



Original Article

## Low-Level Laser Therapy including Laser Acupuncture for Non-Specific Chronic Low Back Pain : Protocol for a Systematic Review



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### ABSTRACT

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#### Keywords:

low level laser therapy,  
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**Background:** Low-level laser therapy (LLLT) including laser acupuncture (LA) has been widely used to treat chronic low back pain (CLBP), but there is no critically appraised evidence of the potential benefits. The purpose of this protocol for a systematic review was to enable the evaluation of the effectiveness of LLLT including LA for non-specific CLBP to identify the potential benefits.

**Methods:** The electronic databases MEDLINE (PubMed), Embase (Ovid), the Cochrane Central Register of Controlled Trials (CENTRAL), Korean medical databases (KoreaMed, KMBASE, KISS, NDSL, KISTI, OASIS), the Chinese database (CNKI), and Japanese databases (CiNII, J-STAGE) are recommended.

**Results:** Randomized controlled trials in LLLT including LA should be included in the searches. All data synthesis and subgroup analyses should be conducted using a Review Manager software. The Cochrane risk of bias tool can be used to evaluate methodological quality of the studies. A risk ratio or mean difference with a 95% confidence interval will show the effects of LLLT including LA.

**Conclusion:** The primary outcome would be pain intensity and functional status/disability due to low back pain. The secondary outcome would be a global measurement of recovery or improvement, quality of life and adverse event.

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### Introduction

Low back pain is a common musculoskeletal disorder affecting 80% of people at some point in their lives. It is estimated that 10% to 20% of affected adults develop symptoms of chronic low back pain (CLBP) that last for more than 12 weeks [1]. In 2017, the American College of Physicians (ACP) developed guidelines to present the evidence and provide clinical recommendations for non-invasive treatments of low back pain, and strongly recommended that non-pharmacological treatments including low-level laser therapy, should be considered for patients with CLBP [2].

Low-level laser therapy (LLLT) including laser acupuncture (LA), also known as photobiomodulation, uses the laser apparatus to aid tissue repair, relieve pain and stimulate acupuncture points [3-5]. One review categorized 399 studies on LLLT published between 2003 and 2013, according to the 10<sup>th</sup> revision of the International Statistical Classification of Diseases and Related Health Problems

[6]. The most common codes used for health insurance purposes were K and M, identifying the use of LLLT in dentistry and in the treatment of pain and musculoskeletal disorders including low back pain [6].

At the most basic level, LLLT including LA acts by inducing a photochemical reaction in the cells, a process referred to as biostimulation or photobiomodulation, that aids tissue repair and relieves pain. Recently, a book review suggested that the pain relief from laser acupuncture therapy was related to an inhibitory effect on peripheral nerves [7].

Despite the widespread use of LLLT including LA for CLBP, the published evidence of clinical efficacy observed through randomized clinical trials (RCTs) is limited [8,9]. In Korea the use of LLLT including LA for CLBP is recommended a Grade C, that means the treatment may be considered, in Clinical Practice Guideline (CPG) published in Korea in 2016 for non-specific CLBP [10]. However, the studies used to form the basis for the recommendations of the CPG in Korea have been reported to

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have used too low energy dose and long treatment interval of LLLT or LA. Furthermore, previous reviews of LLLT excluded studies conducted China, Japan and Korea[8,9]. Databases from China, Japan and Korea should be included to critically evaluate the evidence from RCTs of LLLT including LA for non-specific CLBP. In this article, the methods and plan for a systematic review are described.

## Materials and Methods

### Criteria for considering studies for this review

#### Type of studies

RCTs and quasi-RCTs should be selected in the protocol for reviewing of LLLT including LA for non-specific CLBP. Observational, cohort, case reports, case series, non-RCT, animal and experimental studies should be excluded.

#### Type of participants

Patients aged over 18 suffering from non-specific CLBP should be included in the review and specific CLBP indicated by malignancy, infection, neoplasm, osteoporosis, fracture, inflammatory disorder or neurological syndrome should be excluded. LBP should last for more than 12 weeks.

#### Type of interventions and controls

Articles evaluating LLLT including LA as the primary intervention, should be included. A combined intervention may be included which involves the use of Western medicine, rehabilitation or physiotherapy, and other alternative therapies such as herbal medicine and tuina/chuna.

#### Type of outcome measures

##### Primary outcomes

- 1) Pain intensity measured on a visual analogue scale [11] or the numerical rating scale [12], etc.
- 2) Functional status/disability measured by recognized scales, including the Roland Morris Disability Questionnaire [13], or the Oswestry Disability Scale [14], etc.

##### Secondary outcomes

- 1) Global measurements of recovery or improvement including subjective symptom improvement, measured physical examination (such as range of motion, finger-to-floor distance, degrees of straight leg raising, muscle strength), and overall improvement (such as medication use and use of medical services, work-related outcomes).
- 2) Quality of life measured by validated tools such as the short-form survey instrument 36 [15], or the Euroqol-5D [16].
- 3) Complications and adverse events.

### Search methods for identification of studies

#### Electronic searches

Electronic databases searched should include MEDLINE (PubMed), Embase (Ovid), the Cochrane Central Register of Controlled Trials (CENTRAL), Korean databases (KoreaMed, KMBASE, KISS, NDSL, KISTI, OASIS), the China National Knowledge Infrastructure Database (CNKI), and Japanese databases (CiNii, J-STAGE). RCTs in all languages should be considered for inclusion.

#### Searches of other resources

Reference lists from articles should be scanned to retrieve additional studies. In addition, the WHO International Clinical Trials Registry Platform and Google Scholar should be searched to retrieve relevant articles. Dissertations for degrees should be included. The ClinicalTrials.gov registry should also be searched for any unpublished relevant trials.

#### Search strategy

The search terms are composed of 2 parts. LLLT including LA (e.g., laser, laser acupuncture, laserpuncture, laser needle, low-dose laser acupuncture, LLLT, low-level laser, laser therapy, laser treatment) and chronic lower back pain (e.g., lower back pain, sciatica, radiculopathy, lumbago, backache, back pain, lumbosacral). The detailed search strategy for searching electronic databases is described in the Tables 1-4.

### Data collection, extraction and assessment

#### Selection of studies

At least 2 reviewers should independently screen the titles and abstracts of retrieved studies to exclude any obviously irrelevant articles and make the final decision for inclusion after reading the full text of all potentially eligible articles. In case of disagreement, a third reviewer should be asked to make the final decision for inclusion. Study selection should be documented and summarized in a Preferred Reporting Items for Systematic Reviews and Meta-Analysis flow diagram [17]. All publications retrieved should have the appropriate translation where necessary.

#### Data extraction

At least 2 reviewers should independently extract the data from each clinical trial study using a standard form. Overlapping and duplicate studies should be excluded first and then titles, abstracts and full text should be assessed. Disagreement should be consulted by a third reviewer if necessary.

#### Assessment of risk of bias

The quality of the included studies should be assessed according to the criteria described in the Cochrane Handbook for Systematic Reviews of Intervention [18]. The following items should be assessed: 1) random sequence generation; 2) allocation concealment; 3) blinding of participants and personnel; 4) blinding of outcome assessment; 5) completeness of outcome data; 6) completeness of reporting; 7) other sources of bias. Each trial should be categorized as having a low (L), unclear (U), or high (H) risk of bias.

#### Managing missing data

To obtain missing data, the corresponding author should be contacted. If there is no response, only the available data should be analyzed and impact of exclusion of this data from the article should be described.

#### Assessment of heterogeneity

Clinical heterogeneity in the included RCTs should be assessed by considering the studies that are similar in the setting, participants, interventions and outcomes. If there is no evidence of heterogeneity, a fixed model should be used otherwise a random effect model should be used. If a meta-analysis is possible, the  $I^2$  statistic for quantifying inconsistencies across the included studies should be used. A 50% cut-off point would represent substantial heterogeneity. If heterogeneity is observed, a subgroup analysis should be conducted [19].

Table 1. English Database Search Strategy.

MEDLINE search strategy (PubMed)
<p>#1 Low Back Pain/            #2 Sciatica/            #3 Radiculopathy/            #4 ((lumbar[TIAB] OR lumbosacral[TIAB]            OR lumbo-sacral[TIAB] OR back[TIAB])) AND ((pain*[TIAB] OR ache*[TIAB] OR aching[TIAB]))            #5 backache*[TIAB] OR lumbago[TIAB] OR sciatica[TIAB]            #6 radiculopathy[TIAB] OR radiculitis[TIAB] OR radicular pain*[TIAB]            #7 ("nerve root*" [TIAB]) AND            ((pain*[TIAB] OR avulsion[TIAB] OR compress*[TIAB] OR disorder*[TIAB] OR pinch*[TIAB] OR inflam*[TIAB] OR imping*[TIAB] OR irritat*[TIAB] OR entrap*[TIAB] OR trap*[TIAB]))            #8 #6 OR #7            #9 back*[TIAB] OR lumbosacral[TIAB] OR lumbo-sacral[TIAB] OR lumbar[TIAB]            #10 #8 and #9            #11 #1 OR #2 OR #3 OR #4 OR #5 OR #10            #12 laser[TIAB] OR LLLT[TIAB] OR 'low level leser'[TIAB] OR 'laser therapy'[TIAB] OR 'laser treatment'[TIAB] OR 'laser acupuncture'[TIAB] OR 'laserpuncture'[TIAB] OR 'laser needle'[TIAB] OR 'low dose laser acupuncture'[TIAB]            #13 #11 and #12            #14 randomized controlled trial [PT]            #15 controlled clinical trial [PT]            #16 randomized [TIAB]            #17 placebo [TIAB]            #18 clinical trials as topic [mesh: noexp]            #19 randomly [TIAB]            #20 trial [TI]            #21 #14 OR #15 OR #16 OR #17 OR #18 OR #19 OR #20            #22 animals [mh] NOT humans [mh]            #23 #21 NOT #22            #24 #13 AND #23</p>
CENTRAL (Cochrane)
<p>#1 MeSH descriptor: [Low Back Pain] explode all trees            #2 MeSH descriptor: [Sciatica] explode all trees            #3 MeSH descriptor: [Radiculopathy] explode all trees            #4 (lumbar or lumbosacral or lumbo-sacral or back) near/5 (pain* or ache* or aching):ti,ab,kw (Word variations have been searched)            #5 backache* or lumbago or sciatica:ti,ab,kw (Word variations have been searched)            #6 radiculopathy or radiculitis or radicular pain*:ti,ab,kw (Word variations have been searched)            #7 (nerve root* near/5 (pain* or avulsion or compress* or disorder* or pinch* or inflam* or imping* or irritat* or entrap* or trap*)):ti,ab,kw (Word variations have been searched)            #8 #6 OR #7            #9 back* or lumbosacral or lumbo-sacral or lumbar:ti,ab,kw (Word variations have been searched)            #10 #8 and #9            #11 #1 OR #2 OR #3 OR #4 OR #5 OR #10            #12 laser OR LLLT OR 'low level leser' OR 'laser therapy' OR 'laser treatment' OR 'laser acupuncture' OR 'laserpuncture' OR 'laser needle' OR 'low dose laser acupuncture':ti,ab,kw (Word variations have been searched)            #13 #11 and #12</p>
EMBASE
<p>#1 'Low Back Pain'/exp            #2 'Sciatica'/exp            #3 'Radiculopathy'/exp            #4 ((lumbar OR lumbosacral OR 'lumbo sacral' OR back) NEAR/5 (pain* OR ache* OR aching)):ab,ti            #5 (backache* or lumbago or sciatica):ab,ti            #6 (radiculopathy or radiculitis or radicular pain*):ab,ti            #7 (nerve root* NEAR/5 (pain* or avulsion or compress* or disorder* or pinch* or inflam* or imping* or irritat* or entrap* or trap*)):ab,ti            #8 #6 OR #7            #9 (back* or lumbosacral or lumbo-sacral or lumbar):ab,ti            #10 #8 and #9            #11 #1 OR #2 OR #3 OR #4 OR #5 OR #10            #12 (laser OR LLLT OR 'low level leser' OR 'laser therapy' OR 'laser treatment' OR 'laser acupuncture' OR 'laserpuncture' OR 'laser needle' OR 'low dose laser acupuncture'):de,ab,ti            #13 #11 and #12            #14 'crossover procedure':de OR 'double-blind procedure':de OR 'randomized controlled trial':de OR 'single-blind procedure':de OR (random* OR factorial* OR crossover* OR CROSS NEXT/1 over* OR placebo* OR doubl* NEAR/1 blind* OR singl* NEAR/1 blind* OR assign* OR allocat* OR volunteer*):de,ab,ti            #15 #13 and #14</p>

### Subgroup analysis and the investigation of heterogeneity

If a sufficient number of studies exist, a subgroup analysis should be performed to examine the effect of study methods, risk of bias and clinical differences.

### Data synthesis

All statistical analyses should be performed using the Review

Manager (e.g. Cochrane Collaboration Software, RevMan version 5.3.5). For dichotomous data, the treatment effects should be presented and the risk ratios should be used with a 95% confidence interval (CI). For continuous data, the mean differences should be used with a 95% CI. If outcome variables are measured, standardized mean differences should be used with a 95% CI.

Table 2. Chinese Database Search Strategy.

CNKI
#1 SU=('腰痛'+坐骨神经痛+'神经根病'+背痛) AND SU=(随机) AND SU=('激光针'+激光)
#2 AB=('腰痛'+坐骨神经痛+'神经根病'+背痛) AND AB=(随机) AND AB=('激光针'+激光)
#3 TI=('腰痛'+坐骨神经痛+'神经根病'+背痛) AND TI=(随机) AND TI=('激光针'+激光)

腰痛 : Chinese for 'low back pain or backache or lumbago', 坐骨神经痛 : Chinese for 'sciatica', 神经根病 : Chinese for 'radiculopathy', 背痛 : Chinese for 'backache', 随机 : Chinese for 'random', 激光针 : Chinese for 'laser acupuncture or laser needle', 激光: Chinese for 'Laser'.

Table 3. Japanese Database Search Strategy.

CiNII & J-stage
(腰痛 or 'low back pain' or sciatica or radiculopathy or backache* or lumbago or radiculitis or radicular pain*) AND (レーザー OR レーザー 針 OR laser OR LLLT OR 'low level leser' OR 'laser therapy' OR 'laser treatment' OR 'laser acupuncture' OR 'laserpuncture' OR 'laser needle' OR 'low dose laser acupuncture')

腰痛 : Japanese for 'low back pain or backache or lumbago', レーザー : Japanese for 'laser', レーザー 針 : Japanese for 'laser acupuncture or laser needle'.

Table 4. Korean Database Search Strategy.

KoreaMed
('low back pain' or sciatica or radiculopathy or backache* or lumbago or radiculitis or radicular pain*) AND (레이저 OR 레이저침 OR laser OR LLLT OR 'low level leser' OR 'laser therapy' OR 'laser treatment' OR 'laser acupuncture' OR 'laserpuncture' OR 'laser needle' OR 'low dose laser acupuncture')
KMBASE
(((((ALL=요통) OR [ALL=low back pain]) OR [ALL=sciatica]) OR [ALL=radiculopathy]) OR [ALL=backache*]) OR [ALL=lumbago]) OR [ALL=radiculitis]) OR [ALL=radicular pain*]) AND ((((((ALL=레이저) OR [ALL=레이저침]) OR [ALL=laser]) OR [ALL=LLLT]) OR [ALL='low level leser' ]) OR [ALL='laser therapy']) OR [ALL='laser treatment']) OR [ALL='laser acupuncture']) OR [ALL='laserpuncture'] OR [ALL='laser needle'] OR [ALL='low dose laser acupuncture']))
KISS, NDSL, KISTI, OASIS
(요통 or 'low back pain' or sciatica or radiculopathy or backache* or lumbago or radiculitis or radicular pain*) AND (레이저 OR 레이저침 OR laser OR LLLT OR 'low level leser' OR 'laser therapy' OR 'laser treatment' OR 'laser acupuncture' OR 'laserpuncture' OR 'laser needle' OR 'low dose laser acupuncture')

레이저: Korean for 'laser', 레이저침 : Korean for 'laser acupuncture', 요통 : Korean for 'low back pain or backache or lumbago'.

### Sensitivity analysis

A sensitivity analysis should be performed to check whether including or excluding high risk of bias studies according to predefined criteria, affects the comparison between groups.

### Assessment of reporting biases

Funnel plots should be created and used to evaluate the presence of reporting biases.

### Discussion

In the management of chronic diseases at the primary care, demands for patient satisfaction, evaluation and informed shared decision-making are increasing with the development of therapeutic technology. Non-specific CLBP is one of the conditions that requires long-term management.

LLLT including LA have been used for non-specific CLBP, is non-invasive, painless, and can be easily administered in primary care settings. The incidence of adverse effects of LLLT including LA is low, and similar to that of a placebo, with no reports of serious events [20].

This protocol for a systematic review provides a detailed summary to perform a review of the current evidence supporting the effectiveness

of LLLT including LA in treatment of a patient with non-specific CLBP symptoms. The result of the systematic review of this protocol may benefit patients and healthcare in the treatment of non-specific CLBP.

### Conflicts of Interest

The authors have no conflicts of interest to declare.

### Acknowledgments

No ethical issues are predicted. Findings will be published in a dissertation.

### References

- [1] Deyo RA, Weinstein JN. Low back pain. N Engl J Med 2001;344:363-370.
- [2] Qaseem A, Wilt TJ, McLean RM, Forcica MA; Clinical Guidelines Committee of the American College of Physicians. Noninvasive Treatments for Acute, Subacute, and Chronic Low Back Pain: A Clinical Practice Guideline from the American College of Physicians. Ann Intern Med 2017;166:514-530.
- [3] Woodruff LD, Bounkeo JM, Brannon WM, Dawes KS, Barham CD, Waddell DL et al. The efficacy of laser therapy in wound repair: A meta-analysis of the literature. Photomed Laser Surg 2004;22:241-247.

- [4] Jan T, Lars H. Laser therapy: Clinical Practice and Scientific Background (Jang IS & Shin GB, Trans). Seoul (Korea): Jung Dam; 2011. p. 356-387.
- [5] Baxter GD, Bleakley C, McDonough S. Clinical Effectiveness of Laser Acupuncture: A systematic Review. *J Acupunct Meridian Stud* 2008;1:65-82.
- [6] Han HJ, Kang KW, Kang SY, Kim LH, Jang IS. The Clinical Indication of Low-Level Laser Therapy Using ICD-10. *J Int Korean Med* 2015;36:561-569. [in Korean].
- [7] Jacqueline F, Adrian W, Mike C. Medical Acupuncture: A Western Scientific Approach, 2nd ed (Translated by Lee SH, Kang JW, Kwan SW, Kim GH, Kim TH, Lee JE et al). Seoul (Korea): HANMI Medical Publishing Co.; 2019. p. 260-261. [in Korean].
- [8] Glazov G, Yelland M, Emery J. Low-dose laser acupuncture for chronic non-specific low back pain: a double - blind randomised controlled trial. *Acupunct Med* 2014;32:116-123.
- [9] Ruth M, Weber M, Zenz M. Laser acupuncture for chronic back pain; A double-blind clinical study. *Schmerz* 2010;24:485-493. [in German].
- [10] National Clearinghouse for Korean Medicine [Internet]. Chronic Low Back Pain Korean Medicine Clinical Practice Guideline, 2016, 29. Available from: [http://www.nckm.or.kr/user/fr/pg/detail.do?scpgId=SCPG\\_0000000000000021&pageIndex=3&searchCondition=0&searchKeyword=&kcdSearch=](http://www.nckm.or.kr/user/fr/pg/detail.do?scpgId=SCPG_0000000000000021&pageIndex=3&searchCondition=0&searchKeyword=&kcdSearch=). [in Korean].
- [11] Christoph HK, Christoph H, Felix A, Thomas IS, Daniel S. The visual analog scale allows effective measurement of preoperative anxiety and detection of patients' anesthetic concerns. *Anesth Analg* 2000;90:706-712.
- [12] Farrar JT, Young JP, Lamoreaux L, Werth JL, Poole RM. Clinical importance of changes in chronic pain intensity measured on an 11-point numerical pain rating scale. *Pain* 2001;94:149-158.
- [13] Stratford PW, Binkley JM, Riddle DL, Guyatt GH. Sensitivity to change of the Roland -Morris Back Pain Questionnaire: Part 1. *Phys Ther* 1998;78:1186-1196.
- [14] Ronald M, Morris R. A study of the natural history of back pain. Part I: Development of a reliable and sensitive measure of disability in low back pain. *Spine* 1983;8:141-144.
- [15] Brazier JE, Harper R, Jones NM, O'Carhain A, Thomas KJ, Usherwood T et al. Validating the SF-36 health survey questionnaire: new outcome measure for primary care. *BMJ* 1992;305:160-164.
- [16] Robin R. de Charro F. EQ-5D: a measure of health status from the EuroQol Group. *Ann Med* 2001;33:337-343.
- [17] Liberati A, Altman DG, Tetzlaff J, Mulrow C, Gotzsche PC, Aloannidis JP et al. The PRISMA statement for reporting systematic reviews and meta-analyses of studies that evaluate healthcare interventions: explanation and elaboration. *BMJ* 2009;339:b2700.
- [18] Higgins J, Altman D, Sterne J. Chapter 8: assessing risk of bias in included studies. In: Higgins J, Green S, Editors. *Cochrane Handbook for Systematic Reviews of Interventions Version 5.1.0.*, The Cochrane Collaboration. Chichester (UK): John Wiley & Sons; 2001.
- [19] Deeks JJ, Higgins JPT, Altman DG. Chapter 9: analysing data and undertaking meta- analyses. In: Higgins JPT, Green S (Des.). *Cochrane Handbook for Systematic Reviews of Interventions Version 5.1.0.*, The Cochrane Collaboration. Chichester (UK): John Wiley & Sons; 2001.
- [20] Bjordal JM, Lopes-Martins RA, Joensen J, Couppe C, Ljunggren AE, Stergioulas A et al. A systematic review with procedural assessments and meta- analysis of low-level laser therapy in lateral elbow tendinopathy (tennis elbow). *BMC Musculoskelet Disord* 2008;9:75.