Study Protocol

Cost-Effectiveness of a Whole-Body Vibration Program in Patients with Type 2 Diabetes: A Retrospective Study Protocol

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Abstract: Background: Type 2 diabetes mellitus (T2DM) is a chronic disorder, with patients exhibiting hyperglycemia in fasting and postprandial states. T2DM has several complications, including loss of sensation in more distal body parts. Good peripheral sensitivity is essential as this affects different parameters related to activities of daily living, such as leg strength and balance. The objectives of this project were to assess the effects of an 8-week whole-body vibration (WBV) training program on (1) vibration perception threshold (VPT), (2) balance, (3) strength, (4) lipidic profile, (5) health-related quality of life, (6) diabetic neuropathy, and (7) body composition in T2DM patients. **Methods/Design:** A double-blind, randomized controlled study, with WBV and placebo groups, was carried out. Both groups performed 8 weeks of intervention, with 3 sessions per week, completing a total of 24 sessions. There were two groups: the experimental group, i.e., the WBV group, who received WBV therapy; and the placebo group, who completed a simulated training program that was developed on a Galileo Fitness platform, connected to software displayed on a screen. The participant could see the parameters of the simulated vibration training (duration, amplitude, and frequency), but it was the software that controlled the speakers placed inside the vibration platform. Ninety patients with T2DM (56 males and 34 females) were recruited for the intervention. Participants were assigned equally to the WBV (n = 45) and placebo (n = 45) groups. Primary outcome measures were (1) HbA1c and (2) vibration threshold. Secondary measures were (1) health-related quality of life, (2) balance, (3) strength, (4) body composition, (5) blood pressure, (6) diabetic neuropathy, and (7) lipidic profile. Statistical analysis was carried out by treatment intention and protocol. **Discussion**: This project aimed to investigate the effects of WBV training on HbA1c, vibration threshold, and incremental cost-effectiveness ratio in T2DM patients. In future, guidelines will be provided for the incorporation of the main obtained conclusions into the social-sanitary system and businesses.

Keywords: whole-body vibration; diabetes mellitus; study protocol

1. Introduction

Type 2 diabetes mellitus (T2DM) is a chronic disease characterized by disturbances in metabolism that lead to chronic hyperglycemia. The main symptoms range from predominant insulin resistance with relative insulin deficiency to predominant defective secretion with insulin resistance [1]. In this pathology, the pancreas does not secrete the insulin needed to regulate blood glucose levels. This disease is global, affecting 415 million people worldwide, and its prevalence is increasing in both men and women. According to the International Diabetes Federation, a high percentage of persons suffering from this disease have not yet been diagnosed. Furthermore, World Health Organization (WHO) estimations show that around 642 million people in the world might suffer from T2DM by 2040 [2]. Many reasons could explain this, but the aging population is one of the leading causes of T2DM [3].

T2DM has several complications, and they have been extensively studied. These complications include retinopathy, nephropathy, and neuropathy [4]. Diabetic peripheral neuropathy is defined as "peripheral nerve damage, somatic or autonomic, attributable to DM alone". It includes different clinical entities, such as diffuse neuropathy (e.g., autonomic neuropathy and symmetrical distal sensorimotor polyneuropathy) and focal neuropathy (e.g., entrapment, mononeuropathy, cranial neuropathy, radiculopathy, and plexopathy). This type of complication involves damage to the nerve endings that can lead to a loss of sensation in the most distant body parts, affecting even the small-diameter nociceptive fibers in the skin [5]. This progressive loss of sensation enhances the risk of not being aware of having an injury, and this can become so complicated that it leads to gangrene and, in the most severe cases, to amputation. Loss of sensation affects around 50% of DM patients [6].

Whole-body vibration (WBV) is a kind of activity that involves applying an oscillating force to the body from a WBV machine, which is the actuator (the device that applies the vibration) [7]. Several studies have investigated the effects of this training modality in different populations (e.g., people with musculoskeletal or neurological problems) [8]. WBV therapy has been used in T2DM patients to observe its effects on strength and balance [8,9]. Two previous systematic reviews and one meta-analysis have been focused on analyzing the effects of WBV in T2DM patients [10,11].

To date, no treatment has been found for reversing neuropathy, but some studies have seen some improvements in the vibration perception threshold (VPT) after WBV training [12–14]. The populations in these studies were healthy young people [12], patients with lower back pain [13], and persons with T2DM [14]. Due to loss of sensitivity in the more distal parts of the body, it is interesting to assess how T2DM affects the threshold of sensitivity to vibration.

Therefore, it is essential to measure the vibration perception threshold (VPT) in the most distant body parts. One of the most suitable instruments for assessing VPT is Vibratron II. This inexpensive and accessible vibration sensitivity tester has shown acceptable reliability in other types of populations (e.g., lower back pain) [15]. To our knowledge, this type of instrument has not been used on patients with T2DM.

Likewise, it is essential to find therapies or treatments where blood glucose control can be regulated, since high blood glucose levels cause damage to different organs in the body (e.g., diabetic retinopathy, diabetic nephropathy, or diabetic peripheral neuropathy) [4]. Therefore, it is essential to find therapies that lower the level of glycosylated hemoglobin (HbA1c), which reflects the average blood glucose in the last three months. A previous systematic review with meta-analysis includes different studies that evaluated HbA1c in T2DM patients after applying some physical therapy [16].

These types of complications can affect both health-related quality of life (HRQoL) and health status of the foot. HRQoL in DM can be evaluated by generic questionnaires such as EuroQol-5D-5L (EQ-5D-5L) [17], 12-Item Short Form Survey (SF-12) [18], and 15-D [19], or specific questionnaires such as Diabetes Quality of Life (DQoL) [20]. The health status of

the foot may be evaluated by an examination of the foot or by questionnaires, such as Foot Health Status Questionnaire (FHSQ) [21].

People with diabetic peripheral neuropathy suffer in terms of motor aspects, as it affects even the neuromotor fibers, and this leads to muscle weakness. Because of this, people with DM were found to have a 17% and 14% decrease in the strength of knee flexor and extensor muscles, respectively [22]. This type of problem can affect balance in these people and cause modifications in walking and posture patterns [23], affecting the foot and ankle proprioception [24] or even foot sensitivity [25]. Thus, it is important to evaluate the level of balance and strength in this population. Timed Up and Go (TUG) and Romberg tests are two of the most frequently used assessments to evaluate stability. Both tests have been previously used in people with balance problems, such as the elderly [26,27] and patients with T2DM, where TUG has shown excellent reliability [28]. Regarding strength measurements, the 30-s Chair Stand Test is a great test to assess strength in this population optimally and has demonstrated excellent reliability in patients with T2DM [29]. Therefore, consideration should be given to find some therapy or treatment that can improve or stop this loss of sensation in the more distant body parts.

Therefore, the main objective of this project was to analyze the effects of a WBV program on HbA1c, vibration threshold, and incremental cost-effectiveness ratio in type 2 diabetes patients. Moreover, this study aimed to measure the impact of WBV on body composition, HRQoL, balance, strength, blood pressure, lipid profile, and diabetic neuropathy of patients.

2. Materials and Methods

2.1. Study Design

A retrospective, double-blind, randomized controlled trial was conducted following the "Recommendations for conduct, methodological practices, and reporting of cost-effectiveness analyses: second panel on cost-effectiveness in health and medicine" [30] and the Consolidated Standards of Reporting Trials (CONSORT) Statement [30]. Participants were randomly assigned to the whole-body vibration group (WBVG) and placebo group (PG).

2.2. Ethical Approval

The Bioethics and Biosafety Committee at the University of Extremadura approved the study (approval number: 44/2012), and this investigation was registered with an International Standard Randomised Controlled Trial Number (number: ISRCTN 16866781).

2.3. Sample Size

Sample size computations were estimated using HbA1c. Results showed that a minimum of 80 participants (WBVG = 40 and PG = 40) was required to detect a difference equal to or greater than 0.57 units, accepting an alpha risk and a beta risk of 0.05 in a bilateral contrast [16]. Considering a previous investigation [31], we accepted a typical standard deviation equal to 1, and a pre-post correlation coefficient between means of 0.80. Moreover, a 20% follow-up loss rate was estimated.

2.4. Randomization and Blinding

Participants were randomly (1:1) assigned into two groups: experimental (WBVG) and placebo (PG) by a researcher using a random numbers table. All patients were classified as A or B, respectively, by an investigator who did not participate in either data collection or analysis. Another researcher who was blinded to group assignments led the intervention and applied protocol A or B for every patient.

2.5. Participants

People who participated in the study met the following inclusion criteria: (1) male or female aged from 40 to 85 years old, (2) to be diagnosed with T2DM, and (3) to agree to participate as a volunteer in the study by giving written informed consent.

Additionally, some exclusion criteria were applied:

- To present contraindications to high-intensity exercise participation (e.g., retinopathy, musculoskeletal limitations, severe balance impairments, or high risk of thrombosis)
- To be taking psychotropic or neurotoxic drugs.
- To be exposed to neurotoxins (e.g., industrial accidents, contact with toxic dumps).
- To be receiving radiotherapy treatment.
- To present a high risk of non-diabetic neuropathy (AIDS, uremia, alcoholism).
- To have or have had a job with high exposure to whole-body mechanical vibration.
- To be involved in or have completed a WBV program.

2.6. Interventions

Experimental group (WBVG): The WBVG received WBV training, 3 times a week, for 2 months. The proposed intervention included a progression, which is shown in Table 1.

Table 1. Whole-body vibration training program characteristics.

WBV Training Parameters	Weeks							
	1	2	3	4	5	6	7	8
Vibration frequency (Hz)	12.5	13.5	14.5	15.5	16.5	17.5	18.5	18.5
Number of sets per session	8	5	6	7	8	9	9	9
Duration of sets (s)	30	60	60	60	60	60	60	60
Rest between sets (s)	30	30	30	30	30	30	30	30
Total duration per week (s)	720	900	1080	1260	1440	1620	1620	1620

Placebo group (PG): PG training was similar to others used by previous studies [12,32]. It was explained to the people who participated in the study that they were going to receive a vibration therapy that was below their perceived vibration threshold. PG training was developed on a Galileo Fitness platform, connected to software that was displayed on a screen. The participant could see the vibration training parameters (duration, amplitude, and frequency), but it was the software that controlled the speakers placed inside the vibration platform.

2.7. Measures and Procedures

The following assessments were used to evaluate the effects of WBV and PG training protocols (Table 2).

2.7.1. Randomized Trial Main Measures

Glycosylated hemoglobin (HbA1c): A blood sample extraction was carried out in the morning after an overnight fast to obtain HbA1c. The public health service of Extremadura established the protocol used for blood extraction and subsequent analysis.

Vibration perception threshold (VPT): The instrument Vibration II (Sensortek, In. Clifton, NJ, USA) was used. This device consists of a vibration control device and two vibration modules. The following elements are displayed on the controller: vibration amplitude, vibration regulator, and four different switches. Two of the switches were used to turn the equipment on and adjust the amplitude. A third switch was used to send the vibration amplitude to one module or the other, and the last switch serves as a decoy so that the evaluated person always hears the same sound from the switch, independently of whether the vibration amplitude is changed from one module to another.

Table 2. Assessment schedule for whole-body vibration group (WBVG) and placebo group (PG).

Assessment	Baseline	Acute Effects	Every Training Day	Month 2
Sociodemographic data	x			
Clinical data	x			
Applicability			x	
Safety			x	
Glycosylated hemoglobin	x			x
Incremental cost-effectiveness ratio				x
Anthropometric values				
Height	x			
Weight	x			x
Body Mass Index	x			x
Body composition				
Bioimpedance measurement	x			x
Muscular body percentage	x			x
Fat body percentage	x			x
Lipid profile				
Cholesterol (Total, HDL, and LDL)	x			x
Triglycerides	x			x
Other blood markers	x			x
Diabetic neuropathy				
Vibration perception threshold	x	x	x	x
Michigan neuropathy screening instrument	x			x
Neuropathy Symptoms Score	x			x
Monofilament exam	x			x
Exploration of the feet	x			x
Ankle–Brachial Pressure Index	x			x
Health-Related Quality of Life				
EQ-5D-5L	x			x
SF-12	x			x
15-D	x			x
Diabetes Quality of Life measure	x			x
Foot Health Status Questionnaire	x			x
Physical fitness				
Balance				
Romberg test open and closed eyes	x			x
Timed Up and Go test	x			x
Strength				
30-s Chair Stand Test	x			x
Level of physical activity	x			x
International Physical Activity	x			x

High-density lipoprotein (HDL), low-density lipoprotein (LDL).

Every vibratory module has dimensions of 12.5 × 8.5 × 23.5 cm. Modules can be easily recognized by a label that identifies them as module A or module B. Each module is placed on a carpet so that no vibration is transmitted through the floor and has a 1.5 cm diameter cylinder that protrudes to a height of 9.5 cm. It is on these modules that the person to be evaluated rests his or her big toe pads. Each cylinder vibrates at 120 Hertz, and the amplitude can be modified, being expressed as vibration units. Through the amplitude of the movement, the vibration units were obtained. To do this, the following equation was used: $A = x2/2$ (where A is the vibration amplitude expressed in the unit of measurement of microns (μ), and x is the unit of measurement previously mentioned, vibration unit (vu)).

The protocol used in this study is the *two-alternative forced choice procedure*, the use of which is proposed by the manufacturer of the device. In this protocol, the person being evaluated is asked to place their big toe pads on the cylindrical modules. Once this has been done, a random sequence with labels "A" and "B", provided by the manufacturer, is started in which the assessor alternates vibrating cylinder "A" or "B". The sequence always starts with a high amplitude so that the person being evaluated perceives there to be no problems. From this initial amplitude, we proceed to lower the amplitude by 10% whenever the participant is right, and with each change it is noted whether the person being evaluated is correct or not. If participants are not able to discern which cylinder is vibrating, or fail in their response, there is an increase in the amplitude of the vibration of 5%. The process is continued until the person makes 5 errors.

Once the evaluation process is completed, the VPT is calculated by averaging the last 5 hits and misses, eliminating the lowest hit and highest error. The VPT is the method of

calculating the average alpha-trimmed proposed by the manufacturer and which has been used in studies such as Deng et al. [15,33].

Incremental cost-effectiveness ratio: This variable was computed by dividing the difference between the average costs of each intervention by its effects on the patient's health, which was expressed as the difference in mean quality-adjusted life years (QALYs) gained in both WBVG and PG. Specifically, QALYs are calculated by multiplying life expectancy and participant's quality of life [34]. HRQoL was measured using the EQ-5D-5L questionnaire [17]. The algorithm proposed by the EuroQol group (http://www.euroqol.org/ (accessed on 19 January 2021)) was used to calculate the utilities needed for QALYs computations for every health status set. EQ-5D-5L utility index was computed using the "crosswalking" algorithm of the Spanish EuroQol levels. This utility index ranges from −0.654 (the worst health status, i.e., 55555) to 1 (the perfect health status, i.e., 11111).

2.7.2. Secondary measures

Sociodemographic Data

Persons with T2DM were inquired about personal information such as age, educational level, marital status, disease time of diagnosis, income, etc.

Clinical Data

Applicability: This variable was measured through the percentage of people who participated in and finished the study with its corresponding sessions. If any patient was unable to perform or complete the training program, the cause was written down.

Safety: No problems were recorded during the study, both in the measurements and in the research intervention.

Anthropometric Values and Body Composition

Height and bodyweight were assessed using a stadiometer (Seca 22, Hamburg, Germany). Body Mass Index (BMI) was calculated using the following equation: bodyweight (kg)/height^2 (m).

To evaluate body composition, a bioimpedanciometer Tanita Body Composition Analyzer (TANITA BC-418MA) was used.

Health-Related Quality of Life (HRQoL)

To measure health-related quality of life, we used the following questionnaires:

EQ-5D-5L questionnaire: The EQ-5D-5L is one of the most widely used questionnaires to assess health-related quality of life [17]. This tool is composed of 5 dimensions and a visual analog scale. The dimensions in this questionnaire are mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. For each of the dimensions, each participant has 5 response options, with the first one corresponding to the best health-related quality of life and the last one corresponding to the worst. Each answer option represents a number, with 1 being the best and 5 the worst. The combination of the 5 answers from each dimension will give a final score on the health-related quality of life that the respondent has. This score is computed through the official website of the EuroQol group (http://www.euroqol.org/ (accessed on 19 January 2021)). EQ-5D-5L utility index was calculated using the "crosswalking" algorithm of the Spanish EuroQol levels. This utility index ranges from –0.654 (the worst health status, i.e., 55555) to 1 (the perfect health status, i.e., 11111). The Visual Analogue Scale (VAS) is used as a quantitative health outcome that reflects the patient's self-perception.

SF-12 questionnaire: This instrument is an abbreviated version of the SF-36 questionnaire that consists of 12 questions. This questionnaire is composed of the following dimensions: physical function, physical role, body pain, general health, vitality, social function, emotional role, and mental health; and of two principal components: physical and mental. Both dimensions and components score from 0 (worst health state) to

100 (best health state). This instrument allows the obtainment of a utility index from the SF-6D, which is also ranged from 0 (worst health state) to 100 (best health state) [35].

15-D questionnaire: This is a 15-dimensional questionnaire that includes five different degrees of answer. The final score of this questionnaire ranges from 0 (worst possible quality of life) to 1 (best possible quality of life) [19,36].

Diabetes Quality of Life (DQoL) Measure

The DQoL consists of a 46-item questionnaire that contains four subscales: satisfaction (15 items), impact (20 items), social/vocational worry (7 items), and diabetes-related worry (4 items). Responses are rated according to a 5-point Likert scale, where satisfaction is scored from 1 (very satisfied) to 5 (very dissatisfied). Likewise, impact and worry scales are ranged from 1 (no impact or never worried, respectively) to 5 (always impacted or always worried, respectively) [20].

Foot Health Status Questionnaire (FHSQ)

The FHSQ [21] is a 3-section questionnaire that evaluates the health status of the foot. The first section (13 items) evaluates four dimensions (foot pain, foot function, shoes, and general foot health). The second section (20 items) evaluates another four dimensions (general health, physical activity, social capacity, and vigor). The two sections are evaluated through questions using a Likert-type scale from 0 (worst result) to 100 (best possible result). The remaining section consists of sociodemographic questions. This questionnaire has been translated and adapted to Spanish [37].

Lipid Profile

Through a fasting blood test, the following parameters were analyzed: triglycerides, total cholesterol, high-density lipoprotein (HDL), and low-density lipoprotein (LDL).

Physical Fitness
Balance

Romberg test open and closed eyes: It is an appropriate, accurate, and sensitive tool for measuring the degree of instability caused by central or peripheral vertigo and head trauma [38]. Patients start in a standing position with both feet together. They should cross their arms or hold them close to their body and try to maintain their balance. Participants performed this test with open and closed eyes. This test is scored by counting the seconds for which participants can maintain the standing position with eyes closed. If the patient is unable to maintain balance with eyes closed, the test outcome is positive. Losing balance is considered to be when the participant moves their body away, placing one foot in the direction of a fall, or even falling.

Timed Up and Go Test (TUG): There are different versions of this test, whose main difference is the covered distance [39–41]. In this study, participants performed the 3-m version of TUG [40]. Participants should start from a seated position with their arms and trunk supported on the chair. Then, they should stand at the "go" signal and walk forward for 3 m, turn 180°, and walk back to sit on the chair again. The test was carried out twice, with 1-min rest between trials. The performance was measured as the time used by the participant from the standing start movement until sitting on the chair again with trunk supported. The best outcome was selected for analysis.

Strength

30-s Chair Stand Test: This test was used to evaluate the participant's strength. This test evaluates how many times a subject is able to get up and down from a chair for 30 s. Patients must maintain their back straight, feet supported, and not pushing with the arms during the test [42].

Diabetic Neuropathy

This measurement was evaluated by a combination of the following instruments:

Michigan Neuropathy Screening Instrument (MNSI): This instrument consists of 15 "yes or no" questions that reflect common symptoms of DM (foot sensation, general asthenia, peripheral vascular disease, non-neuropathic symptoms, and vascular indicators). This questionnaire is accompanied by a brief clinical examination that includes: (1) foot deformities inspection, dry skin, callus, infection, or ulceration; (2) semiquantitative assessment of vibration sensation at the dorsum of the big toe (normal, reduced, or absent); (3) grading of ankle reflexes (normal, reduced, or absent). The degree of abnormality is determined by the number of positive responses and the presence of abnormal clinical findings. The higher the score is, the more severe the neuropathy is [43].

Neuropathy Symptom Score (NSS): This tool is a 4-item symptom score that reliably forecasts the existence of polyneuropathy in diabetes [44]. The assessed symptoms are unsteadiness in walking, neuropathic pain, paraesthesia, and numbness. The presence of one of them is scored as 1 point. A score ≥ 1 is considered polyneuropathy existence.

Monofilament exam: It is an inexpensive, non-invasive, and easy-to-use test that allows an evaluation of the loss of protective sensation and the nerve sensitivity to detect vibration and changes in temperature. This exam has been highly recommended to detect peripheral neuropathy in otherwise normal feet [44,45]. A filament is usually placed on the patient's foot skin. If the participant cannot detect the presence of this filament at buckling, this is considered loss of sensation.

Exploration of the feet: This measure includes a dermatological and musculoskeletal exam of the patient's feet and an evaluation of neuropathic and vascular symptomatology. The risk of ulceration is classified based on IWGDF6: 0 = "without risk" (no presence of peripheral neuropathy or foot deformity); 1 = "slight risk" (presence of peripheral neuropathy and/or deformity); 2 = "moderate risk" (additionally, peripheral vascular disease is present); and 3 = "high risk" (presence of ulcer or amputation antecedents) [44–46].

Ankle–Brachial Pressure Index (ABPI)

It is a simple method to screen peripheral arterial disease and evaluate cardiovascular prognosis. ABPI thresholds <0.9 or >1.3 points are highly suspicious for peripheral arterial disease and high cardiovascular risk in DM patients [47].

Level of Physical Activity

International Physical Activity Questionnaire Short Form (IPAQ-SF): It is a 9-item questionnaire, which was developed to simplify the surveillance of physical activity according to a global standard [48] and records the activity at four intensity levels: (1) vigorous-intensity activity (e.g., aerobics); (2) moderate-intensity activity (e.g., leisure cycling); (3) walking; (4) sitting. The "last 7-day recall" version of IPAQ-SF is recommended for physical activity surveillance studies [48].

Test Familiarization and Reliability

Prior to the assessment session, participants performed a standardized warm-up where the procedures were explained to them, which included a specific test trial before the recorded attempt.

Inter-session reliability of VPT was evaluated by repeating the tests one week before evaluating the baseline with participants.

2.8. Statistical Analysis

The mean (±SD) was calculated to represent the characteristics that the participants possessed at the baseline. The analyses that were carried out in the study were the following: (1) intention-to-treat analysis (including all participants), and (2) per-protocol analysis (only with participants who completed intervention and assessments). The following will explain what each type of analysis consisted of:

Intention-to-treat analysis: With this type of analysis, the aim is to make calculations considering all the participants, who were assigned at random. Multiple imputations were applied to impute lost data. A repeated-measures ANCOVA test, with age and baseline values as covariates, was applied to analyze the intervention effects on the different dependent variables assessed. Both statistical significance and effect size (95% confidence interval) were included in the study (group $\times$ time). This was calculated taking into account both interaction effects and time. To define statistically significant differences, the *p*-value was set at below 0.05. On the other hand, sensitivity analyses were performed. This was based on the baseline data of the participants who completed the study in its entirety, to avoid estimation biases.

Per-protocol analysis: This analysis included the same procedures as described above but considering only those participants who completed at least 75% of the sessions.

2.9. Cost-Effectiveness Analysis

To carry out the cost-utility analyses, the guidelines and methodological recommendations of different health economists were followed.

The study was developed considering the direct costs (i.e., medication, primary care visits, and hospital admissions) and health effects of WBV training on HRQoL. Furthermore, the salary of the person hired to perform the intervention was determined in agreement with the set-out guidelines, based on the corresponding collective bargaining. The costs of the necessary material for WBV training implementation were also considered.

First, each group's average costs and effectiveness were calculated as the QALYs earned. Then, the incremental cost-effectiveness ratio was computed. Also, we performed different sensitivity analyses, including a probabilistic analysis done with 1000 repetitions. These outcomes were included in the cost-effectiveness plane, and the acceptability curve was made. Thus, it could be observed which quadrant of the cost-effectiveness plan occupied the WBV training intervention. This outcome indicated if the WBV training had been more costly and effective than the intervention made by the control group (usual care).

3. Discussion

This project aimed to investigate the effects of WBV training on HbA1c, vibration threshold, and incremental cost-effectiveness ratio in T2DM patients. Additionally, this study had as its secondary aim to evaluate the impact of WBV on the body composition, HRQoL, balance, strength, blood pressure, lipid profile, and diabetic neuropathy of participants.

To the best of our knowledge, this was the first study that analyzed the cost-effectiveness of a WBV intervention in T2DM patients including a WBV group and placebo group. There was a study that performed a cost-effectiveness analysis after a physical exercise intervention on the WBV platform [49]. In this article, it was found to be cost-effective, comparing the intervention with standard care. It cannot be determined if the effects produced were due to vibration, physical activity, or mixed therapy, since the control group received the usual care, without adding the physical activity performed by the exercise group on the platform. The main reason for this is the fact that physical exercise was performed while the vibration was taking place. Therefore, this was the first cost-effectiveness study that investigated a WBV intervention in T2DM patients.

4. Conclusions

This research investigated the effects of a WBV program on HbA1c, vibration threshold, and incremental cost-effectiveness ratio in type 2 diabetes patients. Moreover, this study investigated the impact of WBV on the body composition, HRQoL, balance, strength, blood pressure, lipid profile, and diabetic neuropathy of patients.

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