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Effects of Functional Fascial Taping on pain and function in patients with non-specific low back pain: a pilot randomized controlled trial

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Abstract

Objectives: To compare the short-term and medium-term effect of Functional Fascial Taping to placebo taping on pain and function in people with non-specific low back pain.

Design: A pilot randomized controlled trial with a 2-week intervention, and 2-, 6- and 12-week follow-up.

Setting: Individuals with non-specific low back pain recruited from local communities.

Participants: Forty-three participants with non-specific low back pain for more than 6 weeks were randomized into either Functional Fascial Taping group ($n = 21$) or placebo group ($n = 22$).

Interventions: The intervention group was treated with Functional Fascial Taping while the control group was treated with placebo taping. Both groups received four treatments over 2 weeks.

Main outcome measures: Worst and average pain and function were assessed at baseline, after the 2-week intervention, and at 6 and 12 weeks follow-up.

Results: The Functional Fascial Taping group demonstrated significantly greater reduction in worst pain compared to placebo group after the 2-week intervention ($P = 0.02$, effect size = 0.74; 95% confidence interval 0.11–1.34). A higher proportion of participants in Functional Fascial Taping group attained the minimal clinically important difference in worst pain ($P = 0.007$) and function ($P = 0.007$) than those in placebo group after the 2-week intervention. There were no significant differences in either group's disability rating or clinically important difference in average pain at any time.

Conclusions: Functional Fascial Taping reduced worst pain in patients with non-acute non-specific low back pain during the treatment phase. No medium-term differences in pain or function were observed.

Keywords

Low back pain, functional taping, function, placebo

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Introduction

Non-specific low back pain is a common musculoskeletal disorder with a high lifetime prevalence and high recurrence.^{1,2} Pain can hinder movement and disturb neuromuscular activity and motor control³⁻⁶ and thus affect function.^{7,8} Individuals with chronic pain can then experience further disability due to psycho-social problems that result in personal and societal economic burdens.⁹⁻¹² Therefore, limiting pain in magnitude and time is likely to minimize or reverse the negative consequences of non-specific low back pain.

In clinical practice, passive treatments such as massage therapy are commonly used for treating non-specific low back pain.¹³ Some massage treatments applied to the skin overlying tender areas in the lower back have reduced pain, possibly via neurophysiological responses of cutaneous mechanoreceptors.¹³ When massage is performed manually, the duration of force applied to the skin is limited by the therapist and treatment time. Application of tape on the skin may provide an adjunct to the therapist's manual force as it can be applied for longer than massage therapy.

Taping based on a variety of rationales has been used to reduce pain, as well as support and protect injured tissues from further injury.¹⁴ Various taping techniques have been used to treat and prevent musculoskeletal problems in rehabilitation and sports medicine,^{14,15} however, not all kinds of tape applications have the same effects.

Functional Fascial Taping is a taping method that has been proposed to immediately reduce pain and, as a consequence, increase functional movement performance.^{16,17} The Functional Fascial Taping technique follows standard clinical processes of assessment, intervention and re-assessment. Prior to applying Functional Fascial Taping, the direction of taping that provides the greatest reduction in pain on movement is determined. Strips of tape are applied in the same direction to maintain this stretch during daily activities or exercises. Low-level stretching on tissue could remodel the internal architecture of connective tissue.^{18,19}

Functional Fascial Taping has been reported to be clinically effective in several pain conditions,^{16,17,20}

however only in case reports conducted by the originator of the technique, and has yet to be investigated scientifically. This study therefore aimed to investigate the effects of Functional Fascial Taping in treating non-acute non-specific low back pain. This pilot randomized, placebo-controlled trial compared Functional Fascial Taping with placebo taping during a 2-week intervention and follow-up until 12 weeks.

Methods

Individuals with non-specific low back pain were recruited through advertisements and referrals from health professionals in local communities in Melbourne, Australia. Non-specific low back pain is defined as back pain localized between the lowest rib and gluteal creases with or without leg(s) pain and with no definitive cause.²¹ Individuals were considered for inclusion in the study if they were aged between 18 and 65 years with non-acute non-specific low back pain (duration of an episode more than 6 weeks or recurrent low back pain defined as an episode of low back pain longer than 24 hours with at least one month pain-free before and after the episode and multiple episodes over the year)²² and with discomfort during trunk flexion. Individuals with non-acute low back pain were included to minimize the possibility of spontaneous recovery from acute pain, as the majority of individuals with acute low back pain significantly reduce their pain within one month.¹

Volunteers were excluded if they had diagnosed spinal pathology, major trauma, systemic disease, cancer, osteoporosis, inflammatory disease or neurological deficit. Specific exclusion criteria included pregnancy, previous back surgery or waiting for surgery, or active or pending legal proceedings due to their low back pain. Volunteers were also excluded if they had skin sensitivity to tape, dermatitis or a pre-existing skin lesion over the taping area.

All volunteers were screened by telephone interview and the inclusion and exclusion criteria were applied by an experienced orthopaedic physiotherapist. If the volunteer was eligible, the aims of the study, potential benefits and risks, length and commitment required for the study and potential

allocation to placebo were explained. All participants gave written informed consent after their receiving and understanding the written information about the study, and all rights of the participants were protected. Ethical approval was obtained from the University Human Research Ethics Committee.

Participants attended for taping twice weekly for 2 weeks and then returned for follow-up assessment at 6 and 12 weeks. Demographic data, including age, sex, medical history, location and nature of the symptoms were collected at baseline. Other variables that could affect the outcome such as the current treatment and medication were also recorded at baseline.

The sample size was calculated theoretically before the study commenced. A priori sample size calculation assumed a difference in pain intensity between groups of 20 mm with a standard deviation of 22 mm on the visual analogue scale. The α level was set at 0.05 and power at 0.8, this resulted in a sample size of 20 per group. Therefore it was planned to recruit 40 participants for this study.

Participants were randomly allocated into Functional Fascial Taping group or placebo group with a sealed envelope. The outcome assessor was blind to group allocation and was unable to access the sealed envelopes. The treating therapist was advised of which taping procedure to perform just before the participant's first taping session.

Participants were taped according to group allocation by the same treating therapist. The Functional Fascial Taping group received tape with tension applied in a direction assessed by the therapist and generally three direction tapings were applied (Figure 1a). The direction of tape application was determined with the skin distraction test that resulted in maximal pain reduction on trunk flexion. Participants in the placebo group had tape with no tension over their painful area on the lower back (Figure 1b). The only difference between groups was the tension and direction of the tape.

The application of taping for both groups was preceded by a standardized process including: cleaning the skin, applying a hypoallergenic under-tape (MK-FIX, Medical Kinetics, Australia), 3–5 tape layers with rigid strapping tape (MK 38, Medical Kinetics, Australia), and then an anchor tape layer to prevent the rigid strapping tape from

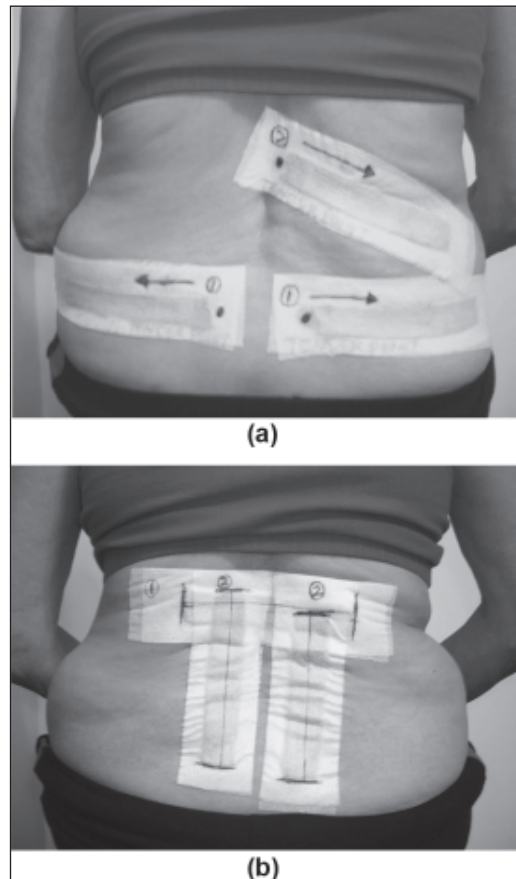


Figure 1. The application of the taping to two conditions. Functional Fascial Taping: taping with tension (a) and placebo taping: without tension (b).

peeling off. During the 2-week intervention, the participants were asked to temporarily stop current treatments except taking medication. Between the end of the 2-week intervention and the end of study, participants were asked to continue usual care.

Participants were instructed to keep the tape on between taping sessions in the 2-week intervention. The tape was reapplied daily by participant's family, friends or themselves according to the therapist's instruction after training in correct taping technique was provided during the initial session. A manual that contained back care and a standardized simple trunk flexion exercise was given to all participants. The trunk flexion exercise was applied to reinforce

the stretching effect of the taping. It was recommended that participants did the trunk flexion exercises during the 2-week taping intervention. However, a warning to stop the exercise was given if the participant felt worse pain during the trunk flexion exercise. Participants were also advised to maintain their usual physical activities during the period of the study.

Primary outcome measures were assessed at baseline, at the end of the 2-week intervention, and at 6 and 12 weeks. Primary outcome measures were low back average and worst pain intensity using a 100 mm visual analogue scale and a functional disability questionnaire using the Oswestry Disability Index.²³ These two measures have documented validity for assessing pain intensity²⁴ and disability.^{25,26}

The participants and the outcome assessor were blind to treatment group until 12-week follow-up. The therapist could not be blinded but gave the same instruction and took the same time to provide the intervention in the Functional Fascial Taping and placebo groups. Participants were instructed not to reveal any information about their treatment to the outcome assessor. To test the success of blinding, participants were asked whether they believed they received Functional Fascial Taping or placebo treatment at the end of the first treatment and at 12-week follow-up. The outcome assessor was also assessed for blinding about participant allocation at the 12-week follow-up.

All statistical analyses were carried out using SPSS for Windows version 15.0 (SPSS Inc., Chicago, IL, USA). Baseline descriptive information (e.g. sex and body mass index) of the two groups was compared using independent *t*-tests or chi-square test, where appropriate. Pain duration was tested with the Mann–Whitney *U*-test due to a large variation among individuals. Chi-square test and Fisher exact test were used to analyse the categorical or proportional difference between the two groups. For each of the primary outcome measures (visual analogue scale and Oswestry Disability Index), the effect of intervention was tested using two-way repeated measures ANOVA in which the between-subjects factor was group (Functional Fascial Taping versus placebo) and the

within-subjects factor was time (0, 2, 6 and 12 weeks). All data analysis was carried out following the intention-to-treat principle. Expectation maximization algorithm was used for finding maximum likelihood estimates of missing values.^{27,28} A 5% level of statistical significance was used in the comparison between the two groups. A Bonferroni-adjusted *P*-value was used in the multiple comparisons over time within groups to control for type 1 error.²⁹ All tests were two-tailed.

An effect size of 0.5 suggests that there has been real change that is clinically important.^{30,31} Therefore, a cut-off point of effect size of 0.5 with 95% confidence interval was employed in this study to examine a significant mean difference between the two groups in pain and function and to determine the magnitude of the effect. An effect was deemed significant if the 95% confidence interval did not include zero.³²

The minimal clinically important difference was used to measure the effectiveness of treatment for an individual.^{30,33} The proportion of participants between the two groups that attained the minimal clinically important difference in pain and function in the primary outcome measures in each group was compared. A 20 mm reduction on a 100 mm visual analogue scale^{34,35} and a 10% change on a 0–100% scale of back pain disability on the Oswestry Disability Index^{26,34,35} was considered to be the minimal clinically important difference.

Results

Ninety-six volunteers were screened for eligibility. More than 50% of volunteers were excluded because they were more than 65 years, or had no forward bending problems, previous back surgery, multiple musculoskeletal disorders or had claimed work-related compensation. After randomization, 21 participants were in the Functional Fascial Taping and 22 in placebo group. Four participants dropped out and did not attend all treatment sessions; two were lost to follow-up. The total withdrawal rate was 14% ($n = 4$ in Functional Fascial Taping group; $n = 2$ in placebo group, Figure 2).

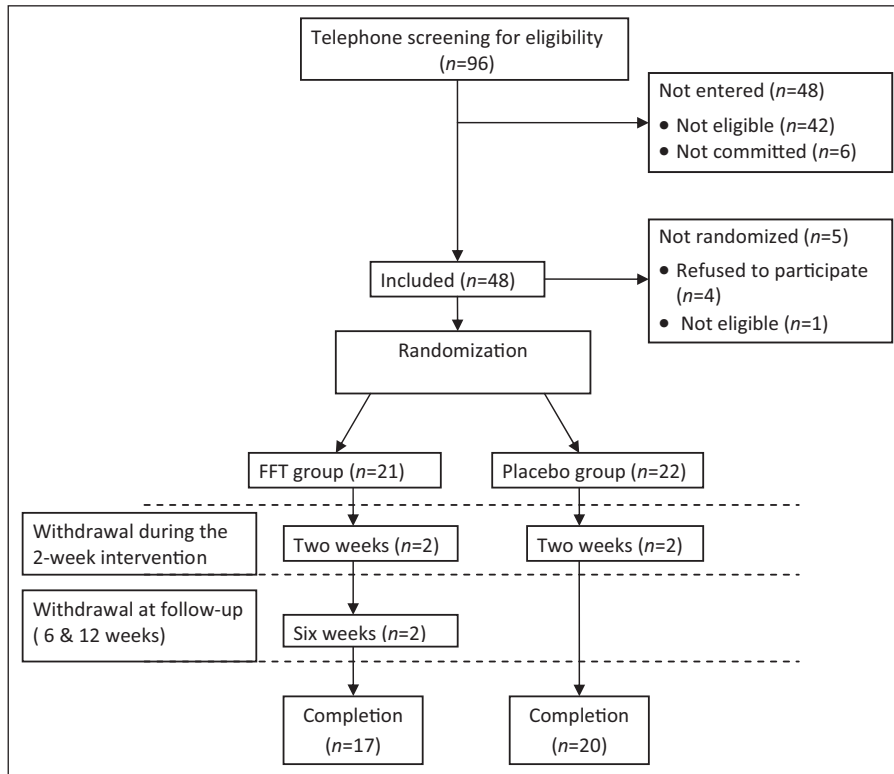


Figure 2. Flow diagram for the recruitment, randomization and follow-up.

There were no significant differences between groups in the following: baseline demographic characteristics, outcome measures between Functional Fascial Taping and placebo groups and number receiving current treatment and medication (Table 1). Baseline characteristics between those that dropped out and those that completed the trial were not significantly different.

The group-by-time repeated-measures ANOVA revealed that worst pain significantly decreased in the Functional Fascial Taping group more than placebo group after the 2-week intervention ($P = 0.02$, effect size = 0.74; 95% confidence interval 0.11–1.34); however, there was no statistical difference between groups at any stages of follow-up. Average pain changed significantly over time in Functional Fascial Taping group but not in placebo group (Table 2). However, no significant differences in average pain were found between the Functional

Fascial Taping and placebo groups after the 2-week intervention and any stages of follow-up. The functional level using Oswestry Disability Index was significantly improved in both groups over time when compared with baseline. Even though there was a larger change in Oswestry Disability Index after the 2-week intervention in the Functional Fascial Taping group than in placebo group, and the effect size (0.61) was larger than 0.5, the 95% confidence interval ($= -0.02-1.21$) crossed zero. Therefore, except the change in worst pain after 2-week intervention, there were no significant differences in either group's change in disability rating or average pain at all time periods (Table 2).

There was no significant difference in the proportion of participants who attained the minimal clinically important difference in average pain between the two groups. However, a higher proportion of participants in the Functional Fascial Taping

Table 1. Demographic characteristics and baseline outcome measures

Variable	FFT group ^a (n = 21)	Placebo group ^a (n = 22)	P-value
Age (years)	45.9 ± 15.4	40.5 ± 13.1	0.218
Sex (male/female) (n)	11/10	9/13	0.451 ^b
Body mass index (kg/m ²)	25.0 ± 5.1	25.5 ± 4.1	0.729
Worst pain (mm)	64.6 ± 20.8	57.9 ± 21.8	0.308
Average pain (mm)	43.1 ± 18.3	41.6 ± 21.1	0.798
Pain duration (weeks) (median (interquartile range))	38.7 (8.3–325)	32.5 (7.5–442)	0.715 ^c
ODI (%)	30.8 ± 10.8	23.8 ± 11.9	0.052
Number receiving current treatment (yes/no)	8/13	6/16	0.449 ^b
Number using current medication (yes/no)	9/12	4/18	0.078 ^b

FFT, Functional Fascial Taping; ODI, Oswestry Disability Index.

^aData presented as mean ± SD.

^bAnalysed by chi-square test.

^cAnalysed by Mann–Whitney *U*-test.

Table 2. Change in pain and function within and between groups (expressed as effect size) over time compared with the baseline

Variable	Time zone compared (weeks)	FFT group within-group change ^a	Placebo group within-group change ^a	Between-group change ^a	P-value	Effect size (95% CI)
Worst pain (mm)	0–2	35.5 ± 22.9 ^b	18.2 ± 23.9 ^b	17.29 ± 7.16	0.020 ^c	0.74 (0.11–1.34) ^d
	0–6	33.9 ± 25.8 ^b	22.6 ± 27.2 ^b	11.26 ± 8.09	0.172	0.42 (–0.19–1.02)
	0–12	36.6 ± 24.8 ^b	30.8 ± 25.2 ^b	5.79 ± 7.63	0.452	0.23 (–0.37–0.83)
Average pain (mm)	0–2	20.4 ± 19.9 ^b	12.9 ± 20.5	7.57 ± 6.16	0.226	0.38 (–0.24–0.97)
	0–6	21.4 ± 19.7 ^b	20.7 ± 19.3 ^b	0.73 ± 5.94	0.903	0.04 (–0.56–0.63)
	0–12	26.4 ± 17.7 ^b	22.8 ± 26.7 ^b	3.62 ± 6.94	0.605	0.16 (–0.44–0.75)
ODI (%)	0–2	13.6 ± 8.0	8.1 ± 10.2 ^b	5.53 ± 2.80	0.054	0.61 (–0.02–1.21)
	0–6	14.6 ± 10.9 ^b	11.2 ± 9.0 ^b	3.36 ± 3.06	0.278	0.34 (–0.27–0.93)
	0–12	15.1 ± 11.0 ^b	12.0 ± 9.3 ^b	3.08 ± 3.11	0.329	0.30 (–0.31–0.90)

FFT, Functional Fascial Taping; CI, confidence interval; ODI, Oswestry Disability Index.

^aData presented as mean ± SD.

^bStatistical significance after Bonferroni adjustment ($P < 0.01$) within groups.

^c $P < 0.05$.

^dEffect size is larger than 0.5 and 95% CI does not include zero indicate clinical significance.

group attained the minimal clinically important difference in worst pain than the placebo group after the 2-week intervention ($P = 0.007$). There was also a higher proportion of participants in the Functional Fascial Taping group that attained the minimal clinically important difference in Oswestry Disability Index than the placebo group after the 2-week intervention ($P = 0.007$) (Table 3).

Participant-blinding was assessed at the end of the first treatment and was not statistically different between Functional Fascial Taping and placebo groups ($P = 0.056$). At 12-week follow-up, there was statistical difference between the two groups, more participants in Functional Fascial Taping than in placebo group correctly guessed their group allocation ($P = 0.016$, Table 4).

Table 3. Number of participants who attained minimal clinically important difference in pain and function between two groups over time

Variable	Time	MCID	FFT group (n)	Placebo group (n)	χ^2	P-value
Worst pain	Week 2	Attained	17	9	7.21	0.007 ^a
		Non-attained	4	13		
	Week 6	Attained	14	15	0.01	0.916
		Non-attained	7	7		
	Week 12	Attained	16	17	0.01 ^b	1.000
		Non-attained	5	5		
Average pain	Week 2	Attained	12	8	1.87	0.172
		Non-attained	9	14		
	Week 6	Attained	12	13	0.02	0.897
		Non-attained	9	9		
	Week 12	Attained	15	13	0.72	0.396
		Non-attained	6	9		
ODI	Week 2	Attained	17	9	7.21	0.007 ^a
		Non-attained	4	13		
	Week 6	Attained	15	12	1.31	0.252
		Non-attained	6	10		
	Week 12	Attained	13	11	0.62	0.432
		Non-attained	8	11		

MCID, Minimal clinically important difference; FFT, Functional Fascial Taping; ODI, Oswestry Disability Index.

^a $P < 0.05$.

^bAnalysed by Fisher's exact test.

Table 4. Assessment of participant-blinding at the end of the first treatment and 12-week follow-up in Functional Fascial Taping and placebo groups

Variable	FFT group (n)	Placebo group (n)	χ^2	P-value
End of the first treatment				
Correct	12	2	5.29 ^a	0.056
Incorrect	1	5		
Unknown	8	15		
12-week follow-up				
Correct	14	5	8.04 ^a	0.016 ^b
Incorrect	1	7		
Unknown	2	8		

FFT, Functional Fascial Taping.

^aAnalysed by Fisher's exact test.

^b $P < 0.05$.

Discussion

This is the first randomized controlled trial to investigate the clinical effect of Functional Fascial

Taping on pain and function. The results of this trial demonstrated that Functional Fascial Taping significantly decreased worst pain more than placebo taping after the 2-week intervention. A higher

proportion of participants in the Functional Fascial Taping group than in the placebo group also reached a minimal clinically important difference in worst pain after the 2-week intervention. There was a significantly higher proportion of participants in the Functional Fascial Taping group who attained minimal clinically important difference in Oswestry Disability Index compared to the placebo group and a trend towards a statistical difference between groups after the 2-week intervention. The effect from Functional Fascial Taping on functional improvement was not maintained in the medium term.

The present pilot study examined not only the short-term (2 weeks) but also the medium-term effect (12 weeks) on pain and function between groups. Previous randomized clinical studies comparing other kinds of taping (e.g. kinesiio taping) to placebo taping only examined the short-term effect on pain, range of motion or disability after tape application and with a very short-term follow-up.^{36,37} Of those studies, one that investigated acute whiplash injury showed a significant difference in pain and cervical range of motion between groups for immediately after the application of the kinesiio tape and at a 24-hour follow-up; however, the authors concluded that the improvement was small and may not be clinically meaningful.³⁶ A study on shoulder pain showed a statistical difference in range of motion of shoulder abduction after tape application but no statistical differences in pain or function between groups after the tape application and over the 6-day follow-up.³⁷ However, the different findings should be interpreted with caution as there were methodological differences between the present study and those studies. First, different populations were investigated for each study. Second, the use of elastic tape compared with non-elastic tape used in this study should be considered. Furthermore, previous studies only applied the tape once or twice.

This study showed pain reduction was not associated with functional improvement. Even though Functional Fascial Taping reduced pain, there was no difference in function between groups. The initial functional disability level in the placebo group was lower than in the Functional Fascial Taping group (Oswestry Disability Index $23.8 \pm 11.9\%$

versus $30.8 \pm 10.8\%$), even though pain intensity was similar. The significant difference in reduction in worst pain after intervention between the Functional Fascial Taping and placebo group only trended towards change in function between the two groups. The trend towards a difference in baseline functional level between groups may be a cause of the non-significant treatment effects on function. Additionally, the sample size was calculated to determine the taping effect on pain and the study may have been underpowered to detect difference in function. Further studies with large sample size will be needed to elucidate the reduction in pain and function simultaneously.

This pilot study had a small sample size at the end of the study as a total drop-out rate was 14%, and differences between the groups for the outcome measures of interest may not be identified. The study had more drop-outs in the Functional Fascial Taping group, although only at the 6-week time ($n = 2$), as two participants dropped out in each group during the intervention.

The present study lacked a non-treatment control group and was unable to differentiate the real effect from taping as the present study only compared Functional Fascial Taping to placebo taping. However, in the present community-based study, with voluntary and non-compensable participants, there would have been high participant burden for participation in a group given no tape and simple trunk flexion exercises. Previous studies have successfully compared outcomes after targeted taping and placebo taping in different musculoskeletal conditions.^{36,37}

The potential mechanism of Functional Fascial Taping remains hypothetical. The application of Functional Fascial Taping involves stretching the skin and underlying tissues in a pain-specific direction. One plausible explanation is that the application of tape on the skin could stimulate large-diameter afferent fibres and then modulate nociceptor input (gate control mechanism). In addition, stretching the skin in a pain-specific direction with Functional Fascial Taping may affect pain perception or it may alter local tissue internal architecture³⁸ as well as stimulate cutaneous mechanoreceptors.³⁹ This last hypothesis is supported by a study that showed skin

stretch caused by patella taping increased cutaneous stimulation and changed muscle activity.⁴⁰ Further research to investigate the potential mechanisms of how Functional Fascial Taping could change pain perception is required.

Placebo effect derived from participants' expectation from the treatment could be another potential mechanism for relieving pain.⁴¹ Blinding participants and the outcome assessor should reduce the placebo bias and an exaggerated treatment effect. It is more appropriate to assess the success of blinding in the early stage of the study than at the end of the study,⁴² as assessing the success of blinding at the end of the study examines treatment effects. In this study, participants did not know their group allocation at the end of the first treatment. After the 2-week intervention, when the worst pain intensity showed greater reduction in Functional Fascial Taping group than placebo group, a higher proportion of participants in the Functional Fascial Taping group correctly guessed their group, and this was also evident at 12-week follow-up. As successful blinding for the outcome assessor was also present ($P = 0.397$), this study minimized bias in outcome.

In this pilot study, Functional Fascial Taping reduced worst pain in patients with non-acute low back pain during the treatment phase. Even though Functional Fascial Taping reduced worst pain, there was no change in average pain and function. This pilot study suggests that Functional Fascial Taping could be used as an adjunct to treatment of non-specific low back pain to reduce pain and improve function when the tape is applied. Further research is required to fully elucidate its role in the treatment of this complex condition.

Clinical messages

- Functional Fascial Taping reduced worst pain for patients with non-acute non-specific low back pain.
- The tape must be applied to have an effect on pain, there was no residual reduction in pain after the taping intervention was completed.

Conflict of interest

We declare that we have no financial affiliation (including research funding). One author (RA) has a commercial organization related to the taping technique used in this study. He had no input into the data collection, analysis or reporting of this randomized clinical trial.

Funding

Tape for this study was provided at cost price by Medical Kinetics, Australia. They had no other input into the study design or results.

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