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# Highlights

- Whole Body Vibration (WBV) has been exhibited to be effective as a co-adjuvant treatment for type 2 diabetes patients (T2DM) patients in primary care.
- There are no published studies on the cost-effectiveness assessment of WBV in primary care.
- The randomized controlled trial reports the cost-effectiveness of a 12-week WBV.
- In the base-case analysis, whole body vibration has been shown to be cost-effective as co-adjuvant when compare with the standard care alone in T2DM patients.
- The robustness of the cost-utility analysis was confirmed with two other possible scenarios.
- The results from this report could help in the decision process of adding this therapy to the standard care for people who suffer from type 2 diabetes. Q1



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Short Communication

# Cost-utility analysis of a 12-week whole-body vibration based treatment for people with type 2 diabetes: reanalysis of a RCT in a primary care context

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## Introduction

Along with nutrition, exercise has long been recognized as a cornerstone for Type 2 Diabetes (T2DM) management in both primary and secondary prevention. Whole-body vibration (WBV) training, a relatively new exercise modality, has been previously tested in different clinical populations with promising results. One of the strengths of this exercise modality is the reduced time and conscious process required to be applied. The research group has previously demonstrated that the addition of a short-term (i.e. 12-wk) WBV-based therapy in a primary care context is feasible, safe and effective to clinically reduce HbA1c and fasting blood glucose, and to improve cardiovascular risk factors in previously sedentary people with T2DM.[1]

Nonetheless, these programs must be considered under limited health system resources. Policy makers frequently select the treatment strategies based on their cost per quality of life-adjusted life-year (QALY), called cost-utility, representing the ratio of the QALYs gained divided by incremental cost of the new treatment compared to another (e.g. standard care). Cost-utility analysis allows health interventions, within and across health care programs, to be compared in terms of their cost and the number of QALYs they offer, thereby permitting finite health care resources to be allocated on a utilitarian 'cost per QALY gained' basis.

Different lifestyle modification programs have showed an acceptable cost-utility ratio.[2,3] Also exercise, resistance, aerobic or combined has showed to be cost-effective among T2DM patients after six month.[4] Unfortunately, there are no studies analysing the cost-effectiveness of WBV-based exercise programs for patients with T2DM. Researchers therefore aimed in this report to conduct an economic evaluation of the

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addition to the standard care of a 12-week of a WBV therapy for sedentary older adults with T2DM. In doing so, the data from a previous randomized controlled trial have been used.[1]

The study procedures are described elsewhere.[1] 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. Fifty patients fulfilled the inclusion/exclusion criteria[1] and were allocated at random to one of the two study group (intervention or control). Participants in both the intervention and control groups had access to the standard care (consisting on outpatient visit for the control of the diabetes-related parameters and on giving advices to improve it – i.e. healthy lifestyle advice including exercise and diet). Participants in the intervention group participated in a 12-week WBV-based program on an oscillating platform (Phyisio Wave 700, Globus, Italy) consisting of three sessions per week with at least one day between sessions. Each exercise session was performed with a frequency ranging from 12 Hz (first month) to 16 Hz (last month) and a peak-to-peak displacement of 4 mm that 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 eight 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. The duration of the sets was progressively increased (30–60 s) with rest periods of 30 s. More details about the performed WBV-based exercise program are published elsewhere.[1]

## Cost-utility analysis results

The 6-dimensional Short-Form 6D (SF-6D) utility index[5] was calculated according to the Spanish tariff proposed by Abellán-Perpiñán et al.[6] Unit costs of the intervention were also recorded. Since societal costs could be considered insignificant for this trial (all participants lived around the area where the intervention was performed and the time for training was of convenience for participants), the chosen perspective for the economic analysis was the health system perspective. Costs in this study were focused on the duration of the program (three months) so no adjustment or discounting was made. No extra costs were computed for room facilities (as the room was facilitated by the primary care center) and no extra costs were computed for recruiting participants (as practitioners did not need any extra time to do it). No further costs from consultation or medication were computed as no statistically significant differences were found between groups. Costs were therefore recorded in Euros based on the salary of the technician for the three months period (i.e. €1800) and the price of the vibratory device (i.e. €5000).

SF-6D utility index was transformed in QALYs by using the area under the curve method.[7] The incremental cost-effectiveness ratio (ICUR) was calculated as the incremental cost of WBV intervention divided by the difference in QALYs between the groups. The 95% confidence interval of incremental QALYs between groups and ICUR were calculated using non-parametric bootstrapping technique and plotted a cost effectiveness acceptability curve with the main aim of calculating the probability that the intervention is cost effective.[8] Although there is not an official cost per QALY threshold in Spain (i.e. a cut-off point below which a health technology represents good value for money), empirical estimations range from €6985 to €53,454/QALY,[9–11] so it has been decided to take the midpoint €23,235 as the benchmark according to which assessing whether the treatment is cost-effective or not.

In the trial, the mean incremental cost per participant was €272 [i.e. intervention group incremental cost (€6800) divided by the number of participants allocated to the intervention group ($n = 25$)]. The incremental QALY was 0.075 (95%CI 0.006–0.10) in favour of the intervention group. The ICUR was therefore 3626.661 (95%CI 2247.933 to 12952.381). Additionally, two sensitivity analyses were performed assuming the following: a) sport technician salary 30% lower and 30 participants in the intervention (best case scenario) and b) sport technician salary 30% higher and 15 participants in the intervention (worst case scenario). The estimated cost utility ratios were €3226.667/QALY of the best scenario and €7413.334/QALY of the worst scenario. The cost-effectiveness acceptability curve (Fig. 1) showed 99% probability that the addition of the WBV-based program to the standard care is an acceptable strategy if the celling of inversion is €23,235/QALY.

The current study is, to the knowledge, the first cost-utility analysis of a WBV-based exercise program for type 2 diabetes patients in a primary care context. In a previous report on the original randomized controlled trial[1] it have been shown that this therapy is effective to improve the functionality and the illness process among a group of volunteers with type 2 diabetes. The main findings of the current analysis of the trial were that the intervention was cost-effective in terms of cost per QALYs when compared with the standard care.

The current study shows 99% of probability of cost-effectiveness using €23,235 per QALY as a threshold. This intervention would be cost-effective even using other commonly threshold used in the Western countries and Unites States. Moreover, the calculated gained QALYs of 0.075 with WBV-based therapy in addition to the standard care as compared with only the standard care was acceptable in comparison with the threshold for minimally important differences (i.e. 0.011–0.097 QALY).[12]

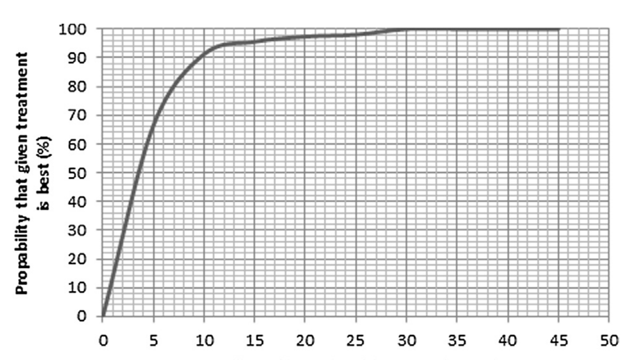


**Fig. 1 – The cost-effectiveness acceptability curve.**

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Extensive sensitive analysis showed that the above commented findings were robust under different assumptions regarding the salary of the sport technician and the people enrolled in the program. When the best scenario was simulated a more attractive incremental cost-utility ratios was achieved. On the other hand, when the worst case scenario (sport technician salary 30% higher and 15 participants in the intervention) was assumed the intervention was still shown to be cost-effective.

In conclusion, the current study shows that the addition of a short-term (i.e. 12-wk) WBV-based exercise program to the standard care is cost-effective as compare with the standard care. Future studies are warranted to confirm the long term effectiveness and cost-effectiveness of this kind of therapies among type 2 diabetes patients.

## Implications for practice

The current study has several implications for diabetes education and health promotion programs. Exercise has been extensively reported as key component in the treatment of diabetes. Nonetheless, these programs must be considered under limited health system resources. This study demonstrates that a WBV-based therapy in a primary care context is cost-effective. The exercise programme showed here could be directly applied in other primary care facilities. Therefore, the results from this report could help in the decision process of adding this therapy to the standard care for people who suffer from type 2 diabetes.

## Author statements

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### *Ethical approval*

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.

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None declared.

### *Competing interests*

The authors declare that they do not have any conflict of interests.

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