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■ Original Article

Efficiency of Associating Therapeutic Patient Education with Rehabilitation in the Management of Chronic Low Back Pain: A Randomized Controlled Trial

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Background: This study aimed to assess the benefits of associating rehabilitation with therapeutic patient education (TPE) to decrease fear-avoidance belief and pain and improve function in adults with chronic low back pain (CLBP).

Methods: This randomized controlled study included 100 patients with CLBP according to the CONSORT (Consolidated Standards of Reporting Trials) guidelines. The patients were divided into two teams: group A that participated in the TPE in association with rehabilitation and group B that received rehabilitation only. Pain and functional amelioration were assessed initially (T0) and at the end of the program (T1) using a visual analog scale at rest, work, and activity, and the Echelle d'Incapacité Fonctionnelle pour l'Évaluation des Lombalgies scale. Psychological and apprehension and avoidance assessments were also conducted, including the evaluation of depression, anxiety, fear-avoidance belief, and kinesiophobia using the Hospital Anxiety and Depression Scale, Fear-Avoidance Beliefs Questionnaire, and Tampa scale of kinesiophobia scale.

Results: The evaluation of progression initially (T0) and then at the end of the program (T1) revealed a significant reduction in pain at rest (P=0.00) and while working (P=0.00) and doing physical activity (P=0.03); a decrease in anxiety (P=0.03), fear-avoidance belief (P=0.03), and kinesiophobia (P=0.02); and an improvement in function (P=0.00) for patients in group A without amelioration of depression (P=0.15). Concerning group B, we identified a significant regression in pain at rest (P=0.001) and while working (P=0.03) and doing physical activity (P=0.00); depression (P=0.01); fear-avoidance beliefs (P=0.00); and kinesiophobia (P=0.002). Comparison between the groups revealed that associating TPE with rehabilitation resulted in a more significant improvement in function (P=0.00), anxiety (P=0.00), fear-avoidance belief (P=0.00), and kinesiophobia (P=0.00).

Conclusion: Associating TPE with rehabilitation improved function and reduced fear, false beliefs, and kinesiophobia of movement in patients with CLBP.

Keywords: Low Back Pain; Chronic; Education; Fear

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INTRODUCTION

Low back pain (LBP) has become a worldwide health issue with a mean global prevalence of 26.9%.[1] Chronic LBP (CLBP) is defined as LBP persisting for at least 3 months, which leads to limitations in activities of daily living. CLBP accounts for approximately 5%–10% of all cases of LBP.[2]

The cause of CLBP is not well established as CLBP is a multifactorial issue related to biopsychosocial influences. It may be induced in part by mechanical disease of the joints and/or soft tissue and by psychosocial stress.

Pain intensity, work-related factors (job satisfaction), and psychobehavioral factors such as depression, fear, false beliefs, fear of pain, and movement are associated with avoidance behavior and anxiety, and could significantly affect the quality of life of patients with CLBP and reduce or even completely stop any physical and social activities.[3]

CLBP management is moving to a multidisciplinary program that includes an educational approach.[4] It includes organized activities such as raising awareness and providing information, learning, and psychosocial support related to the disease and its treatment. Therapeutic patient education (TPE) can modify false beliefs to help patients better understand their disease, thus reducing the influence of fear-avoidance behavior.[5-8]

TPE with psychological support and cognitive behavioral therapy has also been recommended to improve pain intensity and functional loss among people with CLBP.[9] However, the efficacy of this approach in the management of CLBP remains unclear.[4,10]

Thus, this study aimed to assess the benefits of associating rehabilitation with TPE to decrease fear-avoidance belief, kinesiophobia, pain as well as improve function in adults with CLBP.

METHODS

1. Study Design and Recruitment

This study was conducted as a parallel-group randomized controlled trial using Zelen's design. The specific characteristic of Zelen's design (also called the randomized consent design) is that consent to participate is sought only after randomization. The study adhered to the CONSORT (Consolidated Standards of Reporting Trials) guidelines.

The study included 100 patients with chronic back pain with a duration exceeding 12 weeks, according to the French Society for Rheumatology's definition.[11] They were referred to the Department of Physical and Rehabilitation, Medicine of Military Hospital in Tunisia for rehabilitation.

The patients were allocated to either the intervention group (group A) or the control group (group B) using a computer-generated randomization list at a 1:1 ratio.

The sample size was calculated based on the ability to detect a statistically significant difference in the primary outcomes between groups A and B at the 1-year follow-up, a two-sided α=0.05, and a test power of 1-β=0.8. We aimed to have 100 participants from the outpatient clinic to ensure a sample size of at least 50 participants per study arm with data at the 1-year follow-up.

The first group received therapeutic education through a rehabilitation program, and the second group received only rehabilitation. The inclusion criteria were as follows: age >18 years; with CLBP (duration >3 months); with CLBP of common origin; absence of radicular syndrome; failure of medical treatment; without indication for surgical treatment; and provided informed consent to participate. Meanwhile, the exclusion criteria were as follows: a chronic disease contraindicating the efforts such as cardiovascular pathology and neurological disease (epilepsy); secondary spinal pain (infectious or inflammatory diseases, malignancy, and traumatic pathology); sciatalgia; psychiatric and/or behavioral disorders that make the evaluation uncertain; surgical interventions on the spine or on the lower limbs; and patients who did not provide their informed consent to participate in the program.

The patients who met the inclusion criteria were randomized and controlled into the following two parallel groups: intervention group (A) and control group (B).

Local ethical committee of the military hospital of Tunisia is the institution that gave the approval for the study. There is no institutional review board number. All the patients provided informed consent for study participation.

2. Intervention for Group A

Fifty participants allocated to group A were invited to participate in TPE comprising medical exercise therapy and lifestyle coaching in association with rehabilitation. All members received health coaching from a professional coach employed at the medical center. The participants were coached during the treatment phase. Coaching aimed to explain the physiopathology of LBP, encourage lifestyle changes, and consolidate physical activities.

The TPE comprised the following: simplified explanation of the spinal anatomy; definition of LBP and its pathophysiology through an educational video; explanation of the establishment of a vicious circle of CLBP and the mechanism of inadaptation to exercise; presentation of exercises for functional adaptation; an explanation of how to manage pain and emotion and recover the ability to move quickly; make discussion groups answer patients' questions, listen to their fears and beliefs, and attempt to resolve problems caused by LBP; simplified messages to patients during workshops; and a "back guide" that includes important messages from the workshop, illustrations of adapted physical activities, and an educational follow-up program for each patient. (1) Common LBP is not a serious disease. (2) Pain is not necessarily related to the extent of spinal damage. (3) Pain is sometimes very intense and forces you to reduce your activities for a while; however, resting for more than a day or two is useless. Therefore, remaining active is necessary. (4) Many treatments exist that can bring relief, but patients must learn to manage their pain. (5) Fast relief is associated to the ability of patient to make physical exercises. (6) The attitude of the patient can condition the evolution of their pain.

The participants received training 3 times per week for 1 month and

half. Each session lasted 120 minutes per day and included a combination of physiotherapy, strength training, gymnastics, and relaxation exercises to strengthen the back muscles and relieve strain on the spine.

3. Usual Care for Control Group B

The members allocated to group B were referred only to a general rehabilitation program for CLBP in accordance with the recommendations of the National Clinical Practice Guideline for Non-specific LBP.[12,13] The patients did not undergo TPE.

Before being integrated into the rehabilitation program, the patients initially received a physiotherapy session. The rehabilitation program lasted over 5 weeks, with three sessions per week lasting 30 minutes to 1 hour and 15 minutes each. Each session was divided into several phases. A warm-up session of 10 to 30 minutes comprised exercises involving the lower limb, upper limb, and trunk. This preparation time is necessary for cardiovascular preparations. Patients should perform treadmill exercises with progressively increasing intensity. A stretching session of 10 to 15 minutes includes global postural stretching with the solicitation of all muscle groups and joints. Muscle strengthening activity lasted 20 to 30 minutes for reconditioning. The reinforcement is addressed first for the deficient muscles, and then, it involves the whole muscular chain: the abdominal and back muscles. The session ends with muscle relaxation exercises.

4. Data Collection

General characteristics such as age, sex, education level, professional status, job tenure, and cessation of work were documented for each patient. Many scales were used initially (T0) and at the end of the follow-up visit after finishing the rehabilitation program (T1) to evaluate pain, function, anxiety and depression, fear-avoidance belief, and kinesiophobia of patients.

First, the pain visual analog scale (pain VAS) measured pain intensity during the rest, work, and activity on a 100 mm horizontal scale from 0 (no pain) to 100 (maximal pain). Second, the Echelle d'Incapacité Fonctionnelle pour l'Évaluation des Lombalgies (EIFEL) scale is a valid and reliable questionnaire for assessing functional capacity in LBP. It is a French version of the Roland-Morris scale 10. The questionnaire comprises 24 questions. The patient was required to answer each question as a function of the difficulty applicable on the day the questionnaire was completed. Each question equals 1 point, and the total EIFEL score corresponds to the sum. Thus, a score of 24 corresponds to the most unfavorable situation (total functional incapacity associated with their LBP; effect of plaster corset on acute LBP in a less developed country). Third, the anxiety and depression scale (Hospital Anxiety and Depression Scale, HADS) was used. This is a 14-item scale that generates seven items each related to anxiety and depression. Each item on the questionnaire is scored 0–3, indicating that a person can score between 0 and 21 for either anxiety or depression. A cutoff point of 8/21 was fixed for anxiety or depression.

Fourth, the fear-avoidance beliefs questionnaire (FABQ) is a patient-reported questionnaire that specifically focuses on how a patient's fear-avoidance beliefs on physical activity and work may affect and contribute to their lower back pain and resulting disability. The questionnaire comprises16 items, in which a patient rated their agreement with each statement on a 7-point scale, where 0 indicates completely disagree and 6 indicates completely agree. FABQ has a maximum score of 96, with a higher score indicating stronger fear-avoidance beliefs. Lastly, the Tampa scale of kinesiophobia (TSK) assesses self-reported fear of movement in patients with lower back pain. The questionnaire comprises 17 questions. A score of 17 is the lowest possible score and indicates no kinesiophobia or negligible kinesiophobia. A score of 68 is the highest possible score and indicates extreme fear of pain with movement.

We then evaluated the intragroup and intergroup evolution of the various parameters measured. The local committee approved the study, and informed consent was obtained from patients of group A for participating in the education program and follow-up measurements to evaluate the effects, and from group B to participate in a follow-up study to evaluate the effects of usual rehabilitation for CLBP.

5. Statistical Analysis

Data were analyzed using the SPSS software package ver. 11.5 (SPSS Inc., Chicago, IL, USA) and expressed as range, mean, and standard

Table 1. Comparison of patients' characteristics in groups A and B

Characteristic	Group A (n=50)	Group B (n=50)	P-value
Age (y)	45.6±6.7 (28–69)	42.9±8.7 (27–66)	0.45
Sex (male)	40 (80)	36 (76)	0.3
Education level			
Analphabet	2 (4)	3 (6)	
Primary	2 (4)	3 (6)	0.9
Secondary	35 (70)	34 (68)	
University	11 (22)	10 (20)	
Professional status			
Work in office	17	25	
Physical labor	29	19	0.13
Retired patients	4	6	
Job tenure (y)			
<5	1	6	
5–10	4	2	
>10	45	42	0.1
Cessation of work			
No cessation	1	4	
<1 mo	15	13	
>1 mo	34	33	0.3
VAS at rest T0	3.7±2.1	2.64±2.6	0.07
VAS work T0	6.12±2.03	6.36±1.9	0.2
VAS physical activity T0	5.8±2.3	6.5±1.5	0.15
HADS depression T0	3.62±2.7	4.8±2.1	0.06
HADS anxiety T0	7.5±4.7	8.6±3.5	0.14

Values are presented as mean±SD (range), number (%), number, or mean±SD. Group A: patients receiving therapeutic patient education+rehabilitation. Group B: patients receiving rehabilitation only.
SD, standard deviation; VAS, visual analog scale; HADS, Hospital Anxiety and Depression Scale.

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deviation. The correlation between two quantitative variables was performed using the Pearson test, and between two qualitative variables using the chi-square test. The Student t-test was used to determine the association between qualitative and quantitative variables. In the case of small numbers, the Mann-Whitney U test was used. The significance level was set at P<0.05.

RESULTS

Demographic data, including age, sex, education level, professional status, job tenure, and work cessation, were assessed. The characteristics of the patients in groups A and B are presented in Table 1. No significant differences between groups were identified.

1. Evaluation of Progression after Intervention in Groups A and B

1) Evolution after associating the TPE with rehabilitation in group A

A significant reduction in pain at rest, during work or activity, anxiety, fear-avoidance belief, and kinesiophobia was observed for patients in group A between the program starting (T0) and the end of the follow-up visit (T1), except for depression. We also noted a significant improvement in function as measured by the EIFEL scale. Table 2 illustrates the evolution of group A.

2) Evolution after rehabilitation only in group B

The comparison before starting the rehabilitation program (T0) and at the end of the follow-up visit in group B (T1) demonstrated a significant regression in pain at rest or during work or activity (P=0.001, P=0.00, P=0.00, respectively), depression (P=0.01), fear-avoidance beliefs, and kinesiophobia (P=0.00, P=0.002, respectively). Moreover, the function increased significantly (P=0.00). Table 2 illustrates the evolution of group B.

2. Evaluation of the Contribution of Therapeutic Patient Education in Chronic Low Back Pain Care by Comparing Groups A and B

1) Pain and function contribution of the TPE

Comparison between the groups revealed that associating TPE with rehabilitation resulted in a more significant improvement in function (P=0.00), anxiety (P=0.00), fear-avoidance belief (P=0.00), and kinesiophobia (P=0.00). However, the variation in pain (ΔVAS) at work and during physical activity was significantly lower in group B than in group A (P=0.00, P=0.00, respectively). This result is due to the highest initial ΔVAS at work (group A: 6.12±2.03 versus group B: 6.36±1.9) and during physical activity (group A: 5.8±2.3 versus group B: 6.5±1.5). Thus, the difference between T0 and T1 was significantly higher in group B. Table 3 illustrates the results.

2) Psychological, apprehension and avoidance contribution of the TPE

A significant regression in anxiety, fear-avoidance belief, and kinesiophobia was observed for patients who received TPE (group A) compared with group B (Table 3). At the end of these results, we concluded that the improvement was more palpable in the education group.

DISCUSSION

This study assessed the benefits of rehabilitation with TPE for the management of adults with CLBP. The comparison between progression in groups A and B after finishing the program revealed that asso-

Table 2. Comparison between T0 and T1 in groups A and B

Variable	Category	Before program (T0)	After program (T1)	P-value
VAS at rest	Group A	3.7±2.1	1.56±1.6	0.00
	Group B	2.64±2.6	1±1.7	0.001
VAS work	Group A	6.12±2.03	2.5±2.3	0.00
	Group B	6.36±1.9	2.5±2.3	0.00
VAS physical activity	Group A	5.8±2.3	3.3±1.9	0.03
	Group B	6.5±1.5	3.3±1.9	0.00
HADS depression	Group A	3.62±2.7	3.3±2.5	0.15
	Group B	4.8±2.1	3±2.1	0.01
HADS anxiety	Group A	7.5±4.7	5.5±3.8	0.03
	Group B	8.6±3.5	8.5±3.3	0.9
EIFEL	Group A	16.4±4.8	9.8±5	0.02
	Group B	18.02±3.2	12.6±4.2	0.00
FABQ	Group A	41.7±13	22.7±12.6	0.03
	Group B	46.6±8.9	36.6±6.9	0.00
TSK	Group A	43.9±11.5	19.2±11.5	0.02
	Group B	47.3±12.1	40.2±10	0.002

Values are presented as mean±standard deviation. Group A: patients receiving therapeutic patient education+rehabilitation. Group B: patients receiving rehabilitation only.
VAS, visual analog scale; HADS, Hospital Anxiety and Depression Scale; EIFEL, Echelle d'Incapacité Fonctionnelle pour l'Évaluation des Lombalgies; FABQ, fear-avoidance beliefs questionnaire; TSK, Tampa scale of kinesiophobia.

Table 3. Effects of each program in the physical and psychological scales

Variable	Group A (n=50)	Group B (n=50)	P-value
Physical scales			
ΔVAS at rest	2.14	1.64	0.16
ΔVAS work	3.64	3.86	0.00
ΔVAS physical activity	2.50	3.20	0.00
ΔEIFEL	6.60	5.40	0.00
Psychological scales			
ΔHADS depression	1.32	1.8	0.003
ΔHADS anxiety	1.94	0.12	0.00
ΔFABQ	18.98	10.00	0.00
ΔTCK	24.78	7.06	0.00

Group A: patients receiving therapeutic patient education+rehabilitation. Group B: patients receiving rehabilitation only.
VAS, visual analog scale; EIFEL, Echelle d'Incapacité Fonctionnelle pour l'Évaluation des Lombalgies; HADS, Hospital Anxiety and Depression Scale; FABQ, fear-avoidance beliefs questionnaire; TCK, Tampa scale of kinesiophobia.

ciating TPE with rehabilitation significantly improved function, pain during working or doing activity, and decreased anxiety, fear-avoidance belief, and kinesiophobia.

Although literature on CLBP is abundant, the results do not prompt firm conclusions on the precise value of TPE. This is mainly due to the absence of consensus on the educational modalities designed for CLBP. This may be because the concept has changed over time, with a transition from a biomedical model to a biopsychosocial model. Guidelines agree that a better understanding of LBP and its management is pivotal in the care approach adopted by patients and healthcare professionals.[14,15]

Our evaluations were based on the validated scores. Apprehension related to physical or professional activities was evaluated using self-questionnaires such as FABQ[16] and TSK.[17] These questionnaires are valuable for clinical research because they provide reproducible and quantitative measurements. They can also be used as a way to talk with patients and define their expectations to better define the strategies selected by the patients in their adaptation to chronic diseases. However, these evaluations cannot determine what the patient knows, what he/she has understood if he/she knows how to do, or what he/she needs to learn.

In our study, we formed a discussion group of patients with CLBP. The main objectives of TPE were to encourage movement, active self-management programs, and coping strategies and to redefine a treatment plan. Providing patients with a means to manage their disease is a crucial objective in CLBP. It is essential to de-dramatize the situation, provide the patient with support for an appropriate treatment pathway, and help enhance treatment compliance. The educational message must be reassuring and must provide simple notions, such as the pointlessness of staying in bed for more than 2 days, the absence of severity when no "red flags" are present, and the improvement in recovery with light activity that does not worsen pain.[14]

Discussion groups in which patients can share their personal experiences are better suited to the chronic phase of LBP than individual patient education, which did not prove effective in CLBP.[18]

Additionally, booklets with educational goals and routine exercise programs were used. Booklets are relatively inexpensive information vectors. They have been used for decades to help healthcare professionals inform and advise patients with LBP. The educational part of the booklets helps improve the patient's knowledge and reduce their fear-avoidance beliefs.[19-21] Various contents have been validated,[22,23] the "Back Book" is the most frequently used in France[24] and other countries.[8] Information campaigns using the "Back Book" may change beliefs in the general population and decrease complaints related to LBP.[6,25] Routine exercise programs in the booklet also help with educational programs.[19,20,26] The objective was to provide the patient with a home-based roadmap. Even when used alone, these home exercises may be efficient in terms of function, disability, and flexibility at 1 year.[27]

Different tools for educating patients can be used for CLBP.[15] These range from verbal or written information to audiovisual and multimedia formats. Verbal information (based on advice) was the most frequently used tool. However, advice may be effective only in the short term if not accompanied by supervised exercises and personalized follow-up.[28,29] Previous studies have provided a few examples of the use of audio[30] or video formats.[26] Videotapes recommending back exercises improve compliance because they served as reminders and help patients find the time and space for performing the exercises.[26]

Our survey revealed that psychological domains such as depression, anxiety, fear-avoidance beliefs, and kinesiophobia according to HADS, FABQ, and TCK were significantly improved when rehabilitation was associated with TPE (P=0.003, P=0.00, P=0.00, and P=0.00, respectively).

Fear avoidance is the belief that any movement or activity that may provoke pain should be avoided due to the fear of causing pain or reinjury. Patients with pain sensations may be motivated to avoid any new exposure to pain, and the avoidance of fear comprises two components: cognitive avoidance (to avoid pain experience) and behavioral avoidance (to avoid painful activities). In turn, this kind of avoidance of activities also yields many physical and psychological consequences, such as depression, anxiety, and kinesiophobia. According to a systematic review, Wertli et al.[30] have reported that FAB is a prognostic factor for poor outcomes in patients with LBP. Ferrari et al.[31] revealed that FABs are significantly associated with disability.

Dupeyron et al.[15] evaluated the role and impact of TPE in the medical and surgical management of LBP through a literature review. He concluded that TPE could reduce the negative consequences of fear-avoidance behavior and modify physical disability and pain related to LBP and the patient's choice of therapy (e.g., surgery). Moreover, national and international guidelines agree that a better understanding of LBP and its management is pivotal for the care approach adopted by patients and healthcare professionals.[14] This suggests that TPE based on a biopsychosocial model has a positive impact on patient behavior and treatment compliance. Any information that decreases fear and anxiety and encourages active self-management by the patient improves prognosis.

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Moreover, researchers have suggested that TPE reduces the number of hospital days, and few studies have evaluated the cost of TPE in LBP, and the cost/benefit ratio may be favorable.[30]

However, some limitations of this study must be considered. The primary limitation is the relatively small number of participants. Although this has allowed us to obtain statistically reliable results, studies with larger groups should be considered. Second, the assessment of patients, 3 and 6 months after the program may provide information on the long-lasting benefits of TPE and rehabilitation.

In conclusion, associating TPE with rehabilitation improved function and reduced fear, false beliefs, and kinesiophobia of movement in patients with CLBP. Therefore, TPE should be considered for the therapeutic management of this disease.

CONFLICT OF INTEREST

No potential conflict of interest relevant to this article was reported.

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