients [6]. Anticipating a standard deviation of 1.3 based on the results of a large study previously conducted [17], we calculated that 50 participants (25 per group) would provide 70% power to detect a difference of 0.57% as significant at a two-sided, 5% significance level.

2.5. Statistical analysis

Analysis was performed using SPSS version 17.0 (SPSS Inc., Chicago, IL, USA). The significance level was set at $p < 0.05$ for

all analyses. The distribution of the data was examined by the Kolmogorov–Smirnov test. After confirming the normal distribution of the data for all variables, within-group comparisons at baseline were performed using Student’s *t*-test for independent samples for continuous variables or Chi square analysis for qualitative variables and between-groups comparisons after treatment were performed using a mixed-model ANOVA with repeated measurements. Although there was no difference between groups at baseline in years since T2DM diagnosis or age of the participants, we decided to adjust the analysis with these variables because of the possible influence they could have on the course of the T2DM process [18]. In addition to the *p* values, detailed statistics including the mean and 95% confidence interval were calculated to provide a better interpretation of the change between groups during the course of the study. A partial Pearson correlation (adjusted for years since T2DM diagnoses and age of participants) and a linear regression were used to provide a better understanding of the correlation between changes in HbA1c and functional capacity. Effect size was used to determine the magnitude of change and was calculated as the difference between means divided by the pooled standard deviation. Cohen’s coefficient was used to assess the change. A change of 0–0.2 was considered very small; a change of 0.2–0.6 was considered small; a change of 0.6–1.2 was considered moderate; a change of 1.2–2.0 was considered large; and a change of greater than 2.0 was considered very large [19].

Fig. 1. Flow diagram of participation through the study.

Table 3
Effects of a 12-wk WBV intervention on biochemical profile in older adults with T2DM ($n = 39$).

Outcome measures	Baseline			Post-intervention			Between-group difference in change scores from baseline mean (95% CI)	Effect size for between group difference
	Control group ($n = 20$)	Intervention group ($n = 19$)	p^a	Control group ($n = 20$)	Intervention group ($n = 19$)	p^b		
Cholesterol (mg/dl)	203 (55.4)	198 (43.1)	0.736	202 (57.8)	173 (39.1)	0.012	−24 (−5.6 to −41.0)	0.620
Triglycerides (mg/dl)	146 (41.4)	196 (58.2)	0.345	152 (61.7)	139 (95.5)	0.026	−62 (−176.9 to −16.2)	0.166
HDL (mg/dl)	60 (26.3)	55 (13.5)	0.508	54 (14.3)	58 (16.1)	0.683	9 (8.2 to 24.4)	0.229
LDL (mg/dl)	146 (38.8)	131 (41.3)	0.385	139 (38.1)	117 (40.1)	0.439	−7 (−11.8 to −2.5)	0.574
LDL/HDL	2.79 (0.84)	2.25 (0.88)	0.142	2.76 (0.81)	1.99 (0.48)	0.462	−0.29 (−0.35 to −0.16)	1.187
Atherogenic Index	3.79 (1.70)	4.37 (2.43)	0.473	3.93 (1.68)	3.43 (0.61)	0.046	−1.08 (−3.06 to −0.30)	0.406

Values are mean (SD); control group, group that had access to usual care; intervention group, group that had access to the WBV intervention and usual care; HDL, high-density lipoprotein; LDL, low-density lipoprotein.

^a p value from Student's- t for independent measurement.

^b p value from mixed-model ANCOVA with repeated measurements for the time factor adjusted by years since T2DM diagnoses and age of the participants to compare difference between groups.

3. Results

The baseline socio-demographic and socio-economical, clinical and body composition variables of the study participants were compared (Table 1). No statistically significant differences were observed between participants in the two groups of the study.

3.1. Feasibility, safety, adherence, and compliance

Fifty older adults with T2DM were finally randomized into one of two groups (Fig. 1). None of the participants in the intervention group reported any negative health effects during treatment. To be included in the final analysis, a participant needed to complete at least 80% of all sessions. A session was considered to be completed if the participant performed all exercises for the session. In the intervention group, 76% (19 of 25) of all participants completed the 12-wk program. Of the 6 intervention group participants who dropped-out of the program, 5 were participants who had a lack of time and the other moved away. In the control group, 80% (20 of 25) of the participants completed the 12-wk study. The 5 participants dropped-out due to an apparent lack of interest.

3.2. HbA1c, fasting blood glucose and lipid-related cardiovascular risk factors

No statistically significant differences between the intervention and control groups were observed at baseline for HbA1c and fasting blood glucose (Fig. 2) or for lipid-related cardiovascular risk factors (Table 3). Participants in the intervention group exhibited significantly ($p = 0.002$) greater positive changes (lower scores) on the HbA1c at the time of follow-up when compared to the control group, with a mean difference in change scores of -0.55% (95% CI -0.15 to -0.76) between groups and an effect size of 0.236 (Fig. 2). Similarly, fasting blood glucose significantly decreased ($p = 0.029$) in the intervention group at the time of follow-up compared to the control group, with a mean difference in change scores of -33.95 mm/dl (95% CI -51.38 to -3.47) and an effect size of 0.515 (Fig. 2). Pearson correlation coefficient (adjusted for years since T2DM diagnoses and age of participants) revealed a strong correlation between change scores from baseline of these two variables ($r = -0.704$) and linear regression analysis revealed the association of change scores from baseline HbA1c values with change scores from baseline T6MW with a $R^2 = 0.50$ (Fig. 3). While no statistically significant changes ($p > 0.05$) were detected for some of the lipid-related cardiovascular risk factors (i.e., HDL, LDL and LDL/HDL), cholesterol, triglycerides and atherogenic index significantly decreased ($p = 0.031$, 0.026 and 0.046 , respectively) in the

intervention group at the time of follow-up when compared to the control group (Table 3).

3.3. Functional capacity

Table 4 shows the effects of the intervention on the fitness levels of the participants in the study. No statistically significant differences between the intervention and control groups were observed at baseline for fitness variables. Although participants in the intervention group tended to improve their TUG test values at the time of follow-up, no significant difference ($p = 0.273$) was detected when compared with the control group. Contrarily, participants in the intervention group exhibited significantly ($p = 0.004$) greater

Fig. 2. Effects of the 12-wk intervention on HbA1c and fasting blood glucose. The upper graph shows HbA1c (%) with baseline values of 7.01 (0.73) and 7.33 (1.20) for the control and intervention group, respectively, and follow-up values of 7.05 (0.94) and 6.82 (1.06) for the control and intervention group, respectively. The lower graph shows fasting blood glucose levels (mg/dl) with baseline values of 135.85 (24.42) and 149.30 (53.35) for the control and intervention group, respectively, and follow-up values of 151.55 (48.40) and 131.35 (30.03) for the control and intervention group, respectively. # denotes statistically significant differences from ANOVA adjusted by years since T2DM diagnoses and age of participants.

Table 4
Effects of a 12-wk WBV intervention on functional capacity in older adults with T2DM ($n = 39$).

Outcome measures	Baseline			Post-intervention			Between-group difference in change scores from baseline mean (95% CI)	Effect Size for between group difference
	Control group ($n = 20$)	Intervention group ($n = 19$)	p^a	Control group ($n = 20$)	Intervention group ($n = 19$)	p^b		
Time "Up and Go" Test (s)	7.5 (1.6)	8.6 (2.3)	0.087	7.4 (1.5)	8.1 (0.3)	0.273	-0.4 (-1.3 to -0.4)	0.578
Six-Minute Walk test (m)	419 (67.1)	396 (109.9)	0.431	393 (85.1)	420 (98.7)	0.004	51 (9.8 to 82.1)	0.392
30-Sit to Stand Test (number of times)	13.5 (3.3)	12.1 (3.5)	0.213	13.6 (3.8)	15.1 (4.2)	0.011	2.9 (1.1 to 4.7)	0.307

Values are mean (SD): control group, group that had access to usual care; intervention group, group that had access to the WBV intervention and usual care.

^a p value from Student's- t for independent measurement.

^b p value from mixed-model ANCOVA with repeated measurements for the time factor adjusted by years since T2DM diagnoses and age of the participants to compare difference between groups.

Fig. 3. Relationship between HbA1c and functional aerobic capacity as measured by T6MW.

improvements on the T6MW and the 30 s-STS test ($p = 0.011$) at the time of follow-up when compared to the control group.

4. Discussion

A randomized controlled design was used to evaluate the feasibility, safety and effectiveness of a 12-wk WBV-based intervention added to standard care among T2DM patients on glycemic control, lipid-related cardiovascular risk factors and functional capacity in a primary care context. The main findings were that participants in the intervention group experienced a reduction in glycemic variables (i.e., HbA1c and fasting blood glucose) and lowered their cardiovascular disease risk through a reduction in cholesterol, triglycerides and atherogenic index. Moreover, functional capacity level was also improved following the intervention in these participants. Hence, the results of this study are promising and of value to health care practitioners who work with T2DM patients.

Using side-alternating vibration, previous studies on other special populations and untrained individuals have reported improvements in different outcomes with frequencies between 12.6 Hz and 26 Hz [20–22] while non-significant results were achieved with higher frequencies [23,24]. Therefore, considering that we aimed the exercise to be safe for the patients, we decided to start in the lower range (12 Hz) and progressed to 16 Hz for the last month.

HbA1c is considered the optimal way of measuring long-term glycemic control, with HbA1c values of <7.0% accepted as representing good glucose control [25]. Thus, lowering HbA1c in patients with T2DM decreases the absolute risk of developing coronary heart disease by 5–17% and all-cause mortality by 6–15% [26].

We showed that our intervention was clinically effective as participants in the intervention group reduced their HbA1c values up to 7% when compared with the control group. The lowering of HbA1c is consistent with the reduction found in fasting blood glucose levels after treatment in our participants. Other studies have reported slighter changes on HbA1c after the vibration treatment than changes reported in our study after the intervention. For example, Baum et al. [11] found a 0.3% reduction on HbA1c after 8 weeks of WBV training but Behboudi et al. did not find any significant reduction after the same period of time (i.e. 8 weeks) [13]. However, Baum et al. [11] reported a 6.3% reduction on fasting blood glucose after the WBV intervention which is consistent with the results shown in the current study regarding this outcome. On the other hand, the magnitude of HbA1c change after treatment in our study was slightly higher than that reported in a meta-analysis conducted with randomized controlled trials using supervised exercise [5] and consistent with results reported in another meta-analysis [4].

Cardiovascular disease is the leading cause of death among individuals with diabetes [3], and therefore the management of risk factors for the disease is a priority among researchers and practitioners. Although not statistically significant, the higher HDL values and the lower LDL values found among participants in the intervention group compared with those in the control group are similar to results from a large 12-month clinical trial testing the effects of a supervised aerobic and resistance exercise program plus counseling among Italian sedentary T2DM patients [27]. Our results on these two lipoproteins are also consistent with results from two recently published meta-analyses of combined aerobic and resistance exercise for T2DM management [4,5]. Similarly, one of these meta-analysis yielded consistent results with our study regarding triglyceride values, but showed a lower reduction than reported in the current study [5]. These findings, combined with the lower atherogenic index and cholesterol resulting from the WBV intervention, indicate that WBV when combined with elastic resistance training may be as, or more, effective in reducing cardiovascular risk compared to other previously studied forms of exercise. However, further study is needed to make direct comparisons and draw definitive conclusions on this.

As expected from previous studies and reviews of WBV training [8,28,29], our participants experienced an improvement in functional lower limb strength and aerobic capacity after the 12-wk intervention achieving similar functional capacity values as reported in a national study of the general population [30]. It has been hypothesized that in response to the vibration stimulus (tonic vibratory reflex), more motor units are activated leading to a better muscle response [31], which also could enhance insulin sensitivity and glycemic control [7]. This could explain the observed improvements in lower limb strength as measured by the 30 s-STS test and

aerobic capacity as measured by T6MW. Behboudi et al. [13] report slight, although not significant, improvements in aerobic capacity in diabetic patients after an 8-week WBV intervention. Probably the exposure time to the treatment was not enough to achieve significant improvements in this capacity. Along with this, the increase in aerobic capacity could have some implications on HbA1c control [32], thus, supporting the relationship between T6MW and HbA1c shown in the current study.

The results presented from the current study need to be considered in the context of its limitations. The fact that we did not use a population-based approach could limit the generalization of the results. However, the key T2DM-related characteristics of our participants were found to be similar to those presented in a large randomized controlled trial performed within the Mediterranean region [27]. Despite the effectiveness shown in the current study, we have not determined the dose–response relationship for WBV training and therefore further studies are needed to provide optimal WBV-based interventions for T2DM patients. Moreover, further research is needed using a multi-centric approach involving a large sample size to confirm the current results. This could allow for the development of more specific WBV interventions designed for specific conditions related to T2DM such as years since diagnosis or risk for neuropathic development. Finally, analysis of cost-effectiveness is warranted to enhance the decision-making process of policy makers on the implementation of this type of intervention in primary care contexts.

5. Perspective and conclusion

In conclusion, the application of a 12-wk WBV-based intervention in a primary care context is feasible, safe and effective to clinically reduce HbA1c and fasting blood glucose, and to improve most of the lipid-related cardiovascular risk factors (i.e., cholesterol, triglycerides and atherogenic index). Moreover a high correlation between HbA1c and functional aerobic capacity as measured by T6MW exists. In practice, these findings could serve as a model for health care practitioners to implement WBV as an exercise-based management intervention for individuals with T2DM in primary care contexts.

Q3 Contributors

B.P.C. and B.S. designed the study and directed its implementation, including quality assurance and control. J.P.C. helped supervise the field activities and designed the study's analytic strategy. R.A.R. helped conduct the literature review and prepare the Introduction, Materials and Methods sections of the text. M.E.R. prepared the discussion and helped in stat analysis. All authors revised the whole manuscript and added their point of view and further value on it. All authors approved the final version of the manuscript.

Competing interest

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