Management options of chronic low back pain

A randomized blinded clinical trial

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ABSTRACT

الأهداف: مقارنة فعالية برنامجين للتحكم بالآم الظهر السفلية المزمنة.

الطريقة: أجريت دراسة إستطلاعية عشوائية مفردة التعمية في قسم التأهيل، بمستشفى جامعة الملك عبدالله، إربد، الأردن خلال الفترة من فبراير وديسمبر 2010م. تم تقسيم 100 مريض إلى 6 أسابيع لبرنامج تأهيلي شامل (المجموعة الأولى) أو علاج بالتمارين (المجموعة الثانية). تم قياس كلا من درجات السلم التماثلي البصري، ومعدل الألم، والمؤشرات الأولية. كما تم قياس مؤشر أوستري للإعاقة، وتمارين الإلتواء الأمامية والإمتداد، والإنحناء من جهة اليمين واليسار قبل وبعد العلاج والنتائج الثانوية.

النتائج: تطورت المعطيات بشكل إحصائي في المجموعة الأولى بعد العلاج مقارنة مع المجموعة الثانية. إنخفضت درجات السلم التماثلي، و مؤشر أوستري للإعاقة، وماكيقل، والإنحناء الجانبي من جهة اليمين واليسار بشكل إحصائي. رجع العديد من المرضى في المجموعة الأولى إلى عملهم في نهاية الإسبوع السادس بالمقارنة مع المجموعة الثانية. هذا وإستمر الأثر العلاجي لمدة تزيد عن 12 و 24 أسبوع من المراجعة.

خاتمة: ساعد برنامج التأهيل الشامل على تطور مؤشرات الحركة ودرجات الألم في المجموعة الأولى بالمقارنة مع المجموعة الثانية وله أثر فعال في السيطرة على آلام الظهر السفلية المزمنة.

Objective: To compare efficacies of 2 active programs in the management of chronic low back pain (CLBP).

Methods: This prospective, stratified, randomized single-blinded controlled study was conducted in the Department of Rehabilitation Medicine, King Abdullah University Hospital, Irbid, Jordan, between February and December 2010. A total of 100 patients were randomized to either 6-weeks of multidisciplinary rehabilitation (group A) or therapist-assisted exercise (group B). At baseline and 6 weeks, the visual analogue scale (VAS) pain score was estimated, as a primary outcome measure. McGill pain score, Oswestry Disability Index (ODI), trunk forward flexion and extension, left and right lateral bending, were applied before and after treatment and were employed as secondary outcome measures.

Results: All outcome measures significantly improved in group A after treatment, compared with group B. The VAS, McGill, ODI scores, left and right lateral bending decreased significantly, whereas forward and backward bending increased. A significant number of patients returned to work in group A at the end of 6 weeks, compared with group B. These effects were maintained over 12 and 24 weeks of follow-up.

Conclusion: Multidisciplinary rehabilitation improved functional indices and pain scale scores in group A compared with B. This would be an effective strategy in CLBP management.

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Chronic low back pain (CLBP) is the most common cause of long-term disability in many countries worldwide.[1,2] It is a common problem in primary care facilities. Initial evaluation of these patients will reveal the nonspecific or idiopathic CLBP as the most common category, which is entirely different from acute and chronic low back pain with known causes. By definition, CLBP is pain that persists for longer than 12 weeks.[3] In addition to pain, patients typically suffer physical disabilities and psychological distress. They may be unable to work and feel depressed. This nonspecific variety constitutes 70-80% of the total number of cases of CLBP World Wide,[4-7] including the Middle East.[8] In Jordan, it was statistically the most frequent cause of earned sick leave and an occupational hazard among nurses in the main hospital in Amman.[9]

Chronic low back pain is notoriously refractory to conventional drug treatment. It seems that there is no single treatment modality that is effective for all patients; hence, they are often referred to multidisciplinary rehabilitation management programs.[10] Despite this, management of CLBP remains a striking challenge to health care organizations, both in terms of treatment and cost. Owing to the complexity and multifaceted nature of this disorder, it is conceivable that a combination of effective treatment lines, based on the individuals' presentations, could exceed the therapeutic range of any one of these therapies alone.[11] Furthermore, it is demonstrated that when patients participate in their care, they tend to be more satisfied and experience better outcomes.[12]

The current multidisciplinary approach in the management of CLBP, considers it as the consequence of combined effects of multiple arrays of interrelated physical, psychological, social, and occupational factors.[13] These include age, gender, smoking, the concept of pain perception, trend for physical inactivity, and work-place physical demands. For its management, integrative care plans can achieve better outcomes than mono disciplinary care alone. However, what are the ideal components of integrated or multidisciplinary rehabilitation that can be assumed to be the most effective? The answer to this question is not straightforward, as various combinations have been suggested in the literature, although no single combination was proved to be best.[1]

Exercise represents one of the few treatments that are clearly effective in CLBP, leading to significant improvement in pain and disability,[14] yet the type and amount of effective exercise remain unknown. Exercise programs may be intensive versus gentle, and assisted versus unassisted, and the implementation of cognitive behavioral principles positively influences the effect of exercise.[15] The multidisciplinary and exercise programs were reported to be almost equally effective for management of CLBP.[16] The aim of our study is to compare comprehensive and intensive multidisciplinary biopsychosocial rehabilitation versus intensive therapist-assisted exercise programs in the management of CLBP.

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Methods. ***Study population.*** The CLBP patients were referred to the Department of Rehabilitation Medicine, King Abdullah University Hospital, Irbid, Jordan, from rheumatology, orthopedics, neurosurgery, and neurology clinics between February and December 2010. These, together with patients referred by general practitioners were consecutively screened. Inclusion criteria were low back pain persisting at least 12 weeks with or without pain radiating to the leg(s), and an age of 18-65 years. They were evaluated by physical examination, conventional radiographs, and CT or MRI scans of the lumbar spine. Patients with serious spinal pathologies such as malignancy, osteoporosis, vertebral fracture, spinal stenosis, acute herniated disc, spondylolisthesis, spondylitis, and cardiac or respiratory insufficiency, health states that prevented them from performing strenuous exercise, and language problems were excluded. They were determined to be medically stable and evaluated by a neurologist, physiatrist, and experienced physical therapist. After detailed orientation and agreement to participate, each patient signed an informed consent approved by the Institutional Review Board, King Abdullah University Hospital, Jordan University of Science and Technology. The inclusion and exclusion criteria were in accordance with the Declaration of Helsinki.

Design. The study was a prospective, stratified, randomized, single-blinded, controlled clinical trial, designed to examine the efficacies of multidisciplinary rehabilitation and intensive therapist-assisted exercise programs in patients with CLBP. Multidisciplinary rehabilitation is an intensive and comprehensive program, which consists of continuous mode ultrasound 0.9w/cm^2 and frequency of 1 MHz for 10 minutes, and conventional transcutaneous electrical nerve stimulation (TENS) mode for 30 minutes combined with aerobic, resistive, stretching, flexibility and postural exercises, massage, education and occupational therapy. A total of 36 hours of physical exercise, 12 hours of occupational therapy, and 12 hours of education were given. Potential patients were invited for an initial visit to explain the trial and assess eligibility. Patients who met all inclusion criteria and signed informed consent forms were evaluated and stratified according to gender (female or male), age (18-39 and 40-65), visual analogue scale (VAS) pain average score (0-5 and 5-10 cm), and whether or not patients were working (yes or no).[17,18] Subsequently, they were allocated by a separate secretary to a group-based multidisciplinary biopsychosocial rehabilitation program (group A, 50 patients) or intensive therapist-assisted back muscle strengthening exercises (group B, 50 patients) according to a random number chart made for each subgroup.

Patients were evaluated at baseline and after 6 weeks of treatment. Follow-up evaluations were scheduled at 12, and 24 weeks. One physician for each group who was blinded to the treatment group and had no access to the treatment area, performed all physical examinations at trial visits. The groups were treated at separate locations and had no personal contact during treatment. Pharmacologic treatment consisting of gabapentin or pregabalin and COX-2 inhibitors in appropriate dosages were allowed to continue in both arms, however, opioids or opioid-like agents were not allowed. The groups were treated at 2 separate locations, and had no personal contact during treatment.

Treatment. Patients in group A were treated in groups of 6 patients and received a program of combined exercise, education, and pain management that included continuous mode ultrasound for 10 minutes and conventional TENS mode for 30 minutes combined with aerobic, resistive, stretching, flexibility and postural exercises, massage, education, and occupational therapy. They were reassured that there was no serious cause for their backache, and the exercise program was safe and effective. Treatment was scheduled for 6 weeks and divided into 3 periods of 2 weeks each. All components of the group A program were administered by 2 well-trained physiotherapists for 2 hours daily, 5 days per week, for 6 weeks. During the first period, exercise was performed at the study site. Group A was treated in a separate site from group B. At the first session, a preprogram assessment was performed to familiarize patients with the program, set the treatment goals, and the initial intensity for each exercise. The succeeding sessions began with a warm-up and ended with stretching. The major part of the individual session consisted of aerobic training and training to strengthen the muscles in the back, gluteus region, and abdominal wall. The exercises were performed in the supine position, using machines and circuit training. In total, 22 hours of exercises were performed. In addition, patients were provided 1.5 hours to play ball games, 1.5 hours of training in warm water, and 2 hours of baseball stick training. Biweekly lessons on anatomy, postural techniques, and pain management were provided by a physiotherapist and on back care and lifting techniques by an occupational therapist, for a total 10 hours. During the second period, 2-hour exercise sessions were performed thrice a week at the study site, and twice a week at either the patient's home or in a fitness center. During the third period, 2-hour exercise sessions were performed 5 times a week at home or in a fitness center. In total, the patients performed 75 hours of moderate muscle training exercise. The treatment-related cost per patient amounted to 12 hours of therapist assistance.

Group B patients received a program of specific and intensive muscle training exercises to strengthen and shorten muscles in the back and gluteus region.[16,19] The program consisted primarily of body and leg-lifting in the prone position, and exercises involving the piriformis muscle, supplemented with exercises aimed at dynamic contraction of painful muscles. The program did not include stretching or abdominal muscle exercises. The body and leg-lifting exercises were carried out in 6 sets of 10 repetitions and exercises involving the piriformis muscle were executed in 3-6 sets of 15 repetitions. Specially trained therapists encouraged and assisted patients in order to achieve full contraction of painful muscles and arranged the patients in the least painful positions. Initially, the therapist did most of the work, but gradually reduced the amount of assistance, such so that patients progressively took over most of the work. The program ran for 2 hours, 5 times weekly, for 6 weeks. In total, the patients received 22 hours of intensive muscle training exercise. The treatment-related costs per patient amounted to 24 hours of therapist assistance, out of the total 60 hours of training. Evaluations of both groups at baseline and at the end of the sixth week of treatment were arranged. Follow-up evaluations were scheduled at the twelfth and twenty-fourth weeks.

Outcome measures. Landmarks were placed on patients' backs ~10 cm above the iliac crest to measure trunk flexion, and ~5 cm below the iliac crest to measure trunk extension. The Schober index was used to assess anteroposterior spinal mobility. An increase in either landmark reflected an improvement in spinal mobility. Subsequently, right and left lateral bending was measured as the distance between the fingertips and floor in centimeters to assess lateral trunk mobility. Decreased distance reflected an improvement in lateral bending. The primary outcome measure was an improvement in the VAS-pain average at 6 weeks. The VAS-pain average was evaluated using a (0-10 cm or 0-100 mm) VAS for average back pain during the preceding 2 weeks. Pain severity was measured on the 0-10 cm scale with 0 indicating no pain and 10 indicating the worst pain.[20] Additionally, the McGill score was used to describe pain experienced with a minimum score of 0 and a maximum score of 78.[21] The secondary outcome measure was an improvement in functional capacity, which was assessed by using the 10-item Oswestry disability index version 2.0.[22] The VAS and McGill scores, physical examination, and recording of analgesic medication intake[23] were performed at all visits. Ability to work was evaluated as previously described.[24] Patients of both groups were evaluated before and after the application of treatment by 2 different assessment teams who were blinded to each group.

Statistical analysis. Continuous data were described using means ± SD and categorical data using percentages. We used the unpaired Student's t-test to compare groups before and after treatment, and the Fisher's exact test to generate *p*-values for categorical data. Analysis was conducted using the Statistical Package for Social Sciences (SPSS Inc., Chicago, IL, USA) version 11.0. A *p*-value less than 0.05 was considered statistically significant. No dropouts or significant adverse effects were observed in both active groups; so there were no effects on the statistical analysis.

Results. A total of 104 patients were screened for participation. Four patients (2 from each group) did not fulfill the inclusion and exclusion criteria. No patients declined participation. Patients who left before treatment did not differ from the remaining patients with respect to any baseline characteristics. Therefore, a total of 100 patients were stratified and randomized to treatment groups. Fifty patients were allocated to active group A, and 50 patients to active group B. **Figure 1** shows their progress throughout the trial. The average age range was 22-64 years old. Demographic and clinical baseline characteristics of the study population did not show any significant differences between the 2 groups (**Table 1**).

Table 2 shows changes in spinal functional mobility measures, disability index, and pain scores for participants before and after management. The score for intake of analgesic medications did not differ significantly between the 2 groups either at the end of treatment or throughout the total study period.[25] The results demonstrated significant improvement in VAS-pain average in group A compared with group B at the end of treatment. The improvement in VAS-pain average in group A, as a primary outcome measure, was shown as a decrease in the score in the range of 25%, which was significantly different between the 2 groups at the end of 6 weeks of treatment (p=0.0001). A highly significant improvement in the McGill average pain score, as a secondary outcome measure, decreasing by 43% in group A compared with group B at the end of 6 weeks of treatment was documented (p=0.0001). This was even more significant than the VAS score (43% versus 25%). The disability index showed the greatest significant improvement at the end of the treatment period decreasing by 49% as opposed to 43% in the McGill scores and 25% in the VAS scores (p=0.0001) in group A compared with group B. Extension scores

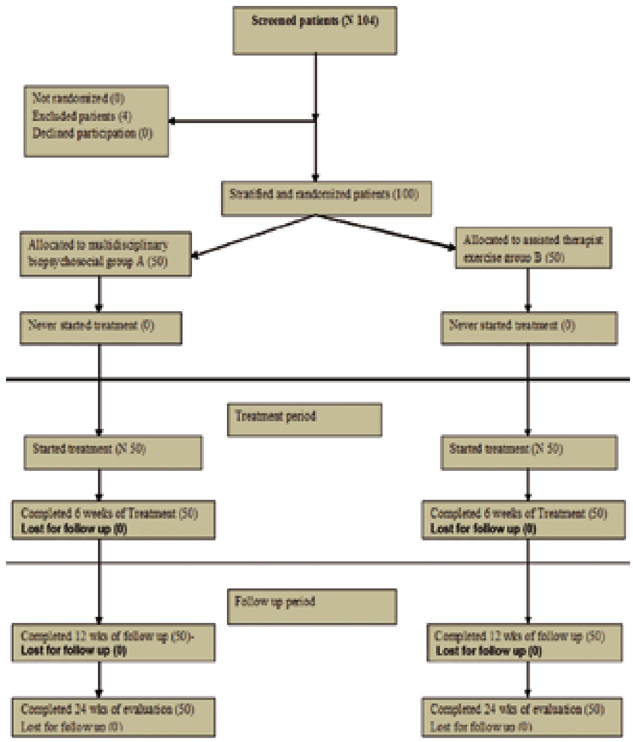

Figure 1 - Progression of patients in a randomized clinical trial comparing a multidisciplinary rehabilitation group (group A), and a therapy-assisted exercise group (group B).

Table 1 - Demographic characteristics of chronic low back pain patients.

Characteristics	Group A n=50	Group B n=50	*P*-value
Gender F/M	33/17	32/18	0.99
Age (years)	49.8±6.2	49.4±5.2	0.73
Weight (kg)	65.2±6.6	64.4±8.2	0.59
Height (cm)	165±9.0	166±8.0	0.56

Data presented as mean ± standard deviation, F - female, M - male

Table 2 - Changes in functional mobility measurements, disability, and pain scale scores in patients with chronic low back pain.

Variables	Before treatment			After treatment		
	Group A	Group B	*P*-value	Group A	Group B	*P*-value
VA pain scale scores	6.0 ± 1.8	6.1 ± 1.9	0.79	4.5 ± 1.2	5.6 ± 1.5	0.0001
McGill pain scale scores	44 ± 12.9	44.1 ±13	0.97	25.2 ±11	36 ± 12.2	0.0001
Oswestry disability scores	39.1± 14.9	39.2 ±15	0.97	20 ± 11.5	31 ± 12.8	0.0001
Extension	3.0 ± 0.9	3.2 ± 0.8	0.24	3.9 ± 0.6	3.5 ± 0.3	0.0001
Flexion	13.5 ± 1.1	13.6 ± 1.0	0.64	15.2 ± 1.2	14.1 ± 0.9	0.0001
R lateral bending	49.1 ± 7.0	49 ± 6.8	0.94	45.2 ± 3.7	47.9 ± 3.0	0.0001
L lateral bending	49.0 ± 6.2	49.2 ± 7.0	0.88	45 ± 4.6	48.2 ± 3.4	0.0001

Data presented as mean ± standard deviation, VA - visual analogue, L - left, R - right

Table 3 - Ability to work among chronic low back pain patients.

Variable	Group A n=50	Group B n=50	*P*-value
	n (%)		
Before treatment	10 (20)	11 (22)	1.00
After 6 weeks of treatment	25 (50)	14 (28)	0.04
12 weeks follow-up	27 (54)	15 (30)	0.02
24 weeks follow-up	30 (60)	17 (34)	0.04

increased by 30% (p=0.0001) and flexion scores increased by 13% (p=0.0001). The least significant changes were noticed as a decrease in the fingertip/floor distance in right lateral and left lateral bending by 8% (p=0.0001).

Ability to work. **Table 3**, showed at baseline, 10 (20%) of patients in group A and 11 (22%) of patients in group B were able to work (p=1.00). Work ability increased at the end of 6 weeks of treatment to 25 (50%) in group A and 14 (28%) in group B (p=0.04). Improvement continued to increase throughout the follow-up period and reached a level of 27 (54%) in group A compared with 15 (30%) in group B at 12 weeks (p=0.03), and 30 (60%) in group A compared to 17 (34%) in group B (p=0.04) at 24 weeks. The significant improvement in the VAS-pain average, McGill pain average, and the disability index was maintained in group A compared with group B throughout the whole follow-up period.

Discussion. During the last 3 decades, various physiotherapeutic modalities have been developed to treat the multifaceted components of CLBP, with variable successes. These modalities consisted of 2 subcategories. The passive subcategory included TENS, ultrasound, massage, education, and joint mobilization, while the active subcategory included stretching, aerobic, resistive, and endurance exercises, and occupational therapy. Both subcategories form the basis of the best-known combinations for CLBP, according to evidence-based medicine, hitherto available.[26-30] Although many different studies probed the efficacy of these physical therapeutic modalities in the treatment of this disorder, very few have used the multidisciplinary approach with high methodological quality. However, comprehensive biopsychosocial approaches seem to be the best modality of interventions to facilitate physical outcome and return to work,[31,32] therefore, combining passive and active modalities, in the setup of high methodological quality could complement each other, thus resulting in comprehensive management of CLBP.

In our study, we compared the efficacy of a multidisciplinary intensive and comprehensive biopsychosocial rehabilitation program and therapist-assisted back muscle exercise program in treatment of CLBP. The multidisciplinary program significantly improved the primary outcome measure of pain (VAS score), and resulted in reduced pain and enhanced mobility and functionality, compared with the therapist-assisted exercise program. The secondary outcome measures of McGill pain score and Oswestry disability index were the most prominent, and demonstrated even more significant differences in favor of the multidisciplinary biopsychosocial rehabilitation program. The right and left lateral, forward, and backward bending scores also favored the multidisciplinary biopsychosocial management approach applied to active group A compared with active group B. The therapist-assisted exercise program showed some tendency to improve the McGill pain score and Oswestry disability index; however, it failed to significantly improve the primary outcome measure of pain or any of the other secondary outcome measures in active group B compared with active group A. Therefore, our current findings are interesting as they demonstrated the efficacy of a comprehensive and intensive multidisciplinary program. Furthermore, the ability to return-to-work was clearly significant in active group A compared with active group B at the end of the study period and throughout the follow-up period. We observed clear trends in the data itself and after further statistical analyses. First, we have to acknowledge the fact that a paired Student's t-test would have been an excellent method to use in this study to gain more understanding of the changes that the multidisciplinary rehabilitation resulted in within group A compared with assisted exercise in group B. However, because of the loss of the raw data, this was not possible and we were obliged to compare the 2 groups before and after treatment by using the unpaired Student's t-test. Second, the results showed variable degrees of improvement among the different outcome measures indicating different responses of patients between the 2 groups; it was more significant in the disability index and pain scales, less significant in right lateral bending and flexion, and least significant in left lateral bending and extension.

There is no agreement regarding the various components of a multidisciplinary biopsychosocial management program.[26] Certain programs included ultrasound, which is used primarily for deep tissue heating; thus, it raises pain threshold and decreases pain perception. In addition, TENS was recommended as a simple non-invasive analgesic technique, it proved more efficient than placebo in reducing pain intensity and improving range of motion.[25] Among primary care physicians, 65% recommended massage, 55% favored ultrasound, and only 38% preferred exercise to be included in multidisciplinary rehabilitation. Even the components of exercise were also variable in different programs of CLBP. Resistive, endurance, stretching, posture, and coordination exercises have become standard in management of CLBP, particularly to improve muscular strength, endurance, and joint mobility.[3] Furthermore; it was associated with increased pain threshold, tolerance, and improvement of patients' mood. Combining resistive and aerobic exercises was more effective than either alone.[33] Similarly, combining resistive, relaxing, stretching, and coordinating exercises was more effective in decreasing pain and disability than applying massage and superficial heating.[34] However, the effectiveness of these modalities in CLBP has been demonstrated in only few randomized, well-controlled studies.[33-36] Therefore, multidisciplinary programs as alternatives to pharmacological management of CLBP are still controversial, and the efficacy of each single modality is inconclusive.

We identified one previous trial[23] that compared the multidisciplinary rehabilitation program and intensive therapist-assisted back muscle exercise program in the treatment of CLBP. However, the components of their program, duration, and results were different from ours. Overall, their results displayed a slight superiority of multidisciplinary biopsychosocial rehabilitation over therapist-assisted back muscle exercises. Another study compared multidisciplinary rehabilitation program and active individual therapy exercise program focusing on flexibility, range of movement, pain coping, strengthening exercises, and functional training. They found a difference in favor of multidisciplinary rehabilitation programs with regard to global assessment, but not with regard to specific measures such as pain, disability, or return-to-work rate.[10] However, our study differs in both the combination of treatment modalities in the multidisciplinary rehabilitation program as well as the duration of treatment.

Potentially confounding factors may operate in any study. In principle, patients' dropout during clinical trial might lead to underestimation as well as overestimation of the effect of the treatment, depending on why the patients left. However, only 4 patients (2 from each group) did not meet the inclusion and exclusion criteria, and therefore these patients were excluded from both groups before start of the study. In addition, no dropout or loss from follow-up was recorded from either group, making it unlikely that patient dropout contributed significantly to the difference in outcomes between the 2 interventional programs. We used a stratified and randomized design to ensure maximal comparability between the 2 groups. The 2 different sites for treatment and different types of professionals and the use of 2 physicians and 2 physiotherapists (2 for each group) performing the inclusion examination are elements of strength rather than weakness in the study. Upon conducting an interventional study, the lack of a control group is a real concern, it is impossible to assess the efficacy of a treatment intervention while you are unable to evaluate the amount of natural recovery that would possibly occur within the control group; however, ethical concerns deterred us from applying this principle. The cost, in hours, of therapist assistance per patient was comparable in the intensive therapist-assisted strengthening back exercise program, whereas participation in the multidisciplinary rehabilitation program was more time-consuming. However, the relatively short duration of the study did not allow the time-consuming effect to operate in our results, although the relatively small sample size of the study and short follow-up period remained as limiting factors.

In our current study, the combined and intensive multidisciplinary rehabilitation program alleviated pain, enhanced mobility, and improved physical functioning. Subsequently, physical disability was prevented, quality of life improved, previous job and home-related daily living activities resumed. The decrease in pain and increase in spinal function and mobility after combining the previously mentioned modalities is important. Few studies examined the combined effect of several physiotherapeutic modalities on spinal function, mobility, and pain scales.[17,37-39] Our present study sheds light on the effects of this particular combination on previously studied pain and functionality measures. Considering the worldwide increase in prevalence of CLBP, and the numerous negative impacts on public health, and its socioeconomic consequences, our results are particularly important. Chronic low back pain is a major cause of absenteeism, disability, and decreased working capacity. Approximately two-thirds of adults experience CLBP at productive times of their lives.[4,7-9] Therefore, the rehabilitation team should focus on patients' return to a meaningful physical, psychological, and functional life. Clearly, the need for further research is paramount, as a deeper understanding of the various cultures and subcultures is essential for developing a more useful structural framework for rehabilitation.[40] Finally by using a biopsychosocial framework, strong evidence is added in favor of recovery expectations and disability management with excellent work participation outcomes.[37] The current multidisciplinary rehabilitation program seems to enhance the prognosis of the treated group. Physical and occupational components of this program complimented the pharmacologic management of CLBP.

In conclusion, our results indicate that the combined, comprehensive, and intensive multidisciplinary biopsychosocial rehabilitation management program improved spinal function and mobility measures and reduced pain scale scores. Despite the previously mentioned limitations, the negative impact on health and the socioeconomic consequences associated with CLBP, are of notable interest. Future studies should probe such combinations in larger samples and multiple centers.

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