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ORIGINAL ARTICLE

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

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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.

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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.

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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 ≥6.5%; or fasting plasma glucose ≥126mg/dL (7.0mmol/L); or 2-hour plasma glucose ≥200mg/dL (11.1mmol/L) during an (75-g) oral glucose tolerance test; or random plasma glucose ≥200mg/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]