ORIGINAL ARTICLE

Use of a non-medicated tape in non-specific low back pain: A single-blind, randomized, placebo-controlled trial

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ABSTRACT

Background and aim: Low back pain (LBP) is prevalent and often non-specific disease. Kinesiology taping shows mixed evidence, and far-infrared (FIR)–reflecting tapes are promising. To evaluate the efficacy of an FIR-reflecting tape (FT) versus standard kinesiology tape (KT) and placebo for chronic non-specific LBP.
Methods: A single-blind trias was conducted evaluating adults patients (aged 30–60 years) with chronic LBP >6 months, NRS 6–10, no radiculopathy or red flags; n=240 randomized (FT, n=80; KT, n=80; placebo, n=80). Tapes were applied to the lumbar region for two 5-day applications separated by a 3-day interval (total 14 days). Outcomes at T0, T1 (day 5), T2 (day 8), and T3 (day 14) included pain (NRS), disability (Roland-Morris Disability Questionnaire, RMDQ), and lumbar range of motion (ROM). Non-parametric analyses (Shapiro–Wilk; Kruskal–Wallis; Friedman) with α=0.05.
Results: All participants completed the protocol with no adverse events. Groups were comparable at baseline. Between-group differences favored FT at all post-baseline time points for NRS, RMDQ, and ROM ($p<0.05$). FT reduced NRS from 8.09±0.89 to 2.19±0.92 at T3 ($p<0.001$), versus KT 8.15±0.84→4.00±1.21 ($p<0.01$) and placebo 7.95±0.83→6.54±1.40 ($p<0.05$). RMDQ improved to 12.13±2.72 with FT ($p<0.001$) vs 15.26±2.75 (KT, $p<0.01$) and 18.33±2.75 (placebo, ns). ROM gains were greatest with FT ($p<0.001$).

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Conclusions: FT tape produced superior pain relief, disability reduction, and mobility gains over 14 days compared with standard kinesiology and placebo tapes. FT tape offers a safe, drug-free adjunct to outpatient LBP care, potentially accelerating pain reduction and functional recovery. (www.actabiomedica.it)

Key words: lumbar, patch, LBP, RMDQ, disability

Introduction

Low back pain (LBP) is a common condition, typically attributed to musculoskeletal or peripheral nervous system issues, affecting individuals across various age groups (1). A significant portion of the population exhibits intervertebral disc degeneration and osteophyte formation, even in younger demographics (2). For instance, by age 47, approximately 97% of individuals exhibit spinal osteoarthritis (3). Although many individuals may remain asymptomatic and not seek medical attention, a substantial number will require professional intervention for this common ailment (4). The interrelationship between disc degeneration and facet joint osteoarthritis (OA) is well documented, yet there is ongoing debate over which pathology initiates the detrimental cycle (1,3). While studies have indicated a higher prevalence of facet joint OA in patients with degenerative disc disease, some individuals present with isolated facet joint OA in the absence of concomitant disc degeneration (2). This complexity is further heightened by the observation that a significant subset of LBP sufferers does not exhibit any pathomorphological correlates, leading to a diagnosis of non-specific low back pain due to the weak clinical and imaging correlations (1,5). Medical management of acute lumbar back pain frequently involves the use of intramuscular steroid injections, non-steroidal anti-inflammatory drugs (NSAIDs), muscle relaxants, and vitamin supplements, particularly B vitamins (6,7). These treatments are frequently complemented by physical therapy to address underlying causes and mitigate symptoms (8,9). Furthermore, in recent years, transdermal patches have emerged as an innovative therapeutic option with widespread recognition in clinical practice (10). Medicated patches deliver their therapeutic effects through transdermal absorption of pharmacologically active (e.g., non-steroidal anti-inflammatory drugs (NSAIDs) (11), local anesthetics (12), or others) or through the localized release of heat. On the other hand, classic non-medicated patches provide structural support to the lumbar region, enhancing stability and reducing the mechanical load on the spine (13-15). The FIT Therapy ® patch and tape (D. FENSTEC s.r.l., Altavilla Vicentina, Italy) are innovative non-medicated devices that utilize biominerals to reflect far-infrared radiation (FIR), helping to alleviate symptoms and promote relief in musculoskeletal or joint pain conditions. The human body naturally emits FIR, and the FIT Therapy ® patch and tape reflect them specifically at wavelengths ranging from 4 to 21μm, with a peak at 11μm.Therefore, these devices act like a mirror to direct the FIR deeper into tissues. This mechanism enhances superficial microcirculation without releasing active drugs or inducing thermal effects. The patch is made from 100% polypropylene non-woven fabric and acrylic adhesive. The tape is made of 86% Poliammide and 16% Elastan, with acrylic adhesive. Both contain reflective minerals and particles of titanium dioxide (over 100nm in size) added to the ink, ensuring no direct skin contact with the particles (16,17). Recent studies have shown that technologies that reflect the body's natural FIR can significantly enhance superficial microcirculation, potentially influencing muscle function and metabolism (18,19). FIR-based therapies have been successfully used for pain relief in various musculoskeletal and articular conditions (20-22). Evidence suggests that FIR promotes the functional recovery of muscle tissue, providing pain relief and myorelaxation, which can be particularly beneficial for conditions such as contractures, strength deficits, and overuse syndromes (17). Despite the promising results, FIR-based patches

and tapes are relatively new, with limited research available on their efficacy in treating musculoskeletal pain. The present study aimed to evaluate the efficacy of FIT Therapy® tape as a non-pharmacological treatment for non-specific low back pain (LBP), comparing its effects on pain with those of commercially available Nasara® kinesiology tape and a placebo tape.

Patients and methods

The study employed a single-blind, randomized, placebo-controlled design to evaluate the effects of FIT Therapy® tape and Nasara® kinesiology tape (considered as a standard of care) on chronic low back pain. The trial was approved by the local Ethical Committee (prot. LBPATCH nr. 658 23/06/2025) and conducted in full compliance with the ethical principles outlined in the Declaration of Helsinki. Inclusion criteria consisted of patients with chronic low back pain persisting for more than six months, likely due to overuse without neurological symptoms and characterized by the following criteria: Numeric Rating Scale (NRS) score between 6 and 10 (i.e. from moderate to severe), localized lumbar pain without radiation, negative Lasegue and Wasserman tests, a recent (<3 months) non-conclusive lumbar-sacral MRI or one showing intervertebral disc degeneration or arthritic changes, age between 30 and 60 years, alert and cooperative patients with no osteo-articular or autoinflammatory conditions, and signed informed consent. Exclusion criteria included pregnant women, clinical diagnostic "Red Flags" (suspected or confirmed infection, neoplastic masses, neuropathies, metabolic disorders inducing low back pain, suspected or confirmed disc herniation, or spinal stenosis with radiculopathy), use of corticosteroids or painkillers during the treatment, and premature tape removal. Patients meeting the exclusion criteria throughout the study were considered drop-offs. A total of 240 patients suffering from chronic low back pain were enrolled and randomly divided into three groups of 80 individuals each. The first group received FIT Therapy® tape, the second group received Nasara® tape, and the third group received a placebo tape. The placebo tape was designed to have a similar appearance to the FIT Therapy ® tape, with the exact dimensions, color, and shape. These tapes were applied to the lumbar region and remained in place for five days, after which they were replaced with new tapes for an additional five days. The same clinician performed the replacements during clinical re-evaluations to ensure consistent tape application and reduceoperator-dependent bias. Clinical evaluation parameters included pain assessment using the NRS, disability assessment due to low back pain using the Roland Morris Disability Questionnaire (RMDQ) (23), and spinal mobility assessment throughflexion-extension, rotation, and lateral bending movements, measured in degrees using an orthopedic goniometer (sensibility: 1°) on the sagittal/coronal plane (Range of Motion, ROM).

Patients were assessed according to the following timeline:

- T0 (Enrollment): eligible patients were invited to participate in the study during an outpatient clinical evaluation. Upon consenting, they completed the informed consent form, and their NRS, ROM, and RMDQ were evaluated. The selected tape, determined by randomization, was applied. Patients removed the tape themselves after five days.
- T1 (5^{th} day): NRS and RMDQ were administered, and ROM was reassessed.
- T2 (8^{th} day): the same clinician reapplied the tape, administered NRS and RMDQ, and reassessed ROM. Patients again removed the tape themselves after five days.
- T3 (14^{th} day): immediate clinical re-evaluation post tape removal was conducted by the same clinician, including NRS, RMDQ, and ROM assessments.
- Immediate post-tape removal evaluations were crucial at both the end of the first and second applications. The intervals between tape applications consistently remained three days.

The primary objective of the study was to assess changes in pain levels (measured using the NRS) within and between the different treatment groups. Secondary objectives included evaluating changes in disability levels (measured by RMDQ) due to low back pain during daily activities and assessing changes in spinal mobility (measured by ROM) within and between groups. The primary endpoint was to determine the potential clinical

improvement in treating chronic low back pain using FIT Therapy® tape compared to traditional tape and placebo. The secondary endpoint involved comparing the effects of FIT Therapy® tape for chronic low back pain with findings from previous studies on the use of kinesiotaping to reduce pain associated with musculoskeletal conditions, including low back pain. Descriptive statistics were calculated for all outcome variables, including the NRS, RMDQ, and ROM in flexion, extension, and lateral bending, assessed across four time points (T0, T1, T2, T3). Normality of distribution was assessed for each variable within the three study groups (FIT Therapy®Tape, Nasara® tape, and placebo tape) using the Shapiro-Wilk test. As none of the variables followed a normal distribution ($p < 0.05$ for all variables across groups), non-parametric tests were employed. Intergroup differences at each time point were evaluated using the Kruskal-Wallis H test, while Friedman's test was applied to assess within-group changes over time for repeated measures. Statistical significance was set at $p < 0.05$.

Results

All patients enrolled in the study completed the proposed protocol, and no drop-outs occurred. All applied patches were well tolerated, and no skin reactions were observed. The Shapiro-Wilk test confirmed that none of the assessed variables followed a normal distribution across the three study groups, necessitating the use of non-parametric tests. The Kruskal-Wallis test revealed statistically significant differences between the groups at all time points (excluding at baseline T0) for the NRS, RMDQ, and all ROM measures ($p < 0.05$). FIT Therapy® tape-treated patients consistently showed greater improvements compared to those in the Nasara® and placebo groups, particularly at T2 and T3.

Pain (NRS)

At baseline (T0), the mean NRS scores were comparable across all groups, indicating a homogeneous distribution of pain severity at the beginning of the study (Table 1) (Figure 1). Specifically, the FIT Therapy® tape group had an initial NRS score of 8.09±0.89, the Nasara® tape group 8.15±0.84, and the placebo group 7.95±0.83. A significant reduction in pain was observed in the FIT Therapy® tape group starting from T1 ($p < 0.01$). By the 5th day, the NRS in this group had decreased to 5.61±0.91, while the Nasara® tape group reported a more modest reduction (6.56±0.98, $p < 0.05$) and the placebo group showed minimal change (7.39±0.99, not significant). Between T1 and T2, the most significant improvement was noted in the FIT Therapy® tape group, with the NRS score further decreasing to 3.61±0.91 ($p < 0.001$). In contrast, the Nasara® tape group showed a reduction to 5±1.21 ($p < 0.01$), and the placebo group continued to show less substantial progress, with a score of 6.98±1.08 ($p < 0.05$). At T3, the FIT Therapy® tape group exhibited the most pronounced reduction in pain, with a final NRS score of 2.19±0.92 ($p < 0.001$), suggesting a significant therapeutic effect. The Nasara® tape group improved to 4±1.21 ($p < 0.01$), while the placebo group continued to stayed behind with a score of 6.54±1.40 ($p < 0.05$), indicating limited efficacy in alleviating pain.

Roland Morris Disability Questionnaire (RMDQ)

Functional disability, as measured by the RMDQ, showed a parallel trend of improvement across the groups, with the most significant reductions observed in the FIT Therapy® tape group (Table 2) (Figure 2). At T1, the RMDQ score in the FIT Therapy® tape group was 16.69±2.58, compared to 17.79±2.74 in

Table 1. Mean NRS scores compared across all groups.

	T0	T1	T2	T3
FitTherapy	8.1±0.9	5.6±0.9**	3.6±0.9***	2.2±0.9***
Nasara tape	8.2±0.8	6.6±1*	5±1.2**	4±1.2**
Placebo	8±0.8	7.4±1	7±1.1*	6.5±1.4*

*, **, ***: $p<0.05$, $p<0.01$, $p<0.001$ T_n vs $T_n^+{}_1$

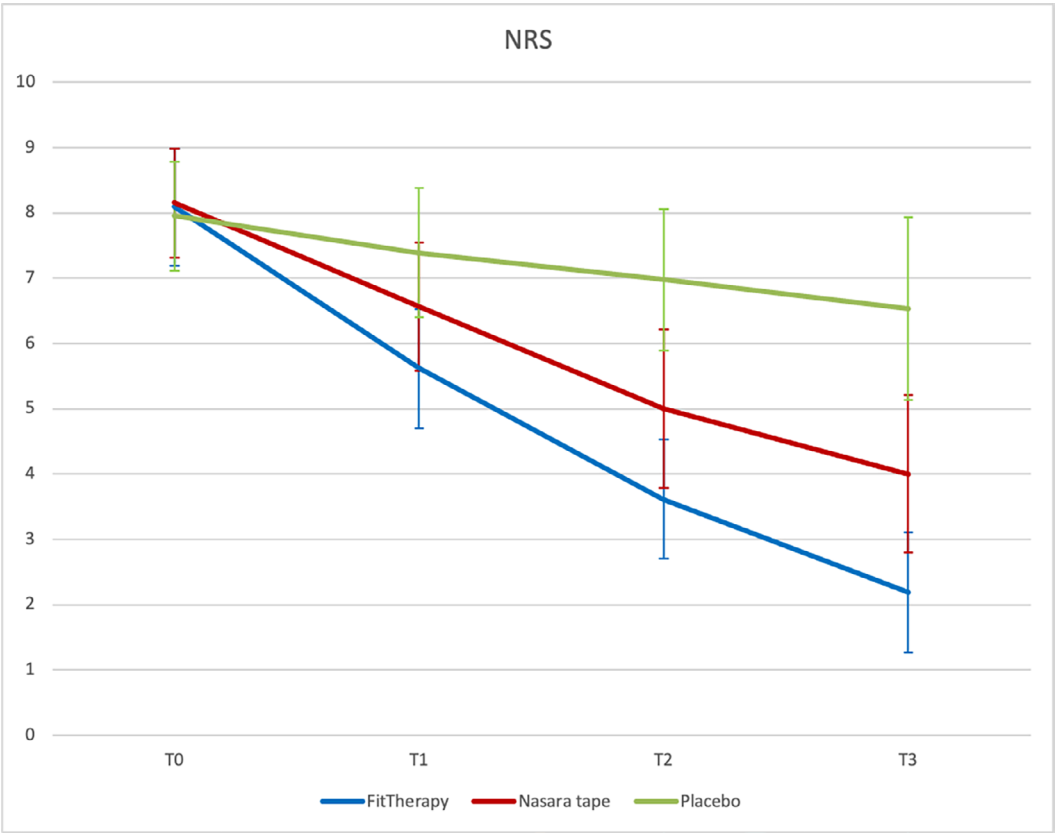

Figure 1. Pain assessment evaluated with the Numeric Rating Scale (NRS) in the three studied populations at T0 (enrollment), T1 (5th day, after the removal of the first patch), T2 (8th day, application of the second patch), and T3 (14th day, removal of the second patch). For all the evaluated intervals, the difference is statistically significant.

Table 2. Mean RMDQ scores compared across all groups.

	T0	T1	T2	T3
FitTherapy	20.2±2.5	16.7±2.6*	14.1±2.7**	12.1±2.7***
Nasara tape	20.2±2.6	17.8±2.7*	16.3±2.8*	15.3±2.8**
Placebo	19.9±2.6	18.9±2.6*	18.3±2.8	18.3±2.8

*, **, ***: p<0.05, p<0.01, p<0.001 T_n vs $T_n^+{}_1$

the Nasara® tape group and 18.90±2.61 in the placebo group ($p < 0.05$ between groups). By T2, the FIT Therapy® tape group experienced a marked improvement, with the RMDQ score decreasing to 14.13±2.72 ($p < 0.01$). The Nasara® tape group also showed improvement, though to a lesser degree (16.26±2.75, $p < 0.05$), while the placebo group exhibited only a marginal reduction (18.33±2.75, not significant). At T3, the FIT Therapy® tape group demonstrated the most considerable reduction in disability, achieving a final RMDQ score of 12.13±2.72 ($p < 0.001$). The Nasara® tape group reached 15.26±2.75 ($p < 0.01$), and the placebo group remained nearly unchanged from T2 with a score of 18.33±2.75 (not significant), underscoring the minimal effect of the placebo intervention on functional improvement.

Range of Motion (ROM)

The range of motion was assessed in spinal flexion, extension, and lateral bending at each time point (T0 to T3) (Table 3) (Figure 3). All patients exhibited baseline restrictions in lumbar spine movement, as is typical for individuals with LBP. At T0, the baseline measurements for spinal flexion, extension, and lateral bending were

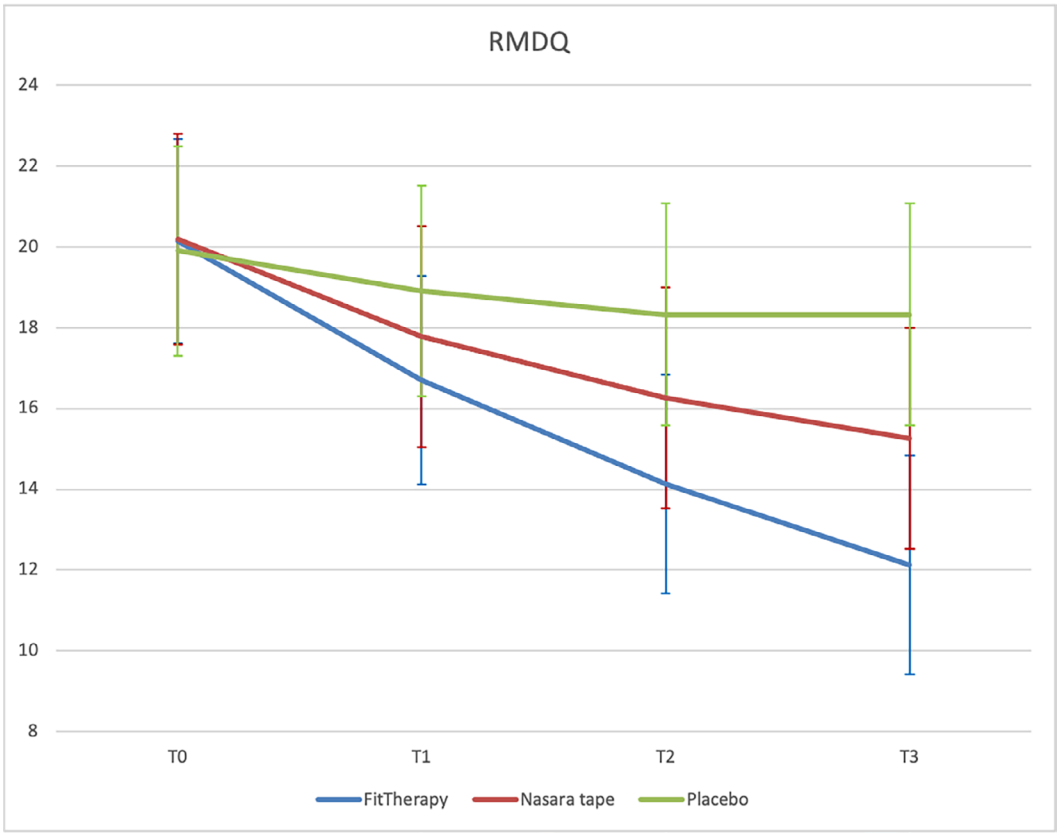

Figure 2. Pain assessment evaluated with the Roland Morris Disability Questionnaire (RMDQ) in the three studied populations at T0 (enrollment), T1 (5th day, after the removal of the first patch), T2 (8th day, application of the second patch), and T3 (14th day, removal of the second patch). For all the evaluated intervals, the difference is statistically significant only for patients treated with the FIT Therapy® tape and with the Nasara® kinesiology tape.

Table 3. Mean ROM (flexion, extension and lateral bending) scores compared across all groups.

FLEXION	**T0**	**T1**	**T2**	**T3**
FitTherapy	35.2±3.0	42.2±3.3	49.1±3.3**	53±3.4***
Nasara tape	34.8±3.3	40.1±.3.3	45.2±3.4*	48.2±3.7**
Placebo	35.2±3.2	36.7±3.2	38.3±3.2	39.3±3.2
EXTENSION	**T0**	**T1**	**T2**	**T3**
FitTherapy	14.9±3.2	19.9±3.2	27.5±3.2**	27.5±2.5***
Nasara tape	14.8±3.1	18.7±3.3	22.2±3.3*	24.7±3.3**
Placebo	15.0±3.1	16.5±3.1	18.2±3.2	19.2±3.2
BENDING	**T0**	**T1**	**T2**	**T3**
FitTherapy	12.2±1.7	15.7±1.7	18.8±1.3**	19.8±0.5***
Nasara tape	12.5±1.7	15±1.9	17.5±1.8*	18.6±1.4**
Placebo	12.8±1.7	13.8±1.7	14.8±1.7	15.8±1.7

*,**,***: $p<0.05$, $p<0.01$, $p<0.001$ T_n vs $T_n^+{}_1$

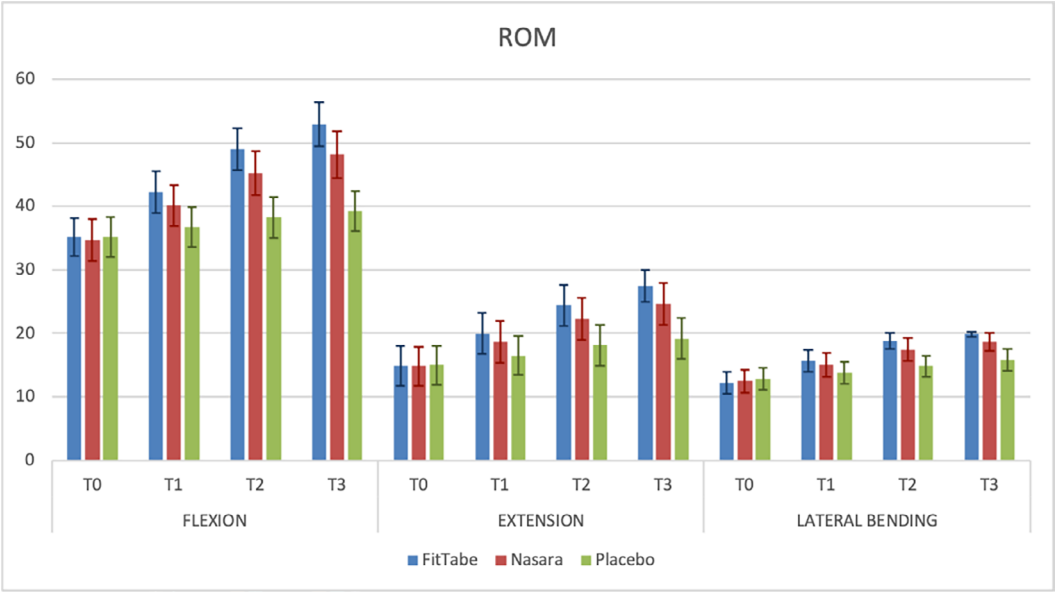

Figure 3. Assessment of Range of Motion (ROM) expressed in degrees in the three studied populations at T0 (enrollment), T1 (5th day, after the removal of the first patch), T2 (8th day, application of the second patch), and T3 (14th day, removal of the second patch). The measurements determined the movements of flexion, extension, and lateral bending. For all the evaluated intervals, the difference is statistically significant only for patients treated with the FIT Therapy® tape and with the Nasara® kinesiology® tape.

recorded as follows: maximum flexion of 60°, maximum extension of -30°, and a lateral bending capacity of 20° on both sides, symmetrically across groups.

Flexion and extension

At T1, a slight but non-significant improvement was observed in all groups. The FIT Therapy® tape group showed a modest increase in flexion-extension range, with a mean flexion value of 42.2±3.3° and extension of -19.9±3.2° ($p = 0.06$). The Nasara® tape group had a flexion of 40.1±3.3° and an extension of -18.7±3.3° ($p = 0.09$), whereas the placebo group showed minimal improvement, with a flexion of 36.7±3.2° and an extension of -16.7±3.1° ($p = 0.18$). By T2, the FIT Therapy® tape group demonstrated a more substantial increase in ROM. Flexion improved to 49.1±3.3° and extension to -27.5±3.2°, with the improvements being statistically significant ($p < 0.01$). The Nasara® tape group also showed a moderate increase, reaching 45.2±3.4° in flexion and -22.2±3.3° in extension ($p < 0.05$). The placebo group, however, exhibited only slight changes, with flexion of 38.3±3.2° and extension of -18.2±3.2° (not significant, $p = 0.12$). At T3, the FIT Therapy® tape group achieved the most significant improvements, with flexion increasing to 53±3.4° and extension improving to -27.5±2.5°, both of which were highly significant ($p < 0.001$). The Nasara® tape group reached 48.2±3.7° in flexion and -24.7±3.3° in extension ($p < 0.01$). The placebo group remained relatively unchanged from T2, with flexion of 39.3±3.2° and extension of -19.2±3.2° (not significant, $p = 0.08$).

Lateral bending

Lateral bending followed a similar trend. At T0, lateral bending was constrained at 12.5±1.7°, almost similar in all groups. At T1, the FIT Therapy® tape group showed a small but non-significant increase in lateral bending, reaching 15.,7±1.7° ($p = 0.07$). The Nasara® tape group demonstrated a slight increase to 15±1.9° ($p = 0.09$), and the placebo group remained virtually unchanged at 13.8±1.7° ($p = 0.15$). By T2, the FIT Therapy® tape group exhibited a notable improvement, with lateral bending increasing to

18.8±1.3°, a statistically significant change ($p < 0.01$). The Nasara® tape group also showed improvement, reaching 17.5±1.8° ($p < 0.05$), while the placebo group demonstrated minimal improvement to 14.8±1.7° (not significant, $p = 0.12$). At T3, the FIT Therapy® tape group reached an average lateral bending of 19.8±0.5°, approaching a normal range of motion, and this improvement was highly significant ($p < 0.001$). The Nasara® tape group demonstrated moderate improvement, reaching 18.6±1.4° ($p < 0.01$). The placebo group, in contrast, showed minimal change with a final lateral bending of 15.8±1.7°, which was not statistically significant ($p = 0.09$).

Discussion

Far Infrared Rays (FIR), a type of radiation naturally released by the human body, are typically dissipated into the environment. The use of materials such as patches, tape, or garments embedded with mineral particles can reflect this radiation back into the body, offering a non-invasive therapeutic approach that can provide benefits for various health conditions. This is thanks to both its thermal and non-thermal effects, both antalgic and anti-inflammatory (24,25). The thermal effects occur when FIR energy is absorbed, raising tissue temperature, which can, in turn, stimulate angiogenesis and improve microcirculation. These processes not only support healing but also promote tissue repair, reduce pain, and improve circulation, making FIR a valuable tool for the treatment of conditions such as back pain, wound healing, and muscle recovery post-exercise (26). In addition to its thermal properties, FIR therapy also exerts non-thermal effects that impact cellular processes. Numerous in vitro studies have shown that FIR can enhance nitric oxide (NO) production by increasing endothelial nitric oxide synthase (eNOS) activity, thereby improving blood microcirculation. Moreover, it increases intracellular Ca^{2+} levels, with consequent elevation of calcium-regulated protein (CaM) levels (27). FIR therapy also reduces oxidative stress and lowers cytokine levels, such as IL-6 and TNF-α, which are involved in inflammation and pain (28). These non-thermal mechanisms demonstrate the potential of FIR therapies to manage chronic pain, reduce inflammation, and support musculoskeletal recovery (20). The FIR-reflecting patches have been shown to be beneficial and well tolerated for skin microcirculation and local oxygen consumption (29). Recent studies have reported the effectiveness of FIR therapy, in particular FIT Therapy® devices in alleviating various musculoskeletal conditions such as back pain, a widespread condition that causes significant discomfort and disability (17). By improving circulation and reducing muscle stiffness, FIR therapy has shown promise for managing musculoskeletal pain (20,30,31) and neurological symptoms, with a general improvement for the quality of life without significant side effects (16). Importantly, recent findings have demonstrated the safety of FIR therapy. For instance, a study investigating the use of FIT Therapy® patches found no adverse effects on the migration of human melanoma cells, highlighting the safety of this therapeutic modality (32). The results of this study demonstrate a clear and statistically significant improvement in pain reduction, functional mobility, and ROM evaluation in patients treated with the FIT Therapy® tape, particularly between T1 (5^{th} day) and T2 (8^{th} day). These findings highlight the potential of FIT Therapy® as an effective therapeutic option for managing LBP, showing superior outcomes compared to both the Nasara® tape and the placebo.

The primary outcome, pain reduction as assessed by the NRS, showed the most marked improvement in the FIT Therapy® tape group. This group showed a notable reduction in pain from baseline (T0) to the final assessment (T3), with a highly significant change ($p < 0.001$). Notably, the largest reductions occurred between T1 and T2, which aligns with the intervention's peak efficacy during this period. In comparison, the Nasara® tape group also experienced a reduction in pain, though to a lesser extent. The placebo group, while showing some decrease in pain scores, demonstrated the least improvement, with scores remaining relatively high. The significant reduction in pain achieved by the FIT Therapy® tape supports its role as a viable non-pharmacological option for LBP management, more effectively than the commonly used kinesiology tapes. Our findings with FIT Therapy® are in line with previous studies on kinesio-taping for musculoskeletal pain, including LBP. However, the degree of pain reduction

observed in our study is notably greater (13,14,33). The RMDQ, which assesses the functional impact of LBP on daily activities, further confirmed the efficacy of the FIT Therapy® tape. The RMDQ score in the FIT Therapy® group decreased significantly from T1 to T3 ($p < 0.001$), reflecting a substantial improvement in patients' functional abilities. This reduction was greater than that observed in the Nasara® tape group and the placebo group, where functional disability remained largely unchanged. This improvement in functional disability is clinically meaningful, as LBP frequently imposes significant limitations on patients' mobility and quality of life. Previous studies have highlighted the impact of non-pharmacological interventions, such as exercise therapy and manual therapy, on reducing disability in LBP patients (34,35). However, the findings suggest that the FIT Therapy® tape could offer a less invasive, complementary intervention that can provide similar functional benefits. All patients initially exhibited hypomobility in the lumbar spine, a common characteristic in individuals with LBP. At baseline, the range of spinal flexion, extension, and lateral bending was significantly limited. By T3, the FIT Therapy® tape group demonstrated the greatest improvement in ROM, particularly in lateral bending ($p < 0.001$). Flexion-extension also improved, indicating that the tape contributed not only to pain relief but also to an enhancement of spinal mobility. The Nasara® tape group showed less improvement, while the placebo group showed minimal change. This improvement in ROM with the FIT Therapy® tape suggests a potential biomechanical role combined with the superficial microcirculation enhancement, promoted by reflected FIR. Moreover, the FIT Therapy® tape enhances proprioception and facilitates more effective movement patterns in the lumbar spine. The results observed for patients treated with Nasara® tape are comparable to studies already present in the literature (14,36). Although the exact mechanism remains unclear, the Nasara® tape likely interacts with cutaneous mechanoreceptors, thereby influencing pain modulation and motor control. In the literature, therapeutic taping for the treatment of LBP is extensively discussed, as the available studies are sometimes contradictory and yield results that are not easily standardized (13,14,33). However, many studies have attributed a key role to taping in the treatment of LBP, reporting encouraging results that align with those of our study for patients treated with Nasara® tape (37). Similarly, the results for patients treated with FIT Therapy® tape generally align with those reported in the existing literature (17). The enhanced therapeutic effect appears to be associated with FIR technology, which represents the main difference between the two devices. The significant improvements observed in both pain and disability over the 2-weeks study period suggest that the FIT Therapy® tape offers a viable alternative to existing treatments for LBP, particularly for patients seeking non-pharmacological options with minimal side effects. While the results of this study are promising, several limitations must be acknowledged. First, the study duration was limited to two weeks, which may not fully capture the long-term effects of the FIT Therapy® tape. Future studies should aim to extend the follow-up period to evaluate the durability of the therapeutic effects observed. Finally, although the placebo-controlled design strengthens the validity of the findings, future studies should consider incorporating additional comparison groups, such as patients receiving pharmacological interventions, to further contextualize the benefits of this treatment.

Conclusions

In conclusion, this study provides strong evidence supporting the efficacy of the FIT Therapy® tape in reducing pain from moderate-severe to mild, improving functional disability, and enhancing spinal mobility in patients with LBP. The FIT Therapy® tape demonstrated superior outcomes compared to both the Nasara® tape and the placebo, with statistically significant improvements across all key clinical measures. These results suggest that the FIT Therapy® tape offers a valuable non-pharmacological treatment option for patients with LBP and may be considered as part of a comprehensive pain management strategy. Further research is needed to explore the long-term effects of the patch and to understand its underlying mechanisms of action better.

Ethic approval: Ethical Committee of the University Hospital of Verona – Italy: prot. LBPATCH nr. 658 23/06/2025

Conflict of interest: The authors declare no conflicts of interest, including with companies supplying FIT Therapy® tape and Nasara® kinesiology tape.

Authors contribution: MR conceived the study, defined the protocol, and acted as the principal investigator, overseeing data collection. UL, MC, EV, and TM analyzed the data, performed the statistical evaluations, and drafted the manuscript. CB and SS contributed to the manuscript preparation, revising its form and ensuring the accuracy of the English translation.

All authors read and approved the final version of the manuscript.

Declaration on the use of AI: The authors declare that they have not used AI for this study.

Consent for publication: All authors have provided their consent for the publication of this study.

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