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Effect of the Combined Intervention with Passive Whole-Body Vibration and Auriculotherapy on the Quality of Life of Individuals with Knee Osteoarthritis Assessed by the WHOQOL-Bref: A Multi-Arm Clinical Trial

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Abstract: The aim of this study was to determine the effect on the quality of life of two non-pharmacological interventions isolated or in combination: (i) passive whole-body vibration exercise (WBVE), and (ii) auriculotherapy (AT). One hundred three participants with knee osteoarthritis

(KOA) were allocated to: (a) a vibration group (WBVEG; n = 17) that performed WBVE (peak-to-peak displacement: 2.5 to 7.5 mm, frequency: 5 to 14 Hz, Peak acceleration: 0.12 to 2.95 g), two days/weekly for five weeks, (b) an AT group (ATG; n = 21), stimulation of three specific auriculotherapy points (Kidney, Knee and Shenmen) in each ear pavilion, (c) WBVE + AT (WBVE + AT; n = 20) and (d) respective control groups (WBVE_CG, n = 15; AT_CG, n = 12; WBVE + AT_CG, n = 18). The participants filled out the WHOQOL-bref Questionnaire before the first and after the last sessions. Statistical differences in the various domains of the WHOQOL-bref were not found. In conclusion, WBVE or AT alone or combined did not contribute in altering the quality of life of individuals exposed to these interventions.

Keywords: mechanical vibrations; auriculotherapy; quality of life; knee osteoarthritis

1. Introduction

Osteoarthritis is the most common joint disorder, whose prevalence increases with age [1]. It is considered a high relevant cause of disability with a high socio-economic impact [2] and the knees are the most affected joints [3]. The main symptoms of knee osteoarthritis (KOA) include, among other, pain, deformation and loss of function [4,5], which may influence the quality of life and the professional work [5,6]. Araújo et al., reported that KOA has a strong negative impact on the daily living activities of the individuals, such as climbing stairs, walking or squatting activities [7,8] leading to an elevated risk for disability. Moreover, these physical manifestations of KOA have a direct impact on wellbeing, including social interactions, mental functioning, and sleep quality [8].

The management of KOA includes a wide range of pharmacological (i.e., paracetamol or non-steroidal anti-inflammatory drugs) and non-pharmacological therapeutic modalities (i.e., lifestyle changes or exercise) or even invasive interventions, such as surgery [9,10].

There is evidence highlighting the effectiveness of physical exercise in reducing pain and improving function in KOA individuals [9,11], but, and due to the aforementioned limitations in daily activities, most of these individuals usually report restrictions in exercising and they use alternatives that allow mitigating their symptoms. Acupuncture [12] and auriculotherapy or ear acupuncture (a type of acupuncture) (AT) are Traditional Chinese Medicine procedures [13–15] and a relatively recent type of exercise, whole-body vibration exercise (WBVE) [12,16–18], have been successfully used to improve clinical conditions of the KOA individuals [19].

Parameters must be considered in the WBVE protocols [20–24] (e.g., frequency, peak-to-peak displacement–D, acceleration peak-a_{Peak}, position, work and rest time and number of bout and sessions). Studies reported improvements in various clinical manifestations related to KOA after WBVE [23,25,26], including the decrease of pain levels, improvements of muscle strength and flexibility, and reduction of number of falls [27–32].

On the other hand, AT is a technique based in stimulation of points (acupoints) located on the ear. In general, AT involves the stimulation of the "corresponding region" (related to the organic dysfunction) and other points related to the clinical conditions [15]. AT has beneficial effects on the pain management [33,34]. Moreover, Li et al., reported improvements on the quality of life after AT in older adults [35]. Yeh et al., showed that acupressure (manual pressure—similarly to seeds) applied at the acupoints of shenmen, sympathesis, kidney, liver, heart, and subcortex was able to improve the physical pain and mental health dimensions of the SF-36 quality of life questionnaire in hypertensive individuals [36].

In view of these arguments, both therapies isolated could have a positive effect, especially on the pain level and quality of life of KOA individuals; however, to our knowledge, only one recent study has combined both therapies to assess their effect in this population group [19]. Authors suggested that these interventions could reduce the pain [19]. Neto et al., used a position where the KOA individuals

remained sitting on a chair with the feet on vibrating platform (VP) base during WBVE and they found a decrease of pain level [19]. This position can be considered a passive WBVE.

Considering the two therapies (WBVE and AT), in the management of KOA and the lack of evidence in this population, the aim of this study was to evaluate the effectiveness of both interventions alone or combined. It is hypothesized that the combination of both interventions (WBVE and AT) would have additional benefits when each one of the isolated interventions were performed on the physical health domain of the quality of life as assessed by the WHOQOL-bref in KOA individuals.

2. Methods

2.1. Individuals and Ethics Committee

Ethics Committee in Research of the Hospital Universitário Pedro Ernesto (HUPE), Universidade do Estado do Rio de Janeiro (UERJ) (Certificado de Apresentação para Apreciação Ética—CAAE-19826413.8.0000.5259) (Registro Brasileiro de Ensaios Clínicos—REBEC: RBR-7dfwct) has approved this work.

2.2. Sample Size

The sample size was determined using the formula $n = [(Z\alpha/2\delta)/E]^2$, where, n = sample size; $Z\alpha/2$—critical value for the degree of confidence, usually: 1.96 (95%); δ—population standard deviation of the variable; E—standard error, usually: ±5% of proportion of cases (absolute precision) or ±5% of the mean [37]. Ten individuals were thus chosen for each group, considering the values (mean ± SD) reported in a previous study that assessed the QoL of individuals with osteoarthritis [38]. Considering a possible decrease in sample size, one hundred and three subjects with KOA diagnosis were recruited (January 2014 to December 2017). The subjects were referred by a clinical physician of the Orthopedics Department of the HUPE/UERJ.

2.3. Inclusion and Exclusion Criteria

As inclusion criteria, the subjects should be ≥40 years old, with clinical diagnosis of KOA (determined by the Ahlback system) [39]. As exclusion criteria, the subjects could not present other musculoskeletal disorders, neurological diseases and no treated hypertension. Those participants that declined to sign the informed consent were also excluded.

2.4. Intervention and Control Groups

Eligible participants (n = 103) were allocated, in order of arrival, by researcher to six groups: (a) WBV group (WBVEG, n = 17), (b) AT group (ATG, n = 21), (c) combined group (WBVE + AT, n = 20), and their respective control group (CG): (d) WBVE_CG (n = 15), (e) AT_CG (n = 12) and (f) WBVE + AT_CG (n = 18), respectively. The individuals were admitted to the study and sent to the group where there were fewer participants. The study can be considered blind because the questionnaire used to assess quality of life (WHOQoL-bref) is self-administered. Furthermore, the participants did not know if they were participating in the CG. After each intervention, it was asked the participants about some discomfort (headache, dizziness, itching, level of pain) as side effect in comparison with the pre intervention condition."

2.5. Passive Whole-Body Vibration Intervention

Protocol was delivered 2 days/weekly (5 weeks) with, at least, 48 h of rest between each passive WBVE session. The subjects were positioned sitting in a chair in front of an side alternating VP (Novaplate Fitness Evolution, DAF Produtos Hospitalares Ltda, São Paulo, Brazil) with a comfortable flexion of knees (approximately 130° knee flexion) and the feet with no shoes (barefoot) on the its base (D of 2.5, 5.0 and 7.5 mm). Their hands were conveniently in contacting with their knees to facilitate the transmission of the mechanical vibration to the whole body (Figure 1A). The individuals performed

one bout of 3 min (work time) in each *D*, and a one-minute rest (rest time) between the bouts (Figure 1B). The frequency daily increased of 1 Hz, from 5 up to 14 Hz (a_{Peak} = 0.12 to 2.95 g) [19] (Figure 1C). The vector sum of the accelerations was measured using a 3-axial accelerometer (Vibration Data logger DT-178A, Ruby Electronics, Saratoga, NY, USA). The subjects of the control group (pWBV_CG) were exposed to the same protocol but with no vibration on the VP (VP turned off).

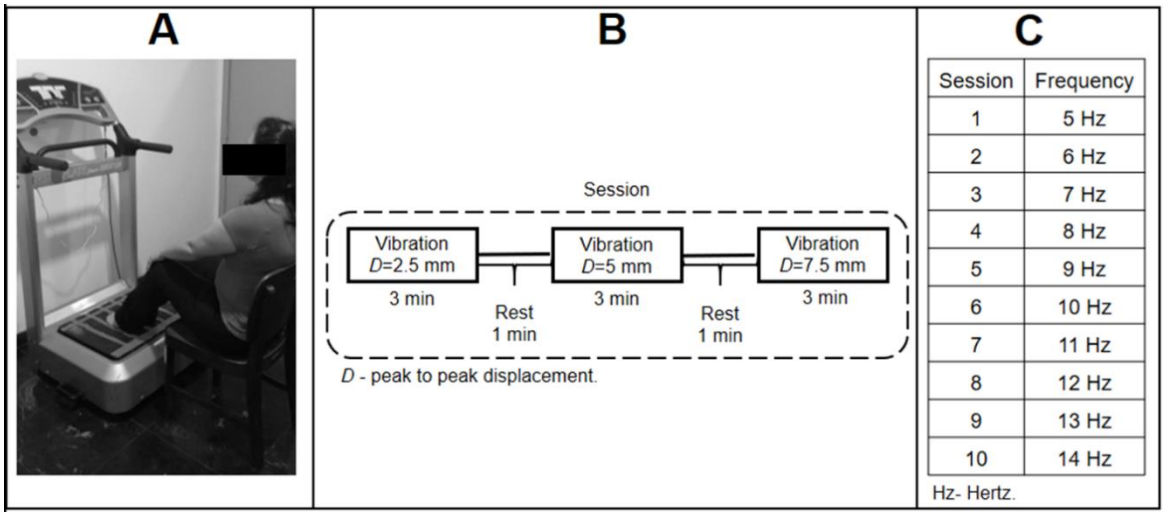

Figure 1. Passive whole-body vibration intervention. (**A**), Subject positioned sitting in a chair in front of an side alternating vibrating platform; (**B**), one bout of 3 min (work time) in each D, and a one-minute rest (rest time) between the bouts; (**C**), The frequency daily increased of 1 Hz, from 5 up to 14 Hz.

2.6. Auricular Intervention

In the auricular intervention (ATG), regions (auriculotherapy points—Knee, Kidney and Shenmen) of the ears of the participants were stimulated with two seeds (*Semen vaccariae*) fixed by adhesive tapes [15]. The location of these auriculotherapy points, the characteristics of the adhesive tapes and their preparations were previously described in detail by Neto et al. [19]. The "knee joint" point is located at the superior crus of the antihelix, at the same level of the superior border of the inferior crus of the antihelix. The "Shenmen" point is located at the bifurcation of the crura of the antihelix. The "kidney" point lies in the upper part of the cymba conchae at the superior portion of the acupuncture point of the small intestine (Figure 2) [40–42]. The auriculotherapy points were visually located by a professional specialized in Traditional Chinese Medicine. Similarly, in the control group, adhesive tapes without seeds were put on the lobe. The individuals submitted to the AT were provided instruction to the treatment and they were instruct to press with fingers the adhesive tapes for 10 min, three times per day (six days) and to remove them one day (the seventh day) before returning to the next intervention.

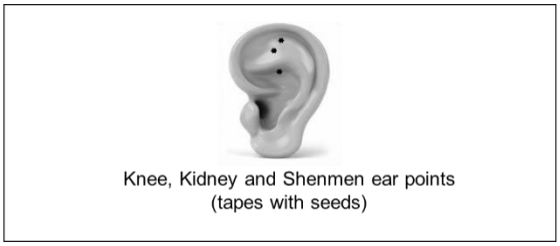

Figure 2. Auricular intervention.

2.7. Combined Intervention

The participants of the combined intervention (WBVE + AT) and the respective control group were simultaneously submitted to both interventions (WBVE and AT interventions) as illustrated in Figure 3.

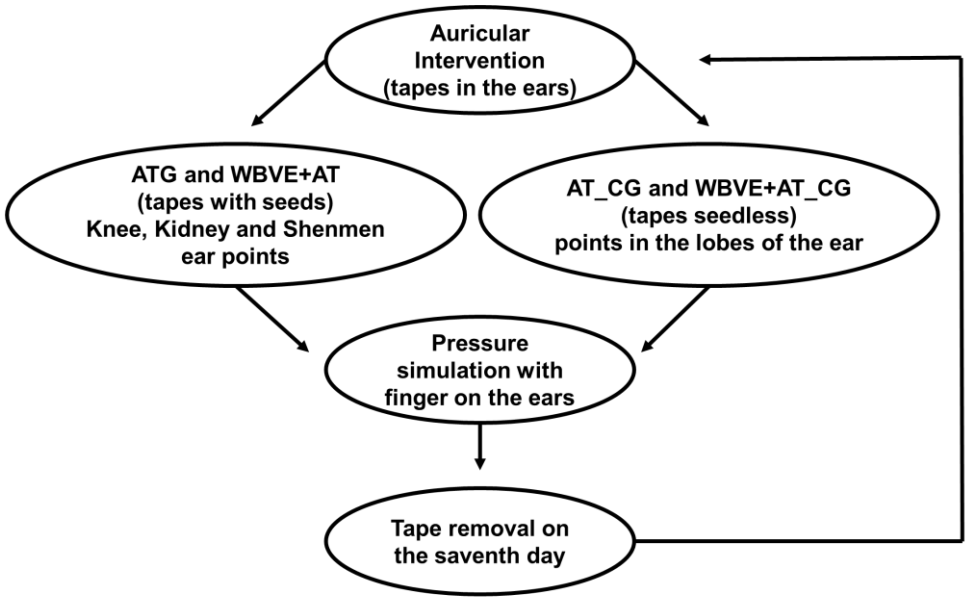

Figure 3. Combined intervention.

3. Outcome Measures

The WHOQOL-bref questionnaire, that consisted of four domains (physical health, psychological health, social relationships, and environment) and two items concerning overall quality of life and general health, was used to evaluate the effects of the interventions on the quality of life. These two items were not included in the calculation of the scores in each domain. The response scales, all five-point Likert type ranging from 1 (not at all/never/very dissatisfied/very poor) to 5 (extremely/always/very satisfied/very good) [43]. Each participant fulfilled the WHOQOL-bref before the first and after the last session of each type of intervention.

Statistical Analysis

The statistical analyses were performed using BioEstat for Windows (versão 5.3, Instituto de Desenvolvimento Sustentável Mamirauá, Belém, para, Brazil). Statistical normality of the data was examined with the Shapiro-Wilk test. $p < 0.05$ was considered statistically significant. The nonparametric Wilcoxon Signed-Rank test was used to compare the means before and after each intervention and the Mann-Whitney test were used to analyze inter-group differences (control groups X interventions groups). Kruskal-Wallis test was used to analyzed the difference between interventions groups.

4. Results

The anthropometric characteristics of the participants are shown in Table 1. Of the 103 participants enrolled, eighty-one participants attended more than 80% of the sessions and performed all assessments. In general, the number of individuals excluded was about the same in each group. The reasons were: (i) the wrong filled of some questions of the WHOQOL-bref questionnaire (15 individuals); (ii) withdrawal due to illness (1 individual with pneumonia and 2 with Chikungunya who show

symptoms similar to osteoarthritis) and (iii) three subjects abandoned the treatment (Figure 4). All participants who answered the questionnaire correctly were included in the analysis.

Table 1. Anthropometric characteristics of the participants.

Subjects (n = 103)	Mean (SD)
Age (years)	65 (8)
Body mass (kg)	85.65 (13.46)
Height (m)	1.57 (0.07)
BMI (kg/m^2)	34.27 (7.99)

SD—standard deviation, BMI—body mass index.

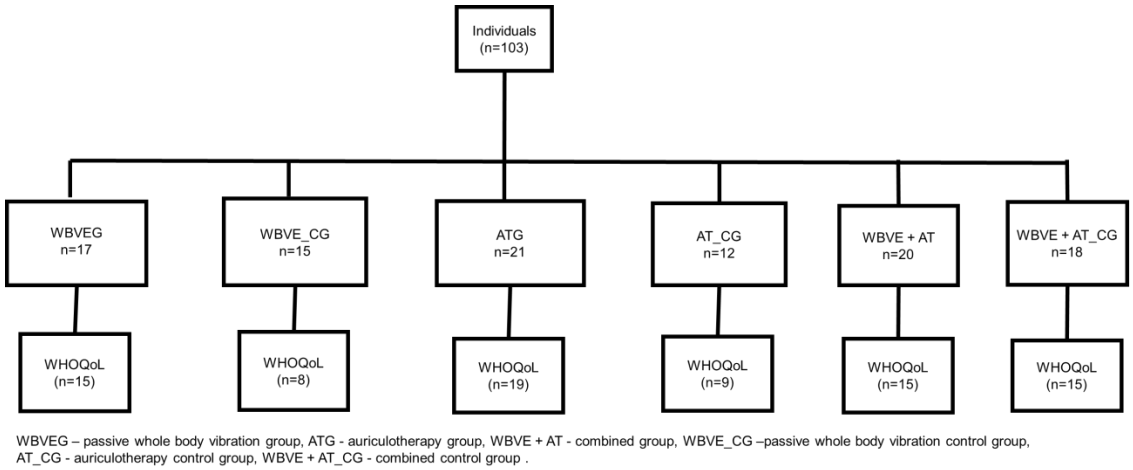

Figure 4. Flowchart with information about the subjects that performed each group.

Figures 5–8 show the effect of the different interventions on individuals' quality of life measured using the WHOQOL-bref questionnaire in their four domains (physical, social, psychological and environmental).

Figure 5A–C show the effect of interventions on the quality of life of individuals as measured by the WHOQOL-bref questionnaire in the physical domain. No significant between-groups differences in the physical domain (p = 0.83) was observed. Figure 5A shows the comparison between the beginning (before) and the end (after) of the protocol in the control groups: ATG_CG (p = 0.24), WBVEG_CG (p = 0.75) and WBVE + ATG_CG (p = 0.51). Figure 5B shows the comparison between the beginning (before) and the end (after) of the protocol in the intervention groups: ATG (p = 0.53), WBVEG (p = 0.22) and WBVE + ATG (p = 0.28). Figure 5C shows the comparison of the treated group with their respective controls in each one of the interventions: ATG_CG × ATG (p = 0.20), WBVEG_CG × WBVEG (p = 0.99) and WBVE + ATG_CG × WBVEG + AT (p = 0.71).

Figure 6A–C show the effect of interventions on the quality of life of individuals as measured by the WHOQOL-bref questionnaire in the social domain. No significant between-groups differences in the social domain (p = 0.19) was observed. Figure 6A shows the comparison between the beginning (before) and the end (after) of the protocol in the control groups: ATG_CG (p > 0.99), WBVEG_CG (p = 0.96) and WBVE + ATG_CG (p = 0.33). Figure 6B shows the comparison between the beginning (before) and the end (after) of the protocol in the intervention groups: ATG (p = 0.72), WBVEG (p = 0.14) and WBVE + ATG (p = 0.59). Figure 6C shows the comparison of the treated group with their respective controls in each one of the interventions: ATG_CG × ATG (p = 0.35), WBVEG_CG × WBVEG (p = 0.48) and WBVE + ATG_CG × WBVEG + AT (p = 0.65).

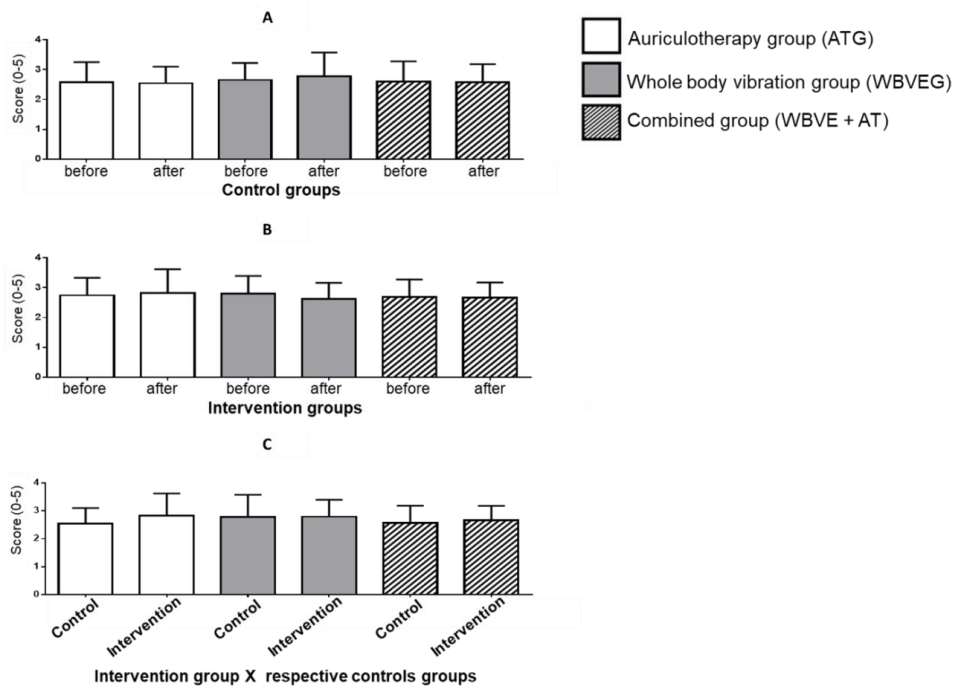

Figure 5. Effect of interventions on the physical domain of the WHOQOL-bref questionnaire. (**A**)—comparison between the beginning (before) and the end (after) of the protocol in the control groups of the interventions. (**B**)—comparison between the beginning and the end of the protocol in the groups submitted to the interventions. (**C**)—comparison of the treated group with their respective controls in each one of the interventions.

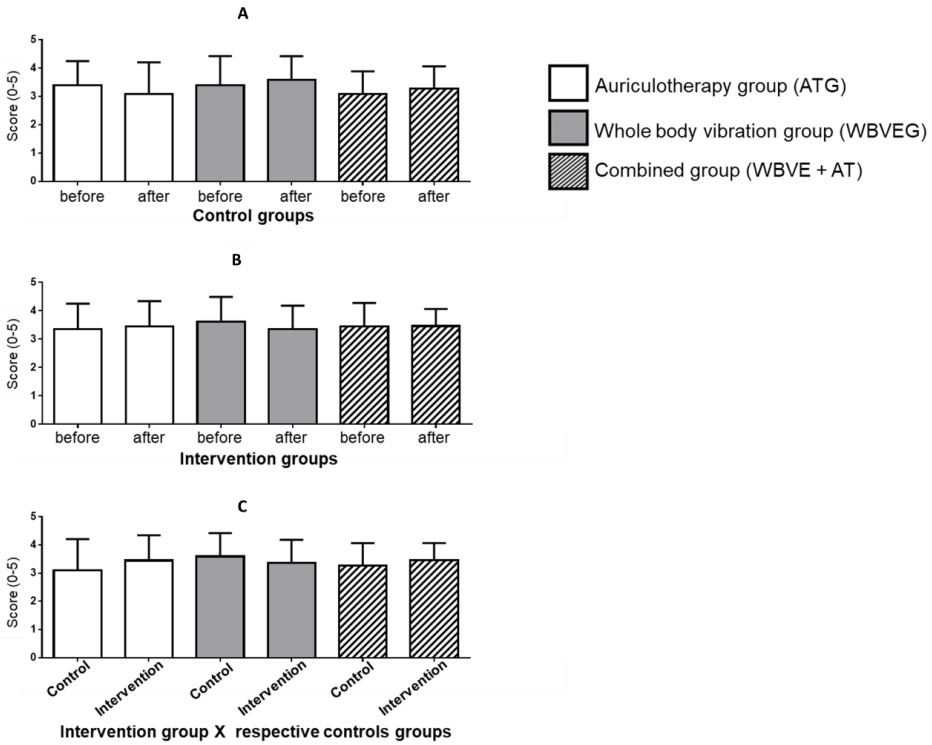

Figure 6. Effect of interventions on the social domain of the WHOQOL-bref questionnaire. (**A**)—comparison between the beginning and the end of the protocol in the control groups of the interventions. (**B**)—comparison between the beginning and the end of the protocol in the groups submitted to the interventions. (**C**)—comparison of the treated group with their respective controls in each one of the interventions.

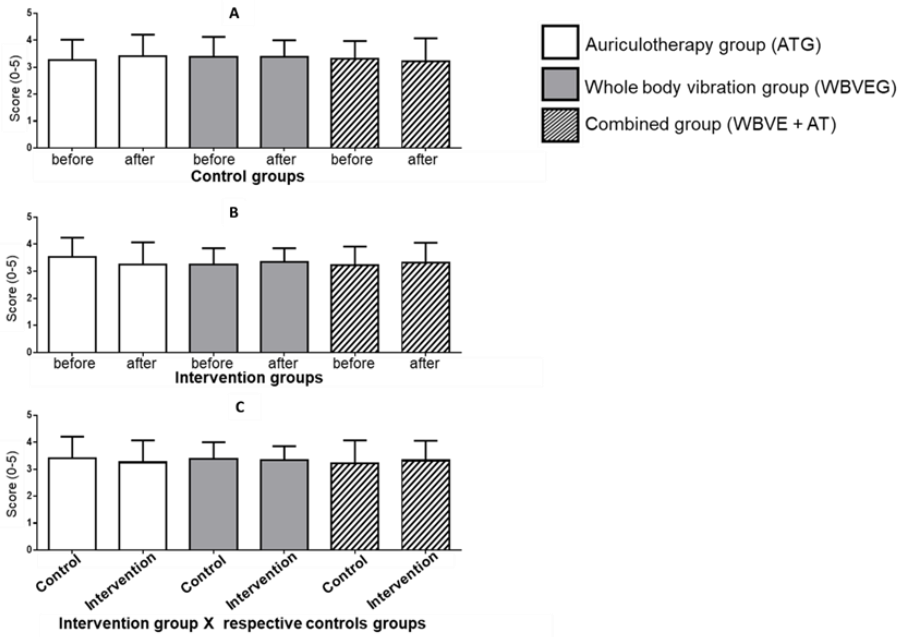

Figure 7. Effect of interventions on the psychological domain of the WHOQOL-bref questionnaire. (**A**)—comparison between the beginning and the end of the protocol in the control groups of the interventions. (**B**)—comparison between the beginning and the end of the protocol in the groups submitted to the interventions. (**C**)—comparison of the treated group with their respective controls in each one of the interventions.

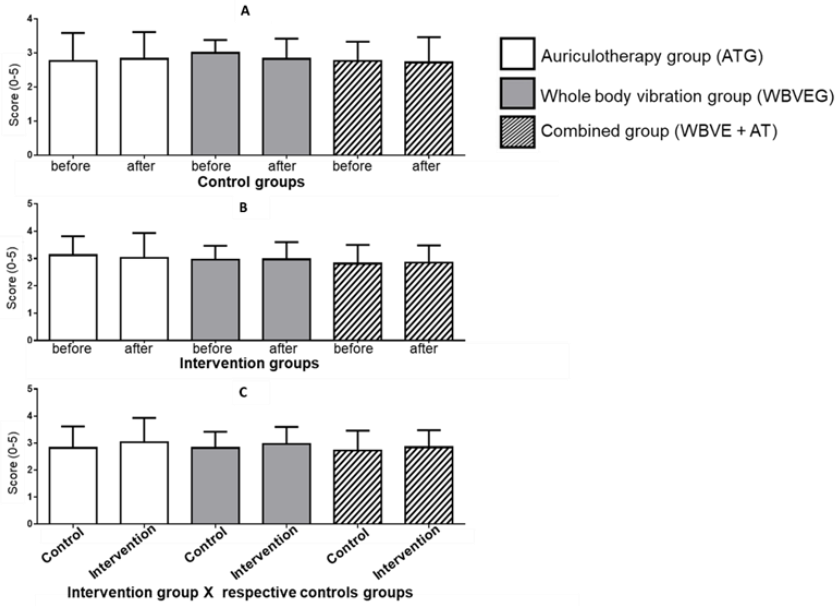

Figure 8. Effect of interventions on the environmental domain of the WHOQOL-bref questionnaire. (**A**)—comparison between the beginning and the end of the protocol in the control groups of the interventions. (**B**)—comparison between the beginning and the end of the protocol in the groups submitted to the interventions. (**C**)—comparison of the treated group with their respective controls in each one of the interventions.

Figure 7A–C show the effect of interventions on the quality of life of individuals as measured by the WHOQOL-bref questionnaire in the psychological domain. No significant between-groups differences in the psychological domain ($p = 0.26$) was observed. Figure 7A shows the comparison between the beginning (before) and the end (after) of the protocol in the control groups: ATG_CG

(p = 0.14), WBVEG_CG (p = 0.87) and WBVE + ATG_CG (p = 0.47). Figure 7B shows the comparison between the beginning (before) and the end (after) of the protocol in the intervention groups: ATG (p = 0.10), WBVEG (p = 0.48) and WBVE + ATG (p = 0.72). Figure 7C shows the comparison of the treated group with their respective controls in each one of the interventions: ATG_CG × ATG (p = 0.38), WBVEG_CG × WBVEG (p = 0.80) and WBVE + ATG_CG × WBVEG + AT (p = 0.87).

Figure 8A–C show the effect of interventions on the quality of life of individuals as measured by the WHOQOL-bref questionnaire in the environmental domain. No significant between-groups differences in the environmental domain (p = 0.46) was observed. Figure 8A shows the comparison between the beginning (before) and the end (after) of the protocol in the control groups: ATG_CG (p = 0.10), WBVEG_CG (p = 0.51) and WBVE + ATG_CG (p = 0.84). Figure 8B shows the comparison between the beginning (before) and the end (after) of the protocol in the intervention groups: ATG (p = 0.18), WBVEG (p = 0.60) and WBVE + ATG (p = 0.53). Figure 8C shows the comparison of the treated group with their respective controls in each one of the interventions: ATG_CG × ATG (p = 0.29), WBVEG_CG × WBVEG (p = 0.62) and WBVE + ATG_CG × WBVEG + AT (p = 0.54).

5. Discussion

The current work evaluated the combined effect of various non-pharmacological interventions (AT, WBVE and combined AT and WBVE) on the quality of life in individuals with KOA. Due to the fact KOA is a degenerative disease, it leads to a progressive functional limitation that used to compromise quality of life [44]. The hypothesis of this study was that the combination of both interventions (WBVE and AT) would have additional benefits on the physical health domain of the quality of life as assessed by the WHOQOL-bref in KOA individuals. The results of the current study suggested that all interventions (alone or in combination) were safe and no side effects were reported. Despite this, non significant inter or intra-group differences were observed in the analyzed domains (physical, social, psychological and environmental) of the WHOQOL-bref.

As reported, several limitations are common complaints that interfere with activities of daily living and recreation in people with KOA [8]. We can find in the literature improvements in physical function [25], pain levels and functionality [27] after WBVE; by contrast, in the current study, the physical domain remained stable after this intervention. One possible explanation to these discrepancies is related to differences in the intervention variables. Recent studies focused on the effects of WBVE intervention on daily physical functions in KOA individuals [45] used higher frequencies (35–40 Hz) than the ones used in the current study. Moreover, Bokaeian et al., also reported improvements in symptoms of osteoarthritis of the knee and functionality; however, no significant differences were in pain or quality of life using a frequency of 25–30 Hz [22]. In the same line, a meta-analysis from Zafar et al. focused on the effect of WBVE in individuals with knee osteoarthritis, authors reported decrements in pain and improvements in function but in most cases the frequency was higher to 25 Hz (range 25–40), only one study used frequencies between 12–14 Hz [46]. In this current investigation non-significant improvements in function was found.

The duration of the protocol is another important parameter to be considered. The duration of the protocol in the present study is lower (five weeks) than the ones that used 8, 12 and 24 weeks [23,24,28].

The position of the participants on the VP may also plays a role on the vibration transmission and therefore on the effects of this type of training. In our study participants were seated on a chair that was in front of the VP. This position was previously used in Neto et al., in which the individual was sat on a chair with flexion of the knees and the feet were on the VP base [19]. The importance of this position is to reduce the load and the impact on the knee joint, providing a pleasurable method and with a possible greater adherence in the practice of physical activity. However, this may have led to a decrease in the effect of vibration due to a decrease of the transmissibility of the mechanical vibration to the individual. In the current study, considering the physical domain (Figure 5A–C) and the environmental domain (Figure 8A–C) of the WHOQOL, both interventions (WBVE and/or AT) did not contribute to alter the physical conditions of the KOA individuals. These findings are in agreement

with Bokaeian et al., [22]. These authors have evaluated several parameters, including the quality of life by means of the WOMAC scale in KOA individuals exposed to WBVE. They also verified no significant difference between the experimental groups in term of quality of life. Jack Farr II et al., have also pointed out that the physical manifestations of KOA have direct impact on aspects of the welfare of the individuals, including social interactions, mental functioning, and sleep quality [8].

Considering the findings with AT, the small number of acupoints (three acupoints), the reduced length (five weeks) of the intervention could contribute to justify the results, in which the AT was not effective to improve the quality of life of the KOA individuals.

The effectiveness of using AT would be related to functional changes in the body, interconnected with neurological theory, the embryological theory, microsystems, the energy theory of TCM [13,15,47]. These biological responses might be considered in the effect of the interventions (WBVE and AT) in the KOA individuals, that could prevent impairments on the quality of life.

The current study has some limitations that must be considered when interpreting the findings, such as the heterogeneity of the sample and the small number of participants. In addition, the participants were not allocated via a rigorous randomization process. The association between the pathophysiology of KOA and the response to the effects of WBVE and AT need to be further studied for a better understanding of these results. Moreover, some physiological parameters were not evaluated after the interventions. Furthermore, only three specific points in the ear were used in the AT, and only some frequencies of the mechanical vibration were used to generate WBVE. It is also relevant to consider that the seated position was used in this current work.

6. Conclusions

Despite of the limitations, it is possible to conclude that WVBE or AT alone or combined did not contribute in altering the quality of life of the individuals exposed to these interventions. However, more studies with other AT protocols and different biomechanical parameters (frequency, peak-to-peak displacement) with longer vibration exposure are needed expand the use of these forms of treatment.

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