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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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 lasted 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 (CNIII, 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, lumbo-sacral). 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 I² 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].
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.

<table>
<thead>
<tr>
<th>CNKI</th>
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<tr>
<td>#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')</td>
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<tr>
<td>#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')</td>
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<tr>
<td>#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')</td>
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Table 3. Japanese Database Search Strategy.

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<tr>
<th>CiNII &amp; J-stage</th>
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<tr>
<td>(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 laser' OR 'laser therapy' OR 'laser treatment' OR 'laser acupuncture' OR 'laserpuncture' OR 'laser needle' OR 'low dose laser acupuncture')</td>
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Table 4. Korean Database Search Strategy.

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<tr>
<td>('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 laser' OR 'laser therapy' OR 'laser treatment' OR 'laser acupuncture' OR 'laserpuncture' OR 'laser needle' OR 'low dose laser acupuncture')</td>
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<tr>
<th>KMBASE</th>
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<tbody>
<tr>
<td>(((((((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 laser]) OR [ALL=therapy]) OR [ALL=treatment]) OR [ALL=acupuncture]) OR [ALL=puncture]) OR [ALL=needle]) OR [ALL=low dose laser acupuncture])</td>
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<table>
<thead>
<tr>
<th>KISS, NDSL, KISTI, OASIS</th>
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</tr>
</thead>
<tbody>
<tr>
<td>('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 laser' OR 'laser therapy' OR 'laser treatment' OR 'laser acupuncture' OR 'laserpuncture' OR 'laser needle' OR 'low dose laser acupuncture')</td>
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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