







Influences of mechanical decompression using different forces on knee joint space, range of motion, and hamstring flexibility in asymptomatic subjects

Influências da descompressão mecânica usando diferentes forças no espaço articular do joelho, amplitude de movimento e flexibilidade dos isquiotibiais em indivíduos assintomáticos

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ABSTRACT | INTRODUCTION: Knee joint decompression is one of the promising methods for the treatment of osteoarthritis. Yet, the most appropriate decompression force is not conclusive. OBJECTIVES: To compare the effect of different distraction force magnitudes on knee joint space, active range of motion (ROM), hamstring flexibility, and self-reported discomfort in asymptomatic subjects. METHODS AND MATERIALS: Twenty-five asymptomatic participants were recruited in this study. The dominant knee was distracted for 30 minutes in a 30° flexion position using three force magnitudes (10%, 20%, and 30% body weight (BW)). The traction forces were randomized with one week in between knee distractions. Joint space, range of motion (ROM), and hamstring flexibility were assessed before, immediately after, and 30 minutes after the distraction. The self-reported discomfort was assessed immediately after the distraction only. RESULTS: Medial joint space, ROM, and discomfort showed a significant difference between different force magnitudes post-distraction. The 20% and 30% BW force magnitudes significantly, but equally, increased joint space and ROM post distraction. The discomfort level was directly related to distraction force magnitude and the least comforting was the 30% BW force. Follow-up data was not significantly different than that for post-distraction. Hamstring muscle flexibility showed a significant. Yet, small increase after the 30% BW distraction force. CONCLUSION: Continued mechanical distraction of the knee joint using force magnitudes of 20% and 30% of body weight was effective in increasing medial joint space, active knee ROM, and hamstring flexibility in asymptomatic individuals. 20% force magnitude was more comfortable than the 30% percent.

KEYWORDS: Flexibility. Knee. Joint Range. Traction. Joints. Ultrasonography.

RESUMO | INTRODUÇÃO: A descompressão da articulação do joelho é um dos métodos promissores para o tratamento da osteoartrite. No entanto, a força de descompressão mais apropriada não é conclusiva. OBJETIVOS: O objetivo deste estudo foi comparar o efeito de diferentes magnitudes de força de distração espaço articular do joelho, amplitude de movimento ativa (ADM), flexibilidade dos isquiotibiais e desconforto autorreferido em indivíduos assintomáticos. MÉTODOS: Vinte e cinco participantes assintomáticos foram recrutados. O joelho dominante foi distraído por 30 minutos em uma posição de flexão de 30° usando três magnitudes de força (10%, 20% e 30% do peso corporal (PC)). As forças de tração foram randomizadas com uma semana de intervalo entre as distrações do joelho. Espaço articular, ADM e flexibilidade dos isquiotibiais foram avaliados antes, imediatamente após e 30 minutos após a distração. O desconforto autorreferido foi avaliado imediatamente após a distração apenas. RESULTADOS: O espaço articular medial do joelho, ADM e desconforto mostraram uma diferença significativa entre as diferentes magnitudes de força após a distração. As magnitudes de força de 20% e 30% de PC aumentaram significativamente, mas igualmente, o espaço articular e a ADM após a distração. O nível de desconforto estava diretamente relacionado à magnitude da força de distração e o menos reconfortante foi a força de 30% do PC. Os dados de acompanhamento não foram significativamente diferentes dos da pós-distração. A flexibilidade muscular dos isquiotibiais mostrou um aumento significativo, mas pequeno, após a força de distração de 30% do PC. CONCLUSÃO: A distração mecânica contínua da articulação do joelho utilizando magnitudes de força de 20% e 30% do peso corporal foi eficaz no aumento do espaço articular medial, ADM ativa do joelho e flexibilidade dos isquiotibiais em indivíduos assintomáticos. A magnitude de força de 20% era mais confortável do que a de 30%.

PALAVRAS-CHAVE: Flexibilidade. Joelho. Faixa Conjunta. Tração. Articulações. Ultrasonografia.

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1. Introduction

Joint distraction is a standard physical therapy procedure for treating different pathological joint conditions. Its application procedures are variable in terms of method (mechanical or manual), mode (intermittent or continuous), and duration of application. Conservative distraction has been primarily applied for spinal dysfunction. 1 Knee decompression using mechanical distraction to increase the space between joint surfaces is one of the passive physical therapy interventions that might provide promising effects for patients having knee OA. This hypothesis could be augmented by the high success rates associated with using decompression to treat spinal discogenic lesions and spondylosis.2 Additionally, promising results have been reported when the decompression techniques were applied surgically to the arthritic ankle and hip joints and have effectively resulted in clinical and structural improvements, which lasted up to 10 years.3

Knee osteoarthritis (OA), being the most common joint OA⁴, is a debilitating pathological joint condition that causes a significant health burden for the affected individual and healthcare providers, in addition to great socioeconomic costs.⁵ The primary target of knee OA treatment is to maintain function, decrease pain, and preserve joint space to postpone knee replacement surgery as long as possible.

Recently, it has been reported that surgical knee joint distraction (KJD) for 6 to 8 weeks resulted in clinical benefits and knee joint structural changes in young patients with advanced knee OA. These benefits include improved function (WOMAC index increased from 45 to 77 points), reduced pain (VAS pain decreased from 73 to 31 mm), and joint structural changes in the form of increased joint space width (2.7 to 3.6 mm), promoted cartilage repair (increased thickness from 2.4 to 3.0 mm) and decreased denuded subchondral bone area (22% to 5%).6 Long-term follow-up studies were conducted and reported persistence of clinical and structural benefits for up to 9 years post KJD. Unfortunately, surgical KJD has the disadvantage of being an invasive procedure that comes at the cost of prolonged bed rest and high risk of infection.⁷

In contrast, non-surgical joint distraction is a procedure implemented as part of a physical therapy treatment program for knee OA and has been recommended by recent clinical practice guidelines.8 Despite its clinical applicability, robust scientific evidence is scarce regarding the effective magnitude of the force of distraction. For example, Alpayci et al. applied continuous and intermittent mechanical traction to patients with advanced knee OA in a fully extended knee joint position, for whom they used a fixed distraction force of 15Kg.⁹ In another study, Khademi-Kalantari et al. applied a 20-minute sustained traction using subjective individualized force magnitude (according to the patient's sensation of joint traction), in a 30° knee flexion position. ¹⁰ This method of determining the distraction force was also adopted in a recent study. 11 Additionally, Aseer and Subramanian assessed the efficacy of intermittent manual traction on the pain, movement, and function in knee OA. In this study, the force of distraction was not measured. Instead, the researchers used manual palpation to determine whether there was separation of the joint bones.1 In a case study that included two knee OA patients, continuous mechanical knee distraction force comprising 6% of the body weight was used as a traction force.12

Thus, based on the current available evidence, there is no consistent method that has been introduced to determine the most effective distraction force magnitude that can be used in treating patients with knee OA. So, this study aimed to explore the effect of different distraction force magnitudes on knee joint space, active ROM, and hamstring flexibility in asymptomatic subjects.

2. Material and Methods

This study was conducted in the polyclinics of a local university between March and July 2023. Participants were recruited from the local university students, teaching staff and employees. The protocol of this study was conducted in accordance with the Declaration of Helsinki of 1964 and was approved by the local ethical committee (H-2022-403). All participants signed a written consent form before the start of the study.

2.1 Study design

Experimental study with repeated measures design.

2.2 Participants

Twenty-five participants (eleven males, and fourteen females) were recruited through poster announcements and verbal communication from the population of the local University. The inclusion criteria were male or female gender, healthy, asymptomatic knee joint, and aged between 17 and 44 years. The exclusion criteria were any trauma or disease in the knee joint, a systematic problem affecting the body joints such as systemic lupus erythematosus, surgery to the lower limbs, deformities such as scoliosis, leg length discrepancy, circulatory disorders such as varicose veins, and pregnancy.

2.3 Procedures

2.3.1 Determination of lower limb dominance

The participant's dominant lower extremity was determined using a simple question "Which leg would you use to kick a ball?". The selected limb will be considered the dominant limb. This method was used in previous work.¹³

2.3.2 Continuous mechanical distraction (decompression) of the knee joint

Merton Elite ACCU-TRAC Traction Unit - Model AT270 (Metron Medical Australia Pty Ltd) was used to perform knee distraction sessions. All Participants received three sessions consisting of 30 minutes of continuous mechanical knee distraction (for the dominant lower limb). 10, 20, and 30% of the body weight were used as the magnitude of the distraction force. Participants received a different distraction force (in random order) every session. The participant assumed a supine position with the treated limb in semiflexion (30° of flexion). The treated limb was supported on an adequate size roll to keep the knee in the flexion position. The knee position angle was measured by a standard goniometer. Pelvis and thigh straps were used to secure the body and prevent slippage during the application of the traction force. A customized leg cuff was placed around the lower leg (proximal to the ankle joint), and a traction rope extended horizontally from the cuff to the traction device (Fig 1). One-week wash-out period separated the three sessions.



Figure 1. Knee distraction

Source: the authors (2024).

2.3.3 Outcome measures

All clinical outcome measures were assessed by a senior physical therapist (assessor) who has 20 years of experience in orthopedic physical assessment. An experienced radiology specialist was responsible for assessing joint space. Both assessors were not aware of the intervention given to the patient they assessed. Joint space, active knee ROM, and hamstring flexibility were assessed three times; before application (preapplication), immediately after the single distraction session (post-application), and after 30 minutes as a short-term follow-up (follow-up). The same outcomes were collected using the same procedures and timing with the three treatment arms. A one-week rest interval was applied between each intervention arm to allow washout of the previous treatment effect. The selfreported discomfort was assessed only post-application.

2.3.3.1 Knee joint space using ultrasound imaging

Dynamic ultrasound imaging was used to assess joint space. This procedure was performed using clinical ultrasonography (LOGIQ, 260496WX5, Philips, Germany), a linear transducer (7.0–12.0 MHz), and a maximum field of view. The sagittal plane protocol of ultrasonography was used. Participants assumed a long sitting position with the tested knee in full extension. The presentation of the hyperechoic bony outline of the femur and tibia has been considered as an important quality assessment for standardized measurement of joint space. This method has been proven to be valid and reliable for assessing knee joint space. ¹⁴

2.3.3.2 Sit and reach test (hamstring flexibility)

The Sit and reach test was used to assess the flexibility of the hamstring muscles. This test is one of the valid and reliable linear flexibility tests, which helps to measure the flexibility of the hamstrings and lower back. It is also a field test, which is easy to administer in a community setting.¹⁵

The participant assumed a long sitting position with the untested lower limb flexed. The foot of the dominant (tested) limb was placed at the edge of a specially designed box and the knee was kept straight.

The participant was asked to lean forward as much as possible keeping the tested knee straight and try to reach as far as possible. The box contains a ruler and an indicator to determine the highest value reached by the participant.

2.3.3.3 Knee joint active range of motion (AROM)

A traditional goniometer was used to measure the active knee joint flexion range. Participants assumed a supine position and the assessor placed the goniometer where the fulcrum was at the level of the lateral femoral condyle, the fixed arm parallel to the femur and the movable arm parallel to the fibula. Then the participants were asked to bend knee and hip joints as much as possible. The traditional goniometer is a valid and reliable measure of joint ROM.

2.3.3.4 Level of comfort

The self-reported discomfort was rated by the participants using a 0-10 scale where 0 indicates least comfort and 10 indicates maximum comfort. Participants were asked to choose the number that represented their comfort after the application of the decompression session. The assessor then recorded the value for further analysis. The 0-10 scale has been widely used to rate comfort level on different occasions.

2.3.4 Statistical analysis

The statistical analysis was performed by an independent blinded statistician. A descriptive analysis of all variables was performed using mean ± SD. Due to the small sample size, the Friedman test was used to assess the within-group differences and the between-conditions differences. In the case of reporting statistical significance, the Wilcoxon signed-rank test with Bonferroni adjustment was used for subsequent analyses. The effect size was calculated using an online website (https://www. socscistatistics.com/effectsize) where values below 0.5 were considered low effect size, 0.5 to 0.8 was considered medium effect size, and 0.8 or more was considered high effect size. The level of significance was p > 0.05%. Statistical analyses were conducted using SPSS version 23.

3. Results

This study was conducted on 25 asymptomatic participants (7 females and 18 males) who were recruited from the Ha'il University Campus. Their demographic data and baseline scores for all outcome measures are listed in Table 1.

Table 1. Demographic data and baseline scores for outcome measures (n=25)

	Mean	SD	Max	Min	95% CI	
					lower	upper
Age (Y)	35.166	8.571	45	21	31.81	38.51
Weight (kg)	78.166	14.18	104	48	72.61	83.72
Height (cm)	1.685	0.084	1.82	1.55	1.64	1.71
ВМІ	32.067	4.331	38.453	22.628	30.36	33.75
AROM (°)	130.916	7.942	145	115	127.79	134.02
Flexibility (cm)	21.333	4.505	27	11	19.65	23.09
Lateral JS (mm)	1.058	0.191	1.49	0.834	-0.017	0.133
Medial JS (mm)	0.843	0.157	1.04	0.464	0.781	0.905

SD: standard deviation, Max: maximum, Min: minimum, Y: year, Kg, Kilogram, cm: centimeter, BMI: body mass index, AROM: active range of motion of the knee joint. °: angle, JS: joint space, mm: millimeter. n: Sample number=25 Source: the authors (2024).

3.1 Between-conditions comparisons post-treatment

There was a statistically significant difference in medial knee joint space, knee active ROM, and comfort level ($\chi 2(2) = 14.08$, p < 0.001; $\chi 2(2) = 15.6$, p < 0.001; $\chi 2(2) = 23.53$, p < 0.001, respectively) between the different experimental conditions. Post-hoc analyses showed that there were statistically significant differences in the medial knee joint space (Fig 2) between 10% and both 20% and 30%, where Z= -2.981, p= .003, and Z=-2.934, p=.003, respectively. Similarly, knee active ROM values demonstrated statistically significant differences between condition A and both condition B and condition C where Z= -2.640, P= .008, and Z= -2.947, P= .003, respectively (Table 2). Additionally, the reported level of comfort was statistically significantly different between the three conditions in favor of condition A. These findings were associated with high effect size (Cohen's d \geq 0.8) as reported in Table 2.

Figure 2. Medial joint space measured before (A), after (B), and at follow up (C)







(A) Pretreatment

(B) Post treatment 20%

(C) Follow up 20%

Source: the authors (2024).

3.2 Between-conditions comparisons at follow-up

There was a statistically significant difference in knee active ROM depending on the force used to apply traction to the knee joint, χ 2(2) = 10.227, p = 0.006. Post-hoc analyses showed statistically significant differences between condition A and condition C, where the Z= -2.98 and p = .003 and high effect size (Cohen's d = 1.19) (Table 2).

Table 2. Post hoc analysis results between traction conditions (10%, 20%, and 30% of body weight) (n=25)

Variable	Time	Results	10% vs 20%		10% vs 30%		20% vs 30%	
MJS	Post-	M±SD	0.865±0.12	1.05±0.08	0.865±0.12	1.05±0.06	1.05±0.08	1.05±0.06
(mm)	treatment	Z & (p)	-2.98 (0.003) * d 1.81		-2.93 (0.003) * 1.95		07 (.937) 0.01	
		Cohens'd						
AROM	Post-	M±SD	131.58±5.4	137.08±4.25	131.58±5.4	138.33±4.32	137.08±4.25	138.33±4.32
(°)	treatment	Z & (p)	-2.64	(.008)*	-2.94 (0.003)*		-1.44 (0.14)	
		Cohens'd	1.13		1.38		0.29	
	Follow-up	M±SD	132.5±6.98	137.33±4.61	132.5±6.98	139.08±3.47	137.33±4.61	139.08±3.47
		Z & (p)	-2.047 (0.041)		-2.98 (0.003) *		-1.36 (0.171)	
		Cohens'd	os'd 0.81	.81	1.19		0.42	
Comfort	Post-	M±SD	9.25±0.92	5.66±1.24	9.25±0.92	2.25±0.82	5.66±1.24	2.25±0.82
	treatment	Z & (p)	-3.77 (0.002) *		-3.08 (0.002) *		-2.96 (0.003)*	
		Cohens'd	3.28		8.03		3.24	

M: mean, SD: standard deviation, AROM: active range of motion of the knee joint, °: angle, MJS: medial joint space, mm: millimeter.

*: significant at p < 0.017 (adjusted)

Source: the authors (2024).

3.3 Within conditions comparisons (effect of time)

3.3.1 Condition A (10% body weight)

There was a statistically significant difference in knee active ROM depending on the time of assessment, χ 2(2) = 9.172, p = 0.010. Post-hoc analysis demonstrated statistically significant difference between the active ROM of the knee joint at follow-up when compared to the pretreatment value (Z=-2.54, p= 0.011, and Cohen's d= 0.21) as reported in Table 3.

3.3.2 Condition B (20% body weight)

There was a statistically significant difference in medial knee joint space and knee active ROM ($\chi 2(2) = 10.511$, p = 0.005; $\chi 2(2) = 7.60$, p = 0.022, respectively) between the different time points (pre-treatment, posttreatment, and follow-up). Post-hoc analysis demonstrated a statistically significant difference in medial joint space between the pre-treatment and post-treatment values (Z=-2.98, p= .003) and between the pre-treatment and follow-up values (Z=-2.66 and p= 0.008). Additionally, there were statistically significant differences in active knee ROM between the pre-treatment and post-treatment values (Z=-2.51, p= .012) and between the pre-treatment and follow up values (Z=-2.40 and p= 0.016), where the Cohen's d values were above 0.8 as reported in Table 3.

3.3.3 Condition C (30% body weight)

There was a statistically significant difference in medial joint space and hamstring flexibility ($\chi 2(2) = 9.23$, p = 0.010; $\chi 2(2) = 11.850$, p = 0.003) between the different time points. Post hoc analysis showed a statistically significant difference in medial joint space values between the pre-treatment and post-treatment (Z= -2.89 and P = .003) and in hamstring flexibility between the pretreatment and the follow-up values (Z=-2.204, P= 0.002) as shown in Table 3.

Table 3. Within group effect (n=25)

	Distraction		Pre vs Post		Pre vs Follow up		Post vs Follow up	
	force							
MJS	20%	M±SD	0.84±0.15	1.05±0.08	0.84±0.15	1.00±0.07	1.05±0.08	1.00±0.07
		Z & (p)	-2.98 (0.003)*		-2.66 (0.008)*		-2.00 (0.045)	
		Cohens'd	1.74		1.36		0.66	
	30%	M±SD	0.84±0.15	1.05±0.06	0.84±0.15	0.982±0.14	1.05±0.06	0.982±0.14
		Z & (p)	-2.89 (0.003) *		-2.19 (0.28)		-1.06 (0.286)	
		Cohens'd	d 1.76		0.95		0.63	
AROM	10%	M±SD	130.9±7.9	131.6±5.4	130.9±7.9	132.5±6.98	131.6±5.4	132.5±6.98
		Z & (p)	-0.94 (0.343)		-2.54 (0.011)*		-1.35 (0.176)	
		Cohens'd	0.09		0.21		0.14	
	20%	M±SD	130.9±7.9	137.1±4.3	130.9±7.9	137.3±4.6	137.1±4.3	137.3±4.6
		Z & (p)	-2.51 (0.012)*		-2.40 (0.016)*		-0.40 (0.68)	
		Cohens'd	0.96		0.98		0.05	
	30%	M±SD	130.9±7.9	138.3±4.3	130.9±7.9	139.1±3.5	138.3±4.3	139.1±3.5
		Z & (p)	-2.80 (0.005)*		-2.20 (0.002)*		-1.37 (0.17)	
		Cohens'd	1.16		1.33		0.19	
Flexibility	30%	M±SD	21.3±4.6	22.9±4.0	21.3±4.6	23.6±4.1	22.9±4.0	23.6±4.1
		Z & (p)	-1.72 (0.085)		-2.20 (0.002) *		-1.37 (0.170)	
		Cohens'd	0.36		0.51		0.16	

M: mean, SD: standard deviation, AROM: active range of motion of the knee joint, °: angle, MJS: medial joint space, mm: millimeter *: significant at p < 0.017 (adjusted)

Source: the authors (2024).

4. Discussion

The current study was conducted to investigate the effect of continuous mechanical knee distraction using different distraction forces. The outcomes of interest were knee joint space, active knee ROM, hamstring flexibility, and self-reported level of comfort. The results showed that medial joint space and active joint ROM increased after 20% and 30% distraction force compared to 10%, while no differences were reported between the 20% and 30% distraction forces. The self-reported level of comfort was better when lower distraction force was used (10%>20%>30%).

The effect of time varied across the different distraction forces. Both the 20 and 30% body weight distraction forces were equally effective in improving the medial joint space and active ROM values after the end of the treatment as well as at follow-up. While the 30% distraction force improved the flexibility of hamstring muscles at follow-up compared to pretreatment.

Up to the authors' knowledge, there are no previous studies that compared different knee joint distraction force magnitudes, which were calculated as a percentage of body weight. This lack of relevant literature might render the comparison difficult. For example, Alpayci and colleagues compared different decompression modes (continuous versus intermittent) on symptomatic patients suffering from knee osteoarthritis where a fixed traction value of 15kg was used with all patients. Other study compared traction effects from different knee joint positions where the traction force was determined subjectively according to the patients' own feeling of traction inside the knee joint.

The authors selected this approach of using body weight to determine the distraction force magnitude because of its convenience and suitability to participants. It also avoids the dependence on the subjective feeling of distraction reported by the patient that was adopted in previous studies. 10,11

Being aimed to identify the most effective knee distraction force, the current study was conducted on asymptomatic subjects. So, the outcomes did not include function or quality of life. Instead, the magnitude of joint separation was the main outcome of interest in addition to knee joint ROM, hamstring flexibility, and self-reported comfort level. The majority of the previous studies investigated ROM.^{1,9,10} Other outcomes such as pain, stiffness, walking characteristics^{17,18}, function^{10,19,20}, and quality of life^{10,21} were reported in other studies.

Similar to the findings of the current study, previous work^{9,10,18} reported a significant difference in ROM after distraction, while no difference was reported at follow-up. In Khademi-Kalantari et al. study¹⁰, the improvement was observed in knee flexion ROM only. Additionally, Rajoria et al. reported a reduction in joint movement restriction following distraction, especially when other traditional therapy was added.¹⁸

It's worth mentioning that only three studies adopted the percentage of body weight as a means to determine the distraction force, where force magnitudes of 6%²² and 1/7^{19,20} of body weight were used. Unfortunately, the outcome measures of these studies were different from the current one. However, these studies similarly reported significant improvement of outcomes including function^{19,20,22}, pain perception^{20,22}, and depression²² in patients with knee OA.

The observed results in the current study could be attributed to the stretching and subsequent elongation of the soft tissues inside and around the knee joint. This elongation can increase ROM, especially in the flexion direction. This can be confirmed by the previous finding that showed a correlation between limited ROM and decreased flexibility of the soft tissues in patients having knee OA. Additionally, knee joint distraction was shown to enhance muslce relaxation and inhibition of reflex muscle contration, which would ease pain sensation.

The distraction force in the current study was applied in a semiflexed knee position (30°). This position is where knee soft tissue structures are at least tense and relaxed. Thus, the distraction force could induce the greatest effect in terms of joint unloading and, hence, increase joint space that was reported in the current study.

The level of comfort may also play a role in enhancing the effect of joint distraction. The more comfort during the procedure, the more muscle relaxation and streatching can result and consequently more joint separation can be achieved.

The current study is a unique attempt to investigate the appropriate distraction force that could effectively distract the knee joint with minimal discomfort. Using force magnitudes as a percentage of body weight instead of a predetermined fixed could be advantageous because it is more convenient and patient-specific. Additionally, the current study assessed an important outcome that was not previously addressed, which is the patient-reported comfort level. As reported previously, the discomfort associated with the distraction could hinder its use. Therefore, assessing the level of comfort along with other clinical outcomes could participate in reaching a balance point where a comfortable, yet clinically effective distraction force can be implemented.

The current study was conducted on asymptomatic subjects and this could limit the generalization of the findings to other groups such as knee OA patients. The sample size is relatively small, and it was not calculated a priori, which may also limit the generalizability of the findings. We recommend future researchers to repeat the same design on different groups of knee OA patients and on larger samples. The gender-related differences in response to traction were not considered, so it is recommended to address gender as a variable in future studies.

5. Conclusion

Continued mechanical distraction of the knee joint using force magnitudes of 20% and 30% of body weight was effective in increasing medial joint space, active knee ROM, and hamstring flexibility in asymptomatic individuals. Furthermore, the 20% force magnitude was more comfortable than the 30% percent.

Authors contributions

The authors declared that they have made substantial contributions to the work in terms of the conception or design of the research; the acquisition, analysis or interpretation of data for the work; and the writing or critical review for relevant intellectual content. All authors approved the final version to be published and agreed to take public responsibility for all aspects of the study.

Conflicts of interest

No financial, legal, or political conflicts involving third parties (government, private companies, and foundations, etc.) were declared for any aspect of the submitted work (including but not limited to grants and funding, advisory board participation, study design, manuscript preparation, statistical analysis, etc.).

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