# Surgery and Clinical Practice

# Evaluation of the Efficiency of Low-Level Laser Therapy in Female Patients with Chronic Pelvic Pain: A Double-Blind, Randomized, Placebo-Controlled Clinical Study

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#### ABSTRACT

**Objective:** In this study, it is aimed to determine the efficacy of Low-level Laser Therapy (LLLT) in the treatment of Chronic Pelvic Pain Syndrome (CPPS), and to evaluate the effects of LLLT on depression, anxiety and quality of life.

*Material and Method:* Female CPPS were included in the study. LLLT was applied to the first group, and placebo (sham operation) was applied to the second group. Patients were evaluated by Visual Analogue Scale (VAS), McGill Melzack Pain Questionnaire (MMPQ), Beck Depression Inventory (BDI) and Beck Anxiety Inventory (BAI) and 36-Item Short Form Health Survey (SF-36), before the treatment, at the end of treatment, and 8 weeks after randomization.

**Results:** The patients included in the treatment group (n = 11) and in the placebo group (n = 8) were calculated as  $38.91 \pm 5.20$  and  $37.25 \pm 6.34$ , respectively. In the treatment group, a significant difference was found between the pre-treatment (VASPre-T) and end of treatment (VASPost-T) pain values and between pre-treatment (VASPre-T) pain values and pain values measured 8 weeks after randomization (VAS8th-week) (p: 0.003, p: 0.003). Additionally, a significant improvement in MMPQ scores was also found in the treatment group. (p: 0.037 and p: 0.008 respectively). When the MMPQ and BDI values in both groups were compared, there was no difference (p > 0.05). Furthermore, it was observed that the level of anxiety (BAI) decreased at the end of the treatment, although not significantly, in the placebo group (p: 0.12), Additionally, significant improvements were observed in terms of SF-36 quality of life scale sub-scores.

**Conclusion:** The results of this study suggest that LLLT, a simple, non-invasive, inexpensive and safe treatment method, can be useful in the treatment of CPPS. Yet, large-scale multi-center studies are needed to support the positive results found in favor of LLLT in this study.

#### Keywords

Chronic pelvic pain syndrome, Low-level laser therapy, Anxiety, Depression.

#### Introduction

Chronic Pelvic Pain Syndrome (CPPS) is a common clinical syndrome that does not occur as a result of menstruation or sexual intercourse, is not associated with pregnancy, is intermittent or continuous for at least 6 months, and is seen in the lower abdomen or pelvis area. With a prevalence of 38 in every 1000 women aged 20-50, CPPS is a common health problem [1]. Its etiology is not fully known, yet the possible risk factors are cited as endometriosis and adenomyosis, adhesions, pelvic congestion syndrome, irritable bowel syndrome, interstitial cystitis, psychological and social problems, and musculoskeletal problems [2]. The presence of a persistent and permanent pain causes despair, loss of workforce and adverse effects on sexual life, reducing the quality of life as a result. Therefore, its treatment and symptom management are very important. In addition to changing the lifestyle, physical therapy methods as well as medical and surgical methods are used in its treatment. Low-level laser therapy (LLLT), a physical therapy modality, has been used for a long time to reduce pain caused by the musculoskeletal system. The mechanism of action of LLLT is described as photobiostimulation. Main effects of LLLT are cited as analgesic, anti-inflammatory, dose-dependent neural stimulative or inhibitive, and tissue healing effects [3]. Recently, studies have been conducted on the use of LLLT outside the musculoskeletal system, as well. It has been used in the treatment of dysmenorrhea, breast cancer-related lymphedema, androgenic alopecia, and oral mucositis, and was found effective [4-8]. The fact that LLLT has almost no side effects gives rise to an increase in its use with each passing day.

In view of the foregoing, it is aimed in this study to evaluate the efficacy of LLLT in the treatment of CPPS, which causes a decrease in the quality of life of, and loss of workforce in, the adult women, and to assess its effect on depression, anxiety, and quality of life.

## **Material and Method**

Female CPPS patients between the ages of 18-45 with a visual analogue scale (VAS) score of  $\geq$ 5 out of 10 and who were examined at the Obstetrics and Gynecology outpatient clinic of the hospital were included in the study. Patients with pains predicated on an objective justification, as well as patients who underwent pelvic surgery, who had psychiatric disease, chronic infection, inflammatory musculoskeletal pain and malignancy, were excluded from the study. Analgesic use was not allowed during the treatment, except for paracetamol, the use of which was recorded, if any.

Detailed information about the study was given to all patients referred to the clinic where the study was conducted with a diagnosis of CPPS. The participants' informed consents were obtained in accordance with the Helsinki Declaration and their demographic information such as their age, gender, occupation, socioeconomic level and number of dependents as well as their clinical information such as their chronic illnesses and medications were recorded.

The patients were divided into two groups via simple randomization using the randomization scheme based on the order of their visits to the hospital, by a researcher other than the author who was blind to clinical and laboratory findings of the participating patients. LLLT (red probe/divergent, 685 nm wavelength, 30 mw output, 6 J/cm<sup>2</sup> dosage, 3-point, 4 minutes 10 seconds to each point) was administered to the treatment (1<sup>st</sup>) group, whereas a placebo (sham operation), during which the device was turned on and the application was made within the specified time, yet the laser beam was blocked with the black tape, was administered to the placebo (2<sup>nd</sup>) group.

In practice, it was planned to use acupuncture points for

standardization so that the differences between patients' heights and weights could be ruled out. In this way, the acupuncture effect was also utilized as a result of the laser generating dosedependent stimulation or inhibition at the acupuncture points. The acupuncture points used in lower abdominal pain were selected for the LLLT treatment. Moreover, number of points to be treated by LLLT was increased in accordance with the points reported to be treated with positive outcomes in the treatment of dysmenorrhea in the literature. As a result, three points, namely CV4 (Guanyuan, midline, 4 cun below umbilicus), CV3 (Zhongji, midline (linea alba), 3 cun below umbilicus), and CV6 (Oihai, midline, umbilicus, 1.5 cun below umbilicus) were determined (Cun is a measure of distance. The width of a person's thumb is 1 cun). The procedure was administered for a total of 12 minutes and 30 seconds in each session and for 10 sessions in total during a period of 2 weeks. Throughout the study, one medical doctor performed the procedure, whereas another medical doctor performed the assessments.

Patients were evaluated by Visual Analogue Scale (VAS), McGill Melzack Pain Questionnaire (MMPQ), Beck Depression Inventory (BDI) and Beck Anxiety Inventory (BAI) and 36-Item Short Form Health Survey (SF-36) Quality of Life Questionnaire, before the treatment (Pre-T), at the end of treatment (Post-T), and 8 weeks after randomization (8th-week).

This study has been conducted with the approval of the Clinical Research Ethics Committee of the hospital, where the study was conducted, and of the Turkish Medicines and Medical Devices Agency.

## **Statistical Analysis**

The statistical analysis of the collected data was carried out using the SPSS 20.0 (Statistical Package for the Social Sciences Version 20.0) software package. Descriptive data were expressed as frequency, percentage, mean ± standard deviation, median, minimum and maximum values. Shapiro-Wilk test was used to determine whether the variables conformed to the normal distribution, based on the number of patients included in each group. Nonparametric tests were preferred as methods of analysis in the analysis of sample size and conformance to normal distribution. Chi-squared test was used to compare the variables of educational status, employment status, income perception, marital status, presence of children, number of children, number of dependents and paracetamol (Parol) use between the treatment and placebo groups, whereas Mann Whitney U test was used to compare age and continuous variables between independent groups. Wilcoxon signed-rank test was used for paired comparisons of dependent groups. The cases where the p (probability) value was below 0.05 were considered to be statistically significant at 95% confidence interval (CI).

## Results

19 of the 60 patients took under review were included in the study. The mean age of the 19 patients included in the study was calculated as  $38.21 \pm 5.60$  (Median: 38.00 Min: 24.00-Max: 45.00) years. The mean ages of the patients included in the treatment

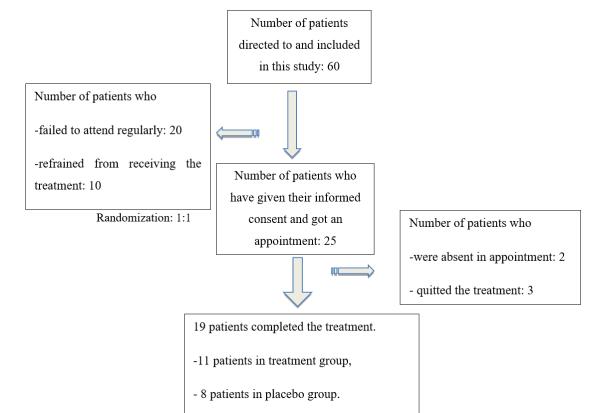
group (n = 11) and in the placebo group (n = 8) were calculated as  $38.91 \pm 5.20$  (Median: 38.00 Min: 33.00-Max: 45.00) and  $37.25 \pm 6.34$  (Median: 39.00 Min: 24.00-Max: 44.00), respectively. There was no significant difference between the treatment and placebo groups in terms of mean age (p = 0.840, Mann-Whitney U Test). The flow diagram of the study is given in Figure 1, and the socio-demographic characteristics of the treatment and placebo groups are given in Table 1.

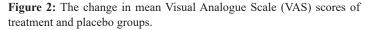
Table 1: Socio-demographic	characteristics	of the study	sample.
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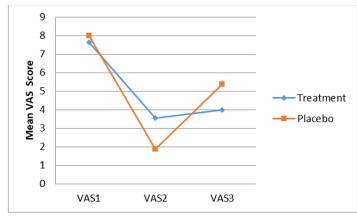
	Treatment group	Placebo group	p-value*
Characteristics	(n=11) n (%)	(n=8) n (%)	
Level of education			
Primary school	6 (54,5)	6 (75,0)	
High school	2 (18,2)	0 (0,0)	0.41ª
University	3 (27,3)	2 (25,0)	0.41
<b>Employment status</b>			
Employed	3 (27,3)	1 (12,5)	0.834 <sup>b</sup>
Unemployed	8 (72,7	7 (87,5)	0.834
Income status			
Low	6 (54,5)	3 (37,5)	0.788 <sup>b</sup>
Middle	5 (45,5	5 (62,5)	0.788
Marital status			
Married	9 (81,8)	6 (75,0)	0,937ª
Single	1 (9,1)	1 (12,5)	0,957
Widowed/Divorced	1 (9,1)	1 (12,5)	
Children			
Yes	11 (100,0)	7 (87,5)	0.870 <sup>b</sup>
No	0 (0,0)	1 (12,5)	0.870

No significant difference was observed between the VAS values of the treatment and placebo groups both at the beginning of the treatment (VAS<sub>pre-T</sub>; p: 0.542) and at the end of the treatment  $(VAS_{Post,T}; p: 0.083)$ . However, a significant improvement was observed in the treatment group 8 weeks after randomization (p: 0.020) (Figure 2). Additionally, in the treatment group, a significant improvement was found between the pre-treatment  $(MMPQ_{Pre-T})$  and end of treatment  $(MMPQ_{Post-T})$  MMPQ total scores and between pre-treatment MMPQ total scores (MMPQ<sub>Pre-T</sub>) and MMPQ total scores measured 8 weeks after randomization (MMPQ<sub>8th-week</sub>) (p: 0.037 and p: 0.008, respectively), whereas no significant improvement was found between the end of treatment (MMPQ<sub>Post-T</sub>) MMPQ total scores and MMPQ total scores measured 8 weeks after randomization (MMPQ<sub>8th-week</sub>) (p: 0.056). On the other hand, in the placebo group, no difference was observed between pre-treatment (MMPQ<sub>Pre-T</sub>) MMPQ total scores and the end of treatment (MMPQ<sub>Post-T</sub>) MMPQ total scores and MMPQ total scores measured 8 weeks after randomization (MMPQ<sub>8th-week</sub>) (p: 0.123, p: 0.10). However, a statistically significant difference was observed in the negative direction between the end of treatment (MMPQ<sub>Post-T</sub>) MMPQ total scores and the MMPQ total scores measured 8 weeks after randomization (MMPQ<sub>8th-week</sub>), that is, the MMPQ did not decrease but increased between the end of treatment and 8 weeks after randomization (p: 0.017) (Figure 3).

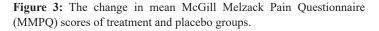
Figure 1: Study flow diagram.

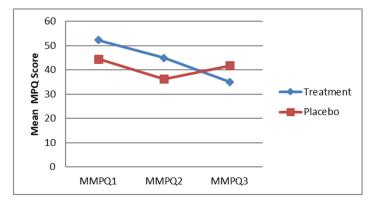






VAS1: VAS<sub>Pre-T</sub>, VAS2: VAS<sub>Post-T</sub>, VAS3: VAS<sub>8th-week</sub>





MPQ1: MMPQ<sub>Pre-T.</sub> MPQ2: MMPQ<sub>Post-T.</sub> MPQ3: MMPQ<sub>8th-week</sub>

In terms of BDI scores, in the treatment group, a significant difference was found between the pre-treatment (BDI<sub>pre-T</sub>) and end of treatment (BDI<sub>post-T</sub>) BDI scores (*p*: 0.028). On the other hand, in the placebo group, it was observed that the BDI scores did not decrease but increased during the period between the end of treatment (BDI<sub>post-T</sub>) and 8 weeks after randomization (BDI<sub>8th-week</sub>), and that the difference was significant (*p*: 0.018). Furthermore, in terms of BAI, in the treatment group, no significant difference was found between the pre-treatment BAI scores (BAI<sub>post-T</sub>), post-treatment BAI scores (BAI<sub>Post-T</sub>) and BAI scores measured 8 weeks after randomization (BAI<sub>8th-week</sub>). On the other hand, in the placebo group, it was observed that the BAI scores did not decrease but increased during the period between the end of treatment (BAI<sub>8th-week</sub>). And the BAI scores did not decrease but increased during the period between the end of treatment (BAI<sub>8th-week</sub>), and 8 weeks after randomization (BAI<sub>8th-week</sub>), and that the difference was significant (*p*: 0.018).

The comparisons of the pre-treatment and post-treatment VAS, MMPQ, BDI and BAI values and the VAS, MMPQ, BDI and BAI values measured 8 weeks after randomization both in the treatment and placebo groups and the results of these comparisons are shown in Table 2 and Table 3.

**Table 2:** Comparison of treatment group's mean VAS, MMPQ, BDI, and BAI scores recorded before the treatment (Pre-T), after the treatment (Post-T), and in the 8<sup>th</sup> week of post-randomization (8th-week).

	Pre-T	Post-T	8th-week	p-value
VAS (Mean±SD)	$7.64 \pm$	$3.55 \pm$	2.90 ±	
	0.92	1.97	2.02	
VAS Pre-T -VAS Post-T				0.003
VAS Pre-T -VAS 8th-week				0.003
VAS Post-T - VAS 8th-week				0.18
MPQ (Mean±SD)	$52.27 \pm$	$44.91 \pm$	35.09 ±	
	18.83	19.04	13.11	
MMPQ Pre-T -MMPQ Post-T				0.037
MMPQ Pre-T -MMPQ Sth-week				0.008
MMPQ <sub>Post-T</sub> -MMPQ <sub>8th-week</sub>				0.056
BDI	$16.91 \pm$	12.55 ±	14.18 ±	
	8.38	7.78	8.61	
BDI Pre-T -BDI Post-T				0.028
BDI Pre-T -BDI 8th-week				0.305
BDI Post-T -BDI 8th-week				0.056
BAI	$22.36 \pm$	17.72 ±	$18.18 \pm$	
	9.27	9.59	10.30	
BAI Pre-T -BAI Post-T				0.153
BAI Pre-T -BAI 8th-week				0.126
BAI Post-T -BAI 8th-week				0.075

**Table 3:** Comparison of placebo group's mean VAS, MMPQ, BDI, and BAI scores recorded before the treatment (Pre-T), after the treatment (Post-T), and in the 8<sup>th</sup> week of post-randomization (8th-week).

	BT	AT	PR	p-value
VAS (Mean±SD)	$8.00 \pm$	$1.88 \pm$	5.38 ±	
	1.07	2.10	2.26	-
VAS Pre-T -VAS Post-T				0.012
VAS Pre-T -VAS 8th-week				0.018
VAS Post-T - VAS 8th-week				0.011
MMPQ (Mean±SD)	$44.50 \pm$	36.25 ±	41.75 ±	
	16.09	18.50	19.64	
MMPQ Pre-T -MMPQ Post-T				0.12
MMPQ <sub>Pre-T</sub> -MMPQ <sub>8th-week</sub>				0.10
MMPQ <sub>Post-T</sub> -MMPQ <sub>8th-week</sub>				0.017
BDI	$21.63 \pm$	$10.50 \pm$	$19.38 \pm$	
	15.74	14.39	15.91	
BDI Pre-T -BDI Post-T				0.09
BDI Pre-T -BDI 8th-week				0.60
BDI Post-T -BDI 8th-week				0.018
BAI	13.13 ±	$8.62 \pm$	17.13 ±	
	8.87	6.91	13.27	
BAI Pre-T -BAI Post-T				0.12
BAI Pre-T -BAI 8th-week				0.35
BAI Post-T -BAI Sth-week				0.018

In terms of quality of life, in both the treatment and placebo groups, no significant differences were observed between the pre-treatment and post-treatment total SF-36 scores and SF-36 scores measured 8 weeks after randomization, whereas there were differences between the scores obtained from the SF-36 subscales (physical functioning, bodily pain, role limitations due to physical health problems, role limitations due to personal or emotional problems, emotional well-being, social functioning, energy/fatigue, and general health perceptions). Accordingly, in the treatment group, there was a significant improvement between the pre-treatment and post-treatment Physical Functioning, Bodily Pain, Social Functioning, and Mental Health subscale scores (p: 0.01, p: 0.008, p: 0.02 and p: 0.006, respectively) and between the pre-treatment Role Limitations Due To Physical Health Problems and Energy/Fatigue subscale scores and the Role Limitations Due To Physical Health Problems and Energy/Fatigue subscale scores measured 8 weeks after randomization (p: 0.024 and p: 0.041, respectively); whereas in the placebo group, there was a significant improvement only between the pre-treatment and post-treatment Social Functioning subscale scores (p: 0.04). Moreover, in the placebo group, post-treatment Physical Functioning, Bodily Pain, and Mental Health subscale scores were observed to have worsened compared to the Physical Functioning, Bodily Pain, and Mental Health subscale scores measured 8 weeks after randomization (p: 0.034, p: 0.043 and p: 0.049, respectively).

### Discussion

LLLT, or photobiomodulation, is a low-energy laser application that uses absorbed red and/or infrared laser beams. It is a non-invasive, inexpensive and practical treatment option with insignificant side effects, if any at all, for various acute and chronic diseases of the musculoskeletal system [4]. Contradictory results have been obtained in terms of the efficacy of LLLT in studies conducted in the past, however nothing but positive results were reported in many recent studies and meta-analyses conducted in respect thereof [3,9]. LLLT's efficacy in chronic painful conditions of the musculoskeletal system such as low back and neck pain, epicondylitis, rheumatoid arthritis, carpal tunnel syndrome and osteoarthritis has been tested and it is currently used in medical applications [3].

In this study, it was hypothesized that LLLT, which is used with positive outcomes in many areas in addition to chronic pain treatment, can also be used in the treatment of CPPS, since it increases NO (nitric oxide) synthesis resulting in a vasodilator effect increasing tissue blood supply, increases tissue and wound healing via cell stimulation, stimulates anti-inflammatory responses, has an analgesic effect, causes smooth muscle relaxation, and gives rise to neuromodulation depending on its dosage and duration of application. A review of the literature did not reveal much information to that respect. Hence, to the best of authors' knowledge, this study is the first randomized placebo-controlled study in which the efficacy of LLLT in the treatment of CPPS was investigated. The results of the study indicated an improvement in CPPS with the use of LLLT. Accordingly, in the treatment group including 11 patients, the pre-treatment and post-treatment mean VAS values and the mean VAS value measured 8 weeks after randomization were determined as 7.64  $\pm$  0.92, 3.55  $\pm$  1.97 and  $2.90 \pm 2.02$ , respectively. It was clinically significant that the VAS value was found to have decreased by more than 50% at the end of the treatment compared to the beginning of the treatment and that this efficacy was found to have maintained 8 weeks after randomization. Besides, no side effects were observed during the treatment. On the other hand, in the placebo group, a decrease was observed in pain levels at the end of the treatment, but the VAS

values were found to have re-increased 8 weeks after randomization. Additionally, the MMPQ, BDI and BAI scores as well as certain SF-36 subscale (physical functioning and bodily pain) scores, which were found to have improved by the end of the treatment, were observed to have deteriorated 8 weeks after randomization. As a reason, the psychological well-being of the patients in the placebo group may have decreased with a temporary decrease in VAS followed by an increase in pain levels 8 weeks after randomization.

There seems to be no consensus on the dose and duration of LLLT even though there are numerous studies conducted in respect thereof. WALT (World Association for Laser Therapy) recommends use of higher doses on the skin surface in order to reach 1-4 J / cm<sup>2</sup> in the target tissue, which is seen as the gold standard for biostimulation, and warns that doses of and above 8 J / cm<sup>2</sup> cause inhibition [10]. For this reason, in this study, it was decided to work with an energy density of 6 J / cm<sup>2</sup>, due to the fact that the target acupuncture points are not located in standardized or sharp localizations and can remain in the depths of the skin and taking into account that the power of the laser decreases from the surface to the depths of the skin. Unlike laser acupuncture, LLLT has a broad dose response curve. In terms of the duration of LLLT application, durations set forth in the previously published studies were taken as reference [4,510].

Today, acupuncture is widely used in the treatment of CPPS. Positive results have been reported in studies conducted on the use of acupuncture in women with endometriosis [11], in men with chronic prostatitis [12], and in both men and women with chronic inflammatory pelvic pain [13]. Guanyuan (CV4), Sanyinjiao (SP6), Taichong (LR3), Zhaohai (KI6) and Qichong (ST30) points were reported to be used in the treatment of endometriosis with acupuncture. Various acupuncture points were reported for use in the treatment of CPPS due to myofascial pain, and it has also been reported that these points generally coincide with the trigger points [14,15]. Despite the fact that there are many acupuncture points in the relevant area, in this study, acupuncture points used in traditional Chinese medicine for the treatment of uterine and lower abdominal pain were used.

In 2016, in a randomized placebo-controlled study, in which the efficacy of LLLT in the treatment of dysmenorrhea was investigated, treatment points were determined as CV4 (Guanyuan) and CV6 (Qihai). In the said study, self-administered LLLT (low-medium power, diode laser 830-904 nm) was applied by the patients using the self-adhesive probes to the aforementioned two points for 20 minutes, 5 days before the beginning of each menstrual period for a period of 3 months. In this study conducted by Shin Y II et al., it was reported that the VAS values were decreased, and that this treatment is a simple, safe and effective non-pharmacological treatment option in patients with dysmenorrhea [4]. In another study conducted in 2012, in which the efficacy of LLLT in the treatment of dysmenorrhea was investigated, LLLT was applied using a similar diode laser device to the same two points for 20 minutes in an hospital environment, 5 days before the beginning of each menstrual period for a period of 6 months, and it was concluded based on the VAS values that LLLT is a useful treatment option in the treatment of dysmenorrhea [5].

In this study, no improvements were recorded in the post-treatment depression and anxiety levels compared to the pre-treatment levels in both the treatment and placebo groups. This result was attributed to the fact that patients manifested mild symptoms at the time of their first visit to the hospital as indicated by the mean scores obtained from both inventories (BDI and BAI mean scores: 16.91  $\pm$  8.38 and 22.36  $\pm$  9.27, respectively). As a matter of fact, the BDI and BAI scores in the placebo group were found to have increased during the period between the end of treatment and 8 weeks after randomization (p = 0.018 and p = 0.018, respectively). The low educational level of the patients as determined in the assessments performed, particularly in the SF-36 Quality of Life Scale, may have negatively affected the attainment of objective results. In the treatment group, a significant improvement was found between the pre-treatment SF-36 Role Limitations Due To Physical Health Problems subscale and SF-36 Energy/Fatigue subscale scores and the SF-36 Role Limitations Due To Physical Health Problems subscale and SF-36 Energy/Fatigue subscale scores measured 8 weeks after randomization, suggesting that the reduction in feeling of pain has led to an increase in workforce and a decrease in fatigue (p = 0.024 and p = 0.042, respectively). Further studies conducted with higher number of patients are needed to obtain more objective results on the effect of LLLT on the quality of life.

The strengths of this study are that it has been the first study in which the efficacy of LLLT in the treatment of CPPS was investigated, that it has also included the assessment of the effects of LLLT treatment on depression, anxiety and quality of life, taking into consideration the relationship between depression and anxiety and chronic pain, and that it has featured a long follow-up period, which allowed the assessment of the subacute effects of LLLT and ensured that the difference of the treatment group from the placebo group could be observed. On the other hand, the limitations of this study are that it included a small number of patients, since it excluded the CPPS cases predicated on a certain disease and diagnosis and the postmenopausal patients, and precluded the use of NSAIDs and required the patients to come to the hospital for the study for 10 days, that it featured sociocultural problems related to treatment such as fearing that the area which the treatment was applied will affect fertility and not meeting the requirement to attend follow-up visits regularly, etc., and that it could not be carried out for longer periods due to COVID pandemic period possibly preventing the achievement of clearer results.

#### Conclusion

In conclusion, the results of this study suggest that LLLT, a simple, non-invasive, inexpensive and safe treatment method, can be useful in the treatment of CPPS, particularly taking into consideration its analgesic effect. Yet, large-scale multi-center studies are needed to support the positive results found in favor of LLLT in this study. In this way, different treatment options can be developed for the treatment of CPPS, which affects women of all ages worldwide.

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