



Original research

## Functional parameters responses after 5 weeks of whole-body vibration and/or auriculotherapy interventions in individuals with knee osteoarthritis: randomized controlled trial

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### Abstract

**Introduction:** Knee osteoarthritis (KOA) is a joint disease that can cause limitations or loss of physical function. Different nonpharmacological interventions have been recommended for the treatment of KOA. Whole-body vibration (WBV) exercises and auriculotherapy (AT) can be effective interventions for managing KOA. **Objective:** This study aimed to evaluate the effects of WBV, AT, and the combination of the two techniques on parameters related to functionality in KOA individuals. The hypothesis was that WBV and AT could improve the functional parameters of KOA individuals. **Methods:** Participants were randomized into four groups (n=108): (i) WBV (GV) using mechanical vibration (MV) with peak-to-peak displacement 2.5, 5.0, and 7.5 mm, frequencies from 5 to 14 Hz and peak acceleration from 0.12g to 2.95g, twice a week, for 5 weeks (n=29); (ii) AT (GA) was performed with mustard seeds at the knee, kidney and Shenmen acupoints on the ear (n=29); (iii) WBV+AT (GAV) (n=23), and; (iv) Control Group procedures (GC) (n=27). **Results:** As a result, significant improvements were observed in functional parameters of individuals with KOA in the Lysholm evaluation, and in the Timed Up and Go test. WBV and AT would be relevant to be included in primary care, as they are effective, and easy to be performed and have a low cost. **Conclusion:** The interventions (WBV, AT, and WBV+AT) can lead to physiological responses that can be associated with improvement in clinical-functional parameters in individuals with KOA.

Keywords: Knee osteoarthritis; auriculotherapy; systemic vibratory therapy; functionality.

### 1. Introduction

Osteoarthritis (OA) is a degenerative joint disease with high prevalence around the world that can limit the ability of individuals to work and fulfill community tasks. It is one of the ten most disabling diseases in developed countries and also in low to middle-income countries (1-3). According to the World Health Organization (WHO), 9.6% of men and 18.0% of women over 60 years of age

have symptomatic osteoarthritis. Furthermore, it is estimated that 80% of these symptomatic subjects will have limitations in their movements and 25% of this population will not be able to perform normal daily activities (WHO). OA commonly affects the metatarsophalangeal, knee, hip, and spine joints, being knee OA (KOA) the most frequent form (WHO). KOA is characterized by micro and macro injuries of the knee joint that lead to degeneration of the extracellular matrix and periarticular soft tissues (4).

The American College of Rheumatology (ACR) and the Osteoarthritis Research Society International (OARSI) recommend the use of pharmacological and nonpharmacological interventions, such as physical activity and alternative therapies to manage KOA (5,6).

Alternative therapies are part of Traditional and Complementary Medicine, focusing on diverse therapeutic resources with an important contribution to global health, including techniques such as acupuncture and auriculotherapy (AT) (7,8). WHO Strategy on Traditional Medicines for 2014-2023 indicates the importance of alternative therapy in the world context (9). AT can be performed with seeds and has been shown to be effective in the management of individuals with KOA (10,11).

Physical exercise (PE) is also a non-pharmacological alternative in the treatment of individuals with KOA as recommended by guidelines (5,6). PE is an important tool in the management of individuals with various chronic conditions, including KOA (12-15). Skou *et al.* (12) argue that physical exercises should be a first-line intervention in the clinical management of individuals with KOA. In addition, Zampogna *et al.* (15) demonstrated that physical exercises and sports are effective in reducing pain and functional capacity in elderly with KOA. Whole-body vibration (WBV) is a safe modality of exercise to populations with various clinical conditions and has been suggested as an adequate intervention for individuals with KOA (16-19). WBV occurs through systemic vibratory therapy, in which mechanical vibration produced in a vibrating platform (VP) is transmitted to the whole body of an individual that is in contact with the base of the VP, generating WBV exercise (20,21)

The benefits of WBV exercise have been highlighted for individuals with fibromyalgia (22), metabolic syndrome (23-26), obese (27), chronic obstructive pulmonary disease (28), stroke (29) and KOA (19,30,31). Some beneficial effects related to WBV exercise have been described, such as increasing the muscle strength (32,33) and bone mineral density (23,34), improving the balance (24,35), flexibility (25,31,36), functional capacity (23,25,31,33,36), reducing fatigue (37) and pain level (29,36).

A combination of intervention techniques is often used in research, such as physiotherapy or exercise and acupuncture (38-40), and WBV and AT (19,29,30). Studies reported benefits of a combined intervention of WBV and AT in KOA individuals, such as a reduction in pain level (29), increased handgrip strength (19), flexibility improvement and functional capacity (30). Regardless, an optimal protocol with these interventions aiming to improve functionality in KOA is not yet established. Thus, the objective of this study was to evaluate the effect of WBV, AT, and the combination of the two techniques on parameters related to functionality in individuals with KOA. This work hypothesized that WBV and AT can improve parameters related to the functionality of individuals with KOA. In addition, the combination of the two techniques (WBV + AT) could enhance the beneficial effects of the isolated interventions.

## 2. Methods

### 2.1 Study design and protocol registration

This is a randomized, interventional, double-blind study, conducted in accordance with the checklist and guideline for randomized clinical trials (CONSORT) (41), approved by the Research Ethics Committee in human beings of the *Hospital Universitário Pedro Ernesto* (HUPE), *Universidade do Estado do Rio de Janeiro* (UERJ) (CAAE 19826413.8.0000.5259) and registered in the *Registro Brasileiro de Ensaio Clínico* (ReBEC): RBR-7dfwct.

## 2.2 Randomization

KOA individuals were randomly allocated through virtual randomization on the website <https://www.random.org>. For randomization to be considered blind, each protocol intervention group was included on the website: (i) WBV protocol - group submitted to WBV (GV); (ii) AT protocol - group submitted to AT (GA); (iii) Combined protocols - group submitted to the combination of the two techniques (GAV), and (iv) Control Group procedures (GC). Randomization was performed by the same professional who monitored the interventions. The professional who evaluated the results (evaluator) and the participants were not aware of the corresponding group. After randomization, participants were referred for initial assessment and started the intervention according to the allocation. After an intervention period of 5 weeks (10 sessions), participants underwent a final assessment, 24 hours after the last session.

## 2.3 Participants

Participants with a diagnosis of KOA according to Ahlbäck's criteria (42), were recruited at the *Departamento de Ortopedia* at HUPE / UERJ and were referred to the *Laboratório de Vibrações Mecânicas e Práticas Integrativas* (LAVIMPI), where the interventions took place. All the procedures were performed from October 2018 up to January 2020. Initially, the participants were informed and oriented about the study and signed the Informed Consent Form (ICF). Subsequently, anamnesis to identify the eligibility criteria, anthropometric measurements, and the first assessment (baseline) were performed.

## 2.4 Eligibility criteria

*Inclusion criteria:* Participants aged  $\geq 40$  years, of both sexes, diagnosed with KOA according to Ahlbäck's criteria (42).

*Exclusion criteria:* Participants diagnosed with untreated systemic arterial hypertension, fear of movements of the VP, severe or disabling clinical disease, clinically evident cardiovascular disease in the last six months manifested by myocardial infarction or stroke, history of deep venous thrombosis or active disease, pacemaker, metallic prosthesis, previous surgery on the knee or lower limbs that prevented the realization of the protocol and major physical limitations that can compromise the participants' safety during the protocol, and the individuals that refused to sign the ICF.

## 2.5 Data collection

The assessments of functionality parameters were carried out using the Lysholm questionnaire, translated and validated to Portuguese (Brazil) and the Timed up and go (TUG) test. The Lysholm questionnaire is a self-reported instrument that contains items related to symptoms and functional limitations of the knee such as pain level, joint swelling, stiffness, and mobility. This questionnaire uses a 100-point rating scale which 95-100 is excellent and  $<64$  is poor (43,44).

The TUG test is an instrument to assess postural control, mobility, balance, and functional capacity (45). To perform the test, the individual gets up from a chair, walks in a straight line from 3 meters away, turns around, walks back, and sits in the chair again. The test was performed twice, and the shortest running time was recorded for analysis (46). This test is highly recommended to assess the functional capacity of individuals with KOA (47-49). The evaluations took place on the same day, before the intervention (baseline) and after the protocol at the final evaluation, (24 hours after the last session).

## 2.6 Intervention protocols

Participants were allocated into 4 groups: AG, GV, GAV, and GC. The protocol lasted 5 weeks (2 weekly sessions).

### 2.6.1 WBV protocol

Participants performed the WBV protocol (GV) seated in an ancillary chair positioned in front of a VP with a side-alternating displacement of the base (Novaplate Fitness Evolution®, DAF Produtos Hospitalares Ltda, São Paulo), with their hands resting on their knees to facilitate the transmission of the mechanical vibration to the whole body and with their feet on the VP base with a comfortable flexion of knees (110° to 120° knee flexion). The biomechanical parameters of the mechanical vibration used in this protocol were: (i) three different peak-to-peak displacements (D) (2.5, 5.0, and 7.5 mm); (ii) frequency at 5 Hz in the first session, and progressively increased by one unit per session to 14 Hz in the last session; (iii) a Peak from 0.12 to 2.95g; (iv) 3 bouts of 3 min of mechanical vibration with 1 min of rest after each bout (50). The VP display was covered with an opaque plate so that the participants were not aware of the frequency or the time of exposure to the mechanical vibration. This group placed seedless adhesive tapes at the same acupuncture points as the GA. The professional who accompanied the intervention instructed the participant to report any discomfort to stop the intervention, if necessary. The participants did not report any discomfort during all the interventions.

### 2.6.2 Auriculotherapy protocol

In the AT group (GA), an adhesive tape with two mustard seeds (*Semen vaccariae*) was placed on the points to be stimulated in both ears (Knee, Kidney, and Shenmen) according to previous studies (19,29,30,36), the point "knee joint" is the corresponding point which 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 point "kidney", located in the upper part of the cymba conchae at the superior portion of the acupuncture point of the small intestine, has a function related to the bones and lower limbs. The point "Shenmen" is an analgesic point and is located at the bifurcation of the crus of the antihelix (51-53)

The tapes were changed in each session. All participants were instructed to manually stimulate the acupoints at least 3 times a day and to remove the tape the day before returning to LAVIMPI. This group performed the same protocol as the GV, but the VP with frequency zero "0", with a coupled device that emits a sound similar to the sound produced by the mechanical vibration.

### 2.6.3 Combination protocols

In this group (GAV), the protocols of the GV and GA were performed concomitantly. In other words, in the GAV, the same biomechanical parameters of the mechanical vibration and the same stimulation of the acupuncture points of the GA (Knee, Kidney, and Shenmen) were used.

### 2.6.4 Control Group procedures

The individuals of the GC had adhesive tapes without seeds fixed in the chosen points in both ears (Knee, Kidney, and Shenmen) as the GV and performed the same protocol as the GV, but the VP with frequency zero "0", with a coupled device that emits a sound similar to the sound produced by the mechanical vibration when the VP is turned on.

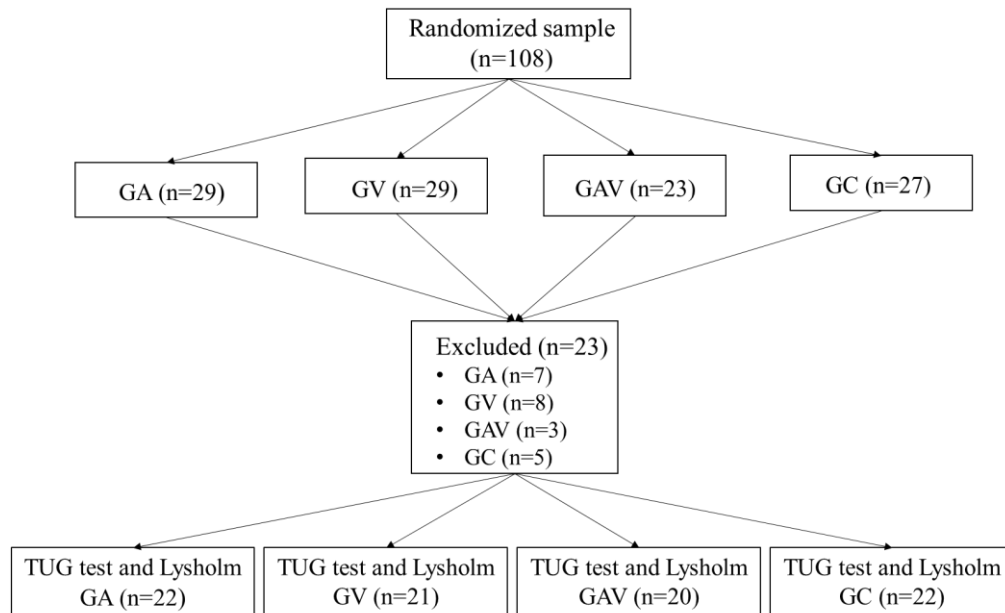
## 2.7 Sample Size

The sample size was calculated using the G-Power® 3.1 software (Franz Faul, Universitat Kiel, Germany), based on the variable TUG test from the study by Janyacharoen *et al.* (54), with a power value of 80% and a two-tailed  $\alpha$  value of 0.05. The calculation identified the need for a total sample

of 90 individuals, with 18 individuals for each group. However, considering a loss of around 15%, 105 individuals were recruited, 21 for each group.

## 2.8 Statistical analysis

For statistical analysis, the difference ( $\Delta$ ) was calculated, considering the values obtained (after – before) the functional assessments (Lysholm and TUG) in all interventions and in the GC. The software used was “R” version 3.5.0. The Shapiro-Wilk normality test was applied to all variables, and they did not present a normal distribution. In this case, the appropriate non-parametric tests (Kruskal-Wallis and Wilcoxon rank sum test with Bonferroni correction). For anthropometric data, the Kruskal-Wallis test and the Chi-square test were performed, comparing the baseline of all groups. Statistically significant differences were considered with  $p < 0.05$ .



**Figure 1. Flowchart of individuals included in the study.** GC - Control Group procedures; GA – Auriculotherapy protocol; GV – ABV protocol (Group subjected to mechanical vibration); GAV – Combined protocols (Group submitted to the two associated techniques); TUG - Timed up and go.

## 3. Results

The study included 108 individuals with KOA, who were randomized into four groups: GC (n = 27), GV (n = 29), GA (n = 29), and GAV (n = 23). Eleven participants discontinued treatment due to the pandemic period (COVID-19), three of the GV, two of the GAV, three of the GA, and three of the GC. One participant of the GC was removed due to suspected COVID-19 infection. Twelve patients interrupted the intervention for personal reasons (five from the VG, one from the GAV, four from the GA, and two from the GC). No participant was excluded due to adverse effects related to the proposed interventions or worsening of signs and symptoms of KOA. The flowchart of individuals throughout the work is shown in [Figure 1](#).

[Table 1](#) shows the anthropometric characteristics of participants from all groups before the first intervention (baseline). No differences among the groups were found. Moreover, no participant used analgesics during the study period.

On the Lysholm scale, a significant difference was observed when comparing all groups ( $p<0.0001$ ). Afterwards, the analysis was carried out among the interventions and in the GC. A significant difference was observed between GC X GV -  $p=0.002$ ; GC X GA -  $p<0.0001$  and GC X GAV -  $p<0.0001$ . When comparing the interventions, significant differences were observed only between GA and GAV ( $p=0.003$ ) and between GV and GAV ( $p=0.036$ ), however, there was no difference between GA and GV ( $p=0.617$ ). Suggesting that the GV, GA and GAV interventions were more efficient than GC, however when comparing between these interventions, the GAV group presented better results. (Figure 2).

**Table 1.** Anthropometric characteristics of participants in the baseline.

Variables	GC (n=22)	GA (n=22)	GV (n=21)	GAV (n=20)	p-value
Sex	F – 20/ M – 2	F – 16/ M – 6	F – 18/ M – 3	F – 15/ M – 5	0.365
Age (years)	68.45 (9.53)	66.09 (6.69)	63.10 (5.70)	62.60 (14.61)	0.243
Body mass (kg)	76.46 (8.35)	84.25 (11.94)	80.16 (17.11)	81.57 (10.87)	0.119
Height (m)	1.58 (0.09)	1.61 (0.05)	1.60 (0.09)	1.59 (0.05)	0.445
BMI (kg/m <sup>2</sup> )	30.82 (5.60)	32.27 (3.49)	31.62 (7.98)	32.60 (5.76)	0.506
RA (score 1-5)	1=16/ 4=5/ 5=1	1=15/ 3=2/ 4=2/ 5=3	1=11/ 2=5/ 4=4/ 5=1	1=15/ 2=2/ 4=2/ 5=1	0.061
LA (score 1-5)	1=16/ 2=2/ 3=2/ 4=2	1=15/ 4=3/ 5=4	1=14/ 2=1/ 3=3/ 5=3	1=16/ 2=2/ 4=2	0.127
ODI (score 1-5)	1=10/ 2=8/ 3=4	1=14/ 2=8	1=12/ 2=2/ 3=3	1=13/ 2=4/ 3=3	0.219
IPAQ (score 1-3)	1=16/ 2=2/ 3=4	1=14/ 2=2/ 3=6	1=15/ 2=2/ 3=4	1=11/ 2=2/ 3=7	0.899

Note: GC - Control Group procedures; GA – Auriculotherapy protocol; GV – WBV protocol (Group subjected to mechanical vibration); GAV – Combined protocols (Group submitted to the two associated techniques); TUG - Timed up and go.; BMI – Body mass index; RA/LA – Ahlback classification of the right and left knee, - (where 1 lighter and 5 more severe) (Ahlback 1968), ODI – Oswestry Disability Index – (Functional disability classification, where 1=minimal disability, 2=moderate disability, 3=severe disability, 4=crippled and bed-bound); IPAQ – International Physical Activity Questionnaire – (level of physical activity, where 1 = low activity, 2 = moderate activity and 3 = high activity). F: female; M: male. For the sex variables, RA, LA, ODI e IPAQ, the test was used Chi-square and for body mass, height and BMI, the Kruskal-Wallis test was used and are expressed as mean (standard deviation). \*Significance level  $p\leq 0.05$ .

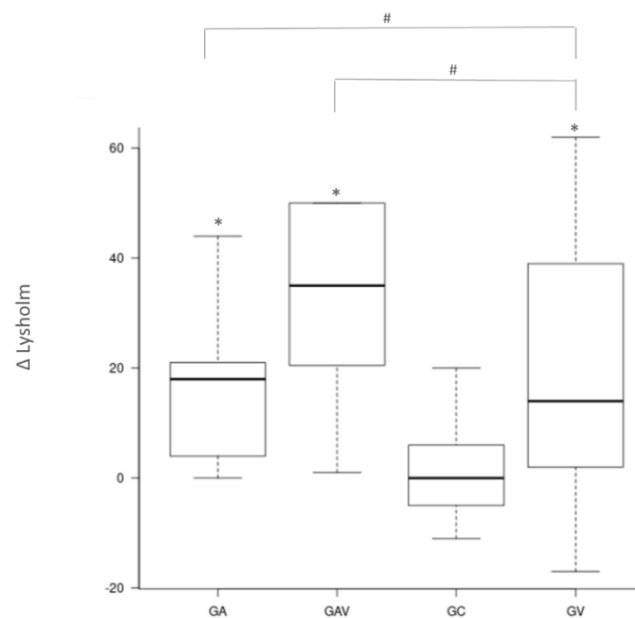
For the TUG test, a significant difference was observed when comparing all groups ( $p<0.0001$ ). Afterward, the analysis between the interventions and the GC was carried out. A significant difference was observed between GC X GV -  $p=0.0009$ ; GC X GA -  $p<0.0001$  and GC X GAV -  $p<0.0001$ . However, no significant differences were observed between the interventions. GA and GV ( $p=0.551$ ), GA e GAV ( $p=0.160$ ) e GV and GAV ( $p=0.425$ ) (Figure 3).

## Discussion

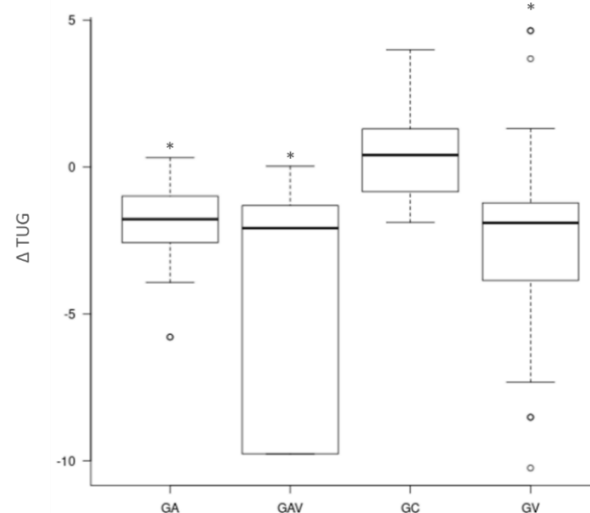
The individual with KOA presents signs and symptoms that can interfere with the individual's functional abilities and daily activities, including limitations such as walking and sitting and rising from a chair (55,56). Considering this, the current study compared two interventions (WBV and AT) and the association of these techniques (WBV + AT) to assess the functional parameters of individuals with KOA. WBV and AT would be relevant to be included in primary care, as they are effective, and easy to be performed and have a low cost.

The results found in the present study regarding the Lysholm questionnaire, showed a significant improvement in the final score of all interventions compared to the GC, suggesting a

beneficial effect regarding the perception of KOA symptoms after the application of the AT, WBV and their association techniques (WBV + AT). Likewise, an improvement was found in the GAV group when compared to the GA and the GV, suggesting that the association of interventions may have potentiated the effect of the two techniques, as between the GA and GV no statistical difference was observed. Similarly, Alves *et al.* (57) also observed improvements in Lysholm scores, however, it was after a plasma application.



**Figure 2. Comparison among the groups of the differences (after and before the interventions) of the Lysholm score.** Δ - difference (after - before) the Lysholm score. \* $p < 0.05$  when compared to the GC - Control Group procedures. # $p < 0.05$  when comparing the interventions (GA - Auriculotherapy protocol, GV - WBV protocol (Group submitted to mechanical vibration) and GAV - Combined protocol (Group submitted to the two associated techniques)).



**Figure 3. Comparison among the groups of the differences (after and before the interventions) of the time to perform the Timed up and go test.** Δ - difference (after - before) the Timed up and go (TUG) test. \* $p < 0.05$  when compared to the GC - Control Group procedures. # $p < 0.05$  when comparing the interventions (GA - Auriculotherapy protocol, GV - WBV protocol (Group submitted to mechanical vibration) and GAV - Combined protocols (Group submitted to the two associated techniques)).

As for the functional parameters (TUG test), the results also showed a benefit of the interventions in relation to the GC, suggesting that the studied interventions (AT and WBV) can bring benefits to this population, associated or not, because when compared to each other, no differences were observed. These results are in agreement with Bhagat et al. (58), who showed an improvement in functional parameters through the TUG test in patients with KOA after using manual therapy techniques, which is considered alternative medicine. (58)

The improvement in the functional parameters found in the present study could be associated with a better muscle activation response promoted by the WBV, which can be explained as a result of the tonic vibration reflex, which is a reflex of muscle contraction by the mechanical vibration (59,60). In addition, in line with Vincent *et al.* (61), the WBV is considered a physical exercise (62), which demonstrated that increases the strength of muscles in the knee region in KOA individuals (61).

AT has been discussed as a low-cost and safe method in various clinical conditions (63). The findings of current work suggest that AT can promote a significant improvement in functional parameters in KOA individuals. Likewise, Viera *et al.* (64); demonstrated in a systematic review that AT can be beneficial in chronic diseases (64).

Moreira-Marconi et al. (19) showed that the combination of AT with WBV can promote an improvement in handgrip strength, in agreement with the results of this study, which showed that the combination of the two techniques had better results when compared to individual therapies concerning disease symptoms.

As a limitation of the study, it is important to highlight that the data from the present study were collected during the COVID-19 pandemic, which made collection difficult, with a loss of approximately 20% of the initial sample, with around 10% due to the pandemic.

As a fact is that both techniques were beneficial and efficient in improving the functional parameters in individuals with KOA. Therefore, as perspectives, it is expected that these interventions could be more used in the management of this population. Furthermore, the strength of this work was to show that two non-pharmacological and non-invasive interventions, could be used to improve the functionality in individuals with KOA, being potentialized when associated.

## Conclusion

According to the findings of this study, 5 weeks of the interventions (WBV, AT, and the association of the two techniques) may trigger responses, which might be responsible for improving the parameters related to the functionality of individuals with KOA. The TUG test presented good results after the interventions. On the other hand, the association of interventions may have potentiated the effect of the two techniques, promoting a better score at Lysholm. Future studies with good methodological quality are needed to better understand these responses in functional parameters.

## Conflict of interest

The authors declare no conflicts of interest.

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