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Low level laser therapy for nonspecific low-back pain (Review)

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[Intervention Review]

Low level laser therapy for nonspecific low-back pain

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ABSTRACT

Background

Low-back pain (LBP) is a major health problem and a major cause of medical expenses and disablement. Low level laser therapy (LLLT) can be used to treat musculoskeletal disorders such as back pain.

Objectives

To assess the effects of LLLT in patients with non-specific LBP.

Search methods

We searched CENTRAL (The Cochrane Library 2005, Issue 2), MEDLINE, CINAHL, EMBASE, AMED and PEDro from their start to November 2007 with no language restrictions. We screened references in the included studies and in reviews and conducted citation tracking of identified RCTs and reviews using Science Citation Index. We also contacted content experts.

Selection criteria

Randomised controlled clinical trials (RCTs) investigating LLLT to treat non-specific low-back pain were included.

Data collection and analysis

Two authors independently assessed methodological quality using the criteria recommended by the Cochrane Back Review Group and extracted data. Studies were qualitatively and quantitatively analysed according to Cochrane Back Review Group guideline.

Main results

Seven heterogeneous English language RCTs with reasonable quality were included.

Three small studies (168 people) separately showed statistically significant but clinically unimportant pain relief for LLLT versus sham therapy for sub-acute and chronic low-back pain at short-term and intermediate-term follow-up (up to six months). One study (56 people)

showed that LLLT was more effective than sham at reducing disability in the short term. Three studies (102 people) reported that LLLT plus exercise were not better than exercise, with or without sham in the short-term in reducing pain or disability. Two studies (90 people) reported that LLLT was not more effective than exercise, with or without sham in reducing pain or disability in the short term.

Two small trials (151 people) independently found that the relapse rate in the LLLT group was significantly lower than in the control group at the six-month follow-up.

No side effects were reported.

Authors' conclusions

Based on the heterogeneity of the populations, interventions and comparison groups, we conclude that there are insufficient data to draw firm conclusions on the clinical effect of LLLT for low-back pain.

There is a need for further methodologically rigorous RCTs to evaluate the effects of LLLT compared to other treatments, different lengths of treatment, wavelengths and dosages.

PLAIN LANGUAGE SUMMARY

Low level laser therapy for low-back pain

Sixty to eighty per cent of people suffer from back pain at some time in their lives. Of those who develop acute low-back pain (LBP), up to 30% will go on to develop chronic LBP. The toll on individuals, families and society makes the successful management of this common, but benign condition an important goal.

Low level laser therapy (LLLT) is used by some physiotherapists to treat LBP. LLLT is a non-invasive light source treatment that generates a single wavelength of light. It emits no heat, sound, or vibration. It is also called photobiology or biostimulation. LLLT is believed to affect the function of connective tissue cells (fibroblasts), accelerate connective tissue repair and act as an anti-inflammatory agent. Lasers with different wavelengths, varying from 632 to 904 nm, are used in the treatment of musculoskeletal disorders.

We included seven small studies with a total of 384 people with non-specific LBP of varying durations. Three studies (168 people) separately showed that LLLT was more effective at reducing pain in the short-term (less than three months), and intermediate-term (six months) than sham (fake) laser. However, the strength and number of treatments were varied and the amount of the pain reduction was small. Three studies (102 people) separately reported that LLLT with exercise was not better than exercise alone or exercise plus sham in short-term pain reduction.

One study (56 people) showed that LLLT was more effective than sham at reducing disability in the short term. Three studies (102 people) compared LLLT plus exercise with exercise plus sham or exercise alone and did not show significant reduction in disability. Two studies (90 people) separately reported that LLLT was not more effective at reducing disability than exercise alone or exercise plus sham in the short-term.

Based on these small trials, with different populations, LLLT doses and comparison groups, there are insufficient data to either support or refute the effectiveness of LLLT for the treatment of LBP. We were unable to determine optimal dose, application techniques or length of treatment with the available evidence. Larger trials that look specifically at these questions are required.

BACKGROUND

Low-back pain (LBP) and related disabilities are major public health problems and major causes of medical expenses, absenteeism and disablement (van Tulder 1995). Sixty to eighty per cent of people suffer from back pain at some time in their lives (Andersson 1997; Waddell 2004). Of all adults complaining of back pain, only about five per cent can be classified as having nerve root pain (using strict diagnostic criteria), with the remainder having back pain with or without referred leg pain, which is commonly referred to as non-specific low-back pain (Waddell 2004). Of those who develop acute LBP, up to 30% will go on to develop chronic LBP. The past 15 years have seen an intensive research effort to identify effective treatments and management strategies for low-back pain (Nachemson 2000).

Acute non-specific LBP is a benign and self-limiting condition. Once serious pathology (red flags) has been ruled out, current guidelines for the management of acute back pain recommend pain management interventions plus reassurance and advice to stay active as the interventions of choice (Waddell 2004). The aim of conservative (non-surgical) treatments for LBP is usually to relieve pain and associated disability. Recommended treatment options are diverse but there is sound evidence for only a minority of these therapies (CRD 2000; Nachemson 2000).

Low level laser therapy (LLLT) is currently used by some physiotherapists as a therapeutic intervention for musculoskeletal disorders such as back pain (Beckerman 1992; Bjordal 2003). Low level laser therapy is a light source treatment that generates light of a single wavelength. It emits no heat, sound, or vibration. Instead of producing a thermal effect, LLLT may act by non-thermal or photochemical reactions in cells. It is also referred to as photobiology or biostimulation (Basford 1989; Baxter 1991). Low level laser therapy is thought to affect fibroblast function and accelerate connective tissue repair (Kreisler 2002). It has also been reported that LLLT has anti-inflammatory effects due to its action in reducing prostaglandin synthesis (Sakurai 2000). Most LLLT lasers are Class 3a or Class 3b (Baxter 1991). Class 3a LLLTs have a power output of less than 5 mW, and Class 3b LLLTs have an output of less than 500 mW. Low level laser therapy lasers can be either visible or invisible.

Some studies suggest that LLLT has a beneficial anti-inflammatory and pain attenuation effect in humans (Ceccherelli 1989; Mizokami 1993). A possible mechanism of the effects of LLLT on pain relief is its anti-inflammatory and connective tissue repair process which have been shown in some in vitro and in vivo studies (Sakurai 2000; Sattayut 1999; Skinner 1996). Research in humans on wound healing and anti-inflammatory effects of LLLT showed conflicting results (Baxter 1991). The effectiveness of laser therapy in painful disorders is still unclear and needs to be examined more rigorously (Beckerman 1992).

OBJECTIVES

1) To assess the effectiveness of LLLT for the treatment of non-specific low-back pain.

2) To explore the most effective method of administering LLLT for non-specific low-back pain, including the optimal:

- dosage
- application techniques
- length of treatment

METHODS

Criteria for considering studies for this review

Types of studies

Published reports of completed randomised controlled trials (RCTs) were included. There were no restrictions on the basis of language or date of trial.

Types of participants

Trials that included male or female subjects aged 18 years and over, with acute (pain for four weeks or less), subacute (pain for one to three months) or chronic low-back pain (pain for longer than three months) were included (van Tulder 2003). Low-back pain was defined as pain localised between the shoulder blades and the folds of the buttocks, with or without radiation to the legs (CRD 2000).

Trials that included subjects with low-back pain caused by specific pathological entities such as infection, metastatic diseases, neoplasms, osteoporosis, rheumatoid arthritis, fracture, inflammatory processes or radicular syndrome were excluded.

Trials that discussed musculoskeletal disorders were included if a separate analysis was reported for low-back pain.

Types of interventions

Low level laser therapy (LLLT) is a light source that generates pure light of a single wavelength with non-thermal effects (Baxter 1991). We included reports of studies that explored the effects of all types of LLLT (Classes I, II, and III), including all wavelengths, compared to another treatment. The comparison interventions were no treatment, sham procedures or other therapeutic interventions.

Types of outcome measures

We chose outcomes for this review based on those recommended by the Cochrane Back Review Group (Deyo 1998). The primary outcomes were:

- Low-back pain measured by visual analogue scale (Huskisson 1974), box scale (Jensen 1989), McGill Pain Questionnaire (Melzack 1987) or other validated quantitative measures.
- Low-back-related disability measured by the Oswestry disability questionnaire (Fairbank 1980), Roland-Morris disability scale (Patrick 1995; Roland 1983) or other validated quantitative measures.

Secondary outcomes were:

- Overall improvement or satisfaction with treatment as rated by either participants or therapists.
- Health-related quality of life as measured by questionnaires such as the SF-12 (Ware 1996), SF-36 (Ware 1992), or EuroQoL (EuroQoL 1990).
- Return-to-work, days of absenteeism, or days of reduced activities (Deyo 1998).
- Physical examination: measuring range of motion, spinal flexibility, or muscle strength.
- Side effects, adverse effects, medication use and health care use.

To be eligible for this review, studies had to have measured at least one of the outcomes.

Search methods for identification of studies

Relevant studies meeting the inclusion criteria were identified by:

- A computer-aided search of CENTRAL (The Cochrane Library 2005, issue 2), MEDLINE (1966 to November 2007), EMBASE (1988 to November 2007), CINAHL (1982 to November 2007), AMED (the Allied and Complementary Medicine Database, 1985 to March 2005) and PEDro- the physiotherapy evidence database (http://www.pedro.fhs.usyd.edu.au/index.html) (to November 2007)
- Screening references given in relevant reviews and identified RCTs.
- Citation tracking of identified RCTs and reviews using Science Citation Index
- Communication with Managing Editor, Back Review Group for additional RCTs.
- Personal contact with content experts.

The search strategy in Appendix 1 was used for MEDLINE(OVID) and CINAHL(OVID), based on van Tulder 2003.

For EMBASE, the search strategy suggested by the Back Review Group (van Tulder 2003) was used. Search words used for the PEDro database were: low back pain, back pain, backache, lumbar, dorsalgia, lumbago, laser, infrared, effectiveness, treatment, therapy. A similar process was used for AMED. Searches in MEDLINE, EMBASE, CINAHL and PEDro were updated by the Cochrane Back Review Group in November 2007 and four potentially eligible trials and two relevant English language systematic reviews were found. Updating the searching phase resulted in one more included study.

Data collection and analysis

Selecting trials for inclusion:

All the citations identified by the above searches were downloaded into a reference manager database. Two authors (ES and RYN), non-blinded to authors and publication journals, independently screened for inclusion, using the pre-specified criteria. If it was clear from the abstract that the study did not meet the selection criteria, it was excluded. If it was unclear from the abstract whether the study met the selection criteria, the full paper was retrieved. Two authors (MAK and SAMH), using the same selection criteria used for the abstract screening, read the full paper and made final selection decisions. Any discrepancies were resolved by discussion, followed, if necessary, by a third reviewer (RYN) if disagreement persisted.

For studies that were excluded following review of the full text, reasons for exclusion were detailed in the Characteristics of Excluded Studies table, with a summary provided in the text of the review.

Assessment of Methodological Quality:

Two reviewers (MAK and SI) independently assessed the methodological quality of each RCT. Disagreements were dealt with by discussion and consensus in review team (ES, AR and RYN).

The 11 criteria recommended by the Cochrane Back Review Group were used to assess the methodological quality of the RCTs (van Tulder 2003). Each criterion was scored as "yes"," no" or "unclear", depending on how successfully the criterion was met. The criteria for evaluating the internal validity and their operationalization are found in Additional Table 1.

If the study provided "unclear" information on methodological criteria, the authors were contacted for additional information. If no response was obtained from authors or if the information was no longer available, these criteria remained 'unclear'.

We had planned a sensitivity analysis to determine whether the overall results were the same when studies above different methodological cut-off points were synthesized (van Tulder 2003), but were unable to because of lack of studies.

Data extraction:

Two reviewers (MAK and SI) independently extracted the data on study design, participants, interventions and outcomes. Data extraction was not blinded to authors and journal of publication. Data were extracted and entered into Review Manager 4.2 for the calculation of summary statistics. Disagreements on the results of data extraction were resolved by consensus. If disagreement persisted, a third reviewer (RYN) was consulted.

Laser characteristics and dosages were recalculated based on the data available in the articles or from personal contacts. The World Association of Laser Therapy (WALT) acknowledges that incomplete dosage reporting is a major problem, and recommends that review authors recalculate laser dosages of primary studies (WALT 2004). We calculated power, density (mW/cm2) and dose (J) for each study. Power density for pulse lasers (mW/cm2) was calculated by multiplying the peak power pulse by the pulse duration and then by the pulse frequency and dividing the total by the spot size on the skin. Power density for lasers with continuous output (mW/cm2) was calculated by dividing the mean power by the spot size on the skin. Dose (J) was calculated by multiplying the mean power by the treatment time per session. Authors were contacted to provide sufficient information for recalculation. Based on the recommended anti-inflammatory dosage for low level laser therapy developed by the WALT (WALT 2005), the minimum dose for irradiating 904 nm lasers to the lumbar spine is 4 J/point. Recommended doses are based on ultrasonographic measurements of depths from skin surface and typical volume of pathological tissue and estimated optical penetration for the different laser types in Caucasians. According to these recommendations, included articles were divided into adequate and inadequate dosing subgroups (see Table 2).

Analysis:

The statistical analysis followed the recommendations of the Cochrane Handbook (CC Handbook 2005) and the Cochrane Back Review Group (van Tulder 2003).

The outcome measures for each RCT were shown as point estimates with corresponding 95% confidence intervals (95% CI). Potential sources of clinical heterogeneity were identified. For studies judged as clinically homogeneous, statistical heterogeneity was tested with the Q test (chi-square) and I2. If data were statistically heterogeneous ($P < 0.1$), reasons for heterogeneity were explored. Regardless of any evidence of statistical heterogeneity, the influence of specific differences between the RCTs was investigated.

Where standard deviation was not reported, we calculated it using reported values of confidence intervals. Meta-analysis was carried out for LLLT plus exercise versus sham plus exercise comparisons.

Because disability and range of motion were measured with similar but not identical instruments, SMD instead of WMD were calculated for pooling the results where possible.

We selected a 20-mm change in pain on a 100-point pain scale, or 30% as the minimum clinically significant difference (MCID) for pain scores, based on Farrar 2001, who suggests an absolute difference of two points on 0 to 10 numeric scale and other studies that suggest that the minimum clinically significant change is not an absolute number but a range that depends on the baseline values and duration of pain (van der Roer 2006).

To create a pooled effect measure, the team examined possible sources of clinical heterogeneity by considering:

- methodological study quality;
- population differences in age, gender;
- duration of symptoms (i.e. acute versus chronic);
- low-back pain aetiology;
- intervention type by laser class, treatment protocol, treatment duration and irradiation sites;
- outcomes (i.e. subject reports of pain and pain relief, range of motion, other measures of performance (i.e. activities of daily living, disability, function), or employment status).

We had planned different sub-group analyses for pain categories (acute, sub-acute or chronic low-back pain), different follow-up durations (short-term - less than three months after randomisation, intermediate-term - between three months and one year, or long-term - longer than one year), and adequacy of laser dosing (adequate and inadequate according to power density and irradiated energy). The sub-group analyses for follow-up durations and laser dosing were only carried out for LLLT plus exercise versus sham plus exercise comparisons. Because of an insufficient number of studies, sensitivity analysis, meta-regression and publication bias tests were not carried out.

When the data could not be entered in the meta-analysis because of clinical heterogeneity, lack of data, or the way the authors of the trials reported the results (for example: no information about standard deviation of the means), we performed a qualitative analysis by attributing levels of evidence to the effectiveness of low level laser therapy, taking into account the methodological quality and the outcome of the original studies (van Tulder 2003):

- **Strong evidence*** - consistent** findings among multiple higher quality RCTs
- **Moderate evidence** - consistent findings among multiple lower quality RCTs and/or one higher quality RCT
- **Limited evidence** - one lower quality RCT
- **Conflicting evidence** - inconsistent findings among multiple trials (RCTs)
- **No evidence** - no RCTs

* There is consensus among the Cochrane Back Review Group Editorial Board that strong evidence can only be provided by multiple high quality trials that replicate findings of other researchers in other settings.

** When more than 75% of the trials report the same findings.

RESULTS

Description of studies

In total, we found seven small trials (384 people) that met the inclusion criteria.

The populations included in the trials had a diagnosis of non-specific LBP, but differed with respect to duration of pain, previous treatments and distributions of age. One study (Longo 1991) was limited to patients with acute pain but the duration was not clear in the report and some patients might have suffered from an acute exacerbation of chronic low-back pain. Another trial included patients with LBP of at least one-month duration (Basford 1999), but the mean duration of pain in the laser and control groups was seven and 13 months respectively. In two studies (Djavid 2007; Soriano 1998), patients with LBP of at least three months duration were included. Two other trials (Gur 2003; Klein 1990) were limited to patients with chronic pain (more than one year). Toya 1994 had no limitations on the duration of pain. The lumbar pain group (41 patients) in this study consisted of lumbago (23), ischiatic neuralgia (9), lumbar musculofascial pain (2), herniated disc (3), lumbar spondylosis (4).

The types of laser, dose, duration and frequency of treatments varied among the studies. Six studies (Djavid 2007; Gur 2003; Klein 1990; Longo 1991; Soriano 1998; Toya 1994) used infrared diode lasers. Only one study used a 1060 nm Nd-Yag laser (Basford 1999). Irradiation energy densities were recalculated based on the information provided in the reports and if possible, directly from authors. Laser doses ranged from 0.1 J (Klein 1990) to 29.9 J (Basford 1999). Only three studies (Basford 1999; Soriano 1998; Toya 1994) used sufficient laser dosage according to WALT 2005 recommendations (Table 2). Basford 1999 used a Nd-Yag laser with some thermal effects. This study was included because the laser dose was sufficient based on WALT recommendations and the laser was considered low level laser by the authors. One study (Djavid 2007) had three arms comparing LLLT, LLLT plus exercise and sham plus exercise. Another study (Gur 2003) had three arms comparing LLLT, LLLT plus exercise and exercise alone. All other studies included a sham (switched off laser) group.

In three studies (Longo 1991; Soriano 1998; Toya 1994), treatment duration was less than two weeks; in others (Basford 1999; Djavid 2007; Gur 2003; Klein 1990) it was about four weeks or more. The number of treatment sessions differed from one session in Toya 1994 to 20 sessions in Gur 2003. All studies irradiated painful areas, except Longo 1991, in which the laser targets were painful areas and trigger points. In two studies (Djavid 2007; Klein 1990), exercise therapy was used in both the laser and control groups. Gur 2003 included three groups: exercise plus laser, laser alone and exercise alone. The exercise programs in these studies were considered to be comparable.

With respect to the outcome measures, pain intensity was measured with a visual analogue scale (VAS) in five studies (Basford 1999; Djavid 2007; Gur 2003; Klein 1990; Soriano 1998). Soriano 1998 measured pain with a VAS but reported the results as the percentage of pain relief. In another study (Toya 1994) pain was graded as exacerbation, little or no change, fair, good, and excellent. Four studies (Basford 1999; Djavid 2007; Gur 2003;

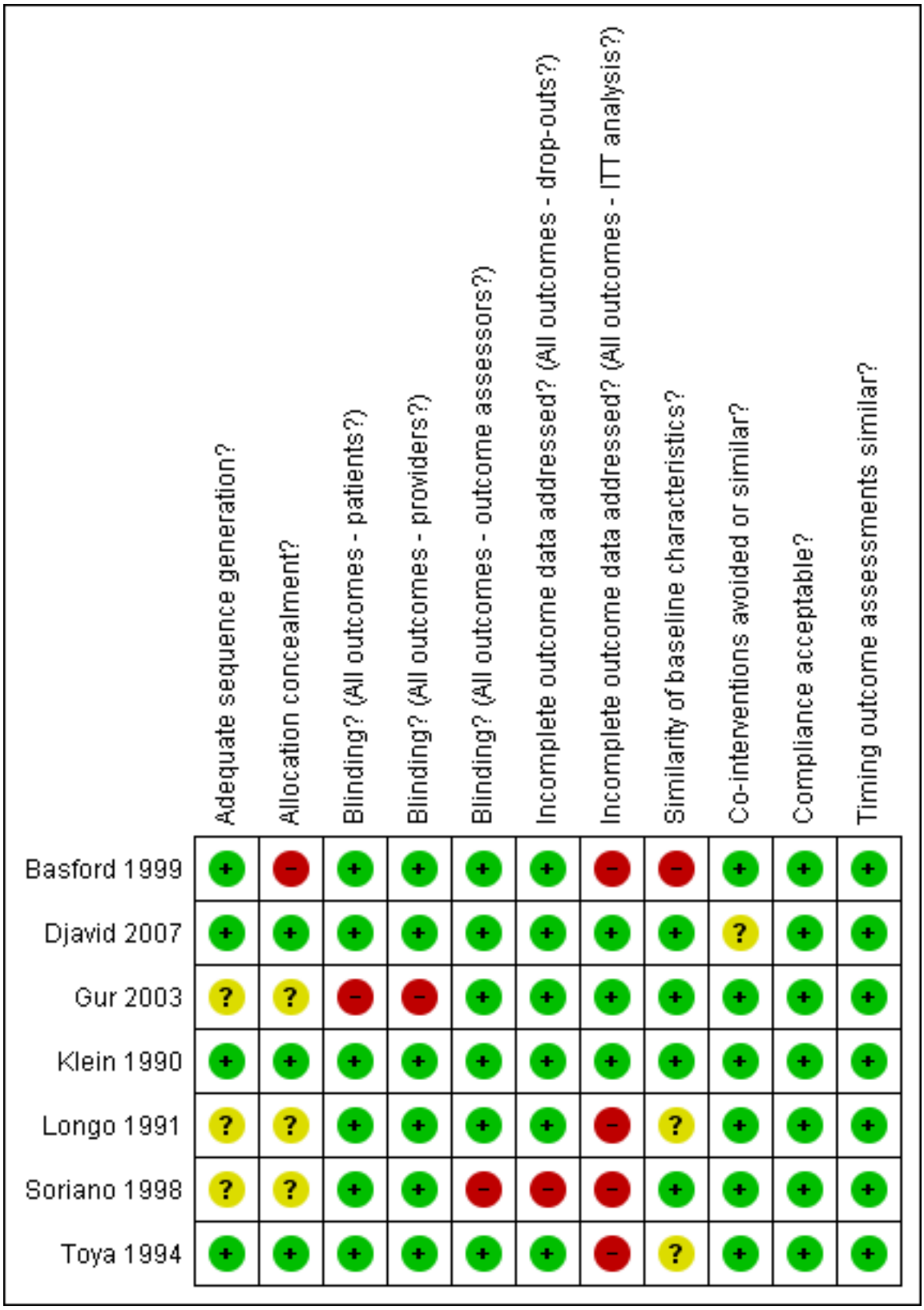
Klein 1990) assessed disability using validated questionnaires and lumbar range of motion. Pain relapse rate was measured in two studies (Longo 1991; Soriano 1998). Only one study reported self-rated overall improvement (Longo 1991). The timing of outcome measures varied from "immediately after the end of sessions" to one year after randomisation.

Details about each included trial are given in the Characteristics of included studies table.

Risk of bias in included studies

The results of the methodological quality assessment are shown in Figure 1. All studies were described as randomised; however the method of randomisation was explicit in only four studies (Basford 1999; Djavid 2007; Klein 1990; Toya 1994). Two studies (Basford 1999; Djavid 2007) used a block randomisation method for patient allocation. We remained unsure about the effectiveness of the randomisation in the Basford 1999 study because there was a big difference in the duration of pain between the two groups (seven months in the laser group and 13 months in the control group). Allocation to treatment groups was concealed in three studies (Djavid 2007; Klein 1990; Toya 1994). Patients and care providers were blinded in all studies except one (Gur 2003). Outcome assessors were blinded in six trials (Basford 1999; Djavid 2007; Gur 2003; Klein 1990; Longo 1991; Toya 1994). The drop-out rate and loss to follow-up in the data analysed were less than 20% in all studies but one (Soriano 1998), where 21% were excluded from final analysis in the control arm, while there were only 11% excluded from the experimental group. Three studies conducted an intention-to-treat analysis (Djavid 2007; Gur 2003; Klein 1990). Toya 1994 had a very short (one day) follow-up and the sum of crude frequencies in the tables were the same as the total number of randomised patients, but we were not sure about the intention-to-treat analysis in this study. For more details about the criteria met in each trial, see Table 1. The number of criteria met in the included studies (van Tulder 2003) ranged from six to 11, so all were considered high quality studies.

Figure 1. Summary of risks of bias



Effects of interventions

Study selection:

Our searches resulted in the identification of 28 reports in CENTRAL, 59 reports in MEDLINE, 107 in EMBASE, 35 in CINAHL, nine in AMED, and 577 in PEDro. After removing duplicates, 142 reports were screened in the next step. After exclusion of irrelevant trials, we obtained hard copies of 34 trials, including 25 English, three German, two Russian, two Polish, one Japanese and one Italian. Of these, 24 were primary studies, but only five trials met the inclusion criteria. Reasons for the exclusion of these studies are explained in the Characteristics of Excluded Studies table. We contacted the primary authors of trials and experts in the field of LLLT to obtain additional information that was not reported in the published studies. One expert informally discussed this review with some other experts in the field of LLLT. One article was found in this phase (Longo 1991).

The updated search to January 2007 resulted in the identification of 14 reports in MEDLINE, 54 in EMBASE, seven in CINAHL and two in PEDro. After removing duplicates and irrelevant studies, four references were evaluated. One study (Djavid 2007) was included. One was excluded and two non-English studies are awaiting assessment, pending the receipt of additional information from the author and will be addressed in a future update of this review.

1. LLLT versus sham treatment

Pain:

Only one study (Basford 1999) measured pain in LLLT and sham groups using VAS (56 people). The patients in this study had chronic low-back pain and the results were reported for short-term follow-up period (one month). This study used adequate laser dosing. Basford 1999 showed a significant decrease in pain measured on a 100-point VAS with a mean difference of -16 (95% CI: -27.95 to -4.05).

One study (Soriano 1998) used adequate laser dosing in elderly patients over 60 years of age. They measured pain with a VAS but reported the results as the percentage of pain relief graded as poor, regular, good and excellent (71 people). In this study, at the six-month follow-up, 44.7% of the patients in the LLLT group and 15.2% of the control group reported excellent relief ($P < 0.01$).

In another study (Toya 1994) with adequate laser dosing, pain was graded as exacerbation, little or no change, fair, good, and excellent (41 people). The sum of the frequencies of patients with 'excellent', 'good' and 'fair' grades was defined as 'effective treatment' frequency. One day after treatment, the percentage of 'effective treatment' was 94% (15/16) in the laser group and 48% (12/25) in the sham group ($P = 0.007$).

In summary, three high quality studies (168 people) separately showed statistically significant pain relief with LLLT in short-term and intermediate-term follow-up compared with sham treatment. All of them used adequate dosing as defined by WALT 2005. Because of the differences in population and pain relief scales, meta-analysis was not possible. There is strong evidence that LLLT provides better pain relief compared with sham treatment, however the effect is not clinically significant. Because of the small trials, clinical heterogeneity, and the unconventional use of outcome measures, future large high quality trials are needed to confirm these findings.

Low back pain related disability:

Pain-related disability was measured using the Oswestry questionnaire in one study (Basford 1999), which showed a significant improvement in disability at one-month follow-up with a mean difference of -8.2 (95% CI: -13.44 to -2.96).

Based on one high quality trial (56 people), there is moderate evidence that LLLT reduced disability more than sham treatment in individuals with (sub)acute or chronic LBP, when compared to a sham treatment.

Relapse rate:

The percentage of relapse was reported in two trials (151 people) (Longo 1991; Soriano 1998). In one trial (Longo 1991), the relapse rates were reported after one month, six months and one year after the beginning of the study. Soriano 1998 reported the relapse rate at the six-month follow-up. Both trials reported that LLLT is statistically significantly more effective than sham for reducing relapse rate at six months, in patients with (sub)acute or chronic low-back pain without neurological symptoms. However, the two trials differed in population and were therefore not statistically pooled. Soriano 1998 included a senior population with chronic LBP and Longo 1991 a working-aged population with acute LBP of undetermined duration. Also, Soriano 1998 used adequate laser dosage while Longo 1991 used inadequate dosage. The study with inadequate dosage reported the largest effect size.

Secondary Outcomes:

One study (Basford 1999) measured range of motion in centimetres using the Schober test (Moll 1971). Comparing lumbar range of motion in short-term follow-up, this study (Basford 1999) used adequate dosing, resulting in a mean difference of -0.2 (95% CI: -2.14 to 1.74).

Therefore, there is little or no difference in range of motion between individuals who received laser therapy and those who received sham therapy.

One study (Basford 1999) reported the perception of benefit, which was assessed using a visual analogue scale (lower values indicated less pain). At the one-month follow-up, there was little or no difference in perception of benefit between the laser and control groups (SMD: -9.5 (95% CI: -20.9 to 1.9).

One study (Longo 1991) measured the overall efficacy of treatment using a composite measure consisting three parts: The intensity of pain with the Ritchie scale (Ritchie 1968), deviation of vertebral column, and functional limitation (80 people). These clinical features completely disappeared or improved in 97.5% of patients in the LLLT group and 37.5% of the control group after one month.

In summary, there was moderate evidence of little or no difference between those who received LLLT and sham treatments for range of motion or perception of benefit, but moderate evidence that LLLT was better than sham treatment on overall improvement in patients suffering from low-back pain. Because of the small trials and the clinical heterogeneity, these findings should be interpreted with caution.

Adverse effects:

One study (Toya 1994) reported neither discomfort related to laser treatment nor an increase in pain in either group. In Soriano 1998, five patients in the LLLT group (two abandoned and three needed to use NSAIDS) and nine patients in the control group (three abandoned and six needed to use NSAIDS) were lost to follow-up.

2. LLLT+exercise versus exercise (with or without sham treatment)

Pain:

Three studies compared LLLT plus exercise with sham plus exercise (Djavid 2007; Klein 1990) or exercise alone (Gur 2003). Two studies (Djavid 2007; Klein 1990) used inadequate laser dosing and compared pain in those who received LLLT plus exercise with those who received sham plus exercise in patients with chronic low-back pain. Klein 1990 used a 7.5-cm VAS (results were transformed to a 100-point VAS to enable pooling of short-term results). Djavid 2007 compared pain at weeks six and 12 after randomisation. The pooled analysis (fixed-effects) of two very small trials (61 people) showed that there was no significant difference in pain relief between those who received LLLT plus exercise and those who received sham plus exercise in patients with chronic low-back pain without neurological symptoms in post-treatment (short-term) follow-up, with WMD of -6.38 (95%CI: -15.68 to 2.91). However, one small trial found that at the 12-week follow-up, after six weeks of no intervention, LLLT plus exercise (21 people) relieved pain better than sham plus exercise (20 people) (mean difference -19.0 (95% CI: -28.22 to -9.78) (Djavid 2007).

Gur 2003 compared LLLT + exercise with exercise alone in short-term follow-up. The sham laser was not used in the exercise group. This study had three arms and reported that using the Multivariate Analysis of Variance method (MANOVA), the difference between the three arms was not statistically significant (the post-therapy means ± SDs were 18 ± 12, 29 ± 13, and 19 ± 14 for LLLT plus exercise, exercise alone, and LLLT alone groups respectively).

In summary, there is strong evidence from three trials that there is no significant difference in pain reduction between LLLT plus exercise and sham plus exercise treatment in short-term follow-up for individuals with chronic LBP. One small trial reported positive effects after 12 weeks, but this finding needs to be replicated in a larger trial.

Low back pain related disability:

Klein 1990 measured pain-related disability using a validated 24-item questionnaire. Djavid 2007 compared disability at weeks six and 12 after randomisation using the Oswestry disability questionnaire, The pooled analysis (fixed-effects) of two trials (61 people) showed no statistically significant difference between LLLT plus exercise and sham plus exercise for patients with chronic low-back pain without neurological symptoms for disability (post-treatment/short-term follow-up) with a SMD of -0.05 (95%CI: -0.56 to 0.45). At the 12-week follow-up, those who received LLLT plus exercise (21 people) reported less disability than those who received sham and exercise (20 people) (SMD -1.59; 95% CI -2.3 to -0.08) (Djavid 2007). However, this finding needs to be replicated in a larger trial.

Gur 2003 compared LLLT plus exercise with exercise alone (no sham laser) in short-term follow-up. The difference between the three arms was not statistically significant (the post-therapy means ± SDs were 14.8 ± 8.6, 13.6 ± 7.2, and 16.7 ± 7.6 for LLLT plus exercise, exercise alone, and LLLT alone groups respectively).

In summary, there is strong evidence from three trials that LLLT plus exercise do not reduce disability for individuals with chronic LBP, when compared to sham plus exercise or exercise treatment alone, in short-term follow-up.

Relapse rate:

We did not find any studies comparing the relapse rates in LLLT plus exercise and sham plus exercise treatment groups.

Secondary Outcomes:

One inadequately dosed study (Klein 1990) measured lumbar range of motion in degrees in the short-term, using a validated computerized isodynamic system. Djavid 2007 compared lumbar flexion range of motion (in degrees) at six and 12-week follow-ups after randomisation, and found no statistically significant difference in any follow-up sessions.

The pooled analysis (fixed-effects) of two trials (61 people) did not show a statistically significant difference in range of motion between individuals with chronic low-back pain without neurological symptoms who received LLLT plus exercise and those who received sham plus exercise (short-term follow-up) with SMD of -0.08 (95%CI: -0.58 to 0.43).

Gur 2003 compared LLLT + exercise with exercise alone (no sham) in short term follow-up. The mean difference of lumbar range of motion in short-term follow-up was -0.06 (95%CI: -0.61 to 0.50).

In summary, based on three high quality trials, there is strong evidence that LLLT plus exercise does not improve lumbar range of motion better than exercise, with or without sham treatment

Adverse effects:

Djavid 2007 and Klein 1990 reported neither discomfort related to laser treatment nor an increase in pain or any adverse reactions in either group.

3. LLLT versus other treatments

Two studies were included under this category. One study (Gur 2003) compared LLLT with exercise. Another study (Djavid 2007) compared LLLT with sham plus exercise.

Pain:

Djavid 2007 (inadequate dosing) measured pain in those receiving LLLT with those receiving exercise (40 people), and did not show any significant differences between the groups in short-term and intermediate-term follow-ups. Gur 2003 (adequate dosing) measured pain in those receiving LLLT with those receiving exercise (50 people) and similarly did not show any significant differences between the two groups. Because there was no sham treatment in the Gur 2003 study, we did not pool the results of the two studies

In summary, there is moderate evidence that LLLT does not reduce pain more than exercise, with or without sham treatment for individuals with chronic LBP.

Low back pain related disability:

Pain-related disability was measured with the Oswestry disability index in Djavid 2007 and the modified Oswestry in Gur 2003. Again, we didn't pool the results because the groups were heterogeneous. However, neither study showed a significant difference in short-term follow-up (WMD of 1.3 (95% CI: -2.76 to 5.36) in Djavid 2007 and 3.1 (95% CI: -1.0 to 7.2) in Gur 2003. Djavid 2007 did find a significant difference at 12-week follow-up in favour of LLLT, with a WMD of -3.3 (95% CI: -6.29 to -0.31).

Therefore, there is moderate evidence from two high quality studies that LLLT is not more effective than exercise or exercise plus sham treatment at reducing disability in patients with chronic LBP in the short-term.

Relapse rate:

We did not find any studies comparing the relapse rates in LLLT with other treatments.

Secondary Outcomes:

Djavid 2007 and Gur 2003 measured lumbar range of motion, but the results could not be statistically combined because of clinical heterogeneity in the comparison groups. There was no significant difference between LLLT and exercises, with or without sham treatment in the short-term. In Djavid 2007, non-significant results remained between LLLT and sham plus exercises at 12-week follow-up.

Therefore, there is moderate evidence from two high quality studies that there is no statistical difference between LLLT and exercise or exercise plus sham treatment in improved lumbar range of motion in patients with chronic LBP in the short-term.

DISCUSSION

We included seven RCTs in the review. The quality of included studies varied, with the number of quality criteria met ranging from six (Soriano 1998) to 11 (Klein 1990). All included studies were small, with sample sizes ranging from 20 (Klein 1990) to 80 (Longo 1991).

Three studies (Basford 1999; Soriano 1998; Toya 1994) compared pain relief in LLLT with sham and all of them showed a statistically significant improvement in pain relief after laser treatment in short-term and intermediate-term follow-ups. Two of these studies (Basford 1999; Soriano 1998) were limited to sub-acute or chronic non-specific low-back pain. Because of the clinical heterogeneity among these studies, quantitative pooling was not possible. However, qualitative analysis suggested there is strong evidence that low level laser therapy may be beneficial for pain relief in patients with sub-acute or chronic non-specific low-back pain. But the trials were small and differed from each other in the definition and duration of low back pain, laser dosage, duration of treatment, and measures used to assess pain relief. In addition, although the studies met the majority of quality items, they performed poorly in randomisation and allocation concealment; it is shown that the inadequacy of allocation concealment in clinical trials is associated with an increased estimate of treatment effect (Moher 1998).

Two studies (Djavid 2007; Klein 1990) compared pain in LLLT plus exercise with sham plus exercise. The pooled analysis of the findings of these studies for short-term follow-up did not show any significant effect in favour of the intervention. The laser dosage was inadequate according to WALT guidelines (WALT 2005) in these two studies. Although Djavid 2007 showed a significant decrease in pain in intermediate-term follow-up (12 weeks after randomisation), the considerable time delay in initiation of LLLT effects puts the results in a questionable light. The LLLT and sham plus exercise arms of this study did not differ in either follow-up.

In all studies reporting pain relief using VAS, the mean difference of pain scores was less than the minimum clinically significant improvement (Farrar 2001). Other systematic reviews on the effects of LLLT on pain showed small and controversial effects on pain relief. The systematic review of the effectiveness of LLLT on rheumatoid arthritis (Brosseau 2006a) suggested that LLLT may be effective at reducing pain relative to placebo, but the results were not statistically significant (WMD -11 mm; 95% CI -18 to 4). Another systematic review investigating the effectiveness of LLLT on joint disorders (Bjordal 2003) concluded that LLLT seemed to be effective in reducing pain due to chronic joint disorders (WMD -29.8 mm; 95% CI -40.7 to -18.9). A Cochrane review on LLLT for osteoarthritis (Brosseau 2006b) reported conflicting results of different studies about the effectiveness of low level lasers for pain.
Therefore, because of the clinical heterogeneity of the studies, the small sample sizes and the small clinical effect sizes, the results of this review and clinical application for LLLT in the management of chronic LBP should be viewed with caution. We found a small number of studies that compared low-back pain-related disability or range of motion. Due to clinical heterogeneity, pooled analysis was only possible for two studies with inadequate dosing (Djavid 2007; Klein 1990), and did not show any significant short-term effects of LLLT on disability measures. Djavid 2007 did show a significant improvement in the 12th week follow-up for those who received LLLT. Basford 1999, which used a higher laser dosage than other studies, showed a significant improvement in disability measures. Bjordal 2003 found that after adjusting for tissue penetration, many laser doses used in many of the trials were too low to have any significant anti-inflammatory effects at target locations.

According to these seven trials, it seems that LLLT effects are clinically modest and should not substitute for other beneficial interventions, such as exercise and intensive multidisciplinary pain treatment programmes for chronic low-back pain, that are supported by strong evidence (Koes 2006).

No serious adverse events were reported in the trials included in this review, but the total sample size of included trials was small for judgment about the safety of this intervention.

Low power lasers are sometimes irradiated to acupuncture points in addition to painful areas. The rationale for laser acupuncture is vastly different from phototherapy. Instead of using the direct effect of light on tissues to initiate a physiological response, in laser acupuncture, the selection of points is based on a diagnostic and therapeutic paradigm defined in acupuncture theories (Chow 2006). Therefore laser acupuncture studies were excluded from the current review.

AUTHORS' CONCLUSIONS

Implications for practice

Low level laser therapy, when contrasted to a sham treatment may be beneficial for pain relief and improved disability in patients with

sub-acute or chronic non-specific low-back, although treatment effects are small. However, when LLLT is added to exercise and compared to exercise therapy, either with or without sham treatments, there appears to be little or no difference between the groups in pain and disability. Clinical heterogeneity and small trials also suggest that the results of this review may not be generalizable to a larger, more diverse, population. Therefore, based on our findings, LLLT should not be substituted for other beneficial interventions.

Implications for research

There is a need for further methodologically rigorous RCTs evaluating different lengths of treatment, different wavelengths and different dosages. Comparison of different LLLT treatments will be more reasonable if dose calculation methods are harmonized. Cost-effectiveness studies are recommended.

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* Indicates the major publication for the study

CHARACTERISTICS OF STUDIES

Characteristics of included studies *[ordered by study ID]*

Basford 1999

Methods	Study design: RCT; Unit of allocation: Patients; Method of randomization: block randomized with a computer generated schedule; Allocation concealment: inadequate; Blindedness: Double-masked
Participants	Randomized = 63; Analysed = 56 Recruitment of patients: announcement in the institutional newsletter and the local newsletter and by referral from local physicians; Enrollment dates: Not stated; Age: Between the ages of 18 and 70 years; Sex: Male and female; Ethnicity: Not stated; Work status: Not stated; Diagnosis of LBP: Localized pain and tenderness in the vicinity of the lumbosacral spine with normal neurologic examination results; Duration of pain: More than 30 days; Previous treatments: No treatment of this problem by a physician, physical therapist, chiropractor or health care provider in the previous 30 days. Analgesic and nonsteroidal antiinflammatory medication use was not encouraged but was monitored as an experimental variable; Exclusion criteria: Surgery (e.g.,fusion), Pending of litigation or workman's compensation issues, Corticosteroids for any reason in the last 30 days, Radicular pain(Described as pain extending below their buttocks, or noted changes in bowel or bladder function or lower extremity strength or sensation.) Women were recruited to be postmenopausal or practicing an effective means of birth control (pregnancy tests were obtained).
Interventions	Both arms of the trial were included: LLLT(27) and sham(29). Intervention group: laser, Three times a week, 4 week schedule by a masked therapist with the subjects removing their shirt and lying prone on a plinth. The therapist scrubbed the lumbar paraspinal muscles with an alcohol-soaked gauze pad; Laser medium:Nd-YAG; Laser model: Laser Biotherapy; Wave length(nm): 1060 nm; Laser mode: Continuous-wave; Output power: 2661 mW; Spot diameter(cm): 2.5; Exposure time(seconds): 90 sec; Anatomic locations: At each of four equally spaced level (a total of 8 points) along the L2 to S3 paraspinal tissues Control group: Irradiated with the same, but inactive laser device
Outcomes	Measurements by: An experienced and masked physician and therapist not involved in the treatment; measured variables: Function(Oswestry disability questionnaire, validated), pain(visual analog scale,validated), lumbar mobility(a modification of the Schober test), changes in medication use , activity level, perception of benefit, pain nature, and any adverse effects from treatment; Follow up sessions: sixth session, twelfth session, 28 to 35 days after the last treatment; Intention-to-treat analysis: no
Notes	Total score: 8

Risk of bias

Bias	Authors' judgement	Support for judgement
Adequate sequence generation?	Low risk	
Allocation concealment?	High risk	C - Inadequate
Blinding? All outcomes - patients?	Low risk	
Blinding? All outcomes - providers?	Low risk	

Basford 1999 *(Continued)*

Blinding? All outcomes - outcome assessors?	Low risk
Incomplete outcome data addressed? All outcomes - drop-outs?	Low risk
Incomplete outcome data addressed? All outcomes - ITT analysis?	High risk
Similarity of baseline characteristics?	High risk
Co-interventions avoided or similar?	Low risk
Compliance acceptable?	Low risk
Timing outcome assessments similar?	Low risk

Djavid 2007

Methods	Study design: RCT; Unit of allocation: Patients; Method of randomisation: block randomisation with a manual schedule; Allocation concealment: adequate; Blindedness: Double blind
Participants	Randomized = 61; Analysed = 58 Recruitment of patients: referral from local physicians; Enrollment dates: Not stated; Age: Between the ages of 20 and 60 years; Sex: Male and female; Ethnicity: Not stated; Work status: Not stated; Diagnosis of LBP: pain in the lumbosacral area of the spine of more than 12 weeks' duration, may or may not have referred characteristics; Duration of pain: More than 12 weeks; Previous treatments: No limitations; Exclusion criteria: Patients with degenerative disc disease, disc herniation, fracture, spondylosis, and spinal stenosis, neurological deficits, abnormal laboratory findings, systemic or psychiatric illness, and pregnancy
Interventions	Three arms of the study were included: LLLT+exercise(21), sham+exercise(20), and LLLT alone(20) LLLT protocol: 12 sessions (i.e., twice a week for 6 weeks); Laser medium:Gallium-Aluminum-Arsenide (GaAlAs) laser; Laser model: not stated; Wave length(nm): 810 nm; Laser mode: continuous; Output power: 50 mW; Laser class: IIIb; Spot diameter(cm): 0.53 cm; Exposure time: 2 min for each point (totally 10 points); Anatomic locations: In each session, a series of standardised fields including eight points in the paravertebral region (L2 to S2-S3) were irradiated by a single laser probe in contact mode; Sham laser: inactive laser probe. Exercise protocol: The first exercise session was conducted by a physiotherapist and were continued at home, taught by the physiotherapist and confirmed by a family member. Exercises included strengthening, stretching, mobilising, co-ordination, and stabilising of the abdominal, back, pelvic, and lower limb muscles, dependent on the clinical findings.
Outcomes	Measurements by: A physicians blinded to group allocation; Measured variables: Pain(10-cm visual analogue scale), lumbar range of motion(Schober Test), disability(10-item Oswestry disability questionnaire); Follow up sessions: at Week 6 (after the last session of intervention) and at Week 12; Intention-to-treat analysis: yes
Notes	Total score: 10

Djavid 2007 *(Continued)*

Risk of bias

Bias	Authors' judgement	Support for judgement
Adequate sequence generation?	Low risk	
Allocation concealment?	Low risk	A - Adequate
Blinding? All outcomes - patients?	Low risk	
Blinding? All outcomes - providers?	Low risk	
Blinding? All outcomes - outcome assessors?	Low risk	
Incomplete outcome data addressed? All outcomes - drop-outs?	Low risk	
Incomplete outcome data addressed? All outcomes - ITT analysis?	Low risk	
Similarity of baseline characteristics?	Low risk	
Co-interventions avoided or similar?	Unclear risk	Unclear from text
Compliance acceptable?	Low risk	
Timing outcome assessments similar?	Low risk	

Gur 2003

Methods	Study design: RCT; Unit of allocation: Patients; Method of randomisation: Not stated; Allocation concealment: not used; Blindedness: Single blind
Participants	N = 75; Recruitment of patients: not stated; Enrollment dates: May 1999 and March 2000; Age: Between the ages of 20 and 50 years; Sex: Male and female; Ethnicity: Not stated; Work status: Not stated; Diagnosis of LBP: self-reported criteria plus information concerning the existence of medical conditions, medication use and the possibility of serious injuries.; Duration of pain: More than one year; Previous treatments: No previous spinal surgery; Exclusion criteria: neurological deficits, abnormal laboratory findings, systemic and psychiatric illnesses, pregnancy
Interventions	Three arms of the study were included: LLLT+exercise(25), exercise alone(25), and LLLT alone(25) Intervention group: laser+exercise, five times a week , 4 weeks; Laser medium:Gallium-Arsenide laser; Laser model: Frank Line IR 30, Fysiomed, Belgium; Wave length(nm): Not stated; Laser mode: Pulsed, 2.1 kHz pulse frequency; Output power: 10 W, 4.2 mW average power; Laser class: IIIb; Spot diame-

Gur 2003 *(Continued)*

	ter(cm): 1.1 cm; Exposure time(seconds): 4 min; Anatomic locations: the L4 to L5 and L5 to S1 apophyseal capsules, dorsolumbar fascia, and interspinous ligaments, as well as the gluteal fascia, posterior sacroiliac ligaments, hamstrings, and gastro-soleus muscles of which pain points were palpated from the low back to the foot Control group: exercise therapy: lumbar flexion and extension, knee flexion, hip adduction exercises, and strength exercises of extremity muscle groups/ first session of the exercises was conducted with a physiotherapist and continued at home by the patients themselves. two sessions a day, making a total of 40 sessions for 4 weeks
Outcomes	Measurements by: A physician who did not know which therapy was taken evaluated the patients; Measured variables: Functioning(Roland Disability Questionnaire (RDQ) and Modified Oswestry Disability Questionnaire (MODQ)), Pain(visual analogue scale (VAS)), Lumbar range of motion(Schober test), flexion and lateral flexion measures; Follow up sessions: one month after therapy; Intention-to-treat analysis: yes
Notes	Total score: 7

Risk of bias

Bias	Authors' judgement	Support for judgement
Adequate sequence generation?	Unclear risk	Not stated in text
Allocation concealment?	Unclear risk	B - Unclear
Blinding? All outcomes - patients?	High risk	
Blinding? All outcomes - providers?	High risk	
Blinding? All outcomes - outcome assessors?	Low risk	
Incomplete outcome data addressed? All outcomes - drop-outs?	Low risk	
Incomplete outcome data addressed? All outcomes - ITT analysis?	Low risk	
Similarity of baseline characteristics?	Low risk	
Co-interventions avoided or similar?	Low risk	
Compliance acceptable?	Low risk	
Timing outcome assessments similar?	Low risk	

Klein 1990

Methods	Study design: RCT; Unit of allocation: Patients; Method of randomisation: a computer generated random numbers table; Allocation concealment: yes; Blindedness: yes
Participants	N= 20 Recruitment of patients: By advertisement; Enrollment dates: Not stated; Age: Between the ages of 21 and 55 years; Sex: Male and female; Ethnicity: Not stated; Work status: Not stated; Diagnosis of LBP: Clinical features of back pain with prolonged maintenance of one posture, such as prolonged sitting, standing, or bending and temporary relief of symptoms with changing positions or walking; Duration of pain: More than one year; Previous treatments: No prior back surgery; Exclusion criteria: Acute exacerbation of chronic LBP, not pregnant, no prior surgery, not >10 pounds overweight, not involved in litigation or disability claims
Interventions	Both arms of the trial were included: LLLT+exercise(10) and sham+exercise(10). Intervention group: laser+exercise, three times a week , 4 weeks; Laser medium:Ga-As laser; Laser model: Omniprobe (laser biostimulation unit); Wave length(nm): 904 nm; Laser mode: Pulsed, 1 kHz pulse frequency, 200 nsec pulse duration; Output power: 2 W; Laser class: I; Spot diameter(cm): 1.1 cm in each head with 10 heads; Exposure time(seconds): 240 sec (4 min) for each point [20 min of total stimulation time for each patient]; Anatomic locations: external over a series of standardized fields designed to include the L4 to L5 & L5 to S1 apophyseal capsules, dorsolumbar fascia, interspinous ligaments, gluteal fascia, posterior sacroiliac ligaments Control group: Home Exercise program: 50 full-forward flexion exercises performed in standing position followed by 25 extension exercises twice a day, walk briskly: 20 min a day, 2 sets of knee flexion coupled with hip abduction each day. Exercises were to be started on the first day of the study and continued at least until completion of all objective and subjective measurements.
Outcomes	Measurements by: a blinded physical therapist ; Measured variables: Disability score(a questionnaire of 24 items(validated)), Pain(VAS(0-7.5 cm)), Lumbar function (range of motion/ isometric torque/ isodynamic velocities), the isotechnologies B-200(a commercially available computerized isodynamic system)/ (validated); Follow up sessions: one month after therapy; Intention-to-treat analysis: yes
Notes	Total score: 11

Risk of bias

Bias	Authors' judgement	Support for judgement
Adequate sequence generation?	Low risk	
Allocation concealment?	Low risk	A - Adequate
Blinding? All outcomes - patients?	Low risk	
Blinding? All outcomes - providers?	Low risk	
Blinding? All outcomes - outcome assessors?	Low risk	
Incomplete outcome data addressed? All outcomes - drop-outs?	Low risk	
Incomplete outcome data addressed?	Low risk	

Klein 1990 *(Continued)*

All outcomes - ITT analysis?	
Similarity of baseline characteristics?	Low risk
Co-interventions avoided or similar?	Low risk
Compliance acceptable?	Low risk
Timing outcome assessments similar?	Low risk

Longo 1991

Methods	Study design: RCT; Unit of allocation: Patients; Method of randomization: Not stated; Allocation concealment:unclear; Blindedness: yes
Participants	N = 120 (40 to each of 3 groups), but only used 2 groups in this review, therefore N = 80 Recruitment of patients: Not stated; Enrollment dates: Not stated; Age: Between the ages of 40 and 65 years; Sex: Male and female; Ethnicity: Not stated; Work status: Not stated; Diagnosis of LBP: acute lumbago with degenerative or traumatic lesions visible in X-ray and without obvious signs of neurologic deficit ; Duration of pain: acute(?); Previous treatments: No previous therapy which interferes with the results of the experiment ; Exclusion criteria: Fracture, luxation, hernia of the nucleus pulposus
Interventions	Two arms of the trial were included: LLLT(40) and sham(40). Intervention group: laser, Treatment begun within 24 hr of the onset of the symptoms once a day for 5 days,then another 5 on alternative days; Laser medium:Diode laser ; Laser model: Not stated; Wave length(nm): 904 nm; Laser mode: Pulsed, 3 kHz pulse frequency, 200 nsec pulse duration; Output power: peak power 72 W (27 W?); Laser class: Not stated; Spot diameter(cm): 0.2 cm(1 cm2 spot area using lens correction); Exposure time(seconds): 5 min/cm2 (of every radiation); Anatomic locations: Intervertebral holes, possible trigger points Control group: simulated laser irradiation
Outcomes	Measurements by: two blinded doctors; Measured variables: spontaneous or induced pain(Ritchie scale for intensity of pain), level of reflected analgesic vertebral deviation(the angel of inclination in an AP X-ray (validation not mentioned)), functional limitation (percentage of normal movement of the sacral-lumbar area (validation not mentioned)); Follow up sessions: after 3 applications, after 5 applications, after one month, after six months, after one year; Intention-to-treat analysis: no
Notes	Total score: 7

Risk of bias

Bias	Authors' judgement	Support for judgement
Adequate sequence generation?	Unclear risk	Not stated in text
Allocation concealment?	Unclear risk	B - Unclear
Blinding? All outcomes - patients?	Low risk	
Blinding?	Low risk	

Longo 1991 *(Continued)*

All outcomes - providers?		
Blinding? All outcomes - outcome assessors?	Low risk	
Incomplete outcome data addressed? All outcomes - drop-outs?	Low risk	
Incomplete outcome data addressed? All outcomes - ITT analysis?	High risk	
Similarity of baseline characteristics?	Unclear risk	Unclear from text
Co-interventions avoided or similar?	Low risk	
Compliance acceptable?	Low risk	
Timing outcome assessments similar?	Low risk	

Soriano 1998

Methods	Study design: RCT; Unit of allocation: Patients; Method of randomisation: Not stated; Allocation concealment: no; Blindedness: yes
Participants	randomized = 85; analyzed = 71 (5/43 dropped out from experimental group; 9/42 dropped out from control group) Recruitment of patients: Not stated; Enrollment dates: Not stated; Age: more than 60 years; Sex: Male and female; Ethnicity: Not stated; Work status: Not stated; Diagnosis of LBP: Not stated ; Duration of pain: >3 months; Previous treatments: The use of analgesic drugs and physical therapy was excluded in both groups, a wash-out period of 5 days was done on any patient on NSAIDs; Exclusion criteria: any suspicious of cancer, any suspicious of osteomyelitis, any suspicious of gout, any suspicious of Paget's disease, any suspicious of collagen disease, symptoms or signs of neurologic deficits in the lower limbs, usage of long acting corticoids within the prior 30 days
Interventions	Both arms of the trial were included: LLLT(38) and sham(33). Intervention group: laser, five sessions a week for 2 weeks; Laser medium:Ga-As diode laser ; Laser model: Not stated; Wave length(nm): 904 nm; Laser mode: Pulsed, 10 kHz pulse frequency, 200 nsec pulse duration; Output power: peak power 20 W, average power:40 mW; Laser class: Not stated; Spot diameter(cm): 1.1 cm?; Exposure time(seconds): 100; Anatomic locations: On painful area Control group: Sham irradiation with a deactivated laser radiation, but the electrical circuit, timer and alarm worked as usual so that to all intents and purposes it was exactly identical to the real system.
Outcomes	Measurements by: Not stated; Measured variables: pain(VAS), Radiologic findings (osteopoenia, osteophytes, narrowing of disc spaces, spondylolisthesis grade 1), physical examination; Follow up sessions: every 1 month for six months; Intention-to-treat analysis: no
Notes	Total score: 6

Soriano 1998 *(Continued)*

Risk of bias

Bias	Authors' judgement	Support for judgement
Adequate sequence generation?	Unclear risk	Not stated in text
Allocation concealment?	Unclear risk	B - Unclear
Blinding? All outcomes - patients?	Low risk	
Blinding? All outcomes - providers?	Low risk	
Blinding? All outcomes - outcome assessors?	High risk	
Incomplete outcome data addressed? All outcomes - drop-outs?	High risk	more than 20% in control group
Incomplete outcome data addressed? All outcomes - ITT analysis?	High risk	
Similarity of baseline characteristics?	Low risk	
Co-interventions avoided or similar?	Low risk	
Compliance acceptable?	Low risk	
Timing outcome assessments similar?	Low risk	

Toya 1994

Methods	Study design: RCT; Unit of allocation: Patients; Method of randomisation: a computer generated schedule; Allocation concealment: adequate; Blindedness: Double-blinded
Participants	randomised = 130; analysed 115, 41 of whom had LBP and were included in this review Recruitment of patients: patients attending their respective institution on an outpatient basis; Enrollment dates: Not stated; between the ages of 18 to 82 y; Sex: Male and female; Ethnicity: Not stated; Work status: Not stated; Diagnosis of LBP: Not stated, Lumbar pain group(41 patients) consisted of Lumbago(23), Ischiatic neuralgia(9), Lumbar musculofascial pain(2), herniated disc(3), lumbar spondylosis(4); Duration of pain: not stated; Previous treatments: no limitations, a wash-out period was done on any patient on medications; Exclusion criteria: not stated
Interventions	Both arms of the trial were included: LLLT(16) and sham(25). Intervention group: laser, single session, no other treatments allowed; Laser medium:Ga-Al-As diode laser ; Laser model: OhLase-3D1(Proli, Japan); Wave length(nm): 830 nm; Laser mode: continuous; Out-

Toya 1994 *(Continued)*

	put power: 60 mW; Laser class: Not stated; Spot diameter(cm): 0.16 cm; Exposure time(seconds): 5 to 10 min (mean of 9.18 min); Anatomic locations: On painful area Control group: Sham irradiation with a deactivated laser radiation, but the electrical circuit, timer and alarm worked as usual and controlled by a locked remote centralised computer
Outcomes	Measurements by: a blinded therapist ; Measured variables: pain graded as exacerbation, little or no change, fair, good, excellent; Follow up sessions: immediately and one day after treatment; Intention-to-treat analysis: no
Notes	Total score: 9

Risk of bias

Bias	Authors' judgement	Support for judgement
Adequate sequence generation?	Low risk	
Allocation concealment?	Low risk	A - Adequate
Blinding? All outcomes - patients?	Low risk	
Blinding? All outcomes - providers?	Low risk	
Blinding? All outcomes - outcome assessors?	Low risk	
Incomplete outcome data addressed? All outcomes - drop-outs?	Low risk	
Incomplete outcome data addressed? All outcomes - ITT analysis?	High risk	
Similarity of baseline characteristics?	Unclear risk	Unclear from text
Co-interventions avoided or similar?	Low risk	
Compliance acceptable?	Low risk	
Timing outcome assessments similar?	Low risk	

Characteristics of excluded studies *[ordered by study ID]*

Study	Reason for exclusion
Bertocco 2002	No LLLT group
Gale 2006	no LLLT group. Infrared therapy
Gallacchi 1981	no clinically important outcomes reported.
Georgiev 1996	Radiculopathy, low-back pain caused by specific pathological entities
Grabowski 1981	Not RCT or CCT
Gurtler 1979	Not RCT or CCT
Kou 1991	Laser acupuncture
Kreczi 1986	No separate analysis for Low back pain
Mika 1990	Not RCT or CCT
Monticone 2004	Sacroiliac dysfunction, including rheumatological, metabolic, infective, degenerative, peripartum and post-traumatic problems. Insufficient explanation of laser therapy protocol
Ohshiro 1992	Not RCT or CCT
Okamoto 1989	No separate analysis for Low back pain
Pashnev 1991	Radiculopathy, low-back pain caused by specific pathological entities. No separate analysis for Low back pain
Raspopovic 2001	No control (sham, no laser, other treatment) group. Non randomised
Snyder 1986	No separate analysis for Low back pain
Snyder 1989	No separate analysis for Low back pain
Tasaki 1991	Not RCT or CCT
Zati 2004	High power laser, Disc displacement

DATA AND ANALYSES

Comparison 1. LLLT versus sham intervention (grouping based on follow-up durations)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Pain (VAS)	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
1.1 Short term follow up (less than 3 months after randomization)	1		Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
2 Low back pain related disability	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
2.1 Short term follow up (less than 3 months after randomization)	1		Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
3 Range of motion (Anterior-posterior flexion)	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
3.1 Short term follow up (less than 3 months after randomization)	1		Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
4 Relapse	2		Risk Ratio (M-H, Random, 95% CI)	Totals not selected
4.1 Short term follow up (less than 3 months after randomization)	1		Risk Ratio (M-H, Random, 95% CI)	0.0 [0.0, 0.0]
4.2 Intermediate-term follow up (3 months to 1 year)	2		Risk Ratio (M-H, Random, 95% CI)	0.0 [0.0, 0.0]
4.3 Long-term follow up (longer than one year)	1		Risk Ratio (M-H, Random, 95% CI)	0.0 [0.0, 0.0]

Analysis 1.1. Comparison 1 LLLT versus sham intervention (grouping based on follow-up durations), Outcome 1 Pain (VAS).

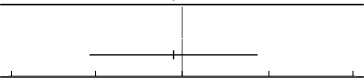
Study or subgroup	LLLT N	LLLT Mean(SD)	sham N	sham Mean(SD)	Mean Difference Fixed, 95% CI	Mean Difference Fixed, 95% CI
1.1.1 Short term follow up (less than 3 months after randomization)						
Basford 1999	27	19.1 (22.8)	29	35.1 (22.8)		-16[-27.95,-4.05]
				Favours LLLT	-20 -10 0 10 20	Favours sham

Analysis 1.2. Comparison 1 LLLT versus sham intervention (grouping based on follow-up durations), Outcome 2 Low back pain related disability.

Study or subgroup	LLLT N	LLLT Mean(SD)	sham N	sham Mean(SD)	Mean Difference Fixed, 95% CI	Mean Difference Fixed, 95% CI
1.2.1 Short term follow up (less than 3 months after randomization)						
Basford 1999	27	14.7 (10)	29	22.9 (10)		-8.2[-13.44,-2.96]
				Favours LLLT	-10 -5 0 5 10	Favours sham

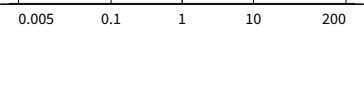
Analysis 1.3. Comparison 1 LLLT versus sham intervention (grouping based on follow-up durations), Outcome 3 Range of motion (Anterior-posterior flexion).

Study or subgroup	LLLT N	LLLT Mean(SD)	sham N	sham Mean(SD)	Mean Difference Fixed, 95% CI	Mean Difference Fixed, 95% CI
1.3.1 Short term follow up (less than 3 months after randomization)						
Basford 1999	27	14 (3.7)	29	14.2 (3.7)		-0.2[-2.14,1.74]



Analysis 1.4. Comparison 1 LLLT versus sham intervention (grouping based on follow-up durations), Outcome 4 Relapse.

Study or subgroup	LLLT n/N	sham n/N	Risk Ratio M-H, Random, 95% CI	Risk Ratio M-H, Random, 95% CI
1.4.1 Short term follow up (less than 3 months after randomization)				
Longo 1991	0/40	5/40		0.09[0.01,1.59]
1.4.2 Intermediate-term follow up (3 months to 1 year)				
Longo 1991	12/40	35/40		0.34[0.21,0.56]
Soriano 1998	14/38	23/33		0.53[0.33,0.85]
1.4.3 Long-term follow up (longer than one year)				
Longo 1991	26/40	38/40		0.68[0.54,0.87]

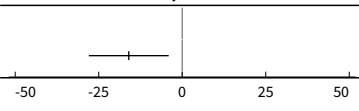


Comparison 2. LLLT versus sham intervention (grouping based on laser dosing)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Pain(VAS)	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
1.1 Adequate dosing	1		Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
2 Low back pain related disability	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
2.1 Adequate dosing	1		Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
3 Range of motion (Anterior-posterior flexion)	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
3.1 Adequate dosing	1		Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
4 Relapse	2		Risk Ratio (M-H, Random, 95% CI)	Totals not selected
4.1 Adequate dosing	1		Risk Ratio (M-H, Random, 95% CI)	0.0 [0.0, 0.0]
4.2 Inadequate dosing	1		Risk Ratio (M-H, Random, 95% CI)	0.0 [0.0, 0.0]

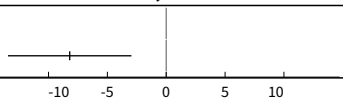
Analysis 2.1. Comparison 2 LLLT versus sham intervention (grouping based on laser dosing), Outcome 1 Pain(VAS).

Study or subgroup	LLLT N	LLLT Mean(SD)	sham N	sham Mean(SD)	Mean Difference Fixed, 95% CI	Mean Difference Fixed, 95% CI
2.1.1 Adequate dosing						
Basford 1999	27	19.1 (22.8)	29	35.1 (22.8)		-16[-27.95,-4.05]



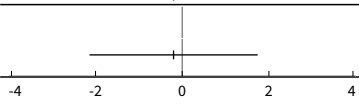
Analysis 2.2. Comparison 2 LLLT versus sham intervention (grouping based on laser dosing), Outcome 2 Low back pain related disability.

Study or subgroup	LLLT N	LLLT Mean(SD)	sham N	sham Mean(SD)	Mean Difference Fixed, 95% CI	Mean Difference Fixed, 95% CI
2.2.1 Adequate dosing						
Basford 1999	27	14.7 (10)	29	22.9 (10)		-8.2[-13.44,-2.96]



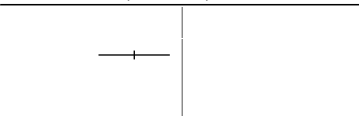
Analysis 2.3. Comparison 2 LLLT versus sham intervention (grouping based on laser dosing), Outcome 3 Range of motion (Anterior-posterior flexion).

Study or subgroup	LLLT N	LLLT Mean(SD)	sham N	sham Mean(SD)	Mean Difference Fixed, 95% CI	Mean Difference Fixed, 95% CI
2.3.1 Adequate dosing						
Basford 1999	27	14 (3.7)	29	14.2 (3.7)		-0.2[-2.14,1.74]



Analysis 2.4. Comparison 2 LLLT versus sham intervention (grouping based on laser dosing), Outcome 4 Relapse.

Study or subgroup	LLLT n/N	sham n/N	Risk Ratio M-H, Random, 95% CI	Risk Ratio M-H, Random, 95% CI
2.4.1 Adequate dosing				
Soriano 1998	14/38	23/33		0.53[0.33,0.85]
2.4.2 Inadequate dosing				
Longo 1991	12/40	35/40		0.34[0.21,0.56]



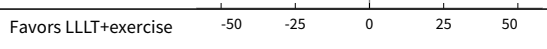
Comparison 3. LLLT+exercise versus sham+exercise (grouping based on follow-up durations)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Pain (VAS)	2		Mean Difference (IV, Fixed, 95% CI)	Subtotals only

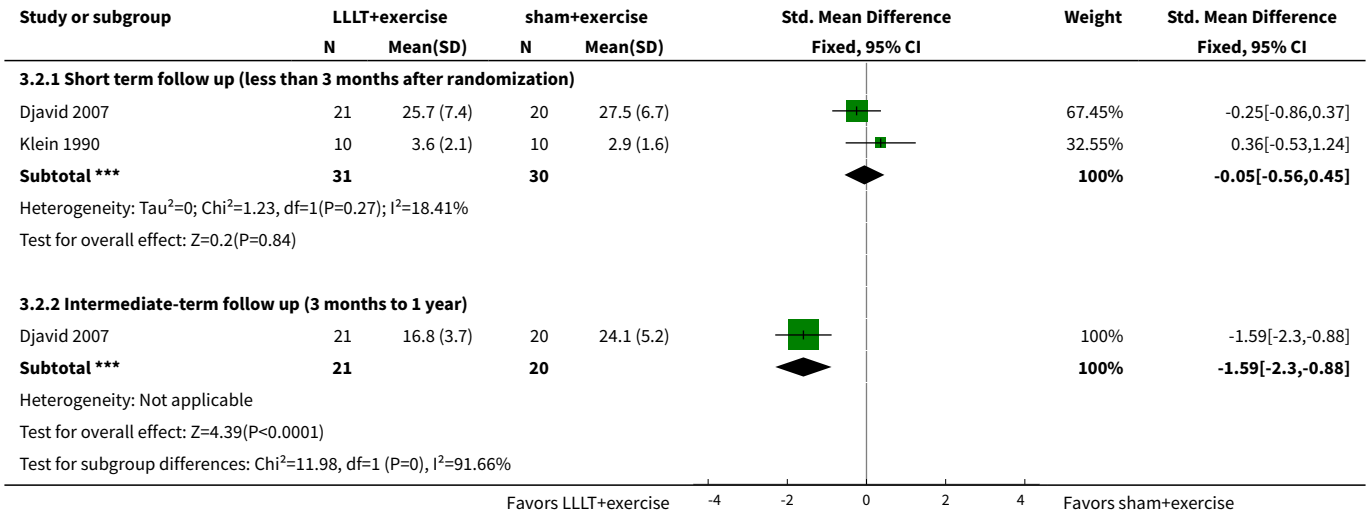
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1.1 Short term follow up (less than 3 months after randomization)	2	61	Mean Difference (IV, Fixed, 95% CI)	-6.38 [-15.68, 2.91]
1.2 Intermediate-term follow up (3 months to 1 year)	1	41	Mean Difference (IV, Fixed, 95% CI)	-19.0 [-28.22, -9.78]
2 Low back pain related disability	2		Std. Mean Difference (IV, Fixed, 95% CI)	Subtotals only
2.1 Short term follow up (less than 3 months after randomization)	2	61	Std. Mean Difference (IV, Fixed, 95% CI)	-0.05 [-0.56, 0.45]
2.2 Intermediate-term follow up (3 months to 1 year)	1	41	Std. Mean Difference (IV, Fixed, 95% CI)	-1.59 [-2.30, -0.88]
3 Range of motion (Anterior-posterior flexion)	2		Std. Mean Difference (IV, Fixed, 95% CI)	Subtotals only
3.1 Short term follow up (less than 3 months after randomization)	2	61	Std. Mean Difference (IV, Fixed, 95% CI)	-0.08 [-0.58, 0.43]
3.2 Intermediate-term follow up (3 months to 1 year)	1	41	Std. Mean Difference (IV, Fixed, 95% CI)	0.20 [-0.42, 0.81]

Analysis 3.1. Comparison 3 LLLT+exercise versus sham+exercise (grouping based on follow-up durations), Outcome 1 Pain (VAS).

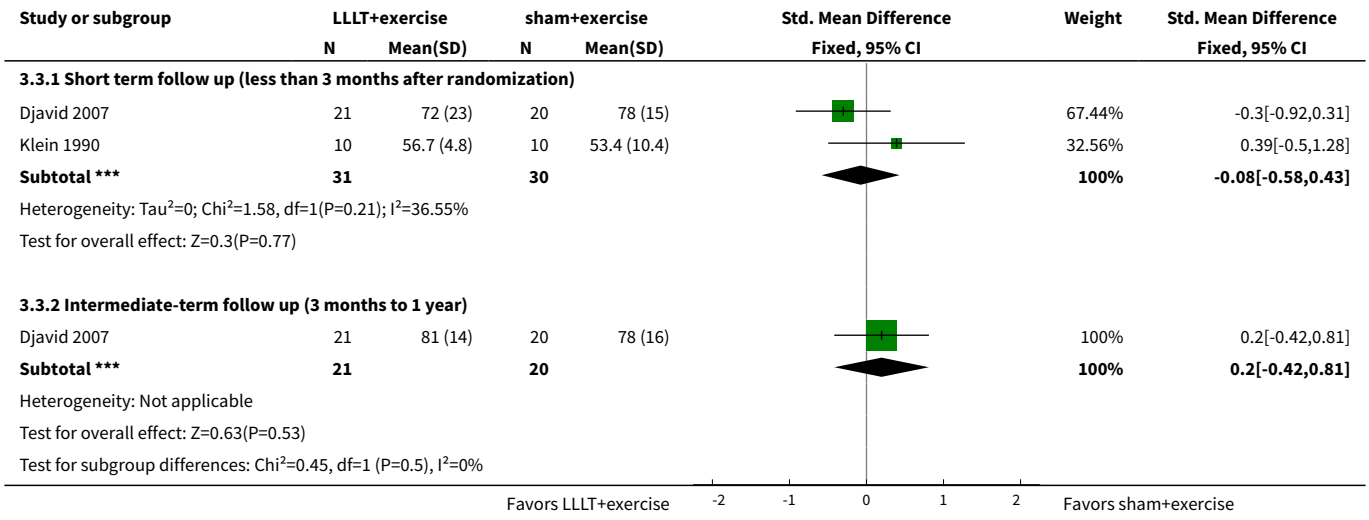
Study or subgroup	LLLT+exercise N	LLLT+exercise Mean(SD)	sham+exercise N	sham+exercise Mean(SD)	Mean Difference Fixed, 95% CI	Weight	Mean Difference Fixed, 95% CI
3.1.1 Short term follow up (less than 3 months after randomization)							
Djavid 2007	21	46 (17)	20	53 (21)		62.79%	-7[-18.73,4.73]
Klein 1990	10	22.7 (18.7)	10	28 (16)		37.21%	-5.34[-20.57,9.89]
Subtotal ***	**31**		**30**			**100%**	**-6.38[-15.68,2.91]**
Heterogeneity: Tau^2=0; Chi^2=0.03, df=1(P=0.87); I^2=0%							
Test for overall effect: Z=1.35(P=0.18)							
3.1.2 Intermediate-term follow up (3 months to 1 year)							
Djavid 2007	21	24 (14)	20	43 (16)		100%	-19[-28.22,-9.78]
Subtotal ***	**21**		**20**			**100%**	**-19[-28.22,-9.78]**
Heterogeneity: Not applicable							
Test for overall effect: Z=4.04(P<0.0001)							
Test for subgroup differences: Chi^2=3.57, df=1 (P=0.06), I^2=71.97%							



Analysis 3.2. Comparison 3 LLLT+exercise versus sham+exercise (grouping based on follow-up durations), Outcome 2 Low back pain related disability.



Analysis 3.3. Comparison 3 LLLT+exercise versus sham+exercise (grouping based on follow-up durations), Outcome 3 Range of motion (Anterior-posterior flexion).



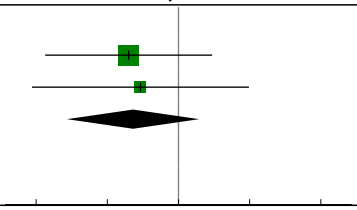
Comparison 4. LLLT+exercise versus sham+exercise (grouping based on laser dosing)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Pain (VAS)	2		Mean Difference (IV, Fixed, 95% CI)	Subtotals only
1.1 Inadequate dosing	2	61	Mean Difference (IV, Fixed, 95% CI)	-6.38 [-15.68, 2.91]
2 Low back pain related disability	2		Std. Mean Difference (IV, Fixed, 95% CI)	Subtotals only

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
2.1 Inadequate dosing	2	61	Std. Mean Difference (IV, Fixed, 95% CI)	-0.05 [-0.56, 0.45]
3 Range of motion (Anterior-posterior flexion)	2		Std. Mean Difference (IV, Fixed, 95% CI)	Subtotals only
3.1 Inadequate dosing	2	61	Std. Mean Difference (IV, Fixed, 95% CI)	-0.08 [-0.58, 0.43]

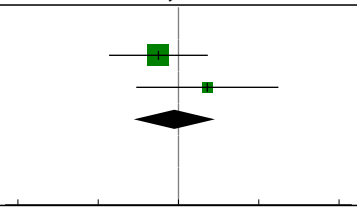
Analysis 4.1. Comparison 4 LLLT+exercise versus sham +exercise (grouping based on laser dosing), Outcome 1 Pain (VAS).

Study or subgroup	LLLT+exercise N	LLLT+exercise Mean(SD)	sham+exercise N	sham+exercise Mean(SD)	Mean Difference Fixed, 95% CI	Weight	Mean Difference Fixed, 95% CI
4.1.1 Inadequate dosing							
Djavid 2007	21	46 (17)	20	53 (21)		62.79%	-7[-18.73,4.73]
Klein 1990	10	22.7 (18.7)	10	28 (16)		37.21%	-5.34[-20.57,9.89]
Subtotal ***	**31**		**30**			**100%**	**-6.38[-15.68,2.91]**
Heterogeneity: Tau^2=0; Chi^2=0.03, df=1(P=0.87); I^2=0%							
Test for overall effect: Z=1.35(P=0.18)							



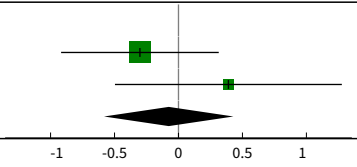
Analysis 4.2. Comparison 4 LLLT+exercise versus sham+exercise (grouping based on laser dosing), Outcome 2 Low back pain related disability.

Study or subgroup	LLLT+exercise N	LLLT+exercise Mean(SD)	sham+exercise N	sham+exercise Mean(SD)	Std. Mean Difference Fixed, 95% CI	Weight	Std. Mean Difference Fixed, 95% CI
4.2.1 Inadequate dosing							
Djavid 2007	21	25.7 (7.4)	20	27.5 (6.7)		67.45%	-0.25[-0.86,0.37]
Klein 1990	10	3.6 (2.1)	10	2.9 (1.6)		32.55%	0.36[-0.53,1.24]
Subtotal ***	**31**		**30**			**100%**	**-0.05[-0.56,0.45]**
Heterogeneity: Tau^2=0; Chi^2=1.23, df=1(P=0.27); I^2=18.41%							
Test for overall effect: Z=0.2(P=0.84)							

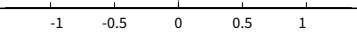


Analysis 4.3. Comparison 4 LLLT+exercise versus sham+exercise (grouping based on laser dosing), Outcome 3 Range of motion (Anterior-posterior flexion).

Study or subgroup	LLLT+exercise N	LLLT+exercise Mean(SD)	exercise N	exercise Mean(SD)	Std. Mean Difference Fixed, 95% CI	Weight	Std. Mean Difference Fixed, 95% CI
4.3.1 Inadequate dosing							
Djavid 2007	21	72 (23)	20	78 (15)		67.44%	-0.3[-0.92,0.31]
Klein 1990	10	56.7 (4.8)	10	53.4 (10.4)		32.56%	0.39[-0.5,1.28]
Subtotal ***	**31**		**30**			**100%**	**-0.08[-0.58,0.43]**



Study or subgroup	LLLT+exercise N	Mean(SD)	exercise N	Mean(SD)	Std. Mean Difference Fixed, 95% CI	Weight	Std. Mean Difference Fixed, 95% CI
Heterogeneity: Tau²=0; Chi²=1.58, df=1(P=0.21); I²=36.55%							
Test for overall effect: Z=0.3(P=0.77)							

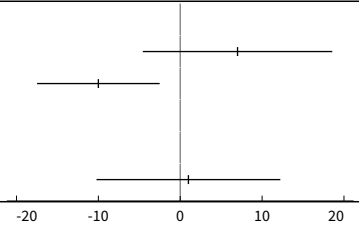


Comparison 5. LLLT versus exercise (grouping based on follow-up durations)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Pain (VAS)	2		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
1.1 Short term follow up (less than 3 months after randomization)	2		Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
1.2 Intermediate-term follow up (3 months to 1 year)	1		Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
2 Low back pain related disability	2		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
2.1 Short term follow up (less than 3 months after randomization)	2		Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
2.2 Intermediate-term follow up (3 months to 1 year)	1		Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
3 Range of motion (Anterior-posterior flexion)	2		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
3.1 Short term follow up (less than 3 months after randomization)	2		Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
3.2 Intermediate-term follow up (3 months to 1 year)	1		Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]

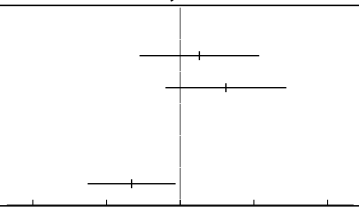
Analysis 5.1. Comparison 5 LLLT versus exercise (grouping based on follow-up durations), Outcome 1 Pain (VAS).

Study or subgroup	LLLT N	Mean(SD)	exercise N	Mean(SD)	Mean Difference Fixed, 95% CI	Mean Difference Fixed, 95% CI
5.1.1 Short term follow up (less than 3 months after randomization)						
Djavid 2007	20	60 (16)	20	53 (21)		7[-4.57,18.57]
Gur 2003	25	19 (14)	25	29 (13)		-10[-17.49,-2.51]
5.1.2 Intermediate-term follow up (3 months to 1 year)						
Djavid 2007	20	44 (20)	20	43 (16)		1[-10.22,12.22]



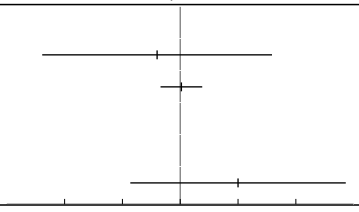
Analysis 5.2. Comparison 5 LLLT versus exercise (grouping based on follow-up durations), Outcome 2 Low back pain related disability.

Study or subgroup	LLLT N	LLLT Mean(SD)	exercise N	exercise Mean(SD)	Mean Difference Fixed, 95% CI	Mean Difference Fixed, 95% CI
5.2.1 Short term follow up (less than 3 months after randomization)						
Djavid 2007	20	28.8 (6.4)	20	27.5 (6.7)		1.3[-2.76,5.36]
Gur 2003	25	16.7 (7.6)	25	13.6 (7.2)		3.1[-1,7.2]
5.2.2 Intermediate-term follow up (3 months to 1 year)						
Djavid 2007	20	20.8 (4.4)	20	24.1 (5.2)		-3.3[-6.29,-0.31]



Analysis 5.3. Comparison 5 LLLT versus exercise (grouping based on follow-up durations), Outcome 3 Range of motion (Anterior-posterior flexion).

Study or subgroup	LLLT N	LLLT Mean(SD)	exercise N	exercise Mean(SD)	Mean Difference Fixed, 95% CI	Mean Difference Fixed, 95% CI
5.3.1 Short term follow up (less than 3 months after randomization)						
Djavid 2007	20	76 (17)	20	78 (15)		-2[-11.94,7.94]
Gur 2003	25	18.6 (3.1)	25	18.5 (3.4)		0.1[-1.7,1.9]
5.3.2 Intermediate-term follow up (3 months to 1 year)						
Djavid 2007	20	83 (14)	20	78 (16)		5[-4.32,14.32]

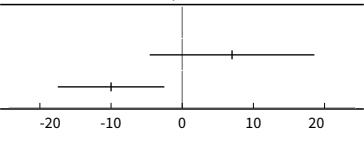


Comparison 6. LLLT versus exercise (grouping based on laser dosing)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Pain (VAS)	2		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
1.1 Inadequate dosing	2		Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
2 Low back pain related disability	2		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
2.1 Inadequate dosing	2		Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
3 Range of motion (Anterior-posterior flexion)	2		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
3.1 Inadequate dosing	2		Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]

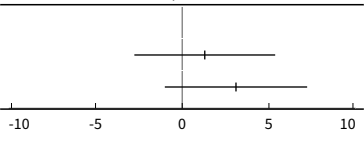
Analysis 6.1. Comparison 6 LLLT versus exercise (grouping based on laser dosing), Outcome 1 Pain (VAS).

Study or subgroup	LLLT		exercise		Mean Difference	Mean Difference
	N	Mean(SD)	N	Mean(SD)	Fixed, 95% CI	Fixed, 95% CI
6.1.1 Inadequate dosing						
Djavid 2007	20	60 (16)	20	53 (21)		7[-4.57,18.57]
Gur 2003	25	19 (14)	25	29 (13)		-10[-17.49,-2.51]



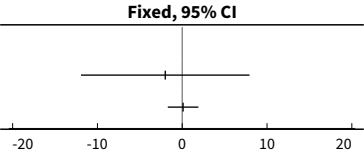
Analysis 6.2. Comparison 6 LLLT versus exercise (grouping based on laser dosing), Outcome 2 Low back pain related disability.

Study or subgroup	LLLT		exercise		Mean Difference	Mean Difference
	N	Mean(SD)	N	Mean(SD)	Fixed, 95% CI	Fixed, 95% CI
6.2.1 Inadequate dosing						
Djavid 2007	20	28.8 (6.4)	20	27.5 (6.7)		1.3[-2.76,5.36]
Gur 2003	25	16.7 (7.6)	25	13.6 (7.2)		3.1[-1,7.2]



Analysis 6.3. Comparison 6 LLLT versus exercise (grouping based on laser dosing), Outcome 3 Range of motion (Anterior-posterior flexion).

Study or subgroup	LLLT		exercise		Mean Difference	Mean Difference
	N	Mean(SD)	N	Mean(SD)	Fixed, 95% CI	Fixed, 95% CI
6.3.1 Inadequate dosing						
Djavid 2007	20	76 (17)	20	78 (15)		-2[-11.94,7.94]
Gur 2003	25	18.6 (3.1)	25	18.5 (3.4)		0.1[-1.7,1.9]



ADDITIONAL TABLES

Table 1. Criteria for internal validity

Criteria
Was the method of randomization adequate? A random (unpredictable) assignment sequence.
Was the treatment allocation concealed? Assignment generated by an independent person not responsible for determining the eligibility of the patients. This person has no information about the persons included in the trial and has no influence on the assignment sequence or on the decision about eligibility of the patient.
Was the patient blinded to the intervention? The reviewer determines if enough information about the blinding is given in order to score a "yes."
Was the care provider blinded to the intervention? The reviewer determines if enough information about the blinding is given in order to score a "yes."
Was the outcome assessor blinded to the intervention? The reviewer determines if enough information about the blinding is given in order to score a "yes."

Table 1. Criteria for internal validity *(Continued)*

Was the drop-out rate described and acceptable? The number of participants who were included in the study but did not complete the observation period or were not included in the analysis must be described and reasons given. If the percentage of withdrawals and drop-outs does not exceed 20% for short-term follow-up and 30% for long-term follow-up and does not lead to substantial bias a "yes" is scored.

Did the analysis include an intention-to-treat analysis? All randomized patients are reported/analyzed in the group they were allocated to by randomization for the most important moments of effect measurement (minus missing values) irrespective of noncompliance and co-interventions.

Were the groups similar at baseline regarding the most important prognostic indicators? In order to receive a "yes", groups have to be similar at baseline characteristics.

Were co-interventions avoided or similar? Co-interventions should either be avoided in the trial design or similar between the index and control groups.

Was the compliance acceptable in all groups? The reviewer determines if the compliance to the interventions is acceptable.

Was the timing of the outcome assessment in all groups similar? Timing of outcome assessment should be identical for all intervention groups and for all important outcome assessments.

Table 2. Laser dosing and characteristics of included studies

Name of study	Laser medium	Wave length (nm)	Laser mode	Output power	Power density	Dose (J/ point)	Adequacy (WALT)
Basford 1999	Nd-YAG	1060	Continuous	2661 mW	542 mW/cm2	29.9J	Yes
Djavid 2007	Ga-Al-As	810	continuous	50 mW	226 mW/cm2	6 J	No
Gur 2003	Gallium-Arsenide	Not stated	Pulsed, 2.1 kHz pulse frequency	peak power 10W	4.2 mW/cm2	1 J	No
Klein 1990	Gallium-Arsenide	904	Pulsed, 1 kHz pulse frequency, 200 nsec pulse duration	peak power 2W	0.4 mW/cm2	0.1 J	No
Longo 1991	Gallium-Arsenide	904	Pulsed, 3 kHz pulse frequency, 200 nsec pulse duration	peak power 72W (27W?)	10 mW/cm2	3 J	No
Soriano 1998	Gallium-Arsenide	904	Pulsed, 10 kHz pulse frequency, 200 nsec pulse duration	peak power 20W	40 mW/cm2	4 J	Yes
Toya 1994	Ga-Al-As	830	continuous	60 mW	3000 mW/cm2	18-36 J	Yes

APPENDICES

Appendix 1. MEDLINE & CINAHL search strategy

1.randomized controlled trial.pt.
2.controlled clinical trial.pt
3.Randomized Controlled Trials/
4.Random Allocation/
5.Double-Blind Method/
6.Single-Blind Method/
7.or/1-6
8.Animal/ not Human/
9.7 not 8
10.clinical trial.pt.
11.exp Clinical Trials/
12.(clin$ adj25 trial$).tw.
13.((singl$ or doubl$ or trebl$ or tripl$) adj25 (blind$ or mask$)).tw.
14.Placebos/
15.placebo$.tw.
16.random$.tw.
17.Research Design/
18.(latin adj square).tw.
19.or/10-18
20.19 not 18
21.20 not 9
22.Comparative Study/
23.exp Evaluation Studies/
24.Follow-Up Studies/
25.Prospective Studies?
26.(control$ or prospective$ or Volunteer$).tw.
27.Cross-Over Studies/
28.or/22-27
29.28 not 8
30.29 not (9 or 21)
31.9 or 21 or 30
32. back pain.sh
33. low back pain.sh
34. back pain.ti,ab
35. backache.ti,ab
36. exp back pain/
37. dorsalgia.ti,ab
38. lumbago.ti,ab
39. (lumbar adj pain).ti,ab
40.or/32-39
41. laser$.sh
42. laser$.tw
43. exp light/
44. infrared.tw
45. ultraviolet.tw
46. monochromatic.tw
47.or/41-46
48.31 and 40 and 47

FEEDBACK

concerns about the conclusions, The Cochrane Library 2008, issue 2 version, 27 May 2008

Summary

Dr. Bjordal voiced this concern: To counter any possible misunderstandings I would like to add the following:. My comments were not approved of after having been taken into consideration, and I do not endorse the review conclusion. In fact, I strongly disagree with the

review conclusion. This is probably the only Cochrane review where 5 out of 6 RCTs with acceptable methodological quality and partly or fully positive results, merits a non-positive review conclusion.

Reply

The Co-ordinating and Managing Editors forwarded this response to Dr. Bjordal: Although most of the trials showed some short term positive results compared with sham therapy, the results were small and not clinically important. Also, there was heterogeneity amongst the populations, doses of LLLT and comparisons that precluded a meta-analysis of the results. Therefore, the reviewers and the Editorial board of the Cochrane Back Review Group concluded that current data did not indicate a firm conclusion in favour of LLLT.

Contributors

Dr Jan Bjordal (submitted concerns)
Dr Maurits van Tulder (Co-ordinating Editor, Cochrane Back Review Group)
Victoria Pennick (Managing Editor, Cochrane Back Review Group)

concerns re analysis and conclusions of review

Summary

June 2007
Dr Bjordal voiced concerns about the accuracy of the analysis and conclusions of this review when it was first published in The Cochrane Library 2007, issue 2. The review authors and the Co-ordinating Editors agreed with the concerns and the review was subsequently withdrawn from The Cochrane Library. The literature search was updated in November 2007 and one newly published study included in the new analysis and conclusions. Dr Bjordal was asked to read the updated review and his comments were taken into consideration for the final review. The updated review is being re-published in The Cochrane Library 2008, issue 2.

Contributors

Dr Jan Bjordal (submitted concerns)
Dr Reza Yousefi-Nooraie (contact author)
Dr Maurits van Tulder (Co-ordinating Editor, Cochrane Back Review Group)
Victoria Pennick (Managing Editor, Cochrane Back Review Group)

WHAT'S NEW

Date	Event	Description
19 January 2011	Amended	Contact details updated.

HISTORY

Protocol first published: Issue 1, 2005
Review first published: Issue 2, 2007

Date	Event	Description
27 October 2008	Amended	contact author's address updated
23 May 2008	Amended	Converted to new review format.
1 February 2008	New citation required but conclusions have not changed	This review was initially published in The Cochrane Library 2007, issue 2. Based on concerns raised by a reader, we withdrew the review, pending re-analysis. The conclusions have not changed substantially. Based on the heterogeneity of the populations, interventions and comparison groups, we conclude that there are insufficient data to draw firm conclusions on the clinical effect of LLLT for low-back pain.

Date	Event	Description
14 November 2007	New search has been performed	In November 2007, we updated the literature search, added one more trial and re-analysed the data.

CONTRIBUTIONS OF AUTHORS

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Development of protocol:Yousefi-Nooraie R, Schonstein E, Heidari K, Akbari Kamrani M, Irani S, Shakiba B, Mortaz Hejri Sa, Mortaz-Hedjri So, Rashidian A, Jonaidi A
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Selection of trials: Yousefi-Nooraie R, Schonstein E
Quality assessment of trials: Mortaz Hejri Sa, Akbari Kamrani M, Heidari K, Shakiba B
Data extraction: Yousefi-Nooraie R, Akbari Kamrani M, Irani S
Data analysis: Yousefi-Nooraie R, Akbari Kamrani M
Interpretation of results: Yousefi-Nooraie R, Schonstein E, Heidari K, Rashidian A, Akbari Kamrani M, Irani S, Shakiba B, Mortaz Hejri Sa, Mortaz-Hedjri So, Jonaidi A, Pennick V
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Review of final manuscripts of protocol and review: Yousefi-Nooraie R, Rashidian A, Schonstein E, Heidari K, Akbari Kamrani M, Irani S, Shakiba B, Mortaz Hejri Sa, Mortaz-Hedjri So, Jonaidi A, Pennick V

DECLARATIONS OF INTEREST

none

SOURCES OF SUPPORT

Internal sources

- Student's Scientific Research Center,Tehran University of Medical Sciences, Iran.
- Institute for Work & Health, Canada.

in kind

External sources

- No sources of support supplied

INDEX TERMS

Medical Subject Headings (MeSH)

Low Back Pain [*radiotherapy]; Low-Level Light Therapy [*methods]; Randomized Controlled Trials as Topic

MeSH check words

Female; Humans; Male