In chronic low back pain, low level laser therapy combined with exercise is more beneficial than exercise alone in the long term: a randomised trial

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Question: Is low level laser therapy an effective adjuvant intervention for chronic low back pain? **Design:** Randomised trial with concealed allocation, blinded assessors and intention-to-treat analysis. **Participants:** Sixty-one patients who had low back pain for at least 12 weeks. **Intervention:** One group received laser therapy alone, one received laser therapy and exercise, and the third group received placebo laser therapy and exercise. Laser therapy was performed twice a week for 6 weeks. **Outcome measures:** Outcomes were pain severity measured using a 10-cm visual analogue scale, lumbar range of motion measured by the Schober Test and maximum active flexion, extension and lateral flexion, and disability measured with the Oswestry Disability Index on admission to the study, after 6 weeks of intervention, and after another 6 weeks of no intervention. **Results:** There was no greater effect of laser therapy compared with exercise for any outcome, at either 6 or 12 weeks. There was also no greater effect of laser therapy plus exercise compared with exercise for any outcome at 6 weeks. However, in the laser therapy plus exercise group pain had reduced by 1.8 cm (95% CI 0.1 to 3.3, $p = 0.03$), lumbar range of movement increased by 0.9 cm (95% CI 0.2 to 1.8, $p < 0.01$) on the Schober Test and by 15 deg (95% CI 5 to 25, $p < 0.01$) of active flexion, and disability reduced by 9.4 points (95% CI 2.7 to 16.0, $p = 0.03$) more than in the exercise group at 12 weeks. **Conclusion:** In chronic low back pain, low level laser therapy combined with exercise is more beneficial than exercise alone in the long term. **[Djavid GE, Mehrdad R, Ghasemi M, Hasan-Zadeh H, Sotoodeh-Manesh A, Pouryaghoub G (2007) In chronic low back pain, low level laser therapy combined with exercise is more beneficial than exercise alone in the long term: a randomised trial. *Australian Journal of Physiotherapy* 52: 155–160]**

Key words: Low Back Pain, Low Level Laser Therapy, Exercise Therapy, Visual Analog Pain Scale, Disability Evaluation, Randomized Controlled Trial (PT)

Introduction

Low back pain is one of the most common reasons for seeking medical care. It affects nearly two-thirds of the population during their lifetime (Coste et al 1994, Hillman et al 1996). Over three months, 90 percent or more of these patients recover. But the remaining patients, up to 10 percent, recover slowly and place large, resource-intensive demands on the healthcare system (Andersson 1999). Chronic low back pain of severe intensity is reported in community surveys by five to eight percent of individuals (Carey et al 2000). By definition, nonspecific chronic low back pain is pain in the lumbosacral area of the spine of more than 12 weeks' duration, may or may not have referred characteristics, and is usually seen with range of motion limitations due to pain (van Tulder et al 1998). Chronic low back pain is generally considered a result of mechanical causes and is not related to an underlying condition such as infection, neoplasm, or fracture. Chronic low back pain is often thought to be the result of disc degeneration, musculoskeletal sprain or strain, or of disorders associated with the movement or position of the spine. The causes of chronic low back pain may stem from nociceptive, neuropathic, or psychological processes, or a combination of these (Grabois 2005).

For patients with chronic low back pain, the complete eradication of pain is rarely achieved and is not the goal of most interventions. Rather, the goals of treatment, which often require a multidisciplinary program, are moderation of pain, increase in activity, and decrease in healthcare utilisation (Sanders et al 1995). Nonpharmacologic therapies, as part of an interdisciplinary program for chronic low back pain, can include physical modalities, exercise, education, transcutaneous electrical nerve stimulation, acupuncture, manipulation, and surgery (Grabois 2005). These are usually utilised as adjunctive therapies and do not necessarily substitute for pharmacotherapy (Owens and Ehrenreich 1991), but controversy remains as to the preferred treatment. Exercise therapy is used widely as a treatment for chronic low back pain (Hayden et al 2005). Several other systematic reviews have supported the role of exercise in patients with chronic low back pain (Faas 1996, van Tulder et al 1997, Carter and Lord 2002, Hayden et al 2005). However, it seems that in some conditions, exercise therapy alone is not sufficient to treat chronic low back pain and it is necessary to combine it with other pharmacologic and non-pharmacologic modalities. In this situation, some other methods have been recommended in a multidisciplinary program (Sanders et al 1995).

Many authors have reported significant pain reduction with low level laser therapy in acute and chronic painful conditions (Gam et al 1993, Bjordal et al 2003, Kreisler et al 2004, Chow and Barnsley 2005, Ferreira et al 2005). Laser therapy has been thought to be useful in the treatment of musculoskeletal disorders through its analgesic,

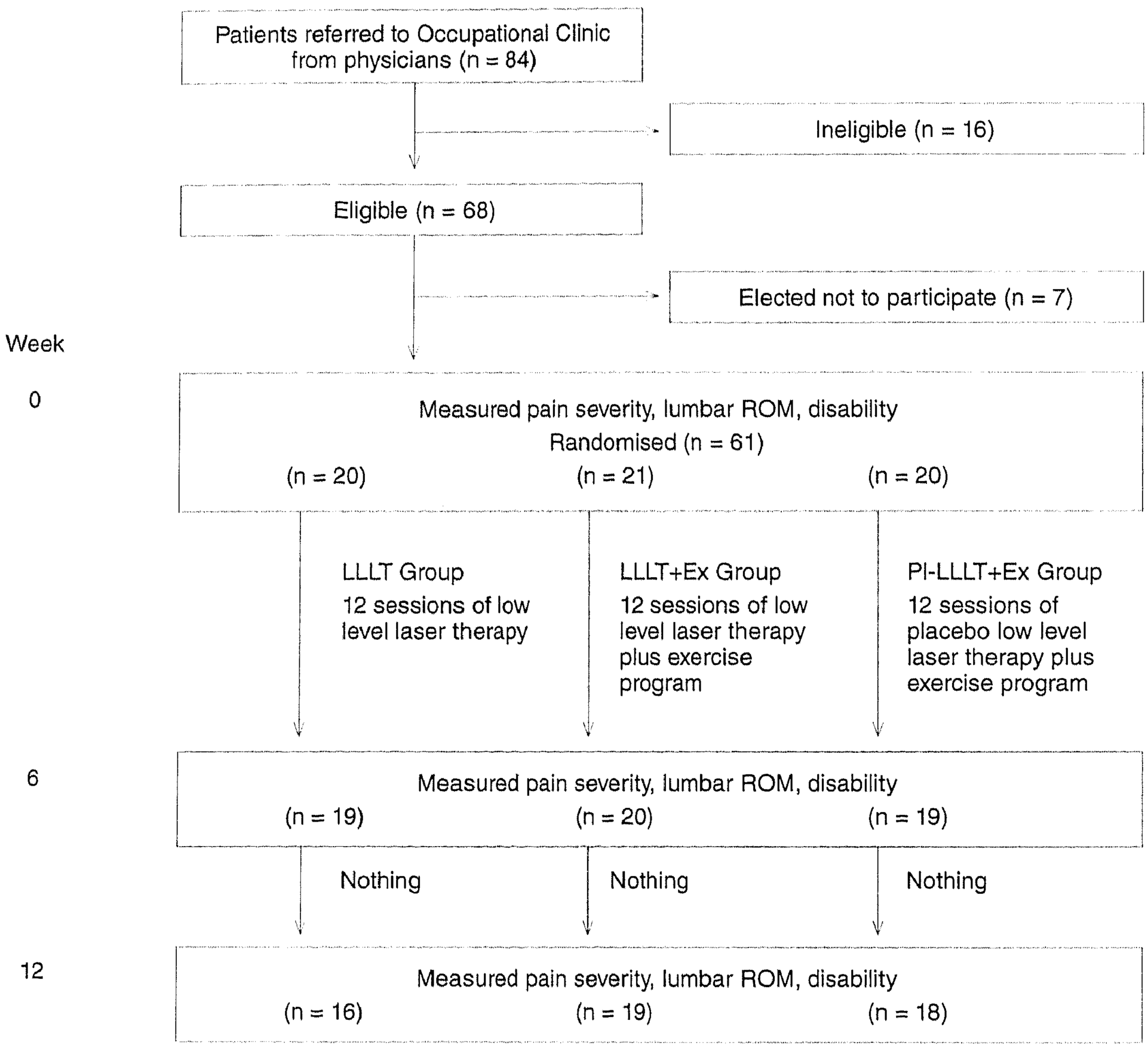

Figure 1. Design of and flow of participants through the study.

myorelaxant, tissue healing, and biostimulation effects (Gam et al 1993, Jacobsen et al 1997, Djavid et al 2003, Chow and Barnsley 2005). It has been suggested that laser therapy may act by stimulating ligament repair (Reddy et al 1998), by anti-inflammatory effects (Sakurai et al 2000, Bjordal and Baxter 2006), and/or by reducing interstitial swelling by stimulating the motoricity of lymphatics (Carati et al 2003, Kaviani et al 2006). There is also *in vivo* and *in vitro* evidence that 830 nm laser inhibits Aδ and C fibre transmission (Tsuchiya et al 1993, Tsuchiya et al 1994). It is possible that laser-induced neural blockade may then lead to long-term altered nociception, analogous to the prolonged analgesia seen in some patients with local anaesthetics (Arner et al 1990). The repeated application of laser may reduce tonic peripheral nociceptive afferent input to the dorsal horn and facilitate reorganisation of synaptic connections in the central nervous system producing pain modulation (Coderre et al 1993, Mense 1993).

Low level laser therapy may also be an effective adjunctive or alternative treatment for chronic low back pain with avoidance of systemic drug use (Basford et al 1999, Gur et al 2003). Because of the significant placebo response rate in clinical trials, non pharmacologic treatments require careful investigation to ascertain effectiveness. However, even though laser therapy is available in many clinics, it has not yet received FDA approval and the efficacy of laser therapy is controversial. Limitations of previous human studies and the application of an inadequate dose in our own previous studies lead us to choose a higher dose. In addition, we were interested in laser therapy as an adjuvant therapy to a conventional modality. The specific research questions for this study were:

1. In chronic low back pain, is low level laser therapy more effective than placebo-laser therapy plus exercise at decreasing pain, increasing lumbar range of motion, and reducing disability?

2. In chronic low back pain, is low level laser therapy plus exercise more effective than placebo-laser therapy plus exercise at decreasing pain, increasing lumbar range of motion, and reducing disability?

Table 1. Characteristics of participants.

Characteristic	LLLT (n = 16)	LLLT+Ex (n = 19)	Pl-LLLT+Ex (n = 18)
Age *(yr)*, mean (SD)	40 (10)	38 (7)	36 (10)
Gender *(M:F)*, n	7:9	12:7	15:3
Body mass index *(kg/cm²)*, mean (SD)	24.6 (2)	26.5 (3.7)	26.1 (3.7)
Duration of LBP *(mth)*, mean (SD)	29 (24)	29 (33)	25 (20)
Educational level, *n* (%)			
none	8 (50)	5 (28)	8 (46)
elementary school	5 (31)	9 (44)	3 (18)
high school	2 (13)	4 (22)	5 (27)
University	1 (6)	1 (6)	2 (9)
History of LBP, *n* (%)	9 (56)	10 (53)	10 (55)
Smoker, *n* (%)	6 (38)	4 (21)	3 (17)

LLLT = low level laser therapy, LLLT+Ex = low level laser therapy plus exercise, Pl-LLLT+Ex = placebo low level laser therapy plus exercise, LBP = low back pain

Method

Design

A randomised controlled trial was conducted (Figure 1). Allocation of participants was concealed; they were divided into three groups using block randomisation with a manual schedule. For every six participants recruited, two were assigned randomly to each group. One group received low level laser therapy alone, one group received laser therapy and exercise, and the third group received placebo laser therapy and exercise. Patients received laser therapy or placebo laser therapy on Saturday and Wednesday for 12 sessions (ie, twice a week for 6 weeks). Both therapist and participant wore protective goggles for safety and to preserve blinding of the therapist and the participants to whether the laser therapy was real or placebo. However, the participants who received laser therapy alone were not blinded. All outcomes were measured on admission to the trial, at Week 6 (after the last session of intervention) and at Week 12 by physicians blinded to group allocation. The protocol was reviewed and approved by the Medical Ethics Board in Tehran University of Medical Sciences.

Participants

Participants were recruited from patients referred by local physicians to the clinic of an Occupational Medicine Department. They were included if they were aged between 20 and 60 years, had low back pain for a minimum of 12 weeks and possessed the ability to give informed consent, understand instructions, and co-operate with treatment. Patients with degenerative disc disease, disc herniation, fracture, spondylosis, and spinal stenosis, neurological deficits, abnormal laboratory findings, systemic or psychiatric illness, and pregnancy were excluded.

Intervention

The first exercise session was conducted by a physiotherapist and thereafter the exercises were continued at home. The exercise program was easily carried out at home without requiring special equipment or access to a gym or fitness facility. Exercises included strengthening, stretching, mobilising, co-ordination, and stabilising of the abdominal, back, pelvic, and lower limb muscles, dependent on the clinical findings (Sahrmann 2001). Participants were taught to do exercises correctly by the physiotherapist. A family member confirmed that the participant carried out the exercises.

Laser irradiation was performed with a Gallium-Aluminum-Arsenide (GaAlAs) λ=810 nm, 50 mW, continuous wave, and 0.2211 cm^2 spot area laser. The power output was calibrated with a thermopile power metre. 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 (Gur et al 2003). In the laser therapy groups, participants were irradiated with the probe emitting a dose of 27 J/cm^2 while the placebo laser therapy group was irradiated with inactive probes. It took approximately 20 minutes to cover the area for each participant.

Outcome measures

Outcomes were pain, lumbar range of motion, and disability. Pain was measured as average low back pain over the past few days using a 10-cm visual analogue scale. The visual analogue scale has been shown to be a reliable and valid measure of pain and consists of a standard 10-cm line with verbal anchors indicating 'no pain' at 0 cm and 'severe pain' at 10 cm (Wewers and Lowe 1990). Participants were asked to estimate their pain severity by placing a mark on the line with severe pain being the worst imaginable pain.

Lumbar range of motion was measured by the same investigator. For the Schober Test, marks were made on the skin 5 cm above and below the L5–S1 junction as the participants stood in a neutral position. Participants then bent forward maximally and the increase in distance between these marks was measured. The maximum active flexion, extension, and right and left lateral flexion was measured with a goniometer.

Disability was measured using the 10-item Oswestry disability questionnaire. Each item is scaled from 0 to 5,

Table 2. Mean (SD) of each group, mean (SD) difference within groups, and mean (95% CI) difference between groups for pain, lumbar range of motion and disability.

Outcome	Groups									Difference within groups						Difference between groups			
	Week 0			Week 6			Week 12			Week 6 minus Week 0			Week 12 minus Week 0			Week 6 minus Week 0		Week 12 minus Week 0	
	LLLT	LLLT +Ex	PI-LLLT +Ex	LLLT	LLLT +Ex	PI-LLLT +Ex	LLLT	LLLT +Ex	PI-LLLT +Ex	LLLT	LLLT + Ex	PI-LLLT + Ex	LLLT	LLLT + Ex	PI-LLLT + Ex	LLLT minus PI-LLLT +Ex	LLLT+Ex minus PI-LLLT +Ex	LLLT minus PI-LLLT +Ex	LLLT +Ex minus PI-LLLT +Ex
Pain severity VAS *(cm)*	7.3 (1.7)	6.2 (1.6)	6.3 (2.0)	6.0 (1.6)	4.6 (1.7)	5.3 (2.1)	4.4 (2.0)	2.4 (1.4)	4.3 (1.6)	–1.3 (2.1)	–1.6 (1.4)	–1.0 (1.3)	–2.9 (2.3)	–3.8 (1.7)	–2.0 (1.7)	–0.3 (–1.1 to 1.7)	–0.6 (–1.9 to 0.7)	–0.9 (–2.5 to 0.7)	–1.8 (–3.3 to–0.1)
Lumbar ROM																			
Schober test *(cm)*	3.9 (0.7)	3.4 (0.9)	3.8 (0.7)	4.9 (1.2)	4.6 (1.1)	4.5 (0.9)	5.5 (1.2)	5.2 (1.0)	4.7 (0.9)	1.0 (0.8)	1.2 (1.1)	0.7 (0.9)	1.6 (0.9)	1.8 (1.0)	0.9 (0.9)	0.3 (–0.5 to 1.1)	0.5 (–0.3 to 1.3)	0.7 (0 to 1.6)	0.9 (0.2 to 1.8)
Flexion *(deg)*	73 (17)	60 (21)	71 (17)	76 (17)	72 (23)	78 (15)	83 (14)	81 (14)	78 (16)	3 (4)	12 (21)	6 (11)	10 (8)	21 (16)	6 (11)	–4 (–16 to 9)	6 (–6 to 17)	4 (–6 to 15)	15 (5 to 25)
Extension *(deg)*	31 (7)	24 (8)	29 (11)	30 (12)	27 (7)	34 (10)	40 (9)	34 (6)	34 (9)	–1 (10)	2 (10)	5 (8)	9 (5)	10 (9)	5 (8)	–6 (–14 to 2)	–3 (–10 to 5)	4 (–2 to 11)	5.0 (–1 to 11)
R lat flexion *(deg)*	34 (10)	29 (9)	31 (9)	41 (7)	34 (8)	36 (11)	43 (15)	38 (8)	34 (10)	7 (7)	5 (8)	5 (10)	8 (14)	9 (9)	3 (7)	1 (–6 to 8)	0 (–7 to 7)	5 (–3 to 14)	6 (–2 to 14)
L lat flexion *(deg)*	30 (8)	27 (9)	30 (10)	39 (9)	34 (10)	36 (10)	42 (15)	40 (9)	37 (10)	9 (6)	6 (9)	6 (7)	12 (10)	12 (8)	7 (8)	3 (–3 to 10)	1 (–5 to 6)	4 (–3 to 12)	5 (–2 to 12)
Disability																			
ODI *(0 to 50)*	33.0 (8.4)	34.0 (9.7)	31.8 (7.9)	28.8 (6.4)	25.7 (7.4)	27.5 (6.7)	20.8 (4.4)	16.8 (3.7)	24.1 (5.2)	–4.2 (4.5)	–8.3 (8.2)	–4.3 (6.5)	–12.2 (7.3)	–17.2 (9.5)	–7.7 (7.3)	0.08 (–5.6 to 5.8)	–3.9 (–9.4 to 1.5)	–4.4 (–11.4 to 2.5)	–9.4 (–16.0 to–2.7)

LLLT = low level laser therapy, LLLT+Ex = low level laser therapy plus exercise, PI-LLLT+Ex = placebo low level laser therapy plus exercise, VAS = visual analogue scale, ROM = range of motion, ODI = Oswestry Disability Index

with higher values representing greater disability (Fairbank et al 1980).

Data analysis

For categorical data, χ^2 tests were used. For continuous variables, one way ANOVA and Tukey's Post Hoc Test were used. Analyses were performed on an intention-to-treat basis and for those participants who were lost to follow-up, missing data were carried forward from Week 0 data. The level of statistical significance was set at a two-tailed p value of 0.05.

Results

Flow of participants through trial

Of 84 referrals, 23 patients did not meet the entry criteria and 61 patients were randomised into one of the three groups (Figure 1). Eight participants withdrew from the trial during the intervention or follow-up period. There was no statistically significant difference between the three groups with respect to demographic data such as age, gender, body mass index, duration of low back pain, educational level, and smoking (Table 1).

Effect of intervention

Group data for the two measurement occasions as well as within- and between-group data are presented in Table 2, while individual data for the two measurement occasions are presented in Table 3 (see eAddenda for Table 3). There was no between-group difference for any outcome measure immediately after the 6-week intervention. There was also no difference for any outcome measure between the low level laser therapy group and the placebo laser therapy plus exercise group after a further six weeks of no intervention. However, in the low level laser therapy plus exercise group pain had reduced by 1.8 cm (95% CI 0.1 to 3.3, $p = 0.03$), lumbar range of movement increased by 0.9 cm (95% CI 0.2 to 1.8, $p < 0.01$) on the Schober Test and by 15 deg (95% CI 5 to 25, $p < 0.01$) of active flexion, and disability reduced by 9.4 points (95% CI 2.7 to 16.0, $p = 0.03$) on the Oswestry Disability Index more than in the placebo laser therapy plus exercise group after another six weeks of no intervention. None of the participants reported any adverse reaction or side effects.

Discussion

This study showed that low level laser therapy plus exercise could decrease pain, increase lumbar flexion, and reduce disability more than exercise alone in the long-term. According to two recently-published summaries of research focusing on treatment of chronic low back pain, it seems that exercise therapy and multidisciplinary treatment regimens (such as back school and functional restoration) can be considered beneficial (Grabois 2005, Hayden et al 2005). The most effective plan seems to be individually designed exercise programs delivered in a supervised format (eg, home exercises with regular therapist follow-up) with adherence encouraged to achieve a high dosage. However, it seems that exercise is not enough to treat chronic low back pain and it is necessary to combine other modalities to obtain the best results.

Adjunct therapies include spinal manipulation, massage, hypnosis, magnet therapy, acupuncture, transcutaneous electrical nerve stimulation, and low level laser therapy. The rationale for the use of laser therapy as an adjuvant treatment for chronic low back pain stems from its beneficial effects on the pain reduction and inflammation process without any significant complication. Unfortunately, previous studies on laser therapy for these conditions are of poor quality. Adequacy of randomisation methods, the comparability of groups at baseline and follow-up sessions, use of complete suitable primary endpoint, adjustment for confounders, and laser irradiation parameters (such as power density, energy density) should be specified in designing these studies and was done so in the present study.

There are some randomised trials of low level laser therapy and chronic low back pain (Klein and Eek 1990, Basford et al 1999, Djavid et al 2003, Gur et al 2003). Basford et al (1999) reported that treatment with low intensity irradiation of Nd:YAG laser resulted in a moderate reduction in pain and improvement in function in patients with non radiating low back pain of more than 30 days' duration (Basford et al 1999). Although their results showed a beneficial effect of laser therapy in reducing pain and disability, they concluded that this effect was limited and decreased with time. In the present study, patients received 12 sessions (two per week) of laser therapy over six weeks, whereas Basford et al performed 12 sessions of laser therapy over four weeks (three per week). Therefore, it seems that one possible mechanism of prolonged effect of laser therapy in chronic conditions is related to using laser less often over a longer period. Furthermore, it seems that to achieve the best results in treatment of chronic low back pain, a combination of interventions are necessary. In a randomised clinical trial, Gur et al (2003) showed that pain decreased significantly after laser therapy plus exercise compared with exercise alone. Our study has shown that low level laser therapy plus exercise achieves better results than exercise alone in reducing pain and disability due to chronic low back pain.

The combination of low level laser therapy and exercise is controversial. Basford et al (1999) showed that laser therapy decreases pain and reduces disability in patients with low back pain. However, they stated that laser therapy does not have a long-term effect. In the present study, we found a benefit of laser therapy six weeks after its cessation. Gur et al (2003) propose that laser therapy does not have any advantage over exercise in the short-term, although they emphasise the importance of active exercise programs in the rehabilitation of chronic low back pain. We suggest that exercise therapy should be combined with laser therapy in the rehabilitation of patients with chronic low back pain.

This clinical trial has some limitations. First we could not find a suitable placebo intervention for exercise. Second, our sample size was too small to detect differences between groups for some outcomes. Therefore low level laser therapy should be investigated in trials with larger sample sizes and longer follow-up periods. Biologic and simulation studies to obtain the most appropriate energy density and wavelength and cellular responses of target tissue are also recommended.

In conclusion, low level laser therapy seemed to be an effective method of decreasing pain and reducing disability in chronic low back pain in combination with exercise compared with exercise alone. We emphasise that laser therapy is an adjuvant intervention and it should be applied with appropriate exercises.

eAddenda: Table 3 available at www.physiotherapy.asn.au

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