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Does tension applied in kinesio taping affect pain or function in older women with knee osteoarthritis? A randomised controlled trial

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ABSTRACT

Objective To analyse the short-term effects of kinesio taping (KT) with tension (KTT) or without tension (KTNT) in older women with knee osteoarthritis (KOA), and compare them to controls who did not receive KT.

Design Randomised controlled trial.

Setting University physiotherapy school clinic.

Participants Forty-five older women (fifteen participants per group) with 66.8 (±5.6) years and clinical diagnosis of KOA were assessed pre, post and 3 days after intervention.

Interventions Participants were randomly allocated to KTT, who received two simultaneous applications of KT with tension on the knee and rectus femoris; KTNT, who received the same application as the KTT group, but without tension and a control group that attended a class on KOA.

Primary and secondary outcome measures Primary outcome was pain intensity and secondary outcomes were knee-related health status, functional capacity, muscle strength and global rating of change.

Results No between-group differences were observed in pain after the first intervention (KTT vs KTNT: mean difference (MD), −1.8 points; 95% CI −4.2 to 0.5; KTT vs control: MD, −1.2 points; 95% CI −3.6 to 1.2; KTNT vs control: MD, 0.66 points; 95% CI −1.7 to 3.0) or 3 days later (KTT vs KTNT: MD, −1.3 points; 95% CI −3.7 to 1.0; KTT vs control: MD, 0.13 points; 95% CI −2.2 to 2.5; KTNT vs control: MD, 1.4 points; 95% CI −0.9 to 3.8). The lack of between-group differences was also found for secondary outcomes.

Conclusion The short-term use of KT with or without tension in older woman with KOA had no beneficial effects on pain and function. These findings call into question the clinical use of KT as a non-pharmacological therapy for this population.

Trial registration number NCT03624075.

Strengths and limitations of this study

- This clinical trial has true randomisation, concealed allocation, biostatistician blinding and no missing data.
- The application of Kinesio taping was well designed and based on the precepts of the creator of the technique.
- This study included a control group that did not receive Kinesio taping, facilitating the interpretation of results.
- Due to the presence of the control group, it was not possible to blind the participants and evaluators.

BACKGROUND

Knee osteoarthritis (KOA) is one of the most prevalent and costly chronic musculoskeletal disorders, especially in older women,[1] and accounts for approximately 85% of the burden of disease worldwide.[2] Joint pain and impaired physical function are the two primary reasons for disability, adversely affecting the quality of life of people with KOA.[3]

According to the latest guidelines, non-pharmacological interventions—including education, weight loss if overweight or obese, structured land-based exercise programmes and other physiotherapy interventions—together with topical non-steroidal anti-inflammatory drugs, are first-line treatments for people with KOA.[4] However, although pharmacological therapies are recommended for pain relief and improved function,[5] compromised patient safety from potential adverse side effects, particularly gastrointestinal and cardiovascular events,[3 6] favour the search for complementary treatments.

Kinesio taping (KT), a non-invasive and non-pharmacological method, is a porous, adhesive elastic bandage that has become popular among physiotherapists in the treatment of various chronic musculoskeletal conditions.[7–9] In patients with KOA, a number of high-quality studies have reported

beneficial effects after KT application, including reduced pain,[10–12] increased physical function[10–12] and greater quadriceps peak torque.[12] According to the creators of the technique, a certain amount of tension is required to generate these therapeutic effects,[13] prompting some researchers to compare the clinical effects of KT with and without tension, the latter being called a placebo group. However, applying KT without tension as a placebo condition seems to be a methodological misunderstanding of the method.[14] Previous studies found no improvement for pain and physical function when both conditions (ie, KT with vs without tension) were compared in people with KOA.[14 15] The lack of a control group (ie, no taping) in these studies precluded interpreting available evidence on the effect of KT tension in these populations.[16]

Therefore, the aim of this study was to analyse the short-term effects of KT with or without tension in older women with KOA, and compare them to controls who did not receive KT. We hypothesised that KT would relieve pain, improve function, and increase muscle strength and global perception of change when compared with no taping, without any differences between both KT conditions.

METHODS

Study design

This was a single-blind randomised controlled trial with concealed allocation, and intention-to-treat analysis, conducted in the university physiotherapy school clinic.[17]

Study population

Participants were recruited between August and December 2018 from the waiting list for KOA physiotherapy treatment at the Federal University of Rio Grande do Norte, Faculty of Health Science of Trairi (FACISA/UFRN) . Inclusion criteria were as follows: non-obese (body mass index <30.0 kg/m^2) and sedentary/irregularly active females according to the International Physical Questionnaire[18]; aged ≥60 years; baseline knee pain score ≥3 on a 10-point Numerical Pain Rating Scale (NPRS); diagnosis of symptomatic KOA based on the clinical criteria of the American College of Rheumatology[19]; and classified with mild or moderate KOA according to Lequesne's Algofunctional Questionnaire.[20]Potential participants were excluded if they met any of the following criteria: previous use of KT for any condition; signs of allergy to KT during testing before the initial evaluation; physiotherapy treatment in the previous 3 months[21]; intra-articular knee injections in the previous 6 months[21]; medical restrictions such as decompensated cardiorespiratory and metabolic diseases, neurological or any other rheumatology dysfunctions; previous hip, knee or ankle surgery; and any other chronic condition that leads to pain.[21] The participants were required to interrupt their medication routine as a prerequisite to taking part in this study.

Patient and public involvement

The patients in this research participated in the study from the recruitment stage. Outcome measures were assessed and informed through a dialogue between researcher and participants, in which the burdens and benefits of participating in the study were discussed.

Procedure

Participants who met the eligibility criteria were randomly allocated to one of the following three groups: without taping (control group), KT with tension group (KTT) and KT with no tension group (KTNT). The randomisation process was generated by a software program and performed by a researcher not involved in data collection. Assignment was concealed by placing the random allocations in opaque sealed envelopes, which were revealed immediately after initial evaluation. To minimise bias, both the therapist responsible for applying the intervention and outcome assessor followed standardised scripts to explain the overall objective of the study.

Outcome measures

The same assessor (researcher 1) performed all evaluations in the morning or afternoon. At baseline, pain, knee-related health status, knee joint perimeter, functional capacity and muscle strength were measured. Immediately after the first intervention, muscle strength and pain were reevaluated. After 3 days, all outcomes assessed at baseline were reevaluated, adding the global rating of change (figure 1). Final evaluations in the KT groups were performed with the bandage on the knee, to minimise the lack of assessor blinding. KT group participants were unaware of which technique they were receiving.

Primary outcome

- Pain: The primary outcome was pain assessed by the NPRS, whereby participants were asked to choose a number between 0 (no pain) and 10 (worst pain possible).[22] They were instructed to report the level of pain while sitting and rising from a chair. The reliability of NPRS is considered excellent (intraclass coefficient - ICC=0.95).[23] The minimum detectable change for this scale is 1.33 points.[23]

Secondary outcomes

- Knee-related health status: This was assessed via the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC), in its Brazilian version,[24] which consists of 24 items divided into three main domains: pain, stiffness and physical function. Each question is scored from 0 to 4, and the total score, given by the sum of the three domain scores, varies from 0 to 96; the maximum score is 96 and high scores mean poor health status.[25] The reliability of WOMAC was either good or excellent (ICC=0.85–0.97).[24] The smallest detectable change ranged from 3.84 to 16.25 points.[24]
- Functional capacity: The 6 min walk test (6MWT) was performed according to American Thoracic Society recommendations.[26] Two cones were placed 30 m apart, and the patients were instructed to walk at their own pace to cover maximum distance in 6 min. During

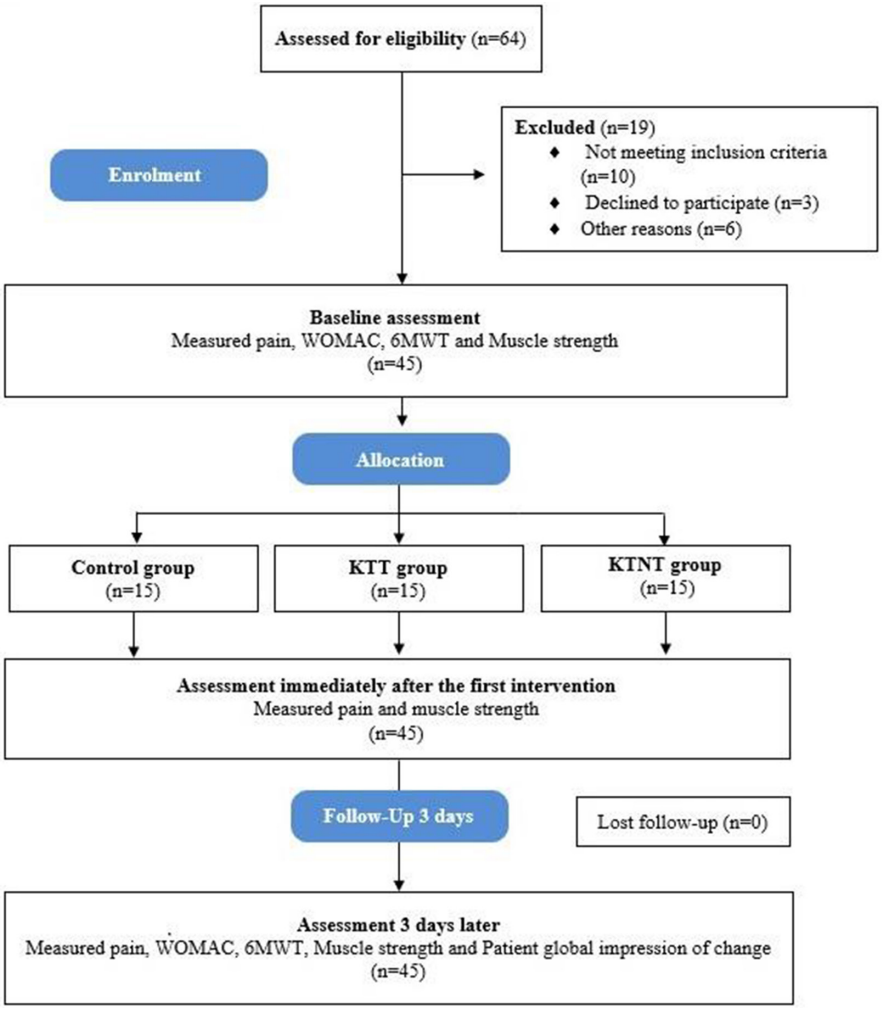

Figure 1 Design and flow of participants through the trial. KTNT, kinesio taping without tension; KTT, kinesio taping with tension; 6MWT, 6 min walk test; WOMAC, western Ontario and McMaster universities osteoarthritis index.

the test, verbal encouragements, such as 'you're doing great' and 'keep it up', were given every minute. Test–retest reliability has been demonstrated to be excellent (ICC=0.99) in patients with knee OA.[27]

- Muscle strength: The isometric strength of the femoral quadriceps was evaluated using a hand-held dynamometer (HHD; Nicholas Manual Muscle Tester, Lafayette Instrument Company, Lafayette, Indiana, USA). The participant was placed in the sitting position on a stretcher, with arms crossed over chest. An ankle stabilisation belt was placed on the evaluated limb to maintain hip and knee flexion at 90°. The HHD was placed 2 cm proximal to the lateral malleolus midpoint, in the anterior region of the ankle (between the malleoli). Maximum isometric strength was then measured in 5 s knee extensions, with continuous verbal encouragement. Subjects performed one practice trial, rested for 30 s and then carried out the three measured trials, the strongest of which was used for data analysis.[28] The results of all trials (kg) were transformed into Newtons (Strength [N]=strength [kg]×9.81) and normalised by body mass (Normalised Strength [N/kg]=Strength [N]÷Body Mass[kg]).[29] It is noteworthy that the HDD proved to be a highly reliable tool (ICC=0.83–0.96).[30]
- Knee joint perimeter: To collect preliminary data to support future randomised controlled trials, knee joint perimeter was measured (see online supplemental material 1). In the supine position, participants remained with their hips in neutral position and knees in full extension, without quadriceps contraction. From that position, the assessor measured the knee at three points: the popliteal fossa fold, and 5 cm above and below it. Each level was assessed three times and the average of each level was used for analysis.[14] The reliability of the knee perimeter was considered high (ICC=0.99).[31]
- Global rating of change: This was assessed via the patient global impression of change. The measure is recommended by the Initiative on Methods, Measurement and Pain Assessment in Clinical Trials group[32] and targets four different domains: pain, function, quality of life and global condition, measured using a 7-point scale (from 'considerably improved' to 'considerably deteriorated').[33]

Interventions

The therapist in charge of the intervention (researcher 2) had previous experience using KT and participated in a 3-hour training module before the start of the study, which consisted of scientific information and practical KT application training. In addition, the therapist obtained certification for the application of the techniques to the study. The presence of a group without tape precluded control group participants and researchers 1 and 2 from being blinded to the treatment.

The participants allocated to the KTT group received two simultaneous KT techniques (Kinesio Tex Gold), both with tension. In the first technique, KT was applied in an 'Y' shape, with 30% tension,[13] following the origin and insertion of the rectus femoris. The upper edge of the tape was 15 cm below the anterosuperior iliac spine, with the 'Y' arms around the patella and meeting at its lower edge. In the second technique (fun cut technique), two tapes with 10% tension were applied.[13] The body of each tape was longitudinally divided into four narrow strips. The first tape was applied to the lateral region of the knee, 15 cm above the joint line, with the body of the tape crossing the anterior region of the knee, with a distance of 2 cm between each narrowest strip. The second tape was applied to the medial region of the knee, following the same procedure as the first tape, both intersecting in the anterior region of the knee (see online supplemental material 1). During application, the volunteers remained in the supine position, relaxed and with full knee flexion and hip extension.

KT was applied to KTNT group participants similarly to the previous group, with no tension on the tape. In the case of bilateral KOA in any of the groups, the most affected member based on the NPRS score was selected to receive the intervention. The tape was left on the volunteers for 3 days,[14] the amount of time usually recommended in clinical practice and in accordance with Kase *et al*[13], after which it can be removed. The control group attended a 60 min class about KOA, where the causes, diagnosis, treatment and general orientation on life habits were explained, as proposed by French *et al*[34].

Sample size and statistical analysis

The sample size was based on a significance level of 0.05 and power of 0.90 to detect clinically significant between-group differences in the pain outcome on the NPRS at two time points.[35] Based on these criteria, 42 participants with KOA (14 in each group) were required, and to allow for possible dropouts during the intervention period, 15 per group.

A blinded biostatistician (researcher 3) performed all analyses using the SPSS, V.20.0. All statistical procedures were performed according to intention to treat principles. The Kolmogorov-Smirnov test was used to evaluate data distribution, and all variables were normally distributed. Between-group comparisons to obtain the average effects were conducted using interaction terms (group vs time interactions) and linear mixed models. The χ^2 test was performed to compare categorical variables. Differences were considered statistically significant when $p<0.05$.

Table 1 Baseline characteristics of the participants

Variables	Control (n=15)	KTT (n=15)	KTNT (n=15)
Age (years)	65.6 (6.7)	66.8 (4.6)	68.1 (5.7)
BMI (kg/m^2)	27.7 (2.2)	28.2 (2.0)	26.7 (2.3)
Classification OA—Lequesne's Algofunctional	6.7 (1.7)	6.0 (1.4)	6.4 (.9)
Symptom duration (months)	108.0 (94.4)	68.7 (57.5)	90.7 (91.7)

Values are mean (SD).
BMI, body mass index; KTNT, kinesio taping with no tension; KTT, kinesio taping with tension; OA, osteoarthritis.

RESULTS

A total of 64 participants were screened and 19 were excluded for the reasons explained in figure 1. Thus, 45 participants matched the eligibility criteria and were randomised.

The demographic characteristics of participants at baseline were similar for all groups (table 1). Means and SD for all the outcome measures at each assessment time point are shown in table 2.

The within-group analysis showed that participants from the KTT and KTNT groups experienced 15% less pain compared with baseline at the first intervention, not reaching the nominated threshold (ie, 30% improvement from the baseline score) for the minimum clinically important change.[35] At the end of the 3-day intervention, both KTT and KTNT groups improved their pain levels and WOMAC scores by 30% and 19% compared with baseline, respectively, which is considered clinically important.[25] For the 6MWT, an average change of 20.6 m and 11.0 m were observed for KTT and KTNT groups, respectively, and only the first result was considerate clinically meaningful.[36] Muscle strength did not significantly change in the intervention groups at any time point (table 3).

In between-group analysis, however, no significant differences were observed for any of the outcomes investigated at the first intervention or 3 days later (table 3). Although a lower pain intensity score was achieved in both KT groups after the first intervention (KTT vs KTNT, mean difference (MD): −1.8 points; 95% CI −4.2 to 0.5) and 3 days later (KTT vs KTNT, MD: −1.3 points; 95% CI −3.7 to 1.0), the mean estimate did not reach the nominated threshold (ie, a 2-point decline in pain severity) for a minimum clinically important difference. In addition, the large width of the 95% CI demonstrates a range of possible effects on pain severity, including individuals who worsened after the applications.

Table 2 Descriptive data at baseline, post first intervention and 3 days later for pain, WOMAC, 6MWT and muscle strength

	Baseline			Post			3 days		
Outcomes	**Control (n=15)**	**KTT (n=15)**	**KTNT (n=15)**	**Control (n=15)**	**KTT (n=15)**	**KTNT (n=15)**	**Control (n=15)**	**KTT (n=15)**	**KTNT (n=15)**
Pain (0–10)	5.4 (1.8)	5.5 (2.4)	6.9 (1.5)	4.6 (2.3)	3.9 (3.1)	5.8 (2.4)	4.5 (2.2)	3.0 (2.5)	4.4 (3.0)
WOMAC (0–96)	41.4 (21.1)	41.9 (12.5)	57.5 (19.6)	–	–	–	36.6 (19.2)	26.3 (10.9)	35.5 (26.5)
6MWT (m)	313.3 (62.1)	332.0 (91.0)	251.9 (133.0)	–	–	–	330.0 (51.4)	353.0 (102.0)	262.2 (126.8)
Muscle strength (N/kg)	2.2 (0.6)	2.4 (0.8)	2.2 (1.2)	2.3 (0.8)	2.5 (0.8)	2.4 (0.9)	2.4 (0.9)	2.7 (0.9)	2.7 (1.1)

Values are mean (SD).
KTNT, kinesio taping with no tension; KTT, kinesio taping with tension; 6MWT, 6 min walk test; WOMAC, Western Ontario and McMaster Universities Osteoarthritis Index.

Table 3 Within and between group differences (95% CIs) at post first intervention, and 3 days later for pain, WOMAC, 6MWT and muscle strength

	Within-group diferences						Between-group differences					
	Post minus baseline			3 days minus baseline			Post			3 days		
Outcomes	**Control**	**KTT**	**KTNT**	**Control**	**KTT**	**KTNT**	**Control-KTT**	**Control-KTNT**	**KTT-KTNT**	**Control-KTT**	**Control-KTNT**	**KTT-KTNT**
Pain (0–10)	–0.2 (–1.7 to 1.3)	–1.6 (–3.1 to –0.07)	–1.3 (–2.8 to 0.1)	–0.2 (–1.8 to 1.2)	–2.4 (–4.0 to –0.9)*	–2.7 (–4.2 to –1.1)	–1.2 (–3.6 to 1.2)	0.66 (–1.7 to 3.0)	–1.8 (–4.2 to 0.5)	0.13 (–2.2 to 2.5)	1.4 (–0.9 to 3.8)	–1.3 (–3.7 to 1.0)
WOMAC (0–96)	–	–	–	–4.8 (–13.6 to 4.0)	–15.5 (–24.3 to –6.7)*	–22.0 (–31.1 to –12.8)	–	–	–	1.1 (–17.0 to 19.3)	10.2 (–7.9 to 28.4)	–9.1 (–27.3 to 9.0)
6MWT (m)	–	–	–	16.7 (2.0 to 31.3)*	20.5 (5.0 to 35.2)*	11.0 (–4.1 to 26.1)	–	–	–	67.8 (–22.2 to 157.8)	–23 (–113 to 67)	90.8 (–7.0 to 180.8)
Muscle strength (N/kg)	0.1 (–0.1 to 0.4)	0.05 (–0.2 to 0.3)	0.2 (–0.09 to 0.5)	0.2 (–0.1 to 0.6)	0.2 (–0.1 to 0.6)	0.4 (0.1 to 0.8)*	–0.1 (–1.0 to 0.7)	–0.1 (–0.9 to 0.7)	0.02 (–0.8 to 0.8)	–0.2 (–1.1 to 0.6)	–0.2 (–1.0 to 0.6)	–0.01 (–0.9 to 0.8)

*P<0.005 when compared 3 days post intervention and baseline at this group.
KTNT, kinesio taping with no tension; KTT, kinesio taping with tension; 6MWT, 6 min walk test; WOMAC, Western Ontario and McMaster Universities Osteoarthritis Index.

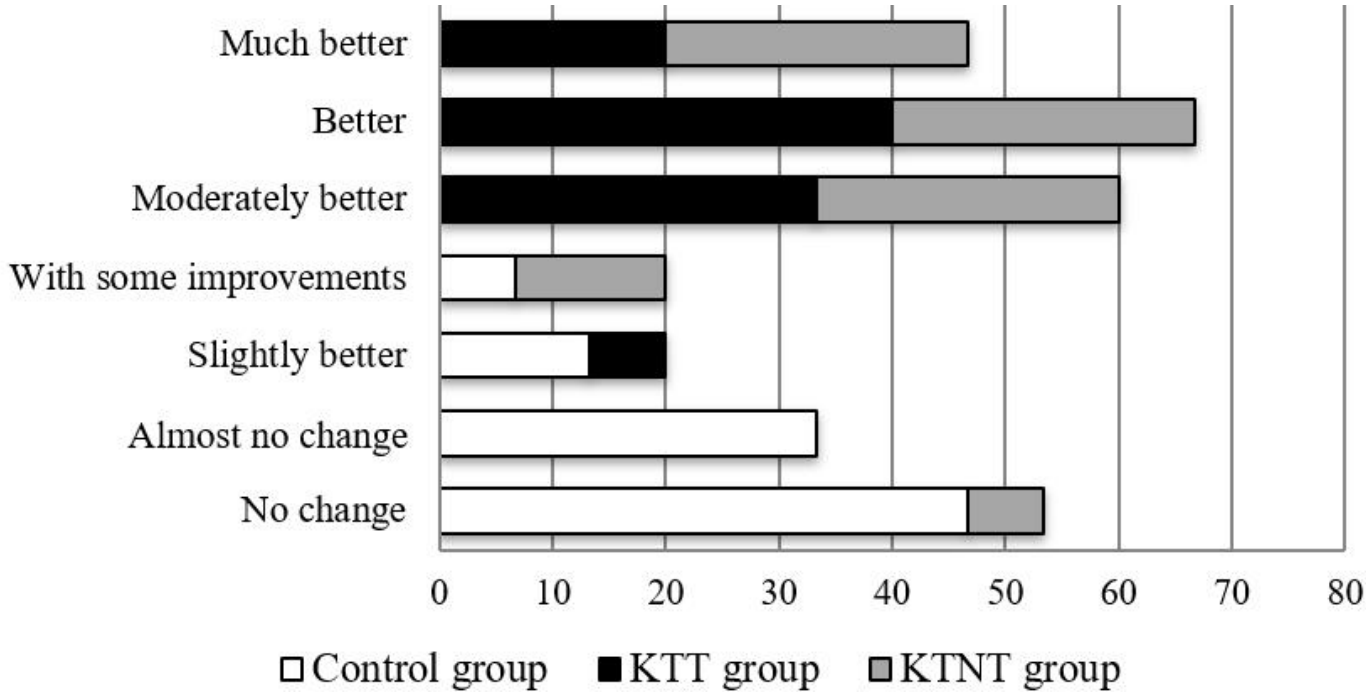

Figure 2 Patient global impression of change at the end of the third day (percentage values). KTNT, kinesio taping group without tension; KTT, kinesio taping group with tension.

Another outcome evaluated was the global rating of change at the end of the third day. No statistical between-group differences were observed (KTT vs control: X^2=8.221; p=0.51; KTNT vs control: X^2=9.107; p=0.69; KTT vs KTNT: X^2=8.00; p=0.78). However, from a descriptive point of view, it can be seen that subjects from both KT groups reported better perception of change when compared with controls, with no changes in the latter (figure 2).

DISCUSSION

This randomised controlled trial aimed to analyse the short-term effects of KT with or without tension in older women with KOA, and compare them to controls who did not receive KT application. Immediately after the first intervention or 3 days later, intergroup comparisons showed no advantage of KTT or KTNT when compared with control group for the primary outcome of pain. These estimates were also maintained for all other secondary outcomes. The use of KT tension did not enhance treatment outcomes at any point in time.

Our results differed from those of previous studies,[10–12] which reported a significant reduction in pain in people with KOA who received KTT, when compared with KTNT. However, these results should be interpreted with caution due to methodological limitations such as the lack of assessor blinding—which can overestimate the real results,[37] and uncertainty about the non-use of analgesic medication by participants during the study. By contrast, Wageck *et al*[14] analysed older people with KOA, and showed that KTT did not able reduce pain, improve function or increase muscle strength, when compared with KTNT. In the present study, in addition to comparing the KTT and KTNT groups, we simultaneously applied more than one overlapping KT technique, similar to Wageck *et al*[14]. According to Kase *et al*,[13] KT should be applied with a small amount of tension (ie, 10%–15%) to generate therapeutic effects and simultaneous application is needed to achieve more than one effect.[13] However, despite following these recommendations, we found no differences between the KT groups. These results demonstrated that the bandage application technique does not appear to influence the outcomes.

One of the strong points of this study was the inclusion of a control group (without KT) who received only orientation about the disease. Only one study[11] showed that applying KTT for three consecutive days improved pain and physical function in people with KOA, when compared with control group. However, the values did not reach clinically important parameters[23 24] to warrant the intervention. In addition, no significant differences were observed for primary outcomes of pain and physical function between KTT and KTNT, similar to our study.

The absence of pain relief after the interventions may explain the non-difference between KT groups and controls for knee-related health status, physical function and muscle strength, given that these outcomes are closely related. It has been previously reported that knee pain may negatively affect the function and muscle strength of people with KOA.[38 39] Several studies have compared the effects of applying KTT, KTNT and/or a control group on quadriceps muscle strength, finding similar to those reported here.[10 11 14]

The present study also assessed, for the first time, KOA patient global rating of change with KT application. Although statistical differences were not observed, most of the older women in the KTT and KTNT groups showed signs of improvement. Curiously, the control group reported having noticed almost no changes. One study[40] showed that KT, regardless of tension or direction of application, can influence stretching of the skin and, in doing so, activate cutaneous receptors, which makes us believe that it affects the perceived recovery of individuals. However, the lack of a placebo group (ie, surgical tape) precludes drawing conclusions about the effects of KT on this outcome.

Despite the strengths of this study (true randomisation, concealed allocation, biostatistician blinding, a control group and no missing data), it has some limitations. Due to the presence of a control group (ie, without tape), it was not possible to blind the participants, assessor and therapists to the treatment. To minimise this bias, the KT groups were assessed with a bandage over their knee, and were unaware of which technique they were receiving. It is also important to underscore that these findings are limited to older women with KOA, preventing extrapolation of the results for men and other clinical conditions. Moreover, the tape was applied only once with a short 3-day follow-up; future research should involve longer protocols for comparison purposes. The sample size may be another limitation of the study, however, our findings were consistent with previous clinical trials that applied similar protocols,[14 15] demonstrating that a larger sample size would not possibly modify the results presented in the present study.

In conclusion, the short-term use of KT with or without tension in older woman with KOA had no beneficial effects on pain and function. These findings call into question the clinical use of KT, regardless of tension, as a non-pharmacological therapy for this population.

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Contributors Study conception and design: YTP, MCS and CAdAL. Data acquisition: YTP, HRFF, CAMS and JOA; data analysis and interpretation: YTP, GMB, HJAS, MCS and CAdAL. Drafting of themanuscript: YTP, GMB and CAdAL. Critical revisions: all authors. Final approval of the article: all authors; obtention of funding: YTP and CAdAL.

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