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Original Research Article

Short-Term Effects of Bright Light Therapy in Adults with Chronic Nonspecific Back Pain: A Randomized Controlled Trial

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Abstract

Objective. The present trial evaluated incorporation of bright light therapy in the treatment of chronic nonspecific back pain (CNBP).

Design. A prospective, randomized, controlled, multicenter, open design with three parallel trial arms was used.

Setting. Subjects received a novel therapeutic, an expected therapeutic ineffective low dose, or no light exposure at three different medical centers.

Patients. A total of 125 CNBP patients reporting pain intensity of ≥3 points on item 5 of the Brief Pain Inventory (BPI) were included.

Intervention. Over 3 weeks, 36 active treatment, 36 placebo controls, and 33 controls received 3 or no supplementary light exposures of 5.000 lx or 230 lx, respectively.

Outcome Measures. Changes in self-reported scores of pain intensity (BPI sub-score 1) and depression (Hospital Anxiety and Depression Questionnaire) were the primary outcome measures. Secondary outcome measures were changes in self-reported overall pain sensation (BPI total score), grade of everyday life impairment (BPI sub-score 2), mood (visual analog scale), and well-being (World Health Organization-Five Well-Being Index).

Results. Changes in pain intensity were higher (1.0 [0.8–1.6]) in the bright light group compared with controls (0.3 [−0.1–0.8]; effect size D = 0.46). Changes in the depression score were also higher in the intervention group (1.5 [0.0–2.5]) compared with controls (0.0 [0.0–2.0]; effect size D = 0.86). No differences were seen in change scores between intervention vs sham group.

Conclusion. The present randomized controlled trial shows that light therapy even in low dose could improve depressive symptoms and reduce

pain intensity in CNBP patients. Further research is needed for optimizing parameters of frequency, dose, and duration of therapeutic light exposure.

Key Words. Chronic Nonspecific Back Pain; Bright Light Therapy (BLT); Depression; Multicenter Trial; Randomized Controlled Trial (RCT)

Introduction

Chronic nonspecific back pain (CNBP) is a common and cost-intensive musculoskeletal syndrome in Western society [1]. It has a lifetime prevalence of up to 80% [2] and for example in low back pain, high rates of repeated occurrence have been reported [3]. Comorbid mental disorders worsen chronic back pain [4]. The mechanisms underlying CNBP are manifold: Mechanical reasons are not the sole triggers as it was demonstrated that 85% of all CNBP cases show no morphologic causes [5]. There is international consensus that the existence of comorbidities such as mood and anxiety disorders are associated with higher levels of perceived pain [6] and psychosocial mechanisms are essential in the chronification of pain [7]. Patients suffering from depression with comorbid pain show longer times to remission [8]. Psychosocial factors such as avoidance behavior and anxiety are closely connected to depression [9] and are evidently more accurate predictors for the development of chronic pain compared with biographical or somatic determinants [10]. More painful courses are associated with higher levels of depression and somatization [11]. It has been reported that 60% of chronic pain patients show manifest symptoms of depression [12], and the prevalence of depression is three to four times higher in low back pain patients than the general population [13].

It is widely accepted that a multimodal approach is required in the treatment of CNBP [3,14]. Incorporation of bright light therapy (BLT) may offer this combined intervention strategy—considering pain, psychosocial, and emotional factors as well as being cost-effective [15]. BLT has proved successful mainly in the treatment of mood disorders [16–19] and has also been of interest in the treatment of a variety of other behavioral syndromes such as eating and circadian rhythm disorders [20–22], as well as headache [23]. The underlying mechanism is thought to be the ability of bright light (BL) to influence the circadian clock, possibly acting by serotoninergic potentiation [24,25]. That BLT could be effective in the treatment of CNBP can most likely be explained by the fact that pain and depression have been shown to share similarities in pathophysiological pathways and the brain regions affected [14,26]. Additionally, melatonin, which strongly depends on the light–dark cycle, contributes to pain control through antinociceptive activity on spinal as well as supraspinal levels [27]. In fact, MT1 and MT2 melatonergic receptors play an essential role in pain regulation by reducing hyperalgesia [28] and modulating inflammation [29]. Various intervention protocols with respect to time, dose, and duration of BLT have been suggested [15,30,31]. Most of BLT-associated research and therapy recommendations have focused on the treatment of seasonal depressive disorder, leaving the question which and whether there is an optimum dose and duration of light therapy in other medical conditions such as CNBP.

With the knowledge that depression and pain are often causally connected and BLT has been shown to be effective in the treatment of depressive disorders and pain, the present multicenter randomized controlled trial (RCT) evaluated the potential of incorporating BLT in the treatment of CNBP to diminish pain intensity and depressive symptoms.

Methods

The study was arranged as a three-center RCT with three parallel trial arms for each of the participating centers. This RCT was designed to prospectively explore and compare the effects of adding a novel therapeutic light exposure with no light exposure to the scope of conventional CNBP treatment. An additional aim was to compare parameters concerning changes of mood and subjective well-being before and after the 3-week intervention.

Participants

Enrollment of patients was conducted at three medical centers with different focuses. A total of 125 patients were recruited from September 2008 to September 2009 from the Rehabilitation Centre Bad Häring, the Private Clinic for Orthopedics in Innsbruck, and the University Hospital for Psychiatry and Psychotherapy (AKH) Vienna, all in Austria. Eligible patients were between 25 and 60 years old and were available for therapy over three consecutive weeks. All patients filled out written informed consent before enrollment into the study. Inclusion criterion was $\geq$3 points on the numeric rating scale of item number 5 of the Brief Pain Inventory (BPI; average pain over the last 24 hours), independent of total pain duration. Exclusion criteria were back pain with 10 points on the numeric rating scale of item number 5 of the BPI, intervertebral disk herniation with indication for operation, symptomatology of cauda equina syndrome, morphologic cause of CNBP such as cancer, limited contractual capability, chronic headache, ophthalmic disease, preexisting neurologic diseases such as epilepsy, preexisting severe depression and suicidal tendencies, sleeping disorders, ophthalmic diseases, acute intake of phototoxic medication, pregnancy and lactation period in women, expected change/starting of pain and/or depression medication, or the indication for an operation. In total, 121 patients who met all selection criteria were included in the study. The project was approved by the ethics committees of the Medical University of Innsbruck (UN3285) and the Medical University of Vienna (311/2008).

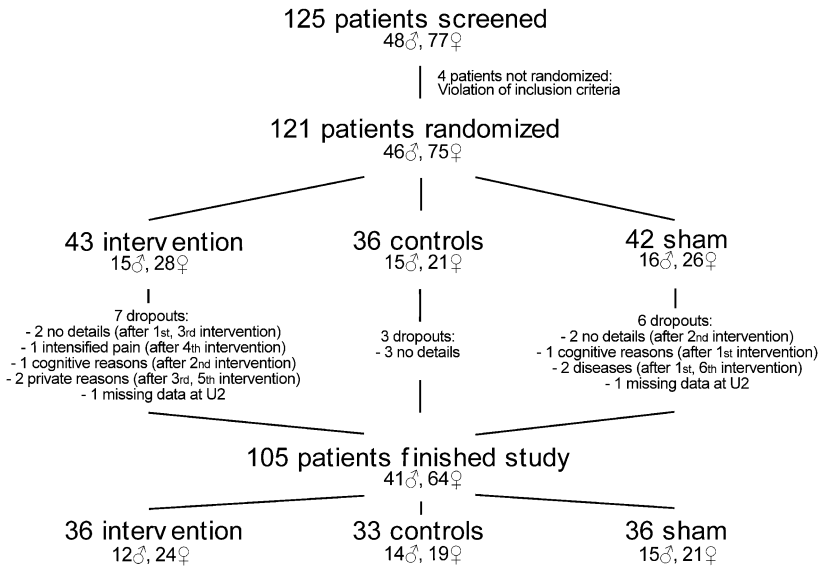

Figure 1 Trial flowchart. U2 = end of the study.

Study Procedure and Measurements

Immediately after inclusion and randomization, patients were screened and anamnestic data collected. The Seasonal Pattern Assessment Questionnaire (SPAQ) was provided to gather information about possible seasonality of symptoms. All questionnaires were self-administered at the respective treatment centers before (U1) and after termination of treatment (U2), which was at 21 ± 2 days after the treatment had started. However, patients were under the supervision of the responsible physician when filling out the questionnaires. The individual medical and overall treatments of patients were set according to their individual requirements.

Light Interventions

Patients assigned to the control group did not receive additional light intervention and followed their pre-study therapy. Patients allocated to the intervention and sham groups also followed their usual treatment, but additionally received respective light interventions. All light exposures (intervention/sham group) were performed in the same light cabin. Specification, intensity, and duration of the applied light therapy were chosen according to recommendations presented in pertinent literature of BLT [32]. The light cabin was equipped with fluorescent lamps with a color temperature of 6,500°K and a color rendering index of >90. Maximum horizontal and vertical illumination was 5,000 lx and the maximum environmental luminance 1,500 cd/m^3. For further specifications of the light cabin, see Leichtfried and coworkers [33]. As a result of constant environmental luminance, no side effects have been reported [33]. According to linear extrapolation of light exposure models (350 cd/m^2 for 2 hours light exposure equals light dose of 1.400 cd/m^2 for ½ hour), time was set to 30 minutes with an illumination of 5.000 lx (1.500 cd/m^3) at eye level for the intervention group [34,35]. Intensity of light intervention in the sham group was set to 230 lx at eye level, an intensity supposed to be ineffective for therapeutic purposes [15]. Variance of respective light situations was ±326 lx for the 5.000 lx situation and ± 15 lx for the 230 lx situation, depending on the viewing direction. Three light interventions per week were performed over three consecutive weeks. Time of light intervention was fixed according to other individual therapeutic interventions. Each participant chose their most practicable light exposure time and used this each day of treatment. Intervention times were between 7:30 AM and 1:30 PM, under the supervision of the responsible physician.

Primary Outcomes and Their Assessment

Changes in pain intensity and depressive symptoms over the 3-week intervention were the primary outcome parameters. The German version of the BPI was used to assess pain intensity [36–38]. Patients were requested to specify and rate their pain, and list the level of impact on their everyday activities on an 11-point grade scale (0–10) ranging from "no" to "full/total" impairment. The change (Δ) of the sub-score 1 of the BPI containing information about pain intensity (arithmetic mean of four respective items) was determined to be the key score in the present study. Cronbach's alpha reliability of the BPI has been reported to range between 0.77 to 0.91 [39]. The depression subscale of the German version of the Hospital Anxiety and Depression Questionnaire (HADS-D) was used to evaluate whether and to what extent participants were suffering from depression. Seven intermingled items associated with depression, each with a rating between 0 and 3 points, are included in the self-assessment questionnaire. The Cronbach's alpha reliability of the German version was reported to be 0.81 [40]. To evaluate the changes in depressive symptoms over the treatment period, the

Table 1 Baseline data of the three study groups at the beginning of the study (U1)

		Control (N = 33)	Intervention (N = 36)	*P* values	Sham (N = 36)	*P* values
Anthropometric data (median (IQR))	Age (years)	52.5 (49.0–58.0)	50.5 (42.0–55.8)*	0.011	47.0 (39.0–54.0)	0.912
	BMI (kg/m^2)	25.7 (23.4–27.8)	24.6 (23.2–30.6)*	0.024	26.3 (23.4–30.0)	0.397
Psychosocial data and pain scores (median (IQR))	HADS-D anxiety score	8.0 (5.25–15.0)	8.0 (5.0–12.0)	0.662	6.0 (4.3–10.0)	0.161
	HADS-D depression score	10.0 (3.25–13.0)	6.0 (3.3–10.8)	0.312	5.5 (2.3–8.8)	0.240
	BPI total score	49.5 (27.0–68.5)	42.5 (25.5–57.3)	0.593	40.5 (28.3–52.8)	0.648
	BPI sub-score 1	4.5 (3.3–5.9)	4.2 (2.9–5.5)	0.777	4.4 (3.6–5.6)	0.778
	BPI sub-score 2	30.0 (14.5–44.75)	26.0 (15.0–39.0)	0.502	24.0 (16.0–33.0)	0.557
Clinical symptoms no. (%)	Pain cervical spine	23 (69.7)	27 (75.0)	0.771	22 (61.1)	0.206
	Pain thoracic spine	4 (12.1)	8 (22.2)	0.294	7 (19.4)	0.772
	Pain lumbar spine	28 (84.8)	27 (75.0)	0.191	31 (86.1)	0.234
	Ischialgia	14 (42.2)	12 (33.3)	0.378	11 (30.6)	0.800
	LBP	18 (54.5)	9 (25.0)†	0.009	15 (41.7)	0.134
Clinical diagnoses no. (%)	Inflammation of SIJ/facet joints	4 (12)	4 (11)	0.880/0.933	3 (8.3)	1.000/0.314
	Damage of bony structures	6 (18.2)	7 (19.4)	0.942	11 (30.6)	0.276
	Disc herniation/ prolapse	5 (14.6)	6 (16.7)	0.176/0.584	8 (22.2)	0.151/0.206

Values represent medians (interquartile ranges) and counts (%), respectively.
Results only refer to comparisons of intervention vs controls and intervention vs sham.
*$P < 0.05$ calculated from chi-square test or Mann–Whitney *U*-test, respectively.
†$P < 0.05$ calculated from chi-square test for comparison of proportions.
BMI = body mass index; BPI = Brief Pain Inventory; HADS-D = German version of the Hospital Anxiety and Depression Questionnaire; IQR = interquartile range; LBP = low back pain; SIJ = sacroiliac joint.

change (Δ) in the depression score was calculated and determined to be the second key outcome.

Secondary Outcomes and Their Assessment

Changes in overall pain sensation, the level of impairment of everyday life as a result of pain, anxiety, mood, and well-being were defined as secondary outcome parameters. Therefore, changes (Δ) of the total BPI score, BPI sub-score 2, HADS-D anxiety score, visual analog scale (VAS), and the World Health Organization-Five Well-Being Index (WHO 5) questionnaire were calculated, respectively.

Sample Size

The estimated sample size of the present study was 120 patients subdivided into the three different trial arms (40 patients each group). Sample size calculation was based on the comparison of two study groups of 40 patients (intervention vs control) with respect to the alteration (Δ) of pain intensity after the 3-week treatment. The expected and clinically relevant progression of scores was defined as follows: It was assumed that an amelioration of one point is expected (average amelioration of scores of 0.05) in 20% of patients in the intervention group and that the variance in the two groups (intervention and control) would be equal. For the sample size calculation, a one-sided $\alpha = 0.025$ was determined. No interim analyses were performed.

Randomization Procedure

The random allocation sequence was generated by employees of the Centre for Statistical Consulting and Continuing Education, University of Health Sciences and Technology Hall in Tyrol. Randomization was done separately at each of the participating centers. An individual inclusion number of a minimum of 15 and maximum of 90 for every center was determined. The statistician allocated the volunteers to one of the three study groups using a random number generator using a 1:1:1 allocation ratio (control—receiving usual treatment and no additional light intervention; intervention—receiving usual treatment and additional novel therapeutic light exposure; sham—receiving usual treatment and

Table 2 Alterations (Δ) in BPI and HADS-D depression scores over study duration

	Control	Intervention	*P* values	Sham	*P* values
Δ HADS-D depression score	0.0 (0.0, 2.0)	1.5 (0.0, 2)*	0.012	1.0 (0.0, 2.0)	0.102
Δ Total BPI score	−0.5 (−4.5, 4.0)	10.5 (1.5, 18.5)*	0.005	6.0 (0.0, 11.5)	0.061
Δ BPI sub-score 1	0.3 (−0.1, 0.8)	1.0 (0.8, 1.6)	0.021	0.5 (0.0, 1.0)	0.150
Δ BPI sub-score 2	−1.5 (−2.5, 3.0)	6.0 (3.0, 12.5)*	0.004	3.0 (1.0, 8.0)	0.055

Values represent median and 95% bias-corrected confidence intervals calculated using bootstrapping technique. Results only refer to comparisons of intervention vs controls and intervention vs sham. *$P < 0.025$ calculated using Mann–Whitney *U*-test. BPI = Brief Pain Inventory; HADS-D = German version of the Hospital Anxiety and Depression Questionnaire.

additional low dose light exposure), thus providing for concealment of allocation to groups. The randomization corresponds to a random sample without putting back. Randomization procedure and a randomization list were sealed until the study had officially ended.

Statistical Analysis

Patients receiving at least seven light interventions and two light exposures per week were included in the per-protocol analyses. Others were counted as dropouts. Statistical analyses were completed by external statisticians who were blinded to treatment allocation (Centre for Statistical Consulting and Continuing Education, University of Health Sciences and Technology Hall in Tyrol). Boxplots were used to determine whether data distributions were symmetrical. As a result of skewness of the distribution, nonparametric tests were used. Results from categorical variables are reported as proportions and continuous variables as medians and interquartile ranges. Comparison of proportions was made using the chi-square test. Comparisons of change scores between groups were assessed using the Mann–Whitney *U*-test for unpaired samples. Bootstrap 95% confidence intervals of the median were calculated by applying the bias correction method. One-tailed *P* values <0.025 were determined to be significant. Additionally, a nonparametric covariance analysis (Quade's nonparametric analysis of covariance) was performed to detect the overall effect on pain corrected for the level of depression. Effect sizes for the main outcome parameters were calculated.

All statistical calculations were done using IBM SPSS Statistics, version 20.0 (IBM Corporation, Chicago, IL, USA) and STATA Data Analysis and Statistical Software version 10.1 (StataCorp, College Station, TX, USA). Effect size was analyzed using G*Power 3.1.7 (Faul, Kiel, Germany).

Results

Patients and Randomization

Of 125 volunteers that were screened, 121 were assigned to the three study groups. In total, 16 patients dropped out of the study for various reasons. Finally, 105 patients, 36 each in the intervention (I; 12♂, 24♀) and sham group (S; 15♂, 21♀) and 33 in the control group (C; 14♂, 19♀), were included in the per-protocol analyses. Figure 1 shows the flow chart of participants including reasons and stages of dropout. All groups were comparable according to pain and depression scores at the beginning of the study (U1). Patients assigned to C were older (52.5 [49.0–58.0] years) than those assigned to I (50.5 [42.0–55.8] years; $P = 0.038$.). Baseline data at the beginning of the study are reported in Table 1. According to the HADS-D depression score, 14 patients (13.5%) showed marginal (score 8–10), 30 patients (28.6%) had evident (score >11), and 60 patients (57.1%) showed no depression (score <8) [41]. According to the SPAQ, 11 (9.1%) and 48 (45.7%) patients were classified to be suffering from subsyndromal seasonal affective disorder (SAD) and SAD at U1, respectively. Of those suffering from SAD, 16 participants were assigned to C, 21 to I, and 11 to S. Among patients with depression, 32 (38.5%) showed a seasonal pattern of symptoms.

Changes in Pain Intensity

Details for BPI scores at U1 and change in scores are shown in Tables 1 and 2. The degree of pain intensity was considered mild to moderate using scores of 4.5 (3.3–5.9) in C, 4.2 (2.9–5.5) in I, and 4.4 (3.6–5.6) in S, on the BPI pain intensity item (BPI sub-score 1). Changes in pain intensity (BPI sub-score 1) were higher (1.0 [0.8–1.6]) in I compared with controls (0.3 [−0.1–0.8], $P = 0.021$). The calculated effect size D was 0.46. No differences were found in change scores between I and S (Figure 2).

Changes in Depression

Details for HADS-D scores at U1 and change scores are shown in Tables 1 and 2.

Alteration of HADS-D depression score over the 3 weeks was higher in patients assigned to the BL intervention (1.5 [0.0–2.5]) compared with controls (0.0 [0.0–2.0], $P = 0.012$). The calculated effect size D was 0.86.

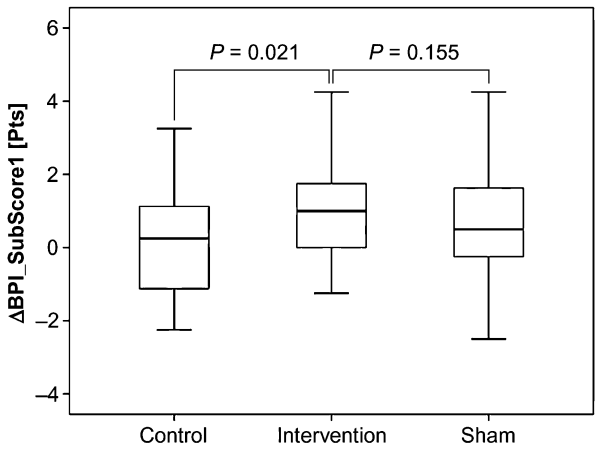

Figure 2 Changes in pain intensity scores (sub-score 1 of the Brief Pain Inventory, BPI) over the 3-week intervention in the different study groups. *P* values only refer to comparisons of intervention vs controls and intervention vs sham calculated using the Mann–Whitney *U*-test.

No differences were found in change scores between I and S (Figure 3).

Changes in the Remaining Pain Scores, Anxiety, Mood, and Well-Being

Total BPI, BPI Sub-Score 2, and HADS-D Anxiety Score

Changes in total BPI score and sub-score 2 over the 3 weeks were higher (10.5 [1.5;18.5] and 6.0 [3.0;12.5], respectively) in I compared with controls (−0.5 [−4.5;4.0], $P = 0.005$ and −1.5 [−2.5–3.0]; $P = 0.004$, respectively). No differences were found in change scores between I and S. Changes in the HADS-D anxiety score were similar in all groups.

Mood (VAS) and WHO Questionnaire (WHO-5)

Changes in self-assessment of mood (VAS) were greater in I (9.5 [14.8; 4.2]) compared with C (−4.2 [−3.2;11.6], $P = 0.006$). Changes in the current psychological well-being, as assessed by the WHO 5 questionnaire, were similar in all groups.

Effect of BLT on Pain Corrected for the Level of Depression

After adjustment for depression, there were significant differences for changes in overall pain sensation (BPI total score, $F = 4.272$, $P = 0.017$) and changes in the grade level of impairment of everyday life as a result of pain (BPI sub-score 2, $F = 4.383$, $P = 0.015$) between the study groups, in particular between the control and intervention groups (Table 3). Changes in the total BPI score were higher (14 [13–31] in nondepressed and 3 [−7–33] in depressed patients) in the intervention group compared with controls (2 [−3.5–10], $P = 0.014$ and −1 [−1.5–10], $P = 0.013$, respectively). Changes in the BPI sub-score 2 were higher (8 [4–13] in nondepressed and 3.5 [−5–23] in depressed patients) in the intervention group compared with controls (0 [−1.5–7], $P = 0.014$ and −2 [−2.5–8], $P = 0.013$, respectively). However, there were no differences between I and C or I and S in pain intensity (BPI sub-score 1, $F = 1.798$, $P = 1.71$), changes in mood (VAS, $F = 2.927$, $P = 0.058$), or changes in the current psychological well-being (WHO 5, $F = 1.016$, $P = 0.366$).

Discussion

The present multicenter RCT investigated the possible benefit of supportive light intervention in addition to conventional therapy for CNBP. Specification, intensity, and duration of the applied light intervention were chosen according to recommendations presented in pertinent literature of BLT [32]. The results show that patients assigned to a BL intervention group exhibited greater declines in all parameters of the BPI compared with controls. Declines in the depression score estimated by the HADS-D were also greater in the intervention group than in controls. Additionally, self-reported mood increased more in the BLT intervention compared with controls over the study duration. Differences were not maintained when BL was compared with sham light exposure. The results indicate that BL exposure can induce effects on pain, depression, and mood in CNBP patients when compared with conventional CNBP

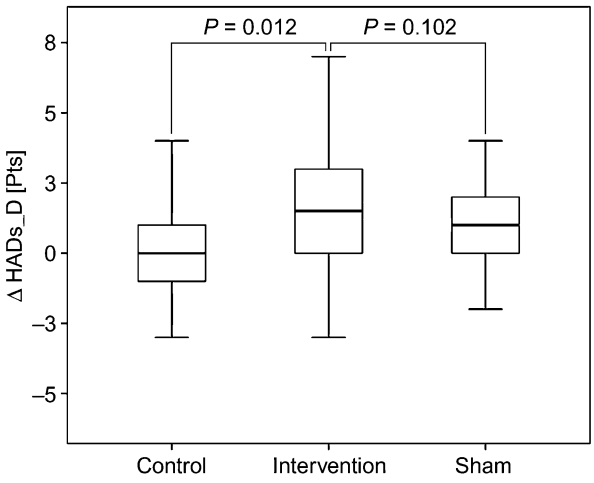

Figure 3 Changes in depression score of the Hospital Anxiety and Depression Questionnaire (HADS-D) over the 3-week intervention in the different study groups. *P* values only refer to comparisons of intervention vs controls and intervention vs sham calculated using the Mann–Whitney *U*-test.

Table 3 Alterations (Δ) in BPI and HADS-D depression scores after correction for depression in the three study groups

	No Depression (HADS-D < 8)			Depression (HADS-D ≥ 8)		
	Control	Intervention	Sham	Control	Intervention	Sham
Δ BPI total	2.0 (−3.5,10.0)	14.0 (13.0,31.0)*	10.0 (1.0,13.0)	−1.0 (−1.5,10.0)	3.0 (−7.0,33.0)	−1.0 (−9.5,7.5)
Δ BPI sub-score1	0.5 (−1.1,1.9)	1.0 (0.8,2.0)	0.9 (0.0,1.8)	0.25 (−0.5,0.5)	1.0 (0.5,1.5)	0.25 (−0.5,0.75)
Δ BPI sub-score2	0.0 (−1.5,7.0)	8.0 (4.0,13.0)*	4.0 (1.5,10.5)	−2.0 (−2.5,8.0)	3.5 (−5,23)	−3.0 (−5.0,9.0)
Δ VAS	0.0 (−4.5,29.0)	−0.5 (−10.0,0.0)	−2.0 (−9.0,0.0)	1.0 (−9.0,19.0)	−9.0 (−27.0,1.0)*	−10.0 (−17.0,10.0)
Δ WHO-5	−2.0 (−8.0,10.0)	−8.0 (−16.0,2.0)	−10.0 (−22.0,−4.0)	−6.0 (−12.0,2.0)	−4.0 (−8.0,4.0)	−4.0 (−4.0,12.0)

Values represent median and 95% bias-corrected confidence intervals calculated using bootstrapping technique. Results only refer to comparisons of intervention vs controls and intervention vs sham.

*$P < 0.05$ calculated using Mann–Whitney *U*-test.

BPI = Brief Pain Inventory; HADS-D = German version of the Hospital Anxiety and Depression Questionnaire; VAS = visual analog scale; WHO 5 = World Health Organization-Five Well-Being Index.

therapy. The fact that none of the advantages could be upheld when compared with the sham light condition challenges the efficacy of the highly intense light, indicating that effects might be at least partly depending on other factors than light intensity only. It is therefore necessary to consider optimum intensity and dosage for therapeutic effects of light interventions in future research.

Adherence among patients in the present trial was very high. The authors suggest that this might be due to the chronic nature of the back pain on the one hand and the innovative and new light device that might have aroused curiosity in chronic pain patients on the other.

To our knowledge, there are only few studies investigating BLT and its consequences on pain scores. Comparable with the present results, Pearl et al. [42] evaluated the effects of BLT in a group of female fibromyalgia patients in a cross-over design and did not find an amelioration of any of the investigated parameters, including pain scores, mood, or sleep ratings [42]. Unlike the light visors used by Pearl et al. that are described to produce wide ranges of light intensity (2.500–5.000 lx), the light cabin used in the present study offers almost constant illumination of 5.000 lx, independent of eye motion [33]. This guarantees an adequate amount of retinal illumination and is crucial for the beneficial effects of light therapy [15]. Despite this innovative light intervention, only small effects were seen. The short intervention time in both trials as well as the known low therapeutic response in both groups of pain patients (fibromyalgia and CNBP) may partly account for the results. Improvements in pain, mood, hormone status as well as autonomic effects could be shown already after 10 sessions of phototherapy (3.000 lx) in children suffering from episodic headache of tension, chronic headache, and migraine [23]. These divergent results claim the need for additional research with respect to optimization of dose, frequency, and timing of BLT for specific groups of chronic pain patients.

Improvements in sensation of pain intensity averaged around 1.0 (0.8–1.6) points in the intervention group. The minimum clinically important difference in patients suffering from fibromyalgia and chronic LBP has been defined as two points on an 11-point scale, corresponding to a pain improvement of 30–35% to be of clinical relevance [43,44]. These data indicate that declines in pain intensity in our patients were below the clinically relevant minimum, also suggesting that the intervention period was either too short or dose, frequency, and timing of the BL intervention were inadequate. In fact, the intended "sham" intervention showed small but similar effects in some of the pain and depression associated scores, suggesting that the sham intervention might have also been of therapeutic value. An intensity low enough to be having no therapeutic effects, as well as bright enough to meet the requirements for a trustworthy placebo situation, has to be considered when designing the placebo light situation. Dim white light intensities <400 lx have been successfully used in several light box studies to act as placebo when testing BL

[45]. The sham condition in the present setting was therefore set to 230 lx. The above given facts emphasize the need for research to determine whether low intense light is really therapeutically ineffective.

Approximately 42% of all patients included showed marginal or noticeable symptoms of depression in the previous week (HADS-D). Strikingly, 27 patients showed seasonality of symptoms without being diagnosed as depressed. It was shown that people without classic depressive symptoms can show seasonal cycles of symptoms. Rohan and co-workers describe this phenomenon as sub-syndromal SAD [46]. Almost half of our total population (45.7%) was classified as having symptoms of SAD and 9.1% had sub-syndromal SAD. We agree with Rohan et al. that it is necessary to use supplementary research methods to increase stringency in the diagnosis of depression, especially those with a seasonal pattern [46].

Interestingly, when the overall effect of pain after correction for the level of depression was calculated, some differences in change scores persisted between the groups. Changes in overall pain and its impact on everyday activities were still different; in particular, change scores were higher in the intervention group compared with controls and therefore not influenced by depression. However, the coexistence of depressive symptoms had an impact on changes in pain intensity and mood. The fact that adjustment for depression influenced outcome of pain intensity as well as mood leads to the following assumptions: If concomitant depression exists in pain patients, it overrides other comorbidities and should be treated preferentially, confirming suggestions for a multimodal approach in the treatment of CNBP [3]. Moreover, there is evidence for poorer courses of both disease patterns if they are coexistent [9]. Interestingly, patients were not comparable with respect to all pain parameters as well as anxiety after being categorized into subgroups, with markedly lower values for nondepressed patients. This even more stresses the overruling influence of depression in pain patients. Pain is not responsible for the increase in depressive symptoms [47], but treatment outcomes are negatively influenced by comorbid pain [48], which can be confirmed by our data. In fact, chronic pain and depression could be risk factors for one another [49]. A possible interaction might be found in an increased pain perception in depressed patients, which was demonstrated in a recent study of Australian women [6]. It remains a great challenge in the treatment of chronic pain that depressed patients do not successfully respond to therapeutic interventions of all medical subspecialties. We believe that comorbid depression with CNBP is sufficient to intensify the sensation of pain and dampens the success of all kinds of pain therapies.

Limitations of the Trial

Several limitations of the trial should be discussed. Although all patients were comparable concerning the main outcome variables, a slight randomization imbalance for the HADS-D anxiety score was detected, indicating slightly lower anxiety levels for patients randomized to the sham group. Secondly, only immediate effects were evaluated, which leaves prolonged effects to be investigated. Thirdly, the often discussed difficulty of finding an appropriate placebo situation in BLT in general should be mentioned. In the present trial, the 230 lx light condition may have been active in addition to mimicking all nonspecific effects of the active treatment [50]. Patients assigned to the different light groups were neither informed of their allocation nor saw the other light intervention, which minimizes the chance of allocation-specific expectations such as the Hawthorne effect. Although baseline treatment was not changed over the trial duration, outcomes were not controlled for adjunctive therapies and comorbidities. Interaction with the therapeutic light intervention cannot be excluded. Dose and duration of the light therapy were determined according to general guidelines for BLT [32], effective in seasonal depressive disorders. Most studies of nonseasonal depression and other conditions use higher doses of BLT for efficacy than that used for SAD [15]. This leaves the discussion whether there is an optimum dose and duration of light therapy in other medical conditions such as CNBP. Weekly intervention frequency with three interventions and at least seven interventions in total was probably too low, which might have masked more robust effects of the treatment.

The strength of the study is that patients assigned to the study are comparable with average patients suffering from CNBP. Primarily orthopedic, primarily psychiatric, and across-the-board approaches were included, guaranteeing inclusion of a great range of different modalities of CNBP treatment. We are in line with Dworkin et al. [51] that psychological characteristics of pain patients have to be individually considered and included in treatment.

In conclusion, the present RCT showed that light therapy might have the potential to be an interesting and noninvasive supplement in the treatment of chronic pain. Nevertheless, the results postulate that further investigation is required for evidence of long term effects and optimum dose, frequency, and timing of light therapy for CNBP patients.

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