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Low-dose laser acupuncture for non-specific chronic low back pain: a double-blind randomised controlled trial

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ABSTRACT

Objective To determine if infrared laser acupuncture (LA) may have a specific effect in reducing pain and disability in treatment of chronic low back pain (LBP).

Methods This was a double-blind sham laser controlled trial performed in general practices in Perth, Western Australia. The participants were 144 adults with chronic non-specific LBP. They were randomised to receive eight once-weekly treatments. Laser machines (20 mW, 840 nm diode, power density 0.1 W/cm²) stimulated points in three treatment groups: sham (0 joules/point), low dose (0.2 J/point) and high dose (0.8 joules/point). Participants were followed-up at 1 and 6 weeks, and 6 and 12 months post treatment. Primary outcomes were pain (Numerical Pain Rating Scale (NPRS)) and disability (Oswestry Disability Inventory (ODI)) at 6 weeks post treatment. Secondary outcomes included numerical rating scale for limitation of activity, global assessment of improvement, analgesic usage and adverse effects after treatment.

Results The analysis showed no difference between sham and the laser groups at 6 weeks for pain or disability. There was a significant reduction in mean pain and disability in all groups at 6 weeks ($p < 0.005$); NPRS: sham (−1.5 (95% CI −2.1 to −0.8)), low dose (−1.3 (−2.0 to −0.8)), high dose (−1.1 (−1.7 to −0.5)). ODI: sham (−4.0 (−7.1 to −1.0)), low dose (−4.1, (−6.7 to −1.5)), high dose (−2.6 (−5.7 to 0.5)). All secondary outcomes also showed clinical improvement over time but with no differences between groups.

Conclusions LA using energy density range (0–4 J/cm²) for the treatment of chronic non-specific LBP resulted in clinical improvement unrelated to laser stimulation.

Trial registration <http://www.anzctr.org.au> ACTRN1261000043033.

INTRODUCTION

Low-level laser therapy (LLLT) is a light source treatment that emits no heat, sound, or vibration but may act via non-thermal or photochemical reactions in cells.^{1–2} There has been criticism that the effect of laser therapy in painful conditions is only a placebo effect³ especially as there is still lack of an obvious mechanism—particularly given lack of sensation during laser treatment. Despite this, there is some experimental evidence of low-level laser inducing anti-inflammatory, antinociceptive, central nervous and lymphatic effects.^{4–12}

Low-level laser stimulation of acupuncture points (LA), using laser emitter devices applied to skin as an alternative to needles, has been commonly used in the last 35 years. Although LA is a subgroup of LLLT, it is considered a separate form of treatment. Instead of using the direct effect of light on tissues to initiate a physiological response, the selection of points is based on a diagnostic and therapeutic paradigm defined by acupuncture theories.^{13–14} Laser machines in the lower power output range are commonly used and anecdotally beneficial results have been reported.

Non-specific chronic low back pain (LBP) was targeted for study as it is common (prevalence of approximately 23%)¹⁵ and associated with significant disability, medical expenses and loss of productivity. It is also commonly treated with acupuncture. Evidence of efficacy for a non-drug, non-invasive treatment that could be used in primary care for this condition would be of great importance.

A position statement on LA by the Australian Medical Acupuncture College

(AMAC) in 1995 stated that 'the optimal energy density for biostimulation, based on current clinical experience, is 4 J/cm²'.¹⁶ A review¹⁷ examining trials of LA in a range of orthopaedic diseases was equivocal, but noted methodological drawbacks in the studies included. In another review¹⁸ of the clinical effectiveness of LA, including eight trials on treatment of myofascial pain, Baxter concluded that 'laser acupuncture can be recommended as an effective treatment (moderate level of evidence) for the reduction of myofascial pain, at least when irradiation is applied at power of at least 10 mW and a dosage of at least 0.5 J/point'.

Few randomised trials have specifically studied LA for treatment of chronic LBP compared to a sham laser control, and have not resolved issues of dose dependence for this condition. A small trial using an infrared laser (1.1 J/point)¹⁹ detected a significant improvement in only one of many pain outcomes measured. Subsequently, the results of another larger trial²⁰ using a 10 mW infrared laser (0.2 J/point) were negative, although questions were raised regarding the possibility of insufficient dosage²¹ and of confounding baseline factors.²² An adjusted analysis showed a benefit for this dose at 6 weeks. It was considered important to perform another quality study resolving these issues with a three-arm design, including a higher dose within Baxter's recommended range and with long-term follow-up.

SUBJECTS AND METHODS

The study was a double-blind, prospective, three-group parallel randomised controlled trial, using sham laser in the control group with other arms using 0.2 and 0.8 J of laser stimulation per point. It was approved by the University of Western Australia Human Research Ethics Committee.

Patient recruitment and selection

Participants were recruited through notices in local community newspapers. Assessment and treatments were conducted at the premises of six general practices in Perth, Western Australia by five general practitioner (GP) therapists.

Inclusion criteria

Participants had chronic non-specific LBP¹⁵ with duration of at least 3 months, and were aged 18–75 years, English literate and non-pregnant. Baseline pain over the previous week was ≥ 3.0 on a numerical rating scale, with maximal pain located between the 12th rib and gluteal fold.

Exclusion criteria

Patients were excluded if they had: (i) fibromyalgia,²³ (ii) regular opioid analgesics (≥ 2 times a week) or opioid patches, (iii) disability support pension for back pain, current worker compensation or motor vehicle insurance claim, (iv) any form of acupuncture

for musculoskeletal problems in previous 6 months, (v) previous involvement in an acupuncture trial, (vi) previous injections for back pain such as facet joint blocks, nerve root or epidural steroid injection within previous year or (vii) previous lumbar spine surgery.

Intervention

All therapists were experienced GPs and members of AMAC; at commencement they received training and a written manual on the trial protocol. Participants were encouraged to attend a maximum of eight sessions (one session a week for 8 weeks) of 15 min duration each. They continued with their usual therapies and analgesics according to their pain, but were requested not to start any acupuncture during the year of follow-up.

A pragmatic Western anatomical approach to acupuncture treatment was used, similar to the previous trial.²⁰ At the start of each session participants were asked to note their average pain experienced during the previous week and indicate current distribution, and report any symptoms since the last treatment. Acupuncture point selection was individualised for each patient. Tender regional and more distal points along radiation pathways of pain were selected. Other acupuncture points depending on additional symptoms reported (eg, headache, other joint pain and psychological issues) were selected at the discretion of the therapist. The points were treated sequentially, with the laser probe resting perpendicularly and in light contact with the skin. No cointervention was used except for general support and information provided as part of each session (see online supplement 1).

Outcome measures

The following measures were applied 1 and 6 weeks, and 6 and 12 months post treatment (immediate, short, intermediate and long-term follow-up).

1. Numerical pain rating scale (NPRS)²⁴ on a box scale from 0–10 describing 'usual level of pain in the last week'.
2. Oswestry Disability Index (ODI).²⁵ This was omitted at 12 months to reduce measurement burden.
3. Numerical rating scale of limitation of activities (NLARS) on a box scale from 0–10 describing 'ability to perform usual activities in the last week'.
4. Global assessment of treatment question on a seven-point Likert scale describing 'how overall the back problem had changed compared to before starting the treatment programme'.
5. Frequency of analgesics taken in previous month.
6. Use of analgesics relative to before starting treatment (decreased, unchanged or increased).

The primary outcomes were (i) pain (NPRS) and (ii) disability (ODI) at 6 weeks.

Adverse effects in the week after each treatment were recorded using a checklist including occurrence of pain flares and other symptoms.

The following measures were recorded only at baseline as predictors of outcome: the short version of the Depression Anxiety Stress Scale (DASS-21),²⁶ a neuropathic pain screening questionnaire (ID pain),²⁷ the Fitzpatrick skin type assessment²⁸ and the International Physical Activity Questionnaire (IPAQ, short format).²⁹

Randomisation/allocation concealment/blinding

As in our previous trial,²⁰ we used laser apparatus modified for use in double-blind research.³⁰ The device was a Ga-Al-As infrared laser diode (830 nm) with power output of 20 mW and power density at probe skin interface of 0.1 W/cm². Three machines were purpose built for the trial (Acupak, Melbourne, Australia) for concurrent use in a number of centres. Each machine had a different on/off coding sequence set by operating a cogwheel dial hardwired at time of manufacture. The laser probe had a red LED decoy light that was lit each time the unit was used regardless of laser operation. The device had a fixed power output; in order to vary dose there was a switch enabling time of operation to be set.

The three treatment arms varied according to laser on/off status and the duration of stimulation and consisted of:

1. Low dose: laser 'on' with 10 s (0.2 J) stimulation given per point.
2. High dose: laser 'on' with 40 s (0.8 J) stimulation given per point.
3. Sham: laser 'off' with 10 or 40 s (0 J) stimulation given per point.

Before commencement of the trial, a random computer-generated sequence was generated for each machine (permuted block randomisation technique, block size=6; each block contained 2× laser 40 s, 2× laser 10 s, 1× placebo 10 s, 1× placebo 40 s). Concealed allocation was performed by method of sequentially numbered sealed opaque envelopes.

The participants, therapists and data entry person remained blind to treatment allocation. At commencement of the trial participants were informed that they had a two in three chance of receiving an active laser treatment. They were unaware that duration of point stimulation would vary between different subjects.

Sample size

Based on data from previous trial,²⁰ for a three-arm parallel study (with SD=2.3 on the numerical pain scale) with $\alpha=0.05$ and $\beta=0.8$, to detect a difference of 1.6 units (moderate effect size) would require a total sample size of 137 allowing for 10% attrition.

Statistical analysis

We used SPSS (V.20) for analyses. Data were checked to ensure they satisfied assumptions for statistical testing and were analysed according to intention to treat. Separate analyses were performed on continuous dependent variables (NPRS, ODI and NLARS) for (a)

all non-missing values and (b) the 'last observed value carried over' method for missing data. Repeated measures analysis of variance (ANOVA) was used to compare treatment groups across time periods for these continuous variables. The χ^2 test for independence was used to compare differences between treatment groups at follow-up times for categorical variables (general anaesthetic and relative analgesic and frequency of use). The Kruskal–Wallis test was used to test the comparability of treatment and follow-up protocols, as well as differences in the counts of adverse effects between groups during the treatment phase.

Methods for subgroup and adjusted analysis

Baseline characteristics were examined to determine if they predicted pain reduction after treatment, specifically, percentage pain change (PPC) from baseline to follow-up. Analysis of covariance (ANCOVA) was used in an adjusted analysis to evaluate PPC at immediate and short-term follow-up across the treatment groups while controlling for the effects of predictive baseline variables.

RESULTS

Participant recruitment and flow

Recruitment, treatment and completion follow-up was conducted from October 2008 to March 2012 (figure 1). After screening for eligibility 144 participants were enrolled and randomised to receive the interventions. A total of 74% of the treatment sessions were performed by the principal investigator (GG). In all, 96% of participants completed five or more treatment sessions. Reasons for participants pulling out of treatment early included unavailability, unwillingness to participate and unrelated illness. One subject pulled out due to an exacerbation of pain. There was an overall 96.5% analysis rate for the primary outcome assessment for pain. Follow-up rate achieved for the whole group was 90% at 12 months. The reasons for participants who were lost to follow-up could not be obtained.

Details of acupuncture points used

Frequently used points³¹ were situated on acupuncture lines which traversed the low back area in the midline (Governing Vessel meridian), paramedially (Bladder meridian) and laterally (Gall Bladder meridian) comprising 13%, 37% and 13%, respectively of all points used. Points on other meridians, *ah shi* points (unclassified tender points) and Extraordinary points comprised 16%, 14% and 7% of total (see online supplement 2).

Number of points used and laser machine calibration

An average of about nine points were used per session, however the total number of points used by therapists varied between the three treatment arms, with larger numbers used in participants allocated shorter stimulation times of 10 s (table 1).

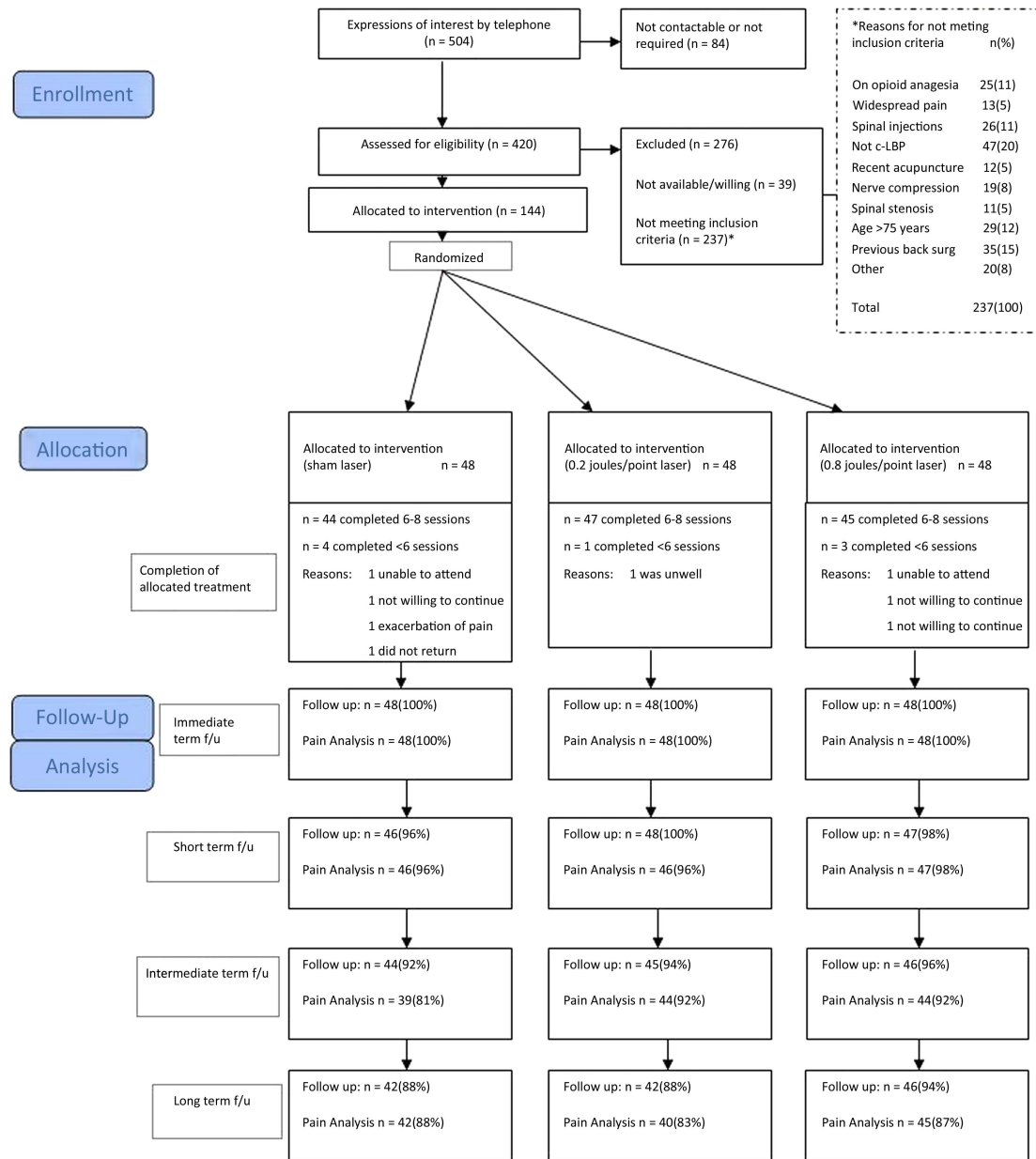


Figure 1 Consolidated Standards of Reporting Trials (CONSORT) flow diagram: laser acupuncture in chronic non-specific low back pain (LBP) for analysis of pain outcomes (NPRS) and loss to follow-up.

Table 1 Number of acupuncture points administered and total energy dose of laser given per treatment group

Trial arm	Dose per point, J	Total no points treated (% total)	Total estimated dose in J per group
Sham (10 s or 40 s)	0.0	3008 (32.0)	0
Low dose (10 s)	0.2	3830 (40.5)	766
High dose (40 s)	0.8	2622 (27.7)	2098

Calibration and validity of settings were checked at the end of the treatment phase. Maximal power outputs of the machines were measured at 22.7, 14.4 and 17.7 mW, respectively. This may have been the result of reduction of power output over time in ageing diodes.³²

Baseline data of demographics and clinical characteristics

Baseline characteristics across groups were generally evenly distributed, however total imbalance greater than 15% was seen in gender, sleep disturbance, antidepressant medication use, Fitzpatrick skin type and depression categories (table 2).

Comparison of adherence to treatment and follow-up schedules between study groups

There were no significant differences between treatment groups in the number of treatments given, duration of treatment and intervals of follow-up.

Comparison of primary outcomes and other continuous outcome measures in the study groups

Mean values for pain and disability in the three treatment groups at baseline and at all follow-up times are presented in table 3. There was no significant difference between groups for pain or disability (ODI) scores at 6 weeks or any other timepoint. All three treatment groups showed reduction in pain and ODI scores across all timepoints ($p < 0.0005$). In the whole cohort there was a clinically significant 28% reduction in pain immediately after treatment, maintained at 26% at 1 year. There was only an approximate 4% reduction in mean ODI scores in the whole cohort, which was maintained at 6 months. There were no differences between groups for NLARS scores at any timepoint but again a significant main effect for time ($p < 0.0005$) (online supplement figure S2). Results were consistent for all continuous outcomes using both imputation methods.

Additional secondary outcomes

There was no significant difference between groups in improvement on the global assessment scale, or in measures of analgesic use (table 4). Across the whole cohort approximately half of the participants

considered that their back had improved at every timepoint after treatment, and approximately one-third considered they had reduced their analgesic use at all follow-up points. There was little change in reported frequency of taking analgesics during the trial.

In the whole cohort there was a flare-up of back pain in the week following 28% of treatments and some other adverse effect after 25% of treatments. However, there was no significant difference in the frequency of flare of pain or other adverse effects between treatment groups.

Adjusted analysis

After adjusting for any imbalance of predictive baseline factors, there was no significant difference between treatment groups on PPC at 1-week and 6-week follow-up. Details of the subgroup analysis will be presented subsequently.

DISCUSSION

This is the largest and most robust RCT of LA for chronic LBP ever conducted. It found no difference in any outcome or adverse effects at any timepoint for

Table 2 Distribution of baseline characteristics across treatment groups

Parameter	Treatment groups		
	Sham (n=48)	Low dose (n=48)	High dose (n=48)
Demographics:			
Male gender, %	60	44	46
Smoking, %	12	15	19
Employed, %	55	50	54
On age or other pension, %	33	46	46
Median age in years (25th/75th percentiles)	53.5 (40/66)	56.5 (47/67)	57.0 (41/62)
Body mass index, mean (SD)	26.2 (3.7)	29.5 (5.3)	27.3 (4.3)
Baseline pain characteristics:			
Participants with pain >2 years, %	81	81	81
Median duration of pain in years	10	10	9
Acute on chronic exacerbation pain, %	13	20	13
Headaches present, %	27	27	29
Neck pain present, %	60	52	62
Sleep disturbance (<6 h sleep), %	38	15	23
Previous and current treatment:			
Previous acupuncture >6 months ago, %	40	54	44
Regular use of simple analgesia, %	17	19	31
Use of antidepressant medication, %	10	23	6
Other baseline outcome measures:			
Fitzpatrick skin type (I–II), %	28	43	31
Neuropathic pain (ID Pain 2–4), %	19	25	23
Low level physical activity (IPAQ), %	23	36	28
Depression: moderate–severe+ (DASS-21), %	13	30	12
Anxiety: moderate–severe+ (DASS-21), %	15	21	10
Stress: moderate–severe+ (DASS-21), %	19	19	8

DASS-21, Depression Anxiety Stress Scale (short form); IPAQ, International Physical Activity Questionnaire.

Table 3 Mean values for pain and disability at baseline and follow-up across treatment groups ('no missing data' dataset)

Trial arm	Data shown	Follow-up				
		Baseline	1 week	6 weeks	6 months	1 year
Pain (NPRS):						
Sham	Mean (N, SD)	4.9 (48, 1.4)	3.8 (48, 2.3)	3.4 (46, 2.1)	4.0 (39, 2.7)	3.7 (42, 2.2)
Low dose	Mean (N, SD)	4.9 (48, 1.5)	3.2 (48, 1.7)	3.7 (46, 2.2)	3.7 (44, 2.3)	3.5 (40, 2.3)
High dose	Mean (N, SD)	5.3 (48, 1.6)	3.7 (48, 1.9)	4.1 (47, 2.4)	4.4 (44, 2.4)	3.9 (45, 2.0)
Total	Mean (N, SD)	5.0 (144, 1.5)	3.6 (144, 2.0)	3.7 (139, 2.2)	4.0 (127, 2.4)	3.7 (127, 2.2)
	Change from baseline, %	0	-28	-26	-20	-26
Disability (ODI):						
Sham	Mean (N, SD)	26 (47, 12)	22 (40, 12)	22 (45, 13)	22 (40, 13)	-
Low dose	Mean (N, SD)	27 (48, 12)	23 (45, 12)	23 (46, 13)	24 (45, 15)	-
High dose	Mean (N, SD)	27 (47, 12)	22 (43, 11)	24 (45, 15)	23 (43, 13)	-
Total	Mean (N, SD)	27 (142, 12)	22 (128, 11)	23 (136, 14)	23 (128, 14)	-
	Change from baseline	0	-4.4	-4.0	-3.7	
Disability (NLARS):						
Sham	Mean (N, SD)	4.3 (48, 2.1)	3.2 (40, 2.2)	2.7 (45, 1.9)	3.3 (39, 2.4)	3.4 (42, 2.6)
Low dose	Mean (N, SD)	4.5 (48, 1.7)	2.4 (44, 1.8)	3.0 (46, 2.2)	3.2 (45, 2.6)	2.6 (40, 1.9)
High dose	Mean (N, SD)	4.2 (48, 2.1)	2.1 (43, 2.0)	3.0 (47, 2.3)	3.4 (44, 2.7)	3.0 (45, 2.4)
Total	Mean (N, SD)	4.3 (144, 2.0)	2.6 (127, 2.0)	2.9 (138, 2.1)	3.3 (128, 2.6)	3.0 (127, 2.3)
	Change from baseline, %	0	-40	-33	-23	-30

NLARS, Numerical rating scale of limitation of activities; NPRS, Numerical pain rating scale; ODI, Oswestry Disability Index.

LA in doses up to 0.8 J/point (energy density 1–4 J/cm²) when compared with sham laser.

This trial strengthens the evidence for a lack of biological effect from laser at this low-dose range when treating chronic LBP. It also supports the influence of non-specific effects that may produce beneficial therapeutic outcomes in some patients, which otherwise may have been falsely attributed to the laser. A 30% PPC has previously been described as a clinically meaningful improvement.³³ In our whole cohort such non-specific effects resulted in a clinically important improvement approached in mean pain scores immediately following the last treatment, which persisted almost at the same level throughout follow-up. There

was a smaller reduction in disability that was probably not clinically important.

A number of factors may have contributed to overall improvement after the intervention, including the placebo effect, the phenomenon of regression to the mean, natural history and effects simply from participating in an experiment (the Hawthorne effect). Some improvement may possibly have resulted from the acupressure-like effects of skin stimulation during examination for tender points.³⁴

In the past LA trials have shown methodological limitations including small sample size, variable blinding and crossover designs. We applied a robust trial design to reduce risk of bias including gold standard

Table 4 Secondary outcome contingency tables (global assessment and analgesic use) for treatment groups across follow-up

Usage	Timescale				
	Baseline	1 week	6 weeks	6 months	12 months
Condition on global assessment, %	Global assessment across follow-up: total (sham, low dose, high dose)				
No change/worse	-	36 (40, 36, 32)	50 (47, 52, 52)	55 (59, 53, 52)	53 (52, 50, 56)
Improved	-	64 (60, 64, 68)	50 (53, 48, 48)	45 (41, 47, 47)	47 (48, 50, 44)
Relative use of analgesics, %	Relative use analgesics across follow-up: total (sham, low dose, high dose)				
Unchanged or increased	-	63 (72, 56, 61)	73 (79, 67, 73)	69 (68, 68, 71)	65 (66, 64, 66)
Decreased	-	37 (28, 44, 39)	27 (21, 33, 27)	31 (32, 32, 29)	35 (34, 36, 34)
Frequency of use, %	Frequency analgesic use across follow-up: total (sham, low dose, high dose)				
Nil-≤1/month	34 (30, 37, 35)	46 (41, 49, 47)	39 (47, 37, 35)	39 (45, 42, 30)	35 (38, 30, 37)
Several/month-once a week	33 (38, 30, 32)	31 (41, 30, 25)	27 (27, 30, 24)	20 (23, 18, 19)	29 (31, 38, 20)
Several/week-daily	33 (32, 33, 33)	23 (19, 22, 28)	34 (27, 33, 41)	41 (32, 40, 51)	36 (31, 32, 43)

randomisation and concealed allocation procedures for this type of research. Participants and therapists were successfully blinded to treatment allocation by using a specially designed device³⁰ ensuring masking the mode of laser emission. Although the duration of laser application to points was not masked, participants remained unaware of this treatment variable and were thus effectively 'blinded'. Therapists who were aware, tended to stimulate larger numbers of points in subjects allocated the shorter-dose treatment. The total laser dose given in the low-dose arm was still one-third of the high-dose arm (table 1), allowing a meaningful investigation of dose dependence. Imputation approaches to manage missing data made no difference to the results. A preplanned, adjusted analysis showed that any baseline imbalance did not affect the primary result in the current trial.

This study had multiple exclusion criteria that may have reduced the external validity of this trial. This was informed by preceding research²⁰ excluding patients on disability support, regular users of any opioid and with previous back surgery or spinal injections. These groups previously demonstrated less improvement after intervention. Our intent was to maximise the chance of detecting a specific effect of laser stimulation, if it existed. A greater improvement in pain or disability was not observed in this trial, however. The reasons for this may have been an exercise cointervention, a larger number of treatment sessions and a higher mean baseline level of pain in the preceding study.

A large number of laser parameters available in treatment may make comparison between trials difficult to interpret. Different laser devices have different radiant power outputs and wavelengths ranging from the visible spectrum to infrared. Dose in joules per point and density of laser irradiation can also vary. Although this study examined the effect of infrared laser diodes using low energy densities for treating this condition, it is still possible that larger energy doses or different wavelengths may be more effective for chronic LBP. A much higher laser dose (8 J Joules \pm 50%/point) for laser therapy of the lumbar spine is recommended by the World Association for Laser Therapy,³⁵ however these recommendations refer to non-acupuncture LLLT. A recent German LA trial of a much higher energy 'laser needle' device failed to show a specific effect of laser treatment.³⁶ Future research also needs to consider LA treatment of other musculoskeletal problems.

This trial only partly clarifies decisions for therapists contemplating purchasing expensive laser pointer machines in the lower energy range to treat back pain. While there appear to be considerable improvements in pain and other measures following treatment using such devices, this trial suggests that the effect is not specifically due to laser at the low dosage commonly used in clinical practice. Scope however remains for

further research to determine dosage windows and conditions that could respond to LA.

Summary points

- ▶ A total of 144 patients with low back pain received either 0.2 or 0.8 J/point infrared laser acupuncture or placebo control.
- ▶ All outcomes improved up to 1 year, with no differences between groups.
- ▶ This low dose of laser has no biological effect, but higher doses should also be tested.

Correction notice This article has been corrected since it was published Online First. The abstract results section has been amended to read: 'at 6 weeks ($p < 0.005$); NPRS: sham (-1.5 (95% CI -2.1 to -0.8))'. The first 'Usage' in Table 4 has been amended to read 'Condition on global assessment, %'. The first Summary point has been amended to read: A total of 144 patients with low back pain received either 0.2 or 0.8 J/point infrared laser acupuncture or placebo control.

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Contributors GG was a PhD candidate and principal investigator, was responsible for the study concept and design and was involved in assessment, the majority of therapy, follow-up, data entry and checking, statistical analysis and drafting the manuscript. JE (Coordinating Supervisor) and MY (External Supervisor) both offered support and advice at all stages of the project, and assisted with revision of the manuscript.

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Provenance and peer review Not commissioned; externally peer reviewed.

Data sharing statement Data sharing: Any further data available on request from the corresponding author at glazog01@student.uwa.edu.au.

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