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Research

Kinesio Taping to generate skin convolutions is not better than sham taping for people with chronic non-specific low back pain: a randomised trial

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KEY WORDS

Kinesio Taping
Randomised controlled trial
Low back pain



ABSTRACT

Question: For people with chronic low back pain, does Kinesio Taping, applied according to the treatment manual to create skin convolutions, reduce pain and disability more than a simple application without convolutions? **Design:** Randomised trial with concealed allocation, intention-to-treat analysis and blinded assessment of some outcomes. **Participants:** 148 participants with chronic non-specific low back pain. **Intervention:** Experimental group participants received eight sessions (over four weeks) of Kinesio Taping applied according to the Kinesio Taping Method treatment manual (ie, 10 to 15% tension applied in flexion to create skin convolutions in neutral). Control group participants received eight sessions (over four weeks) of Kinesio Taping with no tension, creating no convolutions. **Outcome measures:** The primary outcome measures were pain intensity and disability after the four-week intervention. Secondary outcomes were pain intensity and disability 12 weeks after randomisation, and global perceived effect at both four and 12 weeks after randomisation. **Results:** Applying Kinesio Tape to create convolutions in the skin did not significantly change its effect on pain (MD–0.4 points, 95% CI–1.3 to 0.4) or disability (MD–0.3 points, 95% CI–1.9 to 1.3) at four weeks. There was a small difference in favour of the experimental group for the secondary outcome of global perceived effect (MD 1.4 points, 95% CI 0.3 to 2.5) at four weeks. No significant between-group differences were observed for the other secondary outcomes. **Conclusion:** Kinesio Taping applied with stretch to generate convolutions in the skin was no more effective than simple application of the tape without tension for the outcomes measured. These results challenge the proposed mechanism of action of this therapy. **Trial registration:** Brazilian Registry of Clinical Trials, RBR-7ggfkw. [Parreira PCS, Costa LCM, Takahashi R, Hespanhol Junior LC, da Luz Junior MA, da Silva TM, Costa LOP (2014) Kinesio Taping to generate skin convolutions is not better than sham taping for people with chronic non-specific low back pain: a randomised trial. *Journal of Physiotherapy* 60: 90–96]

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Introduction

Chronic low back pain is a very prevalent condition¹ and it is associated with enormous health and socioeconomic costs.² The prognosis of acute low back pain³ is initially favourable with reduction of pain and disability in the first six weeks. After this period, there is a slower improvement in symptoms for up to one year.³ Several treatments are available for people with chronic low back pain. These treatments include: educational programs,⁴ medication,^{5–7} electrophysical agents,⁸ manual therapy,⁹ exercises¹⁰ and others.¹¹ Nevertheless, these treatments have, at best, a moderate effect, thus, more effective treatments are needed for low back pain.^{12,13}

Kinesio Taping¹⁴ is a new method of treatment that is very popular in sports¹⁵ and it has also been proposed for people with low back pain.^{16,17} This technique makes use of elastic adhesive tape, which is applied to the patient's skin under tension.¹⁴ The elastic tape that is used with this technique can be extended up to 140% of its original length.¹⁴ The tape is thin and light, and made of 100% cotton fabric that is porous and does not restrict the range of motion. The tape is adhesive and activated by heat, does not contain latex, and is reported to have similar elasticity to the skin.¹⁴ The tape can last for a period of three to five days and can be used in water. The expansion of the Kinesio[®] Tex Tape is only in the longitudinal direction.¹⁴

During patient assessment, the therapist decides what level of tension will be used. The combination of the stretching capacity of

the Kinesio Tape and its application over stretched muscle will create convolutions in the patient's skin on return to the neutral position.¹⁴ These convolutions, according to the creators of this technique,¹⁴ reduce the pressure in the mechanoreceptors that are located below the dermis, thereby decreasing nociceptive stimuli. Furthermore, it has been proposed that the convolutions alter the recruitment of muscles through inhibitory and excitatory neuromuscular mechanisms.¹⁴ According to the creators¹⁴ of the method, the mechanism is inhibitory or excitatory, depending on the direction of tape application. One study¹⁸ investigated the effect of the direction of Kinesio Taping, but showed that the direction of the tape is unimportant. Nevertheless, the question of whether the convolutions generated by the tape are important remains because the theory that skin convolutions are the mechanism for the Kinesio Taping effects has never been tested in a high-quality, randomised controlled trial.

Therefore, the research questions for this study were:

1. Is Kinesio Taping, applied according to the treatment manual (ie, generating convolutions in the skin by applying Kinesio Tape with a tension of 10 to 15%), more effective than a simple sham application (ie, not generating convolutions in the skin by applying same tape without any tension) in people with chronic low back pain?
2. Are any of the effects observed after four weeks of treatment sustained until 12 weeks after randomisation?

Method

Design

This study was a prospectively registered, two-arm, randomised, sham-controlled trial with blinded assessment of some outcomes. The methods of the study were also pre-specified in a published protocol.¹⁹ A physiotherapist, who was unaware of the treatment allocation, screened people in order to confirm eligibility. This screening involved taking a careful medical history and a physical examination. Those who were eligible were informed about the study procedures and those who agreed to participate in the study signed a consent form. An assessor, who was blinded to the treatment allocation, then collected the baseline data and performed an allergy test on all participants. This allergy test consisted of applying a small patch of Kinesio Tape^a over the skin. Participants kept this patch on for 24 hours and were instructed to remove the patch and call the chief investigators if any allergic reaction occurred. Those without allergic reaction to the patch test were then scheduled to undergo randomisation and attend their first treatment session.

Participants were randomly assigned to their treatment groups according to a randomisation scheme generated by computer and carried out by an investigator who was not involved with the recruitment and treatment of participants. The allocation of the subjects was concealed by using sequentially numbered, sealed and opaque envelopes. On the first day of treatment, the envelope allocated to the participant was opened by the physiotherapist who provided the treatments. This physiotherapist was not involved with the data collection. A blinded assessor assessed clinical outcomes at four and 12 weeks after randomisation. Participants were informed that they would receive one of two different forms of Kinesio Taping application, but were blinded to the study hypotheses (ie, convolutions versus sham taping). Due to the nature of the interventions it was not possible to blind the therapists.

Participants, therapists, centres

People presenting with low back pain of at least three months' duration, aged between 18 and 80 years, of either gender, who were seeking treatment for low back pain were included in this study. People with any contraindication to physical exercise, according to the guidelines of the American College of Sports Medicine,²⁰ were excluded from the study, including: serious spinal pathology, nerve root compromise, serious cardiopulmonary conditions, pregnancy or any contraindications to the use of taping (such as skin allergy).

Three physiotherapists, who were not involved in the initial assessments, treated the participants. The physiotherapists were extensively trained to deliver the Kinesio Taping intervention by two certified Kinesio Taping Method practitioners. These practitioners audited the interventions over the course of the study. The trial was conducted in two outpatient physiotherapy clinics in the cities of São Paulo and Campo Limpo Paulista, Brazil.

Intervention/control

For people with low back pain, the tape can be placed parallel to the spine or in an asterisk pattern.¹⁴ In both groups in this study, the tape was placed bilaterally over the erector spinae muscles, parallel to the spinous processes of the lumbar vertebrae, starting near the posterior superior iliac crest.^{14,19}

Participants in the experimental group were taped according to the Kenzo Kase's Kinesio Taping Method Manual,^{14,19} as presented in Figure 1. This involved the application of an I-shaped piece of Kinesio Tape^a over each erector spinae muscle with 10 to 15% of tension (paper-off tension) with the treated muscles in a stretched position, thus creating convolutions in the skin when the patient returned to the upright position in neutral.

Participants in the control group received the same taping but without tension, as presented in Figure 2. The tape was first anchored close to the posterior superior iliac crest without traction (ie, 0% tension). Then the patient was asked to remain in the standing position and tape was applied over each erector spinae muscle to the level of the T8 vertebra. In this technique, the therapist completely removed the backing paper of the tape in order to remove the tension from the tape.

Participants in each group were asked if the tape was limiting lumbar movement and, if so, the tape was reapplied so that they had unrestricted range of motion. Participants were advised to leave the tape in situ for two consecutive days and then to remove the tape, clean the skin and treat the skin with a moisturising lotion. The participants went without tape for 24 hours to allow the skin to recover appropriately and then returned to the clinic for the tape to be reapplied.

Participants from both groups had the tape reapplied twice per week for four weeks, making a total of eight applications. They were instructed not to change any medication prescribed by their physician and not to seek other treatment for their low back pain during the course of the study. Regular physical activities were allowed, which were also monitored during the treatment sessions.

Outcome measures

Four outcomes were measured: the intensity of pain, which was determined by a numerical rating scale; disability associated with back pain, which was assessed by completion of the Roland Morris Disability Questionnaire²¹; global impression of recovery, which was evaluated by a Global Perceived Effect scale²² and adverse events. The numerical rating scale, the Roland Morris Disability Questionnaire and the Global Perceived Effect scale were

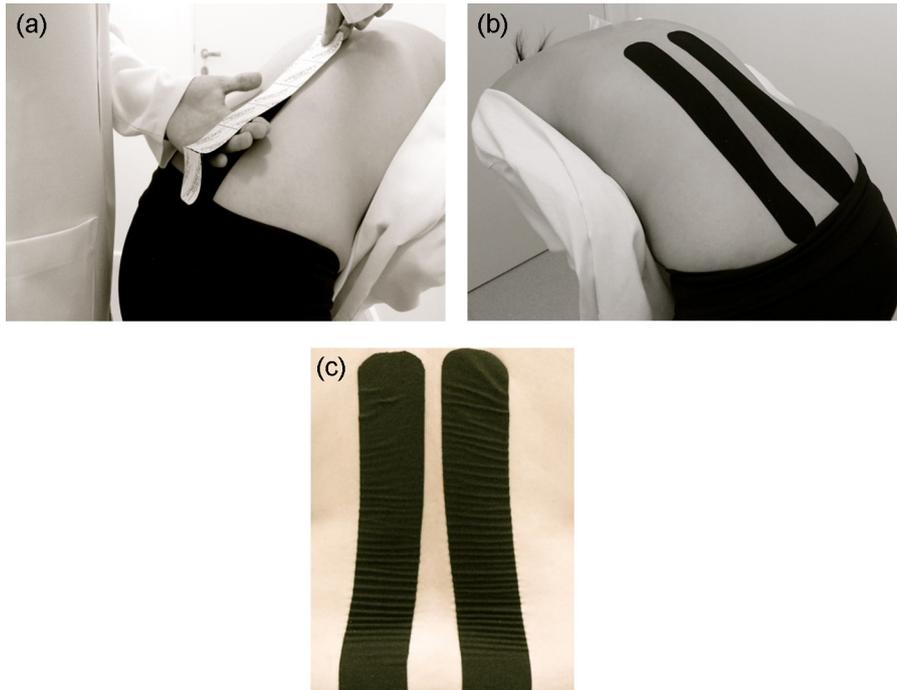


Figure 1. I-shaped Kinesio Tape over each erector spinae muscle with 10 to 15% of tension (paper-off tension) with the treated muscles in stretched position according to Kenzo Kase's Kinesio taping manual.¹⁹

professionally translated, cross-culturally adapted into Brazilian Portuguese, and tested for their measurement properties for people with low back pain in Brazil.²³⁻²⁵

The primary outcomes were pain intensity and disability associated with low back pain, which were measured immediately

after treatments (four weeks). The secondary outcomes were pain intensity and disability associated with low back pain, which were measured 12 weeks after randomisation, and global impression of recovery, which was measured immediately after treatments (four weeks) and 12 weeks after randomisation.

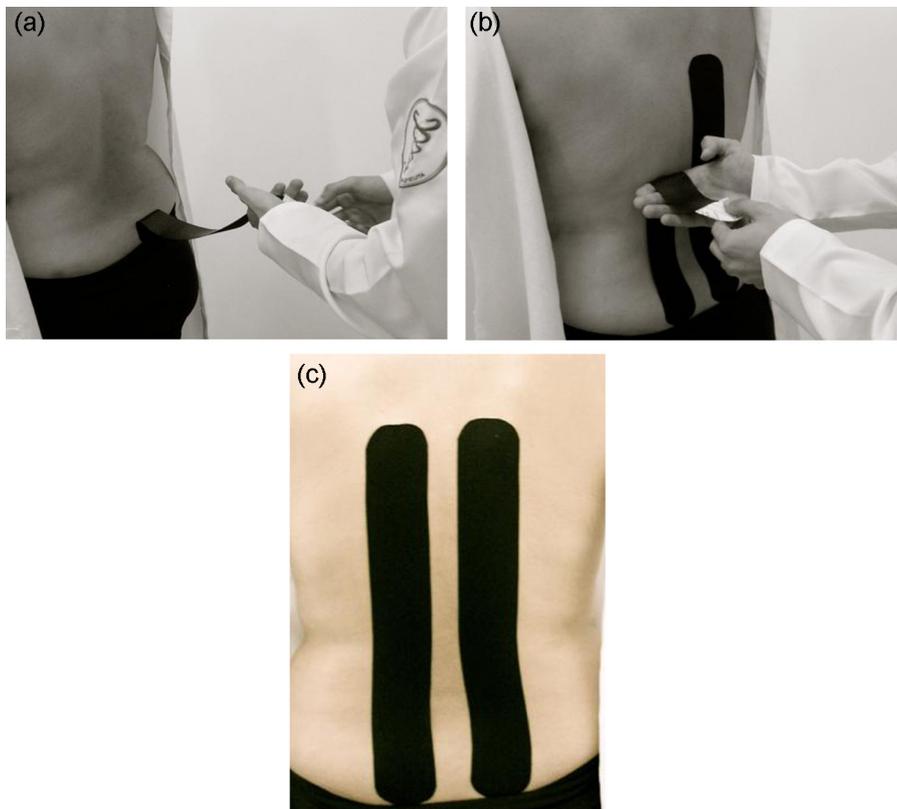


Figure 2. I-shaped Kinesio Tape over each erector spinae muscle with no tension (0% tension) and with the treated muscle in a non-stretched position.¹⁹

Table 1
Baseline characteristics of the participants (n = 148).

Characteristics	Exp (n = 74)	Con (n = 74)
Gender, n female (%)	56 (76)	59 (80)
Age (yr), mean (SD)	51 (15)	50 (15)
Symptom duration (mo), median (IQR)	24 (3 to 360)	36 (3 to 240)
Weight (kg), mean (SD)	74 (14)	70 (11)
Height (m), mean (SD)	1.6 (0.1)	1.6 (0.1)
Marital status, n (%) ^a		
single	10 (14)	16 (22)
married	51 (69)	42 (57)
widowed	5 (7)	9 (12)
divorced	8 (11)	7 (9)
Education status, n (%) ^a		
elementary degree	25 (34)	18 (24)
high school	34 (46)	37 (50)
university	13 (18)	17 (23)
master's degree	2 (3)	2 (3)
Use of medication, n (%)	42 (57)	37 (50)
Physically active, n (%)	24 (32)	32 (43)
Smoker, n (%)	5 (7)	3 (4)
Recent exacerbation of pain, n (%)	39 (53)	42 (57)

^a Percentages may not sum to 100 due to rounding.
Exp = experimental, con = control.

The numerical rating scale for pain²⁶ evaluates the perceived intensity of pain, using an 11-point scale from 0, representing 'no pain', to 10, which is the 'worst possible pain'. Participants were asked to report the level of pain intensity based on the previous seven days.

The Roland Morris Disability Questionnaire²¹ is used to assess disability associated with back pain. It consists of 24 items, which describe common activities that people have difficulty performing due to back pain. The greater the number of activities checked, the greater the level of disability. Participants were asked to fill in the items that applied on the day the questionnaire was completed.

The Global Perceived Effect Scale²² is an 11-point scale ranging from -5, representing 'much worse', to +5, which is 'completely recovered', with 0 representing 'no change'. For all measures of global perceived effect (at baseline and at all follow ups), participants were asked, 'Compared with the beginning of the first episode, how would you describe your lower back today?' This scale has good measurement properties.^{22,27}

Any type of adverse effects, such as allergic reactions or skin problems, were also recorded by asking the participants if they had felt any itching or irritation on the skin where the tape was applied.

Sample size calculation

The study was designed to detect a between-group difference of 1 point in pain intensity measured by the numerical rating scale, with an estimated standard deviation of 1.84 points, and a

between-group difference of 4 points for disability measured by the Roland Morris Disability Questionnaire, with an estimated standard deviation of 4.9 points. The other specifications were: power of 80%, an alpha of 5% and a possible loss to follow up of up to 15%. Therefore, a total of 148 participants (74 per group) were recruited for this study. The estimates used in the sample size calculation were lower than the ones suggested as the minimum clinical important difference in order to increase the precision of the estimates of the effects of the interventions.

Data analysis

The statistical analysis was conducted on an intention-to-treat basis, that is participants were analysed in the groups to which they were randomly allocated. Visual inspection of histograms was used to test data normality and all outcomes had normal distributions. The characteristics of the participants were summarised using descriptive statistics. The between-group differences and their respective 95% CIs were calculated using linear mixed models by using group, time and group-versus-time interaction terms.

Results

Flow of participants through the trial

A total of 184 people were screened for this study. Thirty-six were excluded for the reasons presented in Figure 3. The remaining 148 participants were all evaluated at four weeks (after treatment) and 12 weeks (ie, 0% loss to follow up). Adherence to the eight-planned treatment sessions was high in both groups, with a mean of 7.4 sessions (SD 1.5) in the experimental group and 7.1 sessions (SD 1.9) in the control group.

Three participants, who had passed the initial allergy patch test and commenced treatment, had allergic reactions to the Kinesio Tape^a and missed some treatments. One of these participants was in the experimental group and two in the control group. All participants recovered from the allergic reactions after the removal of the tape without the need for additional interventions such as antihistamines.

The demographic characteristics of the participants are presented in Table 1. The baseline values of the outcome measures are presented in the first two columns of Table 2. The majority of participants were female (78%). The participants had a mean age of 50 years, with an average of two years or more of pain, moderate pain intensity and moderate disability. The groups were comparable at baseline.

Table 2
Mean (SD) for continuous outcomes at all study visits for each group, mean (SD) difference within groups, and mean (95% CI) difference between groups.

Outcomes	Groups						Within-group differences				Between-group differences ^a	
	Week 0		Week 4		Week 12		Week 4 minus Week 0		Week 12 minus Week 0		Week 4 minus Week 0	Week 12 minus Week 0
	Exp (n = 74)	Con (n = 74)	Exp (n = 74)	Con (n = 74)	Exp (n = 74)	Con (n = 74)	Exp	Con	Exp	Con	Exp minus Con	Exp minus Con
Pain, (0 to 10)	7.0 (2.0)	6.8 (2.0)	4.4 (2.8)	4.6 (2.5)	5.4 (2.4)	5.7 (2.5)	-2.6 (3.1)	-2.2 (2.7)	-1.6 (2.9)	-1.1 (2.7)	-0.4 (-1.3 to 0.4)	-0.5 (-1.4 to 0.4)
Disability, (0 to 24)	11.5 (6.2)	10.4 (5.3)	8.3 (6.9)	7.4 (6.4)	8.8 (7.5)	7.4 (6.3)	-3.2 (5.4)	-3.0 (4.6)	-2.7 (5.6)	-3.0 (4.8)	-0.3 (-1.9 to 1.3)	0.3 (-1.3 to 1.9)
Global Perceived Effect, (-5 to 5)	-1.0 (3.2)	-0.1 (2.9)	2.4 (2.4)	1.9 (2.7)	1.2 (2.8)	1.6 (2.5)	3.4 (3.7)	2.0 (3.8)	2.1 (3.4)	1.7 (3.6)	1.4 (0.3 to 2.5)	0.4 (-0.7 to 1.5)

^a Between-group differences are adjusted. Shaded cells = primary outcomes. Exp = experimental, con = control.

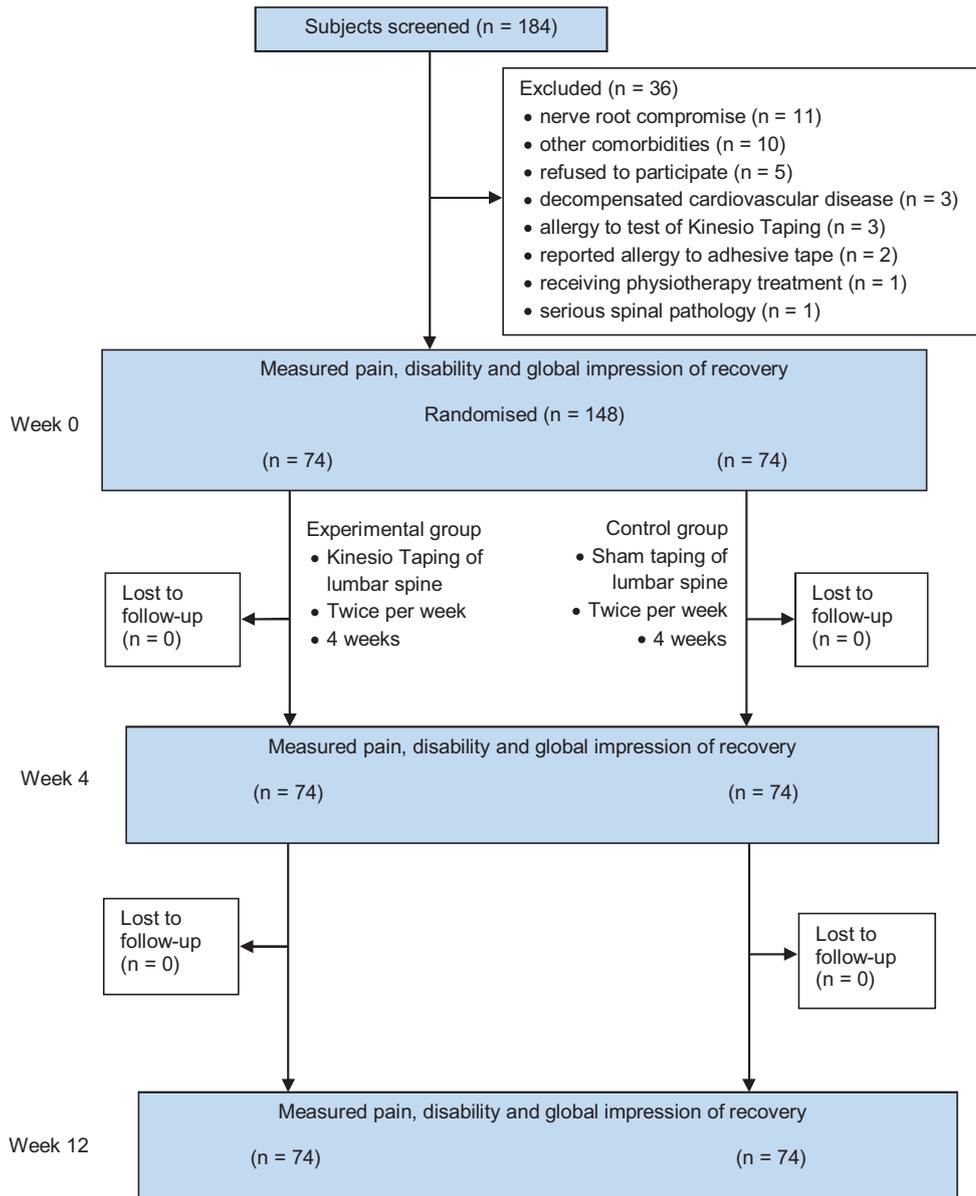


Figure 3. Design and flow of participants through the study.

Effect of intervention

No significant between-group differences were observed for the primary outcomes of pain intensity and disability at four weeks. There was a significant, but small, difference in favour of the intervention group for the secondary outcome of global perceived effect at four weeks, but not at 12 weeks. No significant between-group differences for the remaining secondary outcomes were detected. These results are presented in Table 2, with individual data presented in Table 3 (see eAddenda for Table 3).

Discussion

After four weeks of treatment, both groups in this trial showed similar reductions in the primary outcomes of pain intensity and disability, with no statistically significant differences between the

two treatment conditions. One of the secondary outcomes favoured the experimental group, with better results for the global perceived effect outcome after four weeks of treatment compared with the control group, but this effect was not sustained to 12 weeks.

The results of this trial are consistent with the results of two other trials that evaluated the use of Kinesio Taping in people with chronic low back pain. One study¹⁶ allocated people into three groups (Kinesio Taping and exercises, Kinesio Taping only and exercises only). The outcomes assessed in this study were pain intensity, disability and lumbar muscle activation measured by electromyography. No between-group differences were observed. Another study¹⁷ compared the effect of Kinesio Taping versus the control procedure of the present trial (Kinesio Taping without convolutions) for the outcomes pain, disability and range of motion for trunk flexion. People received only one application of the tape, which remained in situ for one week. This study also did not

identify any differences in favour of the Kinesio Taping. We do not know of any studies that have evaluated the Kinesio Taping Method using the global perceived effect scale.

There are five published systematic reviews^{15,28–31} evaluating the effectiveness of Kinesio Taping; one specifically targeted the treatment and prevention of sports injuries,¹⁵ two examined different clinical conditions,^{29,30} and two looked at musculoskeletal conditions.^{28,31} However, none of these reviews found any clinically worthwhile benefits for this intervention. The studies compared Kinesio Taping with a range of treatments, as well as with no treatment and placebo. These studies were, on average, of moderate methodological quality, with small sample sizes and very small follow-up periods. Regardless of the comparisons used (as well as the outcomes investigated), the results of clinical trials conducted so far have shown no difference or found just a trivial effect in favour of Kinesio Taping. Our group conducted the most updated systematic review³² with the greatest number of clinical trials relevant to musculoskeletal conditions and our conclusions were similar to the existing reviews.

The results of the present study challenge the importance of the presence of convolutions in Kinesio Taping for effectiveness of treatment in people with chronic low back pain. According to the creators of the Kinesio Taping Method¹⁴ these convolutions increase blood and lymphatic flow, and aid in reducing pain. Therefore, applying proper tension is one of the key factors for effective treatment.¹⁴ However, the outcome with convolutions was not superior to the control group and so the improvement seen in both groups cannot be due to tape tension. The results of the present study challenge the theory that these convolutions are part of the mechanism.

To date, the present study is the largest clinical trial conducted on the effectiveness of Kinesio Taping. It was performed without any deviations from the initial protocol.¹⁹ All people who entered the study completed treatment and all completed the follow-up assessments, contributing to unbiased treatment estimates. All methodological steps were taken in order to provide the lowest possible risk of bias. However, due to the nature of the study, it was not possible to blind the therapists and participants, so this could be seen as a limitation of the study. Only one brand of tape was used, which is recommended by the Kinesio Taping Association. Therefore, the authors' are confident that the best and most up-to-date intervention was provided during this study.

Based on the results of this study, for the primary outcomes analysed, it can be concluded that there was no advantage of using the Kinesio Taping to generate convolutions. In clinical practice, it is up to physiotherapists to inform and to discuss with their patients the advantages and disadvantages of the method, taking into account costs as well as patient preferences. The authors of the present study are unaware of any studies of people with low back pain that compare Kinesio Taping versus no intervention as the control condition, and it would be worthwhile to do such a study. Only one randomised trial has compared Kinesio Taping to no treatment, which involved 20 participants with knee pain. The results showed that Kinesio Taping was better than no treatment for the outcomes evaluated. Nevertheless, the quality of this evidence was very low and more studies are needed.³³

The present study is limited to the application of Kinesio Taping alone, which may not reflect the current clinical practice of many therapists. It would be interesting to conduct studies of Kinesio Taping as an adjunct to treatments recommended by clinical practice guidelines^{12,33} for low back pain, such as manual therapy and exercises. Therefore, the present study's research group has recently started another randomised controlled trial in order to respond to this research question.³⁴

What is already known on this topic: Low back pain is common. Kinesio Tape can be applied to cause convolutions of the underlying skin. The developers of Kinesio Tape claim that these convolutions decrease pressure on mechanoreceptors in the underlying tissues and alter recruitment of underlying muscles, thereby reducing pain.

What this study adds: Kinesio Taping over the lumbar erector spinae did not reduce pain or disability in people with chronic non-specific low back pain. There was a small improvement in global perceived effect after four weeks, but this was not sustained to 12 weeks. These results challenge the proposed mechanism of action of Kinesio Taping.

Footnote: ^aKinesio Tex Gold[®] Tape, Kinesio, USA.

eAddenda: Table 3 can be found online at [doi:10.1016/j.jphys.2014.05.003](https://doi.org/10.1016/j.jphys.2014.05.003)

Ethics approval: The Universidade Cidade de São Paulo Ethics Research Committee of UNICID (number PP13603502) approved this study. All participants gave written informed consent prior to data collection.

Source(s) of support: Fundação de Amparo a Pesquisa do Estado de São Paulo (FAPESP), and Conselho Nacional de Desenvolvimento Científico e Tecnológico (CNPq), Brazil.

Competing interests: Nil.

Acknowledgements: This study was funded by the *Fundação de Amparo à Pesquisa do Estado de São Paulo* (FAPESP-Brazil) and *Conselho Nacional de Desenvolvimento Científico e Tecnológico* (CNPq-Brazil). Ms Parreira had her masters scholarship supported by FAPESP. Luiz Carlos Hespanhol Junior is a PhD student supported by CAPES (*Coordenação de Aperfeiçoamento de Pessoal de Nível Superior*), process number 0763–12–8, Ministry of Education of Brazil. Leonardo Costa received a research productivity fellowship from CNPq-Brazil to conduct a series of studies on the effectiveness of Kinesio Taping in people with musculoskeletal conditions. We would like to thank Professor Chris Maher from The George Institute for Global Health, Australia for his insightful comments prior to submission.

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