

A Randomized, Double-Blind Study on the Combined Effects of Low-Level Laser Therapy and Exercise on Pain, Functional Level, and Range of Motion in Patients with Chronic Non-Specific Low Back Pain

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ABSTRACT

OBJECTIVE: To investigate the combined effects of low-level laser therapy (LLLT) in conjunction with an exercise program (LLLT group) compared to exercise alone (control group) on pain, functional level, and range of motion in patients with chronic non-specific low back pain (CNLBP).

METHODS: Sixty participants with CNLBP were randomized and divided into 2 groups: laser group (30 participants) and control group (30 participants). Both groups were assigned the same homework exercises (once a day, 3 days a week for 4 weeks). The assessments were performed at baseline and 4 weeks after low-level laser therapy application 3 times per week for 4 weeks. Pain level (visual analogue scale), functional level (the Oswestry low back pain disability questionnaires Thai version) and range of motion (Schober's test) were evaluated.

RESULTS: The participants who completed the study totaled 60, with 30 in the LLLT group and 30 in the control group. Both groups showed statistically significant differences in improved pain level and functional level ($p < 0.001$) from baseline to the 4th week, with the exception of range of motion in the control group ($p = 0.644$). Outcome of mean difference across the intervention arm for group comparison analysis indicated statistically significant differences in favor of the experimental group across all measures ($p < 0.01$, $p < 0.03$ and $p < 0.01$, respectively).

CONCLUSION: Combining LLLT with exercise significantly reduced pain, improved functional ability, and increased lumbar range of motion, providing a more effective treatment for Thai patients with CNLBP compared to exercise alone. The Minimal Clinically Important Difference for Visual Analog Scale (0.211) and Oswestry Disability Index (0.216) confirmed that the improvements at week 4 were clinically significant beyond natural recovery.

KEYWORDS:

chronic non-specific low back pain, low-level laser therapy, Oswestry, Schober's test

INTRODUCTION

Chronic non-specific low back pain (CNLBP) is a prevalent health issue, with peak incidence occurring around age 30 and the prevalence increasing until ages 60-65, after which it gradually declines^{1,2}. Individuals with back pain have a 24-80% chance of experiencing symptom recurrence within one year¹. This condition not only limits patient function but also imposes a significant socio-economic burden due to lost productivity and increased healthcare costs³.

The primary goals in treating CNLBP are pain reduction, functional improvement, and disease progression prevention. Surgery is typically reserved for patients with severe symptoms, such as weakness, bowel or bladder involvement, or those who do not respond to conservative treatments. Conservative management includes both nonpharmacologic and pharmacologic approaches, with clinical practice guidelines recommending nonpharmacologic methods as the first line of management to reduce pain and enhance daily function. These methods include physical therapy, exercise, acupuncture, cognitive behavioral therapy, and massage⁴⁻⁷. Nonpharmacologic treatments are preferred due to fewer side effects and better cost-effectiveness compared to the pharmacologic options⁴.

Exercise is a recommended practice guideline to enhance mobility and prevent disease progression for treating patients with CNLBP^{8,9}. However, studies have shown that combining exercise with physical therapy devices or other treatment methods can enhance treatment efficacy (synergistic effect). For example, the study by Vallone et al.¹⁰ demonstrated that low-level laser therapy (LLLT) combined with exercise in patients with CNLBP significantly reduced pain levels. In contrast, the meta-analysis by Jang et al. found that some studies reported no significant difference in treatment outcomes between using LLLT combined with exercise and exercise alone¹¹. Both LLLT and exercise are non-invasive,

relatively safe, and widely used in clinical practice. Therefore, further research is needed to optimize treatment effectiveness.

In recent years, laser treatment has gained popularity for its ability to moderate pain and inflammation, including in CNLBP. It works by modulating cellular processes such as reducing pro-inflammatory cytokine release, promoting mitochondrial activity, and enhancing tissue repair¹². Studies have demonstrated that LLLT is an effective treatment for pain without side effects. Various settings, such as laser type, mode, wavelength, energy intensity, and treatment duration, can be tailored to individual patient conditions^{11,13,14}. This study aimed to evaluate the combined effects of LLLT and exercise on pain, functional level, and range of motion and confirm the synergistic effect of combining LLLT and exercise for Thai patients with CNLBP, with the goal of providing clinically relevant insights into the integration of laser therapy as a viable treatment option for this condition.

METHODS

The study described was a simple randomized controlled trial with a double-blind design in which both participants and therapists were blinded. Its purpose was to investigate the effects of LLLT combined with exercise on pain, functional level, and lumbar range of motion in patients aged more than 18 years old with CNLBP for more than 3 months¹⁵. The trial included 60 participants from the outpatient rehabilitation clinic at Ratchaphiphat Hospital who met specific inclusion criteria: no prior LLLT, no recent back trauma or surgery, and no contraindicating underlying diseases, such as lower extremity weakness, malignant melanoma, and epilepsy (Figure 1). Ethics approval was obtained from the Bangkok Metropolitan Administration Human Research Ethics Committee (Project ID: S004h/63). After volunteers agreed to participate in the research project, they received an information sheet explaining the details of the study.

If the participants consented and were willing to join the research, they had to sign an informed consent form in order to indicate their agreement to participate in the study. Sixty participants were randomly (by computer) divided into 2 groups: 30 participants in the LLLT group and 30 participants in the sham laser group, as shown in Figure 1. The experimental group received LLLT combined with exercise, while the control group received a sham laser treatment combined with the same exercise regimen. The first physical therapist administered the treatment, setting the laser machine as specified and activating the sample light to appear the same for both groups. The second physical therapist was responsible for turning the laser on, ensuring that it only worked for the LLLT group, and setting a timer to ensure equal treatment durations for both groups.

Patients were only informed that the laser might alternate between different power levels and wavelengths. Both groups were taught the exercise program by the same physical therapist (first physical therapist). Outcome measurements for both groups were conducted by the same assessor, who was blinded to the group assignments. The gallium–aluminum–arsenide laser used in the study had a probe scan wavelength of 638 nm, continuous mode, and a maximum power wattage of 650 mW¹⁶. Calculated output power for low backs was 120-240 J/spot with a 4-8 J/cm² and 30 cm² treatment area; the calculated treatment time was 6.09-12.18 minutes. In this study, the laser accumulated power per area was 200 J/area and patient treatment time was 10.15 minutes. Laser treatment was administered 3 times a week for 4 weeks¹⁷.

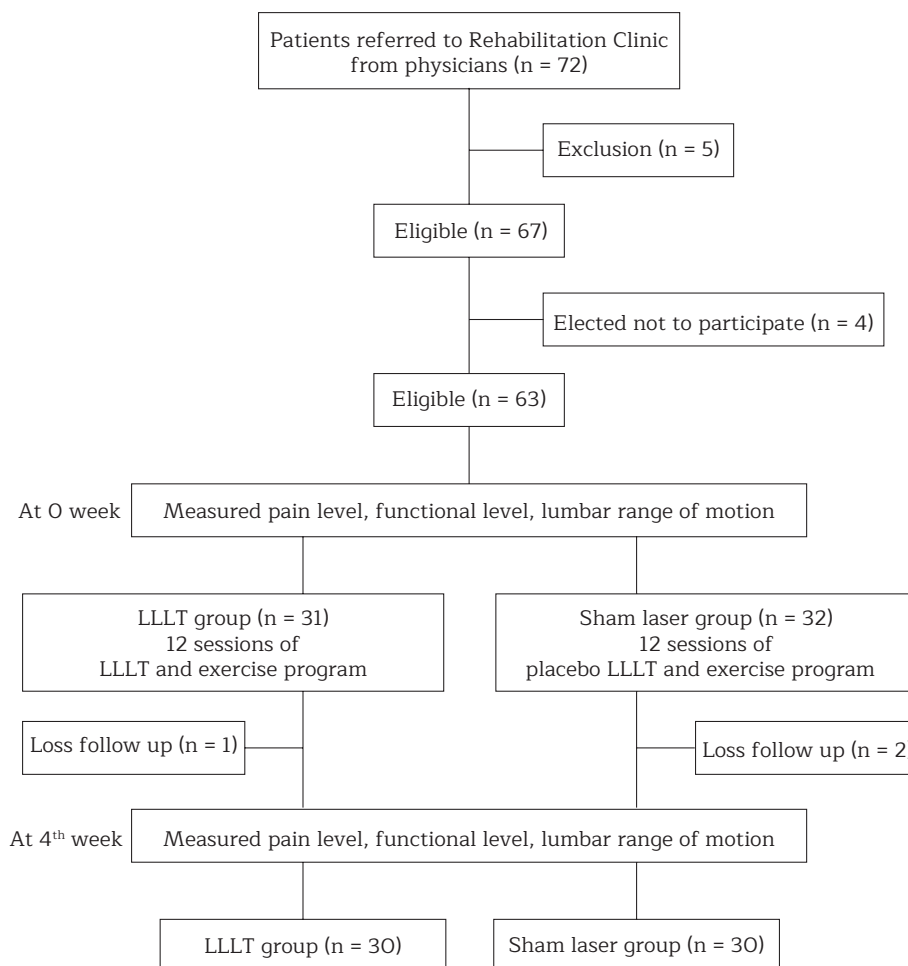


Figure 1 Consort diagram of patients eligible, recruited, numbers followed up and included in analysis

The primary outcomes measured included: the first was pain assessment by Visual Analog Scale (VAS)¹⁸, ranging from 0 (no pain) to 10 (maximum pain). Secondary outcomes were functional assessment by Oswestry low back pain disability questionnaire (Thai version)¹⁹, assessing disabilities across various activities: personal care, lifting, walking, sitting, standing, sleeping, sexual activity, participating in social activities, and traveling. For each section the possible disability score ranged from 0 to 5, and thus the total possible score was 50. The score was calculated as a percentage and sorted into 5 groups that were 0-20% for minimal disability, 21-40% for moderate disability, 41-60% for severe disability, 61-80% for crippling disability, and 81-100% for bed-bound disability. The other secondary outcomes were lumbar range of motion by Schober's test²⁰. In order to conduct the test, the patient was barefoot and standing upright. A mark was made at the lumbosacral junction and then a second mark 10 cm. above it. The distance between the 2 marks on the lower back was then measured during maximum forward flexion. The mean of 3 measurements was used in the study.

Both groups followed a prescribed exercise regimen²¹, which included pelvic tilt exercises, abdominal and back strengthening exercises, and hip flexor relaxation exercises, seen in [Figure 2](#). All the exercises were performed once a day (5 repetitions per set for each exercise, 3 sets per day), 3 times a week for 4 weeks. Compliance with the exercise regimen was recorded in a logbook. Assessments were made prior to and 4 weeks post intervention. Dropout criteria were VAS increased more than 3 levels from baseline, and if a patient received the treatment fewer than 12 times during the intervention's 4 weeks of sessions. The participants were requested to stop other treatments and medications during the sessions.

The sample size used in this study was calculated by STATA 14.2 and referenced from a study of Vallone et al.¹⁰ in 2014. The research design included type I error set to 0.05, type II error set to 0.8, delta at 1.64. The 60 subjects were calculated from a 50 subject minimal sample size with a dropout rate of 20 percent. The demographic characteristics were identified as mean with standard deviation and compared by independent T-test. Treatment outcomes, VAS¹⁸, the Oswestry Low Back Pain Disability Questionnaire (Thai version)¹⁹, and Schober's test,²⁰ were compared pre and post intervention by paired T-test. The differences between the 2 groups were compared by independent T-test. The statistical significance of the study was set at $p < 0.05$.

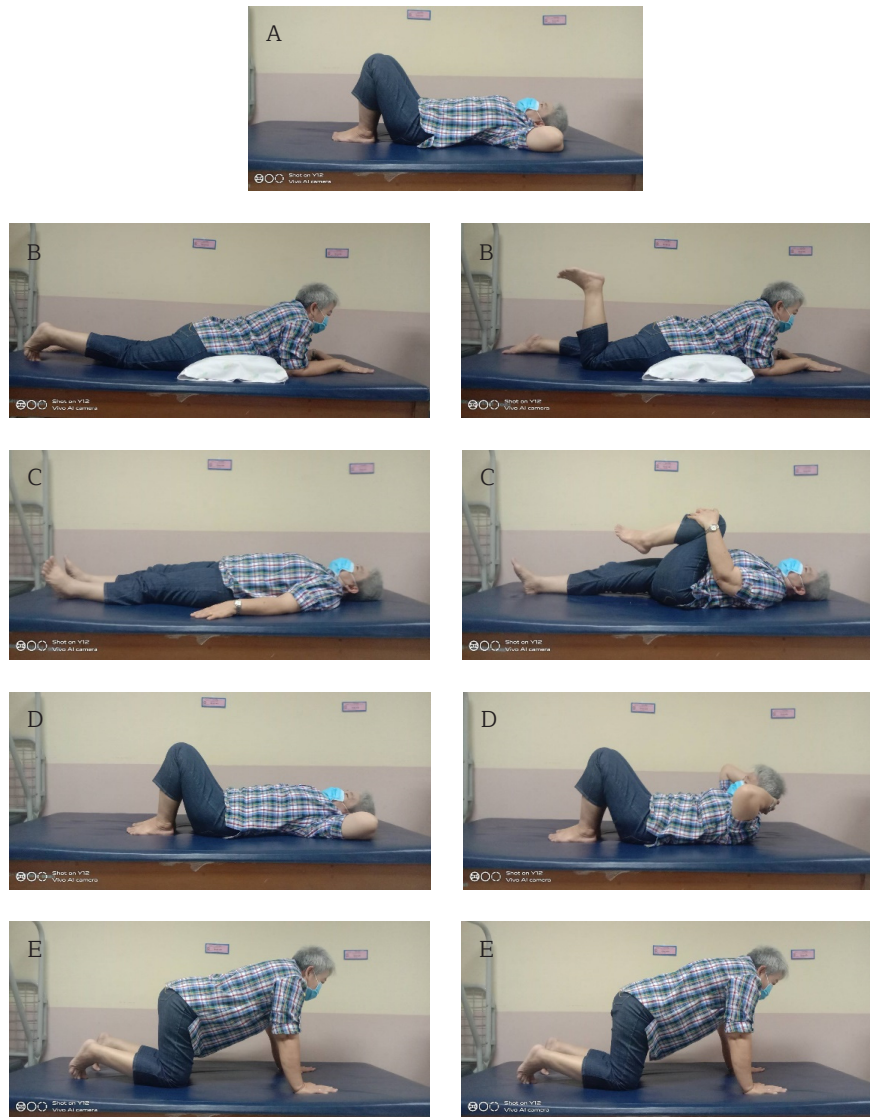


Figure 2 All exercises in exercise program were performed once a day (perform 5 repetitions per set for each exercise, 3 set per day), 3 times a week for 4 weeks.

(A) Posterior pelvic tilt exercise: Lie on your back on the bed with both hands clasped behind your head. Bend both knees with your feet flat on the bed. Inhale while tensing your abdominal and gluteal muscles. Hold for 20 seconds, then relax and exhale.

(B) Anterior pelvic tilt exercise: Lie face down with a pillow under your abdomen. Inhale while bending your dominant knee at a 90-degree angle. Hold for 20 seconds, then exhale as you lower your knee. Repeat on the other side.

(C) Relax hip flexor muscles exercise: Lie on your back with both legs straight. Bend your knee and hip on the dominant side, placing your foot flat on the bed. Then, bend the knee further to bring it toward your chest while extending the non-dominant leg straight. Hold for 20 seconds, then switch sides.

(D) Abdominal muscles exercise: Lie on your back on the bed with both hands clasped behind your head. Bend both knees with feet flat on the bed. Then, curl your body up to touch your forehead to your knees in a sit-up position.

(E) Exercise to control lumbar lordosis: Start on your hands and knees in a kneeling position with your back parallel to the floor. The physical therapist instructs you to contract your abdominal and gluteal muscles while arching and rounding your back, keeping it parallel to the floor. Hold for 20 seconds.

RESULTS

Sixty participants, 30 subjects in the control group and 30 subjects in the experimental group, completed the study (Figure 1). Demographic characteristics are shown in Table 1. There were no statistically significant differences between the 2 groups. Pre- and post-intervention outcomes in the 2 groups were compared. VAS¹⁸, the Oswestry low back pain disability questionnaire (Thai version)¹⁹

and Schober's test²⁰ showed statistically significant improvements after laser treatment ($p < 0.001$), except for Schober's test²⁰ in the control group ($p = 0.644$) (Table 2). Outcome of mean difference across the intervention arm for group comparison analysis indicated statistically significant differences in favor of the experimental group across all measures ($p < 0.01$, $p < 0.03$ and $p < 0.01$) in Table 2.

Table 1 Demographic characteristics

Demographic data	LLLT group (n = 30)	Sham laser group (n = 30)	P-value
Gender: n (percent)			0.584
Male	9 (30)	11 (37)	
Female	21 (70)	19 (63)	
Age (years)	54.93 ± 12.17	55.18 ± 13.15	0.938
Weight (kg)	68.11 ± 14.01	67.51 ± 15.90	0.878
Height (m)	1.58 ± 0.10	1.60 ± 0.12	0.312
BMI (kg/m ²)	27.31 ± 4.51	26.14 ± 5.15	0.359
Educational profile: n (percent)			0.524
Uneducation	0 (0)	1 (3)	
Elementary school	14 (47)	15 (50)	
Middle school	2 (7)	2 (7)	
High school	5 (17)	5 (17)	
Bachelor degree	9 (30)	5 (17)	
Master degree	0 (0)	2 (6)	
Alcohol history: n (percent)			1.000
Drink	3 (10)	3 (10)	
No drink	27 (90)	27 (90)	
Smoking history: n (percent)			0.506
Smoke	2 (7)	1 (3)	
No smoke	26 (87)	26 (87)	
Now smoking	1 (3)	0 (0)	
Use to smoke	1 (3)	3 (10)	

Abbreviations: kg, kilogram; kg/m², kilogram per square metre; LLLT, low-level laser therapy; m, meter; n, number

Table 2 Comparing VAS, Oswestry scale and Schober's test at week 0 and 4th and outcome of mean difference across the intervention arm for group comparison analysis

	Pretest At week 0	Posttest At week 4 th	Difference 95%(CI)	P-value
VAS (mean \pm SD)				
Sham laser	6.24 \pm 1.33	3.79 \pm 1.77	2.45 (1.80, 3.11)	< 0.001
LLLT	6.86 \pm 1.34	2.67 \pm 1.73	4.19 (3.58, 4.79)	< 0.001
VAS: Mean difference	-0.62 (-1.31, 0.70)	1.11 (0.21, 2.02)	P-value < 0.01	
Oswestry score (mean \pm SD)				
Sham laser	14.60 \pm 8.09	7.80 \pm 5.36	6.80 (4.48, 9.12)	< 0.001
LLLT	18.27 \pm 6.40	5.40 \pm 2.63	12.87 (10.64, 15.09)	< 0.001
Oswestry score: Mean difference	-3.67 (-7.44, 0.10)	2.40 (0.21, 4.58)	P-value < 0.03	
Schober's test (mean \pm SD)				
Sham laser	12.70 \pm 2.13	12.50 \pm 2.14	0.21 (-0.70, 1.11)	0.644
LLLT	11.66 \pm 1.36	13.76 \pm 1.87	-2.10 (-2.91, -1.29)	< 0.001
Schober's test: Mean difference	1.04 (0.12, 1.97)	-1.26 (-2.30, -0.23)	P-value < 0.01	

Abbreviations: CI, confidence interval; LLLT, low-level laser therapy; SD, standard deviation; VAS, visual analog scale

Statistical significance, p-value < 0.05

DISCUSSION

LLLT has the potential to reduce pain, lower disability levels, and improve range of motion through several mechanisms. It modulates inflammation by inhibiting pro-inflammatory cytokines and promoting anti-inflammatory mediators, which helps relieve pain and enhance tissue healing. LLLT also stimulates angiogenesis and collagen synthesis, aiding in the regeneration of damaged tissues and improving functional outcomes. Additionally, LLLT can improve nerve function by reducing pain sensitivity and enhancing motor control. LLLT may have psychological benefits, such as reducing anxiety and improving mood. This can indirectly contribute to pain reduction and improved quality of life¹². The superior outcomes of LLLT groups compared to control groups are due to several factors. LLLT directly targets inflammation, tissue damage, and nerve dysfunction. Additionally, LLLT can be combined with other therapies, such as exercise or physical therapy, in order to enhance the overall treatment effect (synergistic effect). Lastly, the placebo effect may be stronger due to the perceived technological advancement and the potential for non-invasive treatment^{12,22}.

Previous studies had shown positive results in treating musculoskeletal diseases with laser therapy^{23,24}. CNLBP findings are consistent with prior studies that demonstrated LLLT's efficacy in pain reduction and functional improvement, such as those by Huang et al.¹³, Hadi et al.¹⁷, and Rubira et al.²⁵. Abdelbasset et al.¹⁵ noted that LLLT reduced pain, enhanced function (measured by the Oswestry Disability Index), and increased lumbar range of motion. In this study, the combination of LLLT and exercise resulted in significant outcomes for patients with CNLBP. Specifically, there was a marked reduction in pain intensity as measured by the VAS, an improvement in functional capacity assessed by the Oswestry Low Back Pain Disability Questionnaire (Thai version), and an enhancement in lumbar range of motion measured by Schober's test; there were no reported side effects during the research participation period. Comparisons of pre- and post-intervention outcomes between the LLLT and sham laser groups showed significant improvements in the VAS, Oswestry Questionnaire, and Schober's test after LLLT and exercise treatment (p < 0.001), except for Schober's test in the sham laser group (p = 0.644).

Additionally, mean difference of post-intervention results indicated statistically significant differences in favor of the LLLT group across all measures. These findings are consistent with studies by Vallone et al.¹⁰, Djavid et al.²¹, and Gur et al.²⁶, confirming the synergistic effect of combining LLLT and exercise for patients with CNLBP. This combination therapy not only enhances pain reduction and functional improvement but also increases lumbar range of motion, demonstrating its effectiveness as a comprehensive treatment approach for managing CNLBP in this population. The placebo effect from LLLT is likely due to patients' belief in the effectiveness of a novel, advanced treatment they had not previously experienced²⁷. This is reflected in improvements in subjective measures, such as pain intensity (VAS) and functional ability (Oswestry Questionnaire), where patients assessed themselves. However, no significant improvements in lumbar range of motion (Schober's test) ($p = 0.644$), as shown in Table 2, which was objectively measured by professionals, were observed in the control group receiving sham laser treatment. LLLT may also offer psychological benefits, such as reducing anxiety and improving mood, indirectly contributing to pain relief and quality of life. The strong placebo effect may be driven by the perceived technological advancement and non-invasive nature of the treatment. These findings emphasize the importance of objective measures, like Schober's test, to accurately assess treatment efficacy, as subjective outcomes are more prone to placebo effects²².

In this study, the Minimal Clinically Important Difference (MCID) was set at 0.211 for the VAS and 0.216 for the Oswestry Disability Index²⁸⁻³⁰. In Table 2, the primary outcome shows a VAS mean difference posttest at week 4 of 1.11, and the secondary outcome, the Oswestry score, shows a mean difference posttest at week 4 of 2.4. Both values exceed the MCID thresholds (0.211 for VAS and 0.216 for the Oswestry Disability Index), indicating that the posttest

outcomes at week 4 reached a clinically significant level and were not due to natural recovery.

These were study limitations that the study did not collect data on the duration of CNLBP or the occupations of the participants in either group, which may have influenced the results. Future studies should evaluate the long-term effectiveness of LLLT in pain reduction while assessing the potential side effects from its prolonged use. Additionally, this study did not compare LLLT with other therapeutic modalities, such as high-level laser therapy, ultrasound diathermy, short-wave diathermy, or alternative treatments like acupuncture. Further research should address these gaps.

CONCLUSION

Combining LLLT with exercise significantly reduced pain, improved functional ability, and increased lumbar range of motion, providing a more effective treatment for Thai patients with CNLBP compared to exercise alone. The MCID for VAS (0.211) and Oswestry Disability Index (0.216) confirmed that the improvements at week 4 were clinically significant beyond natural recovery.

CONFLICT OF INTEREST

The authors report no conflict of interest for this article.

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DATA AVAILABILITY STATEMENT

All data generated or analyzed during this study are included in this article. Future enquiries can be directed to the corresponding author.

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