https://doi.org/10.22365/jpsych.2023.027 / Psychiatriki 2024, 35:54–65

Research article

Efficacy of a conservative physical treatment regimen on psychological status and quality of life in Greek patients with chronic low back pain

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ARTICLE HISTORY: Received 24 April 2023/Revised 23 September 2023/Published Online 14 November 2023

ABSTRACT

Chronic Low Back Pain (CLBP) is a very common health problem that has a great negative impact on the quality of life and the psychological well-being of backache patients. Literature findings have shown that a conventional physiotherapeutic approach is a beneficial choice for CLBP management. This study aimed to examine the short-term effects of conservative physical treatment on depression, anxiety, somatic symptom disorders (SSD), quality of life, pain, and disability in Greek individuals suffering from CLBP. Seventy-five CLBP patients were recruited using random systematic sampling. All subjects received an ultrasound, low-level laser, massage, transcutaneous electrical nerve stimulation (TENS), and an exercise program (sum of 10 sessions, 5 times per week). The intervention was assessed by comparing pre and post-outcome measurements based on the Hospital Anxiety and Depression Scale (HADS), Somatic Symptom Scale-8 (SSS-8), EuroQol 5-dimension 5-level (EQ-5D-5L), Roland-Morris Disability Questionnaire (RMDQ) and Pain Numerical Rating Scale (PNRS) instruments. The mean age of the sample was 60.8 years (±14.4) and nearly one out of four (25.3%) was obese. After the end of the treatment, there were improvements in EQ-5D-5L indices and decreases in HADS, SSS-8, RMDQ, and PNRS scores, which were found to be statistically significant. Greater effect size was found in PNRS (d=0.75), followed by EQ-5D-5L index value scale (d=0.42), SSS-8 (d=0.38), EQ-5D-5L VAS (d=0.36), RMDQ (d=0.29), HADS-A (d=0.16) and HADS-D (d=0.14). Men and women had similar changes in all under-study scales after the treatment, while besides the pain scale, the pre-intervention scores as well as the degree of change in all scores were similar across all Body Mass Index (BMI) levels. In conclusion, convectional physical treatment was found to be an effective option in improving considerably the psychological status and quality of life, while also decreasing functional disability and pain in CLBP patients in the short run.

KEYWORDS: Chronic low back pain, physical modalities, disability, exercise, quality of life, somatic symptom disorders, pain, anxiety, depression.

Introduction

As reported by the Global Burden of Diseases Study 2019 (GBD 2019), pain in the lumbar region was the foremost cause of disability for all ages, showing a rise of 47 % since 1990 and resulting in 64 million disability-adjusted life – years.[1,2] In consistent with the findings of GBD 2019, low back pain (LBP) in Greece was among the five leading reasons for years lived with disability from 2000 to 2016.[3] The great majority of LBP instances (85%) have no known or recognizable pathoanatomical cause, with them being denominated as non-specific, while in the case that the pain lasts longer than twelve weeks, they are defined as chronic LBP (CLBP).[4] Unpleasant pain sensation and limitation in activities of daily living (ADLs) were associated with pain perception

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and psycho-social discomforts of patients with CLBP, which in turn lead to impaired health-related quality of life (HRQoL), psychological states like anxiety, depression, and somatic symptoms disorders (SSD), severe disability, increased healthcare utilization and socioeconomic costs due to work absenteeism, loss of labor and decreased productivity.[3–8] Therefore, chronic low back pain calls for concerted research efforts, founded on the concept of a "biopsychosocial pain syndrome", and particular attention from health policymakers to address its burden as a public health problem.[4,9]

Consistent with clinical practice guidelines and recent systematic reviews, non-pharmacological treatment options are essential parts of CLBP management, including a variety of interventions like physical therapy modalities, exercise programs, and cognitive-behavioral therapy to eliminate the negative impacts mentioned above.[10–12] Specifically, previous studies have shown that single and mainly combined use of transcutaneous electrical nerve stimulation (TENS), therapeutic ultrasound (US), massage, low-level laser, and exercise are effective not only in improving health and psychological status but also in alleviating pain severity and functional disability.[11–18] However, the clinical effect of the aforementioned intervention has not been documented beyond a reasonable doubt. In particular, a systematic review of eighty-three randomized controlled trials identified ambiguous evidence to support the effectiveness of conventional physical treatment for patients with CLBP, concluding that additional trials should be carried out to better comprehend and evaluate its efficacy.[19] Additionally, studies concerning the efficacy of a conventional physiotherapeutic approach in patients with CLBP, implementing physical modalities and exercise, are scanty and lacking in the Greek population.[20] A Greek prospective study of 80 inpatients with LBP, following conservative treatment, demonstrated a substantial improvement in HRQoL even one month later from discharge.[20] In summary, no study to date has examined the short-term effects of a similar approach on psychological status (anxiety, depression, and SSD), pain intensity, and functional disability in Greek individuals with CLBP.

Consequently, the current study aimed to investigate the short-term efficacy of a conservative physical treatment regimen on pain, disability, anxiety, depression, SSD, and HRQoL in CLBP patients for the first time. We hypothesized that subjects undergoing a conservative intervention would demonstrate significant improvement in health and psychological status, pain, and functional disability.

Material and Method

Study design and participants

Given that the available subject pool was limited and placebo control was not ethically desirable, it was conducted a one-group pretest-posttest study design at the outpatient physical therapy unit of TYPET (Greek acronym of the Mutual Health Fund of National Bank of Greece Personnel) in Athens, in which the same dependent variables were assessed in a single group of patients with CLBP before (pretest) and after (posttest) intervention was administered.[21–23] It was calculated that with the sample size of 75 participants, the study will have >95% power to detect significant differences at an effect size of 0.5 or more and a significance level of 0.05. Between 1 April 2021 and 31 December 2021, a total of 150 individuals, who had been referred to the above unit for the management of CLBP by their attending orthopedic doctor, met all the inclusion criteria. Of those 75 participants, aged 26–94 years old, were enrolled in the study with a selection; every second subject was asked to fill in a questionnaire (a random systematic sampling) (figure1).

The conventional intervention was administered to the lumbosacral part by a physical therapist (one-on-one), including massage, ultrasound, TENS, low-level laser, and an exercise program (a sum of 10 sessions including all components of the intervention, 5 times per week). Massage (with deep stroking, wringing, friction, pulling, and rolling techniques) and continuous ultrasound (frequency: 1 MHz, intensity: 1.5 W/cm^2) lasted 15 minutes and 5 minutes, respectively.[18,24–26] Additionally, TENS was applied with four cutaneous electrodes for 20 minutes.[26] Exercise program consisted of a strengthening part of the back and frontal abdominal muscles performed for 20 minutes with a set of 10 repetitions on each exercise (pelvic tilt, abdominal hollowing, knee to chest, oblique crunch, supine plank, bird and dog, cat and camel, lower abdominal and back extension exercises), as well as a stretching part of the hip flexors, hamstrings and lumbar extensors performed for 30 seconds on each muscle group.[13,25,27] Last but not least, the continuous low-level laser was applied with a contact method at four points over both sides of the spinal column for 80 seconds (830 nm, 120 m, 0–50000 Hz).[18,27–29] During the treatment, patients could select to sit in a chair or lie down on a bed in a prone position to control positional intolerance.

The exclusion criteria were subjects with previous spinal surgery or cancer, fibromyalgia syndrome, psoriatic arthritis, rheumatoid arthritis, spinal fracture, cauda equina syndrome, spondylolisthesis, scoliosis less than or at most equal to 20º and ankylosing spondylitis (red flags). All participants were fully informed

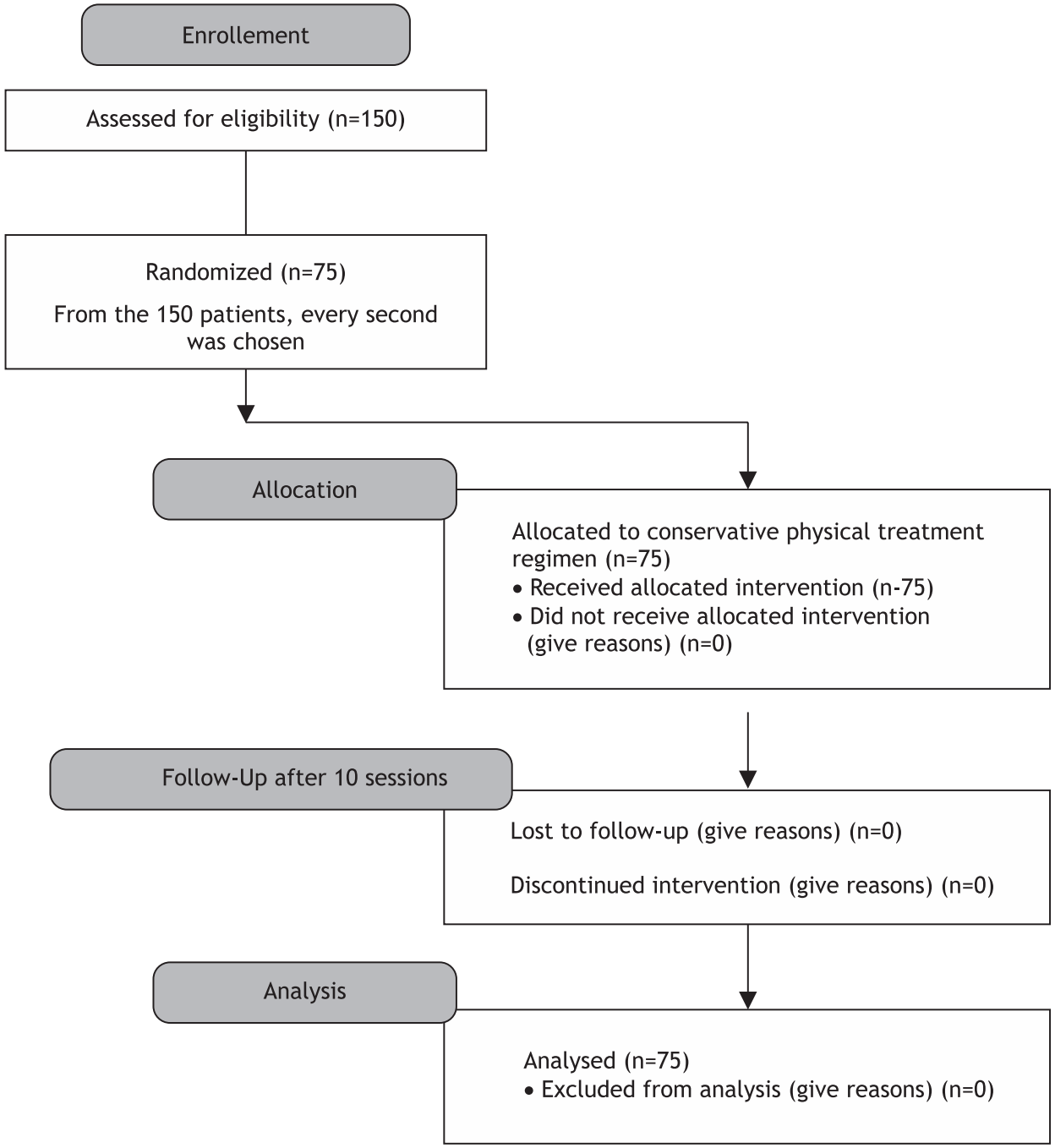

Figure 1. The flow diagram of the study.

about the confidentiality and anonymity of the paper-and-pencil questionnaire and signed a written consent. This research was authorized by the medical ethics board of primary healthcare services of TYPET (ΑΡ.Π.005294/19-10-2020) and the School of Medicine of National and Kapodistrian University of Athens. This survey was carried out according to the principles of the Declaration of Helsinki, bearing in mind the Consolidated Standards of Reporting Trials (CONSORT) statement for reporting randomized trials.[30,31]

Measures

All subjects were evaluated at the beginning (before the intervention) and right after the end of the conservative physical treatment regimen (10th session). The administered questionnaire incorporated demographic information, such as age, height, body weight, gender, educational background, marital and employment status, and physical activity (e.g "How often did you work out more than 30 min a day per week, during the last

year?"), as well as patient-reported outcome (PRO) measures for pain, anxiety, depression, somatic symptom burden, disability, and HRQoL. In particular:

Body Mass Index (BMI) was calculated as the body weight in kilograms divided by the square of the height in meters, classifying three subcategories; normal weight (18.5–24.9 kg/m^2), overweight (25.5–29.9 kg/m^2) and obese (≥30 k/m^2).[25]

The Pain Numerical Rating Scale (PNRS) is a degree of physical discomfort severity (present, best, and worst level of pain during the last 24 hours, whose average represents the patient's overall pain intensity), varying from 0 to 10 (no pain to worst pain you can imagine).[32]

The Somatic Symptom Scale-8 (SSS-8) is a measure to evaluate the degree of SSD during the last seven days, using a five-point Likert scale. Sum points are between 0 to 32, with greater scores indicating a greater burden of SSD.[33]

The Hospital Anxiety and Depression Scale (HADS) is a questionnaire aimed to estimate the severity of depression and anxiety (seven items for each subscale) within the last week in clinical research, using a four-point Likert scale. Total scores vary from 0 to 21, with greater values denoting higher degrees of depression and anxiety.[34]

The EuroQol-5D 5-level edition (EQ-5D-5L) is a standardized questionnaire measuring health profiles. It consists of a descriptive system of 5 subdimensions (mobility, self-care, usual activities, pain/discomfort, anxiety/depression), which evaluates and defines a single health status (3125 levels) varying from 11111 (highest health level) to 55555 (lowest health level) and a vertical 0–100 scale with higher scores indicating better overall health.[35,36]

The Roland - Morris Disability Questionnaire (RMDQ) comprises 24 items assessing functional status in patients with LBP over the past 24 hours. Total points range from 0 to 24, with greater scores corresponding to higher levels of disability due to LBP.[37]

All PRO measures have previously been cross-culturally validated within the Greek population and have been recommended for utilization across patients with CLBP.[38–41]

Statistical analysis

Quantitative variables were summarized in mean (Standard Deviation) and in median (interquartile range), while Qualitative variables were summarized in absolute and relative frequencies. The Kolmogorov-Smirnov criterion was used to evaluate the normality assumption. Non -Non-parametric Wilcoxon signed tests were used for pre-post intervention comparisons of all under-study-scales because the data were not normally distributed. Repeated measurements analysis of variance (ANOVA) was used to assess the variations watched closely in all under-study scales and their association with gender and BMI over the follow-up period. Bonferroni correction was adopted in case of multiple testing to control for type I errors. Repeated measurement analysis was conducted after logarithmic transformations of the scales. Cohen's d was adopted to assess the clinical significance of the intervention effects, whose values of 0. 20, 0. 50 and 0. 80 are suggestive of small, medium, and large effect sizes, accordingly.[42] All reported p-values are two-tailed. Statistical analyses were completed using SPSS statistical software (version 22.0) and a minimum level of significance was set at $p<0.05$.

Results

The sample consisted of 75 participants (response rate=100%), 48 females and 27 males, with an average age of 60.8 years (SD=14.4 years). Their features are presented in table 1. Nearly one out of four (25.3%) was obese. Married were 60% of the participants and 32% were employed. Moreover, university alumni were 32.4% of the sample and 24.3% were MSc/PhD holders. 49.3% of the sample was working out more than two times a week, during the last year, for more than 30 minutes (table 1).

Table 1. Sample characteristics.

	N (%)
Gender	
Men	27 (36.0)
Women	48 (64.0)
Age (years), mean (SD)	60.8 (14.4)
BMI (kg/m^2), mean (SD)	27.3 (6.0)
BMI	
Normal	29 (38.7)
Overweight	27 (36.0)
Obese	19 (25.3)
Married	45 (60.0)
Educational level	
At most college	32 (43.2)
University	24 (32.4)
Postgraduate studies	18 (24.3)
Employed	24 (32.0)
During the last year, how often did you work out more than 30 min a day?	
None	12 (16.0)
1–2 times per month	14 (18.7)
Once a week	12 (16.0)
More than once a week	37 (49.3)

SD: Standard Deviation; BMI: Body Mass Index

SSS-8 score diminished significantly after the intervention, indicating improvement in patients' somatic symptom burden (table 2). Also, considerably less anxiety and depression levels had patients after the intervention. Pain levels decreased importantly after the intervention and patients' health condition improved significantly according to both 0 to 100 health status scale and EQ-5D-5L index value score. Synchronically, the disability index decreased substantially after the intervention, suggesting significant improvement in patients feeling disabled. The greater effect size was found in the pain scale (d=0.75), followed by the EQ-5D-5L index value scale (d=0.42).

Men and women had similar changes in all under-study scales after the treatment (table 3). Additionally, before the intervention, men and women had similar scores in all under-study scores except for the SSS-8 score, which was significantly higher in women. After the intervention, men and women had similar scores in all under-study scores. Also, substantial decrease in the SSS-8 score, in RMDQ, and the pain scale had both men and women, after the intervention. On the contrary, depression scores diminished significantly after the intervention only in men, whereas EQ-5D-5L index value and EQ-5D-5L VAS were improved solely in women after the intervention.

The degree of change in pain scale differed importantly across the BMI levels. More specifically, the decrease was greater in the obese participants (table 4). However, before the intervention, pain was significantly different among the three BMI levels and more specifically, the obese participants had substantially greater pain compared to the participants with normal BMI (p=0.009). In the rest of the scales, i.e., besides the pain scale, the pre-intervention scores and the degree of change in all scores were similar across all BMI levels. Furthermore, after the treatment, no significant differences were observed in any of the under-study scales among the BMI levels. SSS-8 score and RMDQ decreased considerably in normal and overweight participants, anxiety score only in overweight participants, and pain score in normal and obese participants. EQ-5D-5L VAS was improved solely in overweight participants, whereas EQ-5D-5L index value was increased only in obese participants.

Discussion

To the best of our knowledge, this was the first single group pretest-posttest study in primary care examining the efficacy of a conservative physical treatment regimen on pain, disability, anxiety, SSD, and HRQoL in Greek patients with CLBP. Overall, the findings demonstrated that somatic symptom burden, anxiety and depression levels, pain severity, and functional disability were statistically significantly alleviated, and in addition, HRQoL was importantly improved after the conventional physiotherapeutic approach.

Although physical therapy modalities (massage, ultrasound, TENS, low-level laser, exercise program) are frequently used widespread in the treatment of CLBP, their effects are debatable, as Middelkoop et al,[19] Khadilkar et al,[43] Yousefi-Nooraie et al,[44] Saragiotto et al,[45] Ebadi et al,[46] Hayden et al,[47] and Furlan et al[48] reported in their systematic reviews. However, our results strengthen the findings of previous studies in patients with CLBP, emphasizing that a combination of different physical modalities has yielded beneficial effects in the short run.[49,50] In a pooled meta-analysis, Jauregui et al[51] highlighted that TENS was a beneficial choice in alleviating pain intensity in CLBP. Similarly, an Indian randomized controlled study of thirty patients with CLBP detected more satisfactory results in pain severity after adding ultrasound to exer-

Table 2. Participants' scores pre and post intervention.

	Pre		Post			Z	P+
	Mean (SD)	Median (IQR)	Mean (SD)	Median (IQR)	Effect size d		
SSS-8 score	9.33 (4)	9 (6–12)	7.81 (4.11)	7 (4–11)	0.38	–3.22	0.001
HADS-Depression score	6.12 (3.17)	6 (4–8)	5.68 (3.25)	6 (3–7)	0.14	–2.07	0.038
HADS-Anxiety score	5.53 (3.6)	5 (3–7)	4.95 (3.62)	5 (2–7)	0.16	–2.14	0.032
RMDQ	7.67 (4.42)	7 (4–10)	6.35 (4.66)	6 (3–9)	0.29	–3.24	0.001
PNRS (0-10 scale)	4.67 (2.03)	5 (3–6)	3.2 (1.9)	3 (2–5)	0.75	–5.00	<0.001
EQ-5D-5L VAS	70.49 (14.64)	70 (60–80)	75.76 (14.32)	80 (70–85)	0.36	-4.12	<0.001
EQ-5D-5L index value	0.67 (0.15)	0.69 (0.59–0.76)	0.74 (0.15)	0.75 (0.68–0.83)	0.42	-4.17	<0.001

+Wilcoxon signed test; SSS-8: Somatic Symptom Scale-8; HADS: Hospital Anxiety and Depression Scale; RMDQ: Rolland-Morris Disability Questionnaire; PNRS: Pain Numerical Rating Scale; EQ-5D-5L VAS: EuroQol-5D 5 level Visual Analog Scale

Table 3. Changes in all under study scales associated by gender.

		Pre		Post					
	Gender	Mean (SD)	Median (IQR)	Mean (SD)	Median (IQR)	F (df_1, df_2)$^{++}$	P^{++}	F (df_1, df_2)‡	P‡
SSS-8 score	Men	8.96 (3.82)	8 (6–12)	7.78 (4.65)	6 (4–12)	12.79 (1,73)	0.024	0.92 (1,73)	0.915
	Women	9.54 (4.12)	9 (7–12)	7.83 (3.82)	7 (4.5–10.5)		0.005		
	F(df_1, df_2)$^{+}$	0.43 (1,73)							
	P^{+}	0.041		0.055					
HADS-Depression score	Men	6.26 (3.49)	6 (3–8)	5.52 (3.45)	5 (3–7)	6.90 (1,72)	0.025	1.04 (1,72)	0.312
	Women	6.04 (3.01)	6 (4–8)	5.77 (3.17)	6 (3–7)		0.187		
	F(df_1, df_2)$^{+}$	0.03 (1,72)							
	P^{+}	0.859		0.646					
HADS-Anxiety score	Men	5.41 (3.65)	5 (3–7)	4.59 (3.87)	4 (2–7)	5.67 (1,72)	0.054	0.56 (1,72)	0.457
	Women	5.6 (3.61)	5.5 (3–7)	5.15 (3.5)	5 (2–8)		0.181		
	F(df_1,df_2)$^{+}$	0.36 (1,72)							
	P^{+}	0.793		0.426					
RMDQ	Men	7.48 (4.26)	7 (5–10)	6.48 (4.89)	6 (3–9)	12.62 (1,72)	0.047	0.11 (1,72)	0.738
	Women	7.77 (4.55)	7.5 (4–11)	6.28 (4.58)	6 (3–8)		0.002		
	F(df_1,df_2)$^{+}$	0.01 (1,72)							
	P^{+}	0.806		0.974					
PNRS	Men	4.63 (1.67)	5 (3–6)	3.3 (1.81)	3 (2–5)	27.68 (1,73)	0.003	0.06 (1,73)	0.801
	Women	4.69 (2.22)	5 (3–6)	3.15 (1.96)	3 (2–5)		<0.001		
	F(df_1, df_2)$^{+}$	0.28 (1,73)							
	P^{+}	0.718		0.597					
EQ-5D-5L VAS	Men	71.48 (15.31)	70 (65–80)	75.78 (14.61)	75 (70–85)	8.95 (1,72)	0.087	0,05 (1,72)	0.824
	Women	69.94 (14.38)	70 (60–80)	75.74 (14.3)	80 (68–85)		0.010		
	F(df_1, df_2)$^{+}$	0.01 (1,72)							
	P^{+}	0.880		0.970					
EQ-5D-5L index value	Men	0.68 (0.12)	0.69 (0.58–0.76)	0.72 (0.15)	0.74 (0.65–0.82)	8.56 (1,72)	0.328	1.83 (1,72)	0.180
	Women	0.67 (0.16)	0.69 (0.59–0.76)	0.75 (0.15)	0.77 (0.68–0.86)		0.001		
	F(df_1, df_2)$^{+}$	0.04 (1,72)							
	P^{+}	0.650		0.416					

$^{+}$F(df_1, df_2) and p-value for group effect, $^{++}$F(df_1, df_2) and p-value for time effect, ‡F(df_1, df_2) and p-value for differences in the degree of change among the groups (repeated measurements ANOVA); SD: Standard Deviation; IQR: Interquartile Range; SSS-8: Somatic Symptom Scale-8; HADS: Hospital Anxiety and Depression Scale; RMDQ: Rolland-Morris Disability Questionnaire; PNRS: Pain Numerical Rating Scale; EQ-5D-5L VAS: EuroQol-5D 5 level Visual Analog Scale.

Table 4. Changes in all under study scales associated by BMI levels.

		Pre		Post					
	BMI	Mean (SD)	Median (IQR)	Mean (SD)	Median (IQR)	F (df_1, df_2)$^{++}$	P^{++}	F (df_1, df_2)‡	P‡
SSS8 score	Normal	8.69 (3.27)	8 (6–11)	7.03 (3.46)	6 (4–9)	12.59 (1,72)	0.022	0.07 (2,72)	0.935
	Overweight	8.93 (3.88)	8 (6–12)	7.44 (4.15)	6 (4–11)		0.019		
	Obese	10.89 (4.88)	9 (7–13)	9.53 (4.64)	10 (5–13)		0.127		
	F (df_1, df_2)$^{+}$	2.17 (2,72)							
	P^{+}	0.182		0.239					
Depression score	Normal	5.55 (3.17)	5 (4–7)	5.48 (3.46)	6 (3–7)	6.54 (1,71)	0.388	0.48 (2,71)	0.622
	Overweight	6 (3.04)	6 (4–8)	5.37 (2.71)	6 (4–7)		0.127		
	Obese	7.16 (3.27)	7 (5–9)	6.44 (3.7)	6 (4–10)		0.058		
	F (df_1, df_2)$^{+}$	0.79 (2,71)							
	P^{+}	0.244		0.733					
Anxiety score	Normal	5.52 (3.99)	6 (2–7)	4.45 (3.19)	4 (2–7)	3.65 (1,71)	0.102	1.48 (2,71)	0.234
	Overweight	5.52 (3.53)	5 (3–7)	4.41 (3.28)	5 (2–6)		0.024		
	Obese	5.58 (3.25)	6 (4–7)	6.56 (4.4)	6 (3–10)		0.764		
	F (df_1, df_2)$^{+}$	0.54 (2,71)							
	P^{+}	0.856		0.335					
Roland-Morris Disability Index	Normal	7.83 (4.94)	7 (4–11)	5.69 (4.46)	5 (2–8)	12.00 (1,71)	0.002	0.80 (2,71)	0.453
	Overweight	7.63 (3.92)	8 (5–10)	6.56 (4.37)	6 (3–10)		0.024		
	Obese	7.47 (4.49)	7 (5–9)	7.11 (5.47)	6 (4–8)		0.387		
	F (df_1, df_2)$^{+}$	0.13 (2,71)							
	P^{+}	0.961		0.689					
PNRS	Normal	3.97 (2.15)	4 (3–5)	2.79 (1.95)	3 (2–4)	38.64 (1,72)	0.002	4.27 (2,72)	0.018
	Overweight	4.67 (1.8)	5 (3–6)	3.89 (1.95)	4 (3–5)		0.059		
	Obese	5.74 (1.76)	6 (5–6)	2.84 (1.5)	3 (2–4)		<0.001		
	F (df_1, df_2)$^{+}$	2.95 (2,72)							
	P^{+}	0.011		0.103					
EQ-5D-5L VAS	Normal	72.55 (14.73)	75 (60–85)	76.93 (14.07)	80 (70–85)	10.08 (1,71)	0.112	0.13 (2,71)	0.876
	Overweight	72 (12.87)	70 (60–85)	77.78 (12.51)	80 (70–85)		0.050		
	Obese	65.21 (16.27)	69 (50–80)	70.83 (16.74)	75 (70–80)		0.061		
	F (df_1, df_2)$^{+}$	2.19 (2,71)							
	P^{+}	0.160		0.200					

Continues

Table 4. Continued.

	BMI	Pre		Post					
		Mean (SD)	Median (IQR)	Mean (SD)	Median (IQR)	F (df_1, df_2)$^{++}$	P^{++}	F (df_1, df_2)‡	P‡
EQ-5D-5L index value	Normal	0.7 (0.17)	0.69 (0.67–0.78)	0.74 (0.19)	0.76 (0.68–0.87)	13.81 (1,71)	0.162	1.22 (2,71)	0.302
	Overweight	0.68 (0.11)	0.71 (0.57–0.77)	0.73 (0.12)	0.75 (0.66–0.81)		0.091		
	Obese	0.63 (0.14)	0.66 (0.5–0.74)	0.74 (0.14)	0.73 (0.71–0.83)		0.004		
	F (df_1, df_2)$^{+}$	0.20 (2,71)							
	P+	0.444		0.981					

$^{+}$F(df_1, df_2) and p-value for group effect $^{++}$F(df_1, df_2) and p-value for time effect ‡F(df1, df_2) and p-value for differences in the degree of change among the groups (repeated measurements ANOVA); SD: Standard Deviation; IQR: Interquartile Range; BMI: Body Mass Index; SSS-8: Somatic Symptom Scale-8; HADS: Hospital Anxiety and Depression Scale; RMDQ: Rolland-Morris Disability Questionnaire; PNRS: Pain Numerical Rating Scale; EQ-5D-5L VAS: EuroQol-5D 5 level Visual Analog Scale

cise as a treatment choice for CLBP than exercise alone.[52] Additionally, two recent randomized controlled trials extended this body of knowledge in the treatment of CLBP, denoting that conventional physical therapy modalities accompanied with exercise showed statistically significant improvements in pain, depression, and functional disability in a sample of seventy and sixty individuals with CLBP, respectively.[49,50]

In the current study, it was observed a statistically substantial decrease in somatic symptom burden after treatment with medium effect sizes for both sexes, normal and overweight participants, which is inconsistent with the results of longitudinal research among eighty-four inpatient orthopedic patients with CLBP.[53] Specifically, it was claimed that German inpatients with CLBP, following a regular rehabilitation program (medication, group and individual physiotherapy lasting 3–4 weeks), benefited on SSD scores (using Somatization subscale of Symptom Check-List-90) at the post-treatment measurement with medium to large effect sizes.[53] Our partially differing outcomes compared to the findings cited previously might be attributed to methodological differences due to dissimilar population characteristics, sampling methods, study sizes, interventions, and self-reported questionnaires for somatic symptom burden.[53]

It is generally recognized that a conventional physiotherapeutic approach in CLBP patients, using physical modalities, massage, and exercise, has favorable effects on psychological measures of depression and anxiety in the short run.[13,27,53] Namely, a Turkish single-blind randomized controlled trial of sixty individuals with CLBP found that the application of therapeutic ultrasound with exercise was an effective choice in reducing depressive symptoms (3 times per week for 6 weeks).[13] More recently, an Indian randomized controlled study of 330 subjects with CLBP revealed that exercise and laser therapy (three times a week for four weeks) seemed effective in decreasing depression scores.[27] Additionally, longitudinal data from Germany (a sample of 84 CLBP inpatients) yielded statistically substantial enhancements for depression and anxiety scores after treatment, supported with medium to large effect sizes.[53] Apart from differences in the methodological design, the present study extends this body of knowledge, revealing substantial but less pronounced enhancements (small size effects) in anxiety (solely in men) and depression (overweight participants).

Furthermore, it is well-established that conservative physical treatment has demonstrated positive pain reductions in individuals with CLBP,[13,15,18,24,25,27,54–59] which we were able to replicate in the current study with medium to large effect sizes. In particular, Sahin et al[15] in

their randomized controlled trial, divided 104 subjects with CLBP into two groups; the physical therapy (received TENS, ultrasound, hot pack, exercise, medication) and the control (received medication and exercise). After the completion of the treatment (a total of 10 sessions, 5 times per week), they reported that pain levels, using a visual analog scale (VAS), were substantially lower to a greater extent in the physical therapy group. Similarly, in a recent pilot study of thirty-nine female CLBP patients, Minobes-Molina et al[54] mentioned that both treatments, including traditional trunk or specific stabilization exercise plus physical modalities, showed beneficial effects on alleviating pain in the 10th session. An equivalent tendency was also found in a study of thirty female patients with subacute and chronic LBP (with comparable methodological characteristics to ours), denoting that routine physical therapy seemed to be a beneficial choice for easing pain levels.[24] Contrary to our outcomes, in a trial carried out by Szulk et al,[29] the implementation of standard physiotherapy in twenty subjects with CLBP showed no significant differences in terms of perceived pain severity, using VAS. This discrepancy may reflect the dissimilarities in study size and self-reported questionnaire; our larger study sample and the use of PNRS may exhibit a significant effect size between assessments, resulting in more definitive conclusions about the treatment's efficacy.[54]

Parallel to the literature, in the present study it was observed a substantial decline in functional disability after treatment with medium effect sizes for both sexes, overweight and normal patients in respect of BMI distribution in the study sample.[15,24,25,56,57,59,60] In trials by Köroğlu et al[26] and Sahin et al,[60] the application of an exercise program plus physical therapy modalities was seen to significantly diminish functional disability after intervention in forty and seventy-five CLBP patients, respectively. Similarly, trials on the effectiveness of conservative physical treatment, have shown a statistically substantial improvement in disability scale at the end of the 10th session, while higher levels of BMI before intervention negatively affected the post-treatment disability scores, which is in consistent with our outcomes.[59,61]

Finally, our results strengthen the findings of previous studies among individuals with CLBP, reporting that the contribution of the convectional physiotherapeutic approach demonstrates substantial improvements in HRQoL.[20,25,57,58] In a prospective study of eighty Greek inpatients with LBP, following conservative treatment, there was observed statistically significant improvement in HRQoL in the short run and one month later, using the SF-36 questionnaire.[20] Additionally, Onat et al[57] and Yilmaz Yelvar et al[58] noted in their randomized controlled trials (forty-four and twenty-two subjects, respectively) that a convectional intervention was an effective approach in the treatment of CLBP, improving quality of life. Namely, Yilmaz Yelvar et al[58] reported that effect sizes from a pre-post comparison in the control group were medium for HRQoL (using Nottingham Health Profile), which is consistent with our finding. Last but not least, an equivalent study of Dilekçi et al[25] revealed similar positive results in EQ-5D-3L index value and EQ-5D-3L VAS variables after treatment.

The current study has a few limitations. First, the generalization of the outcomes to CLBP patients in different clinical settings or Greek regions should be faced cautiously, as a result of conducting the study at a single primary healthcare unit in Athens and the lack of a representative sample of the Greek population. Second, the one-group pretest-posttest design of this study and the absence of a follow-up process did not permit clarification of the long-terms effects of conservative treatment on SSD, anxiety and depression, pain, disability, and HRQoL. Further prospective cohort studies are needed to better comprehend those outcomes. Third, the over-representation of women, albeit random systematic sampling, may affect the conclusions drawn from the study, which restricts the representativeness and generalizability of the results.

Conclusion

In summary, our findings provide important evidence, consistent with the literature, that a conservative physical treatment regimen has favorable short-term effects on psychological measures of anxiety, depression, and SSDs and, in addition, pain levels, functional disability, and HRQoL in individuals with CLBP. Future large and long-term prospective researches are needed to assess and clarify the long-term effects of the treatment in the clinical management of CLBP.

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Ερευνητική εργασία

Η αποτελεσματικότητα ενός συντηρητικού προγράμματος φυσικοθεραπείας στην ψυχολογική κατάσταση και στην ποιότητα υγείας Ελλήνων ασθενών με χρόνια οσφυαλγία

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ΠΕΡΙΛΗΨΗ

Η χρόνια οσφυαλγία αποτελεί ένα πολύ σύνηθες πρόβλημα υγείας, έχοντας σοβαρή επίπτωση στην ποιότητα ζωής και στην ψυχολογική κατάσταση των ασθενών αυτών. Τα ευρήματα από τη βιβλιογραφία έχουν δείξει ότι μια συντηρητική φυσικοθεραπευτική προσέγγιση είναι μια ευεργετική επιλογή στη διαχείριση της χρόνιας οσφυαλγίας. Ο σκοπός αυτής της μελέτης ήταν να εξεταστούν οι βραχυπρόθεσμες επιδράσεις ενός συμβατικού προγράμματος φυσικοθεραπείας στην κατάθλιψη, στο άγχος, στις διαταραχές των σωματικών συμπτωμάτων (SSD), στην ποιότητα ζωής, στον πόνο και στην ανικανότητα Ελλήνων ασθενών με χρόνια οσφυαλγία. Με συστηματική τυχαία δειγματοληψία επιλέχθηκαν 75 ασθενείς με οσφυαλγία. Όλοι οι συμμετέχοντες έλαβαν υπέρηχο, laser χαμηλής έντασης, μάλαξη, διαδερματικό ηλεκτρικό νευρικό ερεθισμό (TENS) και πρόγραμμα ασκήσεων (ένα σύνολο 10 συνεδριών, 5 ημέρες την εβδομάδα). Η παρέμβαση αξιολογήθηκε συγκρίνοντας τις πριν και μετά μετρήσεις των κλιμάκων Νοσοκομειακής Μέτρησης Άγχους και Κατάθλιψης (HADS), Κλίμακας Σωματικών Συμπτωμάτων (SSS-8), EuroQol 5-dimension 5-level (EQ-5D-5L), Roland-Morris Disability Questionnaire (RMDQ) και Pain Numerical Rating Scale (PNRS). Η μέση ηλικία του δείγματος ήταν τα 60,8 έτη (±14,4) και περίπου 1 στους 4 ήταν παχύσαρκοι (25,3%). Με το πέρας της θεραπείας, παρατηρήθηκαν βελτιώσεις στους δείκτες του EQ-5D-5L και μειώσεις των τιμών των HADS, SSS-8, PNRS και RMDQ, οι οποίες βρέθηκαν να είναι στατιστικώς σημαντικές. Μεγαλύτερο μέγεθος επίδρασης (effect size) παρατηρήθηκε στην κλίμακα PNRS (d=0,75), ακολουθούμενο από τον δείκτη EQ-5D-5L index value scale (d=0,42), SSS-8 (d=0,38), EQ-5D-5L VAS (d=0,36), RMDQ (d=0,29), HADS-A (d=0,16) και HADS-D (d=0,14). Οι άνδρες και οι γυναίκες παρουσίαζαν παρόμοιες αλλαγές σε όλες τις υπό εξέταση κλίμακες μετά την παρέμβαση, ενώ εκτός της κλίμακας του πόνου, τα σκορ πριν την παρέμβαση καθώς και ο βαθμός τροποποίησης όλων των υπολοίπων σκορ ήταν παρόμοια ανεξαρτήτως από την κατηγοριοποίηση βάσει του Δείκτη Μάζας Σώματος. Συμπερασματικά, ένα συντηρητικό πρόγραμμα φυσικοθεραπείας φάνηκε να αποτελεί μια ωφέλιμη επιλογή για τη βελτίωση της ψυχολογικής κατάστασης και του επιπέδου ποιότητας της υγείας, όπως επίσης και της ελάττωσης της λειτουργικής ανικανότητας και του πόνου των Ελλήνων ασθενών με χρόνια οσφυαλγία βραχυπρόθεσμα.

ΛΕΞΕΙΣ ΕΥΡΕΤΗΡΙΟΥ: Χρόνια οσφυαλγία, πρόγραμμα φυσικοθεραπείας, κατάθλιψη, άγχος, Διαταραχές Σωματικών Συμπτωμάτων, ποιότητα ζωής.

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