Lasers Med Sci (2014) 29:671–679
DOI 10.1007/s10103-013-1378-2

ORIGINAL ARTICLE

Short-term therapeutic effects of 890-nanometer light therapy for chronic low back pain: a double-blind randomized placebo-controlled study

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Received: 11 January 2013 / Accepted: 18 June 2013 / Published online: 3 July 2013

Abstract We conducted a double-blind randomized placebo-controlled study to investigate the effects of short-term 890-nm light therapy in patients with chronic low back pain in a rehabilitation clinic. Thirty-eight women and 22 men with chronic low back pain (mean age, 60.3 years; range, 32–80 years) received 40-min sessions of hot-pack therapy combined with active or placebo 890-nm light therapy (wavelength=890 nm, radiant power output=6.24 W, power density=34.7 mW/cm^2 for 40 min, total energy=83.2 J/cm^2) over the lower back three times weekly for 2 weeks. Participants were assessed before and after treatment by using a range of motion measurements, a visual analog scale evaluation of pain, the Multidimensional Fatigue Inventory, the Biodex Stability System, the Fear-Avoidance Beliefs Questionnaire, repeated chair-rising times, the Frenchay Activity Index, the Oswestry Disability Questionnaire (ODQ), and the Osteoarthritis Quality of Life Questionnaire. The severity of disability based on the ODQ score was used as the primary clinical outcome measurement. Compared to the baseline measurements, participants in the treatment group reported significant reductions in fear-avoidance beliefs regarding physical activity (P=0.040) and work (P=0.007) and in the severity of disability (P=0.021). Treatment with hot-pack therapy and 890-nm light therapy was associated with reductions in the severity of disability and fear avoidance beliefs in patients with chronic low back pain.

Keywords Low back pain · Light therapy · Effects · Fear-avoidance · Disability

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Introduction

Low back pain affects 60 to 80 % of adults during their lifetime, and is one of the most prevalent ailments in society [1]. Low back pain causes activity limitations and disability, and imposes a substantial financial burden on patients and health care systems [2], the majority of which stems from patients' disabilities, rather than treatment costs [3]. Although most patients with low back pain recover spontaneously within 1 to 3 months, regardless of the treatment or treatment type, 3 to 10 % develop chronic low back pain [4]. The etiology and underlying pathology of low back pain are often unclear, and may be multifactorial [5]. The psychological, occupational, and social impacts of chronic low back pain increase with the duration or severity of the condition [6].

Low back pain is a multifaceted phenomenon that causes psychological distress, physical impairment, and social limitations [7]. According to the International Classification of Functioning, Disability and Health (ICF), a functional health status consists of dynamic biopsychosocial interactions among the components of body functions and structures, activities, participation, and personal and environmental factors [8]. Therefore, the major goal in the management of low back pain is to enable patients to resume their daily activities and maintain an optimal functional health status [8, 9].

Physical modalities are common treatments for musculoskeletal disorders to ameliorate pain and improve functional performance. Light energy exerts biochemical, bioelectrical, bioenergetic, and biostimulatory effects [10]. Mechanisms by which light therapies have been shown to relieve pain

include increases in microcirculation and nitric oxide synthesis, the enhanced release of endorphins, the modulation of nerve transmissions, and the modulation of key mediators of inflammation, such as inhibitory cyclooxygenase and prostaglandin E2 [11]. Because it promotes tissue healing and produces anti-inflammatory and analgesic effects, light therapy is commonly used to treat musculoskeletal conditions [12–15]. Light therapy has been shown to be an effective treatment for various musculoskeletal disorders, including lateral epicondylitis [16], temporomandibular joint pain [13], carpal tunnel syndrome [17], and delayed onset muscle soreness [12]. The use of 890-nm light therapy was approved by the United States Food and Drug Administration for the treatment of minor muscle and joint pain in 2002 [18]. Previous studies have shown that 890-nm light therapy reduces pain [19] without detrimental systemic cardiovascular effects [20].

However, to date, ICF health status criteria have not been evaluated in investigations of the therapeutic effects of light therapy for chronic low back pain [21–23]. Therefore, we conducted a double-blind randomized placebo-controlled study to examine the short-term therapeutic effects of 890-nm light therapy based on ICF-related outcome measures in patients with chronic low back pain. We hypothesized that short-term hot-pack therapy combined with 890-nm light therapy would improve assessment scores for body structures and functions, activities and participation, and health-related quality of life (QOL) for low back pain patients, compared to treatment with hot-pack therapy only.

Methods

Study design and participants

Our study was approved by the Institutional Review Board for the Protection of Human Subjects at Shin Kong Wu Ho-Su Memorial Hospital (SKWHS) (IRB number: 20121211R). Written informed consent was obtained from each participant. Patients with chronic low back pain were recruited from the clinic of the Department of Physical Medicine and Rehabilitation at SKWHS in Taipei, Taiwan.

The participants were selected based on the following inclusion criteria: (1) nonspecific chronic pain in the posterior torso, below the 12th rib and above the gluteal folds with or without radiating pain or numbness in the lower limb; (2) being 18 to 85 years of age; and (3) symptoms that are persisting for more than 12 weeks. Lumbar radiographic examination with anteroposterior and lateral views was performed for all the participants. Those meeting any of the following criteria were excluded (1) low back pain accompanied by specific pathological conditions, such as an infection, inflammation, rheumatoid arthritis, fracture, or tumor; (2) a self-reported history of malignancy, vertigo, stroke, or other condition that may impair postural stability; (3) a history of low back surgery with an implant; (4) pregnancy or plans to become pregnant during the course of the study; or (5) having received concurrent treatment for low back pain by another health care professional.

Participants were randomly assigned to either the treatment group (active light therapy) or the placebo group (inactive light therapy) by block randomization by using a block size of 4 through a computer-generated random number. Each participant's group assignment was initially concealed. An envelope was opened for each consecutive participant to reveal the participant's group assignment to an investigator at the beginning of the study. The group assignments were not revealed to the participants. The outcome measures were assessed both before and after the 2-week interventions were completed. The investigator who conducted the therapy was not blinded to the allocation of each participant.

Outcome measures

We evaluated participants according to ICF-related variables, such as impairment, limitation of functional performance, restriction of participation, and health-related QOL. The assessments were performed by an investigator who was blinded to the treatment group assignment of the participants.

Body functions and structures

Lumbar active range of motion assessments, including forward flexion, extension, and right and left rotations, were measured in degrees using a Back Range of Motion instrument [24].

A 100-mm visual analog scale (VAS) was used for low back pain assessment. The anchor terms of the VAS were 0 (*no pain*) and 10 (*maximal pain imaginable*). Higher VAS scores indicated greater pain intensity.

The Multidimensional Fatigue Inventory (MFI) was used to assess fatigue [25]. The MFI contains 20 visual 5-point Likert statements that cover different aspects of fatigue, including general fatigue, physical fatigue, reduced activity, reduced motivation, and mental fatigue. A higher MFI score indicates greater fatigue.

The Fear-Avoidance Beliefs Questionnaire (FABQ) was used to measure fear-avoidance beliefs regarding physical activity and work [26]. The FABQ is a 16-item questionnaire with two subscales. The FABQ physical activity subscale contains four items that assess fears, avoidance attitudes, and beliefs regarding general physical activity. The FABQ work subscale contains seven items that assess fears, avoidance attitudes, and beliefs regarding occupational activity. Higher scores for the physical activity (range, 0–24) and work

(range, 0–42) subscale evaluations indicate greater fears, avoidance attitudes, and beliefs. The content of the work subscale was modified to reflect housework performance for unemployed participants.

Postural stability and dynamic balance were assessed using the Biodex Stability System (BSS) [27, 28]. The BSS uses an unstable platform to evaluate postural control. The BSS measures the degree of tilt of a platform on which the participant stands along the anteroposterior and mediolateral axes to obtain an overall stability index. Greater postural variability results in a higher overall stability index, which indicates reduced ability to balance on the platform.

The BSS evaluates dynamic balance through assessments of dynamic limits of stability that are demonstrated as the participant moves a cursor on a monitor screen back and forth from a centered box to peripheral boxes that appear successively in random order. Higher scores for the limits of stability indicate better control of dynamic balance. We used the most stable BSS resistance level (level 8) to measure participants' postural stability and dynamic balance. A bipedal stance was used on the platform, and the test was performed with bare feet and open eyes. The feet positions were recorded for each participant, to ensure an identical stance for both the stability and the dynamic balance evaluations. For each measurement, the participants were allowed one practice attempt, followed by one formal test.

Activities and participation

Chair-rising times were assessed by measuring the time required for participants to rise five times from a seated position in a standard chair to a standing position as quickly as possible, without using their arms for support [29]. Longer chair-rising times represented greater limitations of physical function.

The Frenchay Activities Index (FAI) was used to evaluate extended activities of daily living, such as indoor domestic activities, outdoor domestic activities, and outdoor social activities [30, 31]. The FAI contains 15 items, with overall scores ranging from 0 to 45. Higher overall FAI scores indicate higher activity levels.

The Oswestry Disability Questionnaire (ODQ) was used to evaluate the degree to which low back pain affected the participants' ability to manage daily activities [32]. The ODQ contains ten questionnaires, with overall scores ranging from 0 to 100. Considering that certain cultural differences may be inherent in a questionnaire that was originally developed for a Western population, the severity of the ODQ was classified into five categories in our study, according to a previous study on chronic low back pain conducted on a Taiwanese population [33]. The severity of disability was obtained by separating the total scores into the following five categories: minimal disability (0–11), moderate disability (12–22), severe disability (23–32), crippled (33–43), and bed bound (≥44) [33].

The Osteoarthritis Quality of Life Questionnaire (OA-QOLQ) was used to assess the impact of osteoarthritis (OA) on QOL [34]. The OA-QOLQ consists of a 22-item one-dimensional questionnaire that evaluates a patient's psychological characteristics, including their sense of frustration, fear, loss of independence, the impact of their OA on others, and their level of annoyance regarding living with their disorder. A higher OA-QOLQ score indicates a greater impact of OA on QOL.

Personal factors

Age, sex, education level, marital status, work status, smoking and drinking habits, and comorbidities were recorded for all participants, and their body mass index was calculated.

Interventions

Each participant was positioned supine on a standard bed with clothes removed. A moist heating pad (14×27 in.) was placed under light-emitting pads of the Anodyne Therapy Professional System 480 (Anodyne, Tampa, FL, USA), and were positioned at the lower back (Fig. 1). The light therapy device used eight flexible therapy pads that were held in place with neoprene straps. Each pad consisted of 60 superluminous gallium-aluminum-arsenide diodes (13 mW per diode per 22.5 cm^2 pad) that emitted 890-nm light energy with 780 mW of power (radiant power output=6.24 W, power density=34.7 mW/cm^2 for 40 min, total energy=83.2 J/cm^2). All participants received three 40-min hot-pack treatments weekly for 2 weeks. The light device was used for all the participants, but electrical power was supplied to the Anodyne unit for the treatment group only. Six 40-min sessions of hot-pack therapy were conducted for 2 weeks at the end of the study for the placebo group.

An investigator blinded to the participants' group assignments evaluated the ICF-related variables before and after the 2-week treatment was completed (Fig. 2). Neither the participants receiving the treatment nor the investigator were aware of the operating status of the light-therapy unit during the treatment and data collection periods of the study. Disability severity measured using the ODQ was used as the primary outcome measurement, and fear-avoidance beliefs measured using the FABQ were used as the secondary outcome measurements.

Sample size

We required 22 participants in each arm to detect the mean difference in score between the two groups; the mean scores were 12.2 for the treatment group, and 17.9 for the placebo group [33]. The pooled standard deviation was 6.7 in a

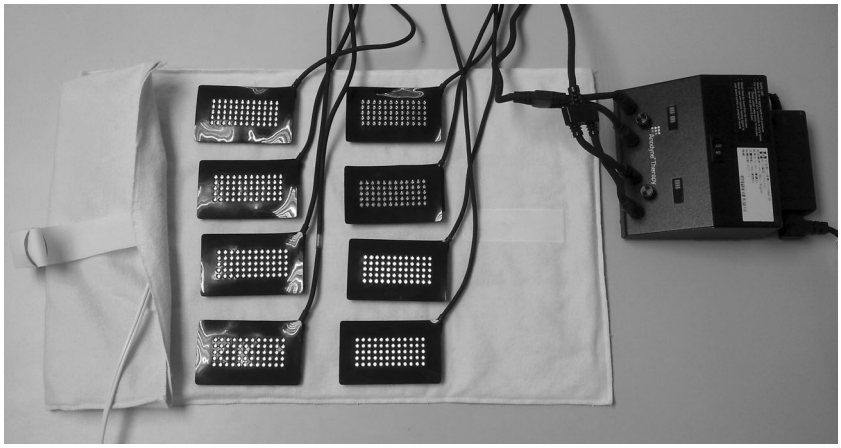

Fig. 1 A moist heating pad was placed under eight flexible light-emitting pads of the Anodyne unit, which was held in place with neoprene straps at the lower back of supine participants

previous study [33], with a significance level of 5 % (two-tailed) and a statistical power of 80 %.

Statistical methods

The results of our evaluations are expressed as the mean ± standard deviation. Chi-squared tests or *t* tests were used to compare the differences in the data between the treatment and placebo groups according to demographic and baseline variables. Paired *t* tests were used to compare the intervention effects based on the primary and secondary outcome measures within and between the study groups. The level of statistical significance was set to $P < 0.05$.

Results

Each group initially comprised 35 participants. However, of the 70 participants selected, 7 declined to participate because of unavailability, and 3 declined for unstated personal reasons before the start of the assessment and intervention. Excluding the declining participants, the treatment group included 33 participants, and the placebo group included 27 participants. Thirty-eight women and 22 men were enrolled, aged from 32 to 80 years, with a mean age of 60.3 years. No statistically significant differences in age, sex, education level, marital status, occupation, comorbidity, smoking and drinking habits, or body mass index

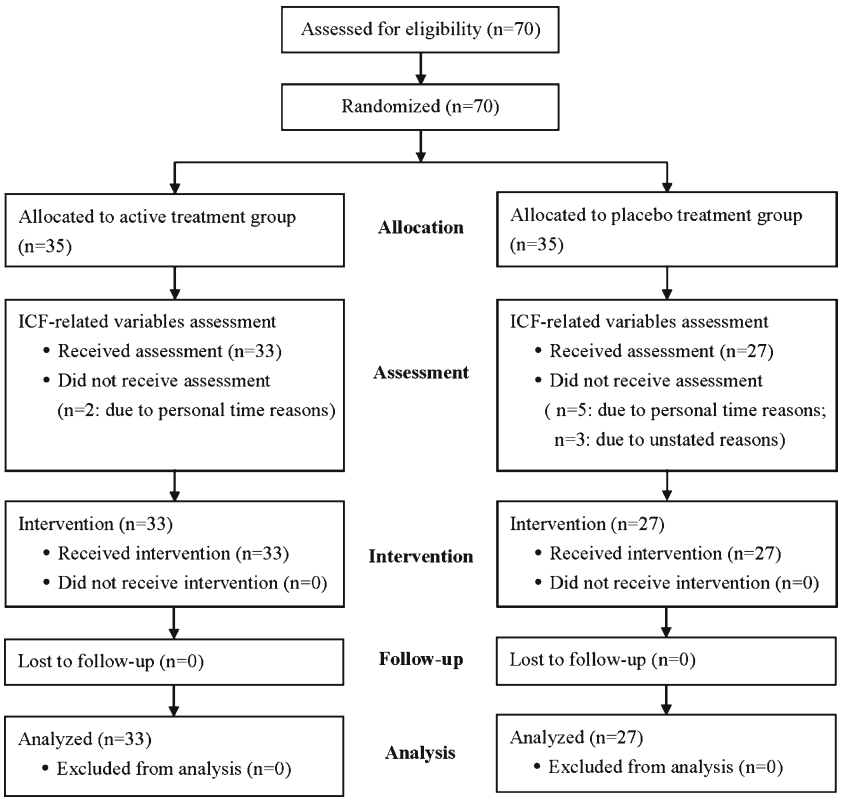

Fig. 2 Trial profile. *ICF* International Classification of Functioning, Disability and Health

were observed between the treatment and placebo groups (Table 1).

The scores at each time point for each group for each outcome measure and the means between the group differences based on 95 % confidence intervals are summarized in Table 2. No significant differences in baseline scores for lumbar active range of motion, VAS, MFI, FAI, ODQ, physical activity (repeated chair-rising), postural stability and dynamic balance (limits of stability), or OA-QOLQ were observed between the study groups. All participants completed the entire course of treatment (Table 2).

Compared with the results of the baseline assessments, significant reductions were observed in the treatment group for fear-avoidance beliefs for physical activity (P=0.040) and work (P=0.007), as measured using the FABQ. Significant reductions were also observed in the treatment group for the severity of disability, as assessed using the ODQ (P=0.021). However, compared with the baseline measurements, no significant effect was observed between the groups at the 2-week follow-up assessments for the other variables assessed (Table 2). No systemic or local side effects were noted during or after treatment.

Table 1 Demographic data of study participants

	Treatment group (n=33)	Control group (n=27)	P value
Sex			
Female	19 (58)	19 (70)	0.306
Male	14 (42)	8 (30)	
Age (years)	60.1±14.2	58.5±10.6	0.635
Weight (kg)	62.6±8.7	62.0±11.2	0.814
Height (cm)	161.6±8.1	160.3±6.9	0.529
BMI (kg/m^2)	23.9±2.7	24.0±4.1	0.914
Married			
Yes	27 (82)	22 (81)	0.973
Education level			
Below 9th grade	17 (52)	14 (52)	0.979
Above 9th grade	16 (48)	13 (48)	
Employed			
Yes	10 (30)	6 (22)	0.481
Smoker			
Yes	3 (9)	4 (15)	0.492
Drinker			
Yes	3 (9)	1 (4)	0.405
Comorbidity			
None	17 (52)	10 (37)	0.369
≦2	8 (24)	11 (40)	
≧3	8 (24)	6 (22)	
Pain radiation in lower limb			
Yes	23 (70)	21 (78)	0.481

Values are n (%), except for age, weight, height and BMI, where values are mean ± SD

BMI body mass index.

Discussion

First demonstrated by Mester et al. in 1968 [35], the clinical application of light therapy has become popular. In recent years, a trend among practitioners has emerged toward the use of light-therapy devices with light-emitting diodes because of the lower costs associated with the irradiation of large-surface areas, compared with treatments using laser-based light-therapy devices [11, 29, 36]. We evaluated the short-term effect of hot-pack therapy combined with light therapy by using an 890-nm light-emitting diode-based device on chronic low back pain by using a double-blind randomized placebo-controlled study. Our results showed that the 890-nm light therapy group experienced statistically significant reductions in the severity of disability and fear-avoidance beliefs for physical activity and work compared with the placebo group. The results of our study indicate that short-term 890-nm light therapy and hot-pack treatment reduced chronic low back pain, as evidenced by improvements in body functions and participation, according to the ICF criteria.

Infrared wavelengths of light penetrate human skin more efficiently than red wavelengths do [36], and previous research showed a significant increase in microcirculation following 20 min of light therapy [37]. Our previous study indicated that 40 min of light therapy using light-emitting diodes produces no detrimental systemic cardiovascular effects [20]. We used the 890-nm light-emitting diodes for the 40-min light therapy in this study, and no adverse effects were observed following the short-term treatments. Most patients with chronic low back pain who require medication for pain relief are likely to be middle-aged or older, and are at high risk for both adverse gastrointestinal and cardiovascular effects [38]. Therefore, the observed reductions in fear-avoidance beliefs and the severity of disability, with no accompanying detrimental effects on systemic cardiovascular health or other adverse effects, indicate that 890-nm light therapy is a safe treatment for chronic low back pain in middle-aged and older patients, despite the presence of cardiovascular comorbidities.

A growing consensus indicates that psychological factors, such as catastrophizing and fear-avoidance beliefs, play greater roles in the transition from acute to chronic low back pain than the severity of the pain [39]. Such observations indicate that the process of chronicity is triggered by catastrophizing perceptions of pain that initiate a cycle of fear regarding re-injury and the onset of additional pain associated with safety-seeking behaviors, such as hypervigilance and avoidance [40]. Fear-avoidance beliefs in patients with

Table 2 Comparison of changes of scores in body function, activities, participation, and quality of life for study participants

	Before treatment			Changes after treatment			
	Treatment group	Placebo group	*P* value	Treatment group	Placebo group	Mean difference between groups (95 % confidence interval)	*P* value
Body functions							
Range of motion							
Flexion	25.0±9.2	26.0±8.9	0.674	0.6±5.4	−2.6±9.0	−3.1 (−7.0, 0.7)	0.133
Extension	12.1±5.6	11.3±5.4	0.623	−0.1±4.5	1.0±4.5	1.1 (−1.3, 3.5)	0.382
Rotation (R)	28.4±12.9	29.3±10.9	0.776	−0.3±6.4	−1.1±8.7	−0.8 (−4.8, 3.2)	0.677
Rotation(L)	27.5±11.7	27.5±11.7	0.964	−2.4±8.4	−1.1±11.6	1.3 (−4.0, 6.6)	0.629
Visual analog scale	7.8±2.4	7.9±1.7	0.929	0.73±1.4	0.4±1.1	−0.3 (−1.0, 0.3)	0.295
Multi-fatigue inventory							
General fatigue	10.3±3.7	11.7±3.4	0.144	−0.2±1.9	−0.2±2.3	0.1 (−1.0, 1.1)	0.927
Physical fatigue	12.1±3.3	13.2±3.6	0.255	−0.4±1.3	−0.0±1.2	0.4 (−0.3, 1.0)	0.274
Reduced activity	9.8±2.2	11.1±3.0	0.054	0.3±1.1	0.1±1.4	−0.3 (−0.9, 0.4)	0.443
Reduced motivation	10.7±1.8	10.9±1.7	0.626	−0.5±1.3	0.01±1.2	−0.5 (−1.1, 0.2)	0.141
Mental fatigue	10.6±1.7	11.4±2.2	0.152	−0.1±1.3	−0.4±1.1	−0.3 (−1.0, 0.3)	0.293
Biodex stability system							
Postural stability	0.5±0.2	0.5±0.5	0.846	0.2±0.7	−0.1±0.4	−0.3 (−0.6,0.02)	0.068
Dynamic limit of stability	41.1±11.2	39.6±11.2	0.698	2.2±16.8	1.0±12.4	−1.1 (−9.0, 6.7)	0.773
Fear-avoidance behavior questionnaire							
Physical activity	12.4±5.7	11.5±6.3	0.583	−1.0±4.3	1.0±3.0	2.1 (0.1, 4.1)	0.040*
Work	9.8±7.7	9.0±9.3	0.746	−1.7±4.6	1.9±5.4	3.7 (1.0, 6.3)	0.007**
Activities and participation							
5 repeated chair-rising times	15.9±3.6	16.8±5.1	0.430	−0.3±3.4	−1.5±3.8	−1.2 (−3.1, 0.7)	0.212
Frenchay activities index	32.2±10.5	33.5±10.5	0.628	1.9±6.1	1.5±5.5	−0.4 (−3.4, 2.6)	0.782
Oswestry disability questionnaire	2.3±1.0	2.6±1.2	0.245	−0.4±0.7	−0.1±0.3	−0.3 (−0.6, −0.1)	0.021*
Osteoarthritis quality of life	3.8±6.2	5.9±7.2	0.234	−0.5±3.0	−0.6±1.6	−0.1 (−1.4, 1.1)	0.814

Values are expressed as mean ± SD or mean (95 % confidence interval).

*P <0.05; **P <0.01

chronic low back pain have been shown to be associated with weakened muscle strength, decreased walking speed, diminished physical task performance, and increased disability [41], which have in turn been shown to significantly affect occupational performance, treatment outcomes, health-related QOL, and patients' return to work following functional rehabilitation programs [42, 43].

Our findings represent the first report of the effectiveness of short-term light therapy for the reduction of fear-avoidance beliefs and the severity of disability. However, the reason for this reduction in fear beliefs is unclear. The possible mechanisms for the reduction of pain following light therapy include the following: (1) increased endogenous opioid neurotransmitter production [43]; (2) enhanced thermal pain threshold [44] and local blood circulation [45]; (3) increased oxygen consumption [46] and ATP production [47] at the cellular level; and (4) anti-inflammatory effects [48]. The attentional and interpretive processes of pain and nociceptive input to the cerebral cortex are complex, and are related to the subjective experience of pain [49]. Therefore, our participants felt possibly less pain upon moving after light therapy, thereby becoming less afraid of moving afterward. Alternatively, expectations generated after light therapy through cortical responses specifically related to pain processing [50] may have diminished their subsequent perception of pain.

The effects of phototherapy are time-dependent [51]. Light therapy initiates the release of nitric oxide, with subsequent subcellular and cellular biochemical and physiological changes [52]. Multiple variables affect the clinical therapeutic effects of light therapy, such as the light source, the wavelength of light, total energy, power, energy density, the size of the exposure area, the method of application (contact mode or non-contact mode), the total number of treatment sessions, the frequency of treatment, and the duration of each treatment session [11, 53, 54]. We used a higher dose of total energy (83.2 J/cm^2) per treatment in this study compared with previous studies that have used doses of 4 to 36 J/cm^2

[21–23]. At this higher energy level, ICF-related components of body function and participation, such as fear-avoidance beliefs and the severity of disability, improved in the treatment group compared with the placebo group. In addition, we administered a higher dose of photo energy over a shorter total duration of treatment compared with previous studies (2 vs 4 to12 weeks, respectively) [21–23]. We also conducted fewer treatment sessions, compared with previous studies (6 vs 10 to 20 sessions) [21–23]. Further studies on light therapy for chronic low back pain should ideally investigate the use of longer treatment durations and different energy levels, treatment frequencies, wavelengths of infrared light, and placements of the light therapy pads, in addition to combinations of treatments using other therapeutic modalities, such as exercise.

This study used reliable, valid, patient-centered measurements based on the ICF model, including self-reported and functional performance-based assessments [55]. Self-reported assessments, such as the FABQ, the FAI, the ODQ, and the OA-QOLQ, represent the gold standard for the measurement of perceived health status and health-related QOL. Indices and questionnaires used in this study each have justification [24, 25, 28, 31, 34]. We also used functional assessments to objectively measure activity, such as repeated chair-rising times, and body functions such as the lumbar range of motion, postural stability, and dynamic balance. These assessments, which have demonstrated acceptable validity and reproducibility [56], are well suited for measuring the functions of disabled and elderly patients, and are not influenced by cultural and demographic factors. We recruited relatively middle-aged to old participants. For safety reasons, we used the most stable resistance level (level 8) to measure their postural stability and dynamic balance by using the BBS.

Our findings are subject to several limitations. First, we applied light therapy for 2 weeks only. Whether longer durations of treatment would produce the same results remains uncertain. Second, most conservative treatment approaches for chronic low back pain use multiple treatment modalities involving some form of exercise. Our use of hot-pack therapy combined with light therapy as the sole treatment for our study may not be clinically plausible. Further studies comparing the effects of co-interventions, such as light therapy combined with exercise, are warranted. Third, we did not include an evaluation of environmental factors, as recommended under the ICF structure, which may have affected our findings. Finally, because light therapy produces tangible heat, participants in our light therapy group may have perceived an additional sensation of heat during treatment. We concede that any perceived increase in heat by the participants in the treatment group may have confounded our results. Treatment with superficial heat, such as the use of heat wraps or heated blankets, has been shown to be effective for short-term pain relief and back-related functional performance [57]. We added the simultaneous hot-pack treatment to the intervention for our study to avoid the potential confounding thermal effects of blinded light monotherapy, but thermal effects clearly resulted from the light therapy dose used in our study. Thus, the limits of current light-emitting diode technology prevented the precise evaluation of the effects of light therapy alone. However, the possible synergistic effects of light therapy-induced heat and hot-pack treatment may have some relevance for clinical care. Our findings should motivate future studies with alternative designs for the evaluation of light therapy for chronic low back pain.

In conclusion, the combination of short-term 890-nm light therapy and hot-pack treatment reduced chronic low back pain, compared with hot-pack treatment combined with placebo light therapy. The reductions in chronic low back pain were associated with reductions in the severity of disability and fear avoidance beliefs.

Acknowledgments This study was supported by grants from Shin Kong Wu Ho-Su Memorial Hospital (SKH-8302-99-DR-41) and the National Science Council, Taiwan (NSC 99–2628-B-002-061-MY3). The authors have no competing interests to declare. We thank Professor Alan Tennant BA for permission to use the OAQOL in the present study.

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