

Effects of an active kinesitherapy exercise program adapted to chronic low back pain patients: Single-group quasi-experimental pre-post design study.

Efectos de un programa de ejercicios de cinesiterapia activa adaptada a pacientes con dolor lumbar crónico: Estudio de diseño pre-post cuasiexperimental de un solo grupo.

Mario Manuel López Mesa, Javier J. Cabrerizo Fernández, Yolanda Robledo do Nascimento

Physiotherapy and Occupational Therapy at the Henares University Hospital. FIIB HUIS HUHEN, Madrid (Spain)

Abstract. The review of scientific literature on physical exercise in the treatment of chronic low back pain indicates that exercise programs can be a therapeutic option for reducing disability. Kinesiotherapy could be effective in the long term, especially when integrated into programs tailored to low back pain. However, research results are often unsatisfactory because they do not address the most relevant clinical issues for primary and secondary care professionals dealing with daily low back pain. These unexplored priorities leave a gap in clinical practice, hindering the effective implementation of evidence-based treatments. Objective: To evaluate the efficacy of adapted active kinesiotherapy in the treatment of chronic low back pain, analyzing improvement in disability considering both minimally clinically significant differences and minimally clinically important differences and determining the proportion of patients experiencing clinically relevant improvements or deteriorations. Methodology: A prospective longitudinal study was conducted with a pre and post-intervention physical rehabilitation assessment at the University Hospital of Henares (Coslada, Spain). The sample consisted of 30 patients, of whom 24 completed the study and 6 did not attend sessions. The mean age of the participants was 57.33 years, 75% were women, and the average body mass index was 25.78. The rehabilitation program consisted of adapted active kinesiotherapy exercises for low back pain, carried out over three months, with two 60-minute sessions per week. To analyze differences in disability levels before and after treatment, assessed with the Roland Morris questionnaire, paired t-tests were performed. Statistical differences were determined for the total sample and subgroups according to percentage improvement ranges. Improvements were classified as "much better" ($\geq 30\%$), "noticeably better" (25-29%), and "somewhat better" (15-24%). A scatterplot and linear regression were used to model the relationship between "% improvement" and "score difference," determining thresholds for clinical changes. Results and conclusions: The 1.67-point improvement in the Roland Morris score indicates a clinically significant impact. However, the average improvement for the entire sample was 17%, indicating an early but not significant clinical improvement. 37.5% of patients did not experience clinically significant improvements (67% of them with low levels of pre-treatment disability). However, 82.5% of patients showed clinically relevant improvements: 12.5% with "somewhat better" improvements and 50% with "much better" improvements. According to the study's linear regression, a difference of 3.11 points indicates "much better" improvements and 1.42 points indicates "somewhat better" improvements.

Keywords: Exercise program, active kinesiotherapy, chronic low back pain, disability, Roland Morris questionnaire.

Resumen. La revisión de la literatura científica sobre el ejercicio físico en el tratamiento del dolor lumbar crónico indica que, los programas de ejercicio físico pueden ser una opción terapéutica para reducir la discapacidad. La cinesiterapia podría ser efectiva a largo plazo, especialmente cuando se integra en programas de ejercicios adaptados al dolor lumbar. Sin embargo, los resultados de las investigaciones son frecuentemente insatisfactorios porque no se abordan las cuestiones clínicas más relevantes para los profesionales de atención primaria y secundaria que tratan el dolor lumbar diariamente. Estas prioridades no exploradas dejan un vacío en la práctica clínica, impidiendo la aplicación efectiva de tratamientos basados en evidencia. Objetivo: Evaluar la eficacia de la cinesiterapia activa adaptada en el tratamiento del dolor lumbar crónico, analizando la mejora en discapacidad considerando tanto las diferencias mínimas clínicamente significativas como las diferencias mínimas clínicamente importantes y determinando la proporción de pacientes que experimentan mejoras o empeoramientos clínicamente relevantes. Metodología: Se realizó un estudio prospectivo y longitudinal con evaluación pre y post intervención de rehabilitación física en el Hospital Universitario del Henares (Coslada, España). La muestra consistió en 30 pacientes, de los cuales 24 completaron el estudio y 6 no asistieron a las sesiones. La edad media de los participantes fue de 57,33 años, el 75% eran mujeres, y el índice de masa corporal promedio fue de 25,78. El programa de rehabilitación consistió en ejercicios de cinesiterapia activa adaptada para el dolor lumbar, realizado durante tres meses, con dos sesiones semanales de 60 minutos cada una. Para analizar las diferencias en el nivel de discapacidad antes y después del tratamiento, evaluadas con el cuestionario de Roland Morris, se realizaron pruebas t para muestras relacionadas. Las diferencias estadísticas se determinaron para el total de la muestra y por subgrupos según tramos de mejora porcentual. Se clasificaron las mejoras como "mucho mejor" ($\geq 30\%$), "notoriamente mejor" (25-29%) y "algo mejor" (15-24%). Se utilizó una gráfica de dispersión y una regresión lineal para modelar la relación entre "% de mejora" y "diferencia de puntuación", determinando los umbrales de cambios clínicos. Resultados y conclusiones: La mejora de 1,67 puntos en la puntuación de Roland Morris indica un impacto clínicamente significativo. Sin embargo, el promedio de mejora de la muestra completa fue del 17%, indicando una mejora clínica incipiente pero no importante. El 37,5% de los pacientes no experimentaron mejoras clínicas significativas (67% de ellos con niveles bajos de discapacidad en pretratamiento). No obstante, el 82,5% de los pacientes mostró mejoras clínicas relevantes: un 12,5% con mejoras "algo mejor" y un 50% con mejoras "mucho mejor". Según la regresión lineal del estudio, una diferencia de 3,11 puntos indica mejoras "mucho mejor" y de 1,42 puntos indica mejoras "algo mejor".

Palabras clave: Programa de ejercicios, cinesiterapia activa, dolor lumbar crónico, discapacidad, cuestionario de Roland Morris.

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Mario Manuel López Mesa
mariomlopezm@gmail.com

Introduction

Low back pain, affecting 9.4% of the global population, is a highly prevalent condition and one of the leading causes of years lived with disability worldwide. Classified as the sixth pathology with the highest disease burden, it stands out for its significant impact on public health, requiring appropriate attention and prevention to address its implications (Carpio et al., 2018). It is a frequent reason for consultation in Primary Care, generating a significant burden on the National Health System. In Primary Care clinical practice, it is observed that the overwhelming majority of patients, up to 85%, present with nonspecific low back pain, implying that they experience pain in the lumbar region without an identifiable underlying cause. It is essential to understand that lumbar pain can manifest in various clinical courses, from acute, covering a period of up to four weeks, through subacute, extending between four and twelve weeks, to chronic, persisting for more than twelve weeks from the onset of the low back pain episode (Junta de Castilla y León, 2018).

Although the majority of cases have a favorable evolution in four to six weeks with minimal therapeutic interventions, between 5% and 10% of patients develop chronic disabling symptoms. The annual incidence of first episodes ranges from 6.3% to 15.3%, while any episode of low back pain affects 1.5% to 36% of the population. Furthermore, it is the leading cause of activity limitation and work absenteeism in many countries. These data underline the importance of effectively addressing the prevention and treatment of low back pain in the National Health System to mitigate its socioeconomic impact (Junta de Castilla y León, 2018).

In the adult Spanish population (over 20 years), the prevalence of point-in-time low back pain is estimated at 14.8%, with a 95% confidence interval (CI) ranging from 12.2% to 17.4%. Additionally, the probability of experiencing at least one episode of low back pain in a 6-month period in Spain is 44.8% (95% CI, 39.9-49.8). Among Spanish adults, 7.7% are estimated to suffer from chronic low back pain, according to a 95% confidence interval ranging from 4.7% to 11.6%. On the other hand, the prevalence of low back pain with inflammatory characteristics in this population is 0.8% (95% CI, 0.6-1.0) (Humbría et al., 2002).

Regular physical activity improves agility and dynamic balance, prevents and reduces the risk of falls, and increases physical and cardiorespiratory capacity. Additionally, it enhances mobility, reduces pain levels, and improves joint range of motion, providing benefits that result in improved performance of daily activities and greater autonomy for patients (Brandao de Loureiro et al., 2022; Cerda et al., 2021; Cortez et al., 2021; López and Rodríguez, 2023; Masyitah et al., 2024). Numerous scientific studies have provided evidence that implementing physical exercise programs plays a crucial role in maintaining and developing essential physical capacities, thus preventing the deterioration of quality of life in the elderly population. These programs not only help preserve physical functionality but also promote a more positive perception of health and overall well-being. As we age, regular physical activity becomes even more important, as it helps prevent various chronic diseases and conditions associated with aging, combating sarcopenia, increasing strength, reducing body fat in overweight or obese individuals, and lowering the risk of age-related diseases in older adults (Aboarrage et al., 2024; Pleticosic-Ramírez et al., 2024; Suryadi et al., 2024). Furthermore, regular exercise improves mobility, strength, and endurance, which are critical factors in maintaining independence and autonomy in daily activities. The relationship between physical activity and a higher quality of life is clear: older individuals who exercise regularly report higher levels of satisfaction with their health and well-being. This is due not only to the physical benefits but also to the positive effects of exercise on mental health, including increased vitality and reduced stress, anxiety, and depression (Araque-Martínez et al., 2021; García & Froment, 2018; López et al., 2023; Mastrantonio et al., 2022; San Esteban & Lluch, 2014; Suryadi et al., 2024).

In the literature review on the "importance of physical exercise in the treatment of nonspecific low back pain" conducted by members of the Rehabilitation Unit of the Alcorcón Foundation Hospital (Madrid), it is indicated that despite the heterogeneity of patients and the limitations of available studies, in chronic low back pain, active programs, especially physical exercise, are the best therapeutic alternative to improve pain and reduce disability (García and Alcántara, 2003). Kinesiotherapy is more effective in the long term than passive modalities, particularly when included in multidisciplinary programs aimed at facilitating the return to daily activities and reintegration into work. Exercises, supervised by physiotherapists or performed at home, conducted in sessions lasting 20 to 90 minutes, 2 to 5 times a week, combining stretching, progressive strengthening, lumbar stabilization, and exercises for abdominal, spinal, pelvic, and lower limb muscles, are the most commonly used and effective. Additionally, in groups of 4 to 10 patients, these treatments are more cost-effective than individual ones (García and Alcántara, 2003; Hernández and Zamora, 2017; Pérez, 2006). Similar evidence and recommendations regarding the benefits of these exercises in chronic low back pain are provided in other recent reviews, such as those by Carreño and García (2022), Jiménez-Gutiérrez and Redruello-Guerrero (2020), Ojeda and Jerez (2022).

Recent clinical studies conducted in outpatient hospital physiotherapy services have shown the beneficial effects of therapeutic exercises in patients with low back pain. A study by Cuenca et al. (2023) implemented a group therapeutic exercise protocol to reduce pain intensity and disability in patients with back pain in a hospital healthcare setting. The mobility and stabilization exercises for the lumbar area showed statistically significant differences in pain intensity and disability, with a moderate to large effect size. Another recent study by Ballestra et al. (2022) highlights the importance of

implementing exercise protocols in realistic and sincere settings that provide positive expectations for achieving good results. Additionally, it emphasizes the need for frequent follow-ups, controlled activity developed in appropriate settings, and adequate attention and communication with patients, which are associated with better recovery outcomes. Other physiotherapeutic techniques have also yielded satisfactory results in patients with low back pain. For example, orthopedic manual therapy has been shown to improve low back pain, mechanical hyperalgesia, and conditioned pain modulation (Martínez-Pozas et al., 2023).

Clinical research treating of chronic low back pain is crucial to improving medical care and patient's quality of life, but it still faces significant challenges. Despite numerous studies and resources invested, success in treatment remains limited. An analysis of the scientific literature shows that many studies optimistically assume the efficiency of healthcare resources. For example, labeling a treatment simply as "exercise" is considered sufficient to assume its effectiveness, without defining specific criteria such as intensity, frequency, or type of exercise (Serrano et al., 2011).

A key reason for these unsatisfactory results is that governmental authorities, industry, and funding agencies often determine research priorities, whose objectives do not meet the practical needs of healthcare personnel and patients. Although these bodies include healthcare personnel in the research process, they frequently do not address the most relevant clinical issues for primary and secondary care professionals who treat low back pain daily. These unexplored priorities leave a gap in clinical practice, hindering the effective application of evidence-based treatments (Henschke et al., 2007). To improve the usefulness of clinical studies, it is essential that reports on chronic low back pain trials provide more concrete and relevant data. Scientific articles should include the mean differences, the analysis of variables and their relationship with magnitudes, which are considered minimal clinically relevant differences. Additionally, they should report on the proportion of patients who improved or worsened beyond the predefined thresholds of minimal clinically relevant variation and on the standardized mean difference (Froud et al., 2011). Variations in different health conditions, which are often evaluated in clinical practice and research, should be interpreted beyond their statistical relevance. The minimal clinically important difference considers and highlights the patients' perspective regarding treatments and their health status, integrating them into the decision-making process (Salas et al., 2021).

In clinical practice, it is fundamental to interpret the clinical relevance of changes from the beginning to the end of treatment. This involves using objective estimates based on clinical differences in variables, providing results both in terms of minimally clinically significant differences (mean differences between pre-and post-treatment scores that the patient perceives as "a little worse" or "a little better," i.e., the point at which improvement or worsening begins) and in terms of minimally clinically important differences (mean differences between pre-and post-treatment scores that the patient perceives as "much worse" or "much better").

Given that these data are crucial for primary and secondary care professionals to develop more effective treatments, an experimental study is conducted to evaluate the efficacy of active kinesiotherapy adapted to low back pain with the purpose of providing evidence on the average differences in various levels of disability and pain, performing an analysis of the results that considers both minimally clinically significant and important differences in patients, and highlighting the proportion of those who improved or worsened beyond the predefined clinically relevant thresholds. We consider it necessary to conduct this research, as well as new experimental studies addressing these specific areas, in order to improve clinical priorities and healthcare in the rehabilitation and management of low back pain. This will allow for better alignment between research and clinical practice, optimizing patient outcomes.

We hypothesize that an adapted active kinesiotherapy protocol would show positive effects on the disability of patients suffering from chronic low back pain. Thus, the primary objective of this study was to evaluate the efficacy of adapted active kinesiotherapy in improving disability in patients with chronic low back pain by analyzing minimally clinically significant differences and minimally clinically important differences in disability levels before and after treatment, to determine the clinical relevance of the observed changes in patients. The secondary objective was to identify and quantify the proportion of patients who experience clinically relevant improvements or deteriorations in their levels of disability following the intervention.

Material and Methods

Study Design

A prospective, longitudinal study with pre- and post-intervention assessments of physical rehabilitation was conducted at the University Hospital of Henares (Coslada, Spain), part of the Health Service of the Community of Madrid (Spain), to evaluate the effectiveness of adapted active kinesiotherapy for low back pain. This study was carried out in the hospital's physiotherapy facilities, where patients participated in active kinesiotherapy sessions specifically designed to improve patient disability. During the study, physiotherapists guided patients through exercises, adapting them to individual needs and focusing on controlled movements to strengthen muscles, increase mobility, and reduce pain.

The sample size calculation was performed using the JAMOVI 2.3 program (The Jamovi Project, 2007). This calculation was based on an analysis comparing related samples at two measurement points (pre-treatment and post-treatment).

An expected effect size between 0.597 and 0.769 (d), a statistical power of 90%, and a maximum alpha error rate of 0.05 were considered. The resulting sample size was 24 patients. Assuming a 15% loss, the final sample size was set at a minimum of 29 patients.

The study adhered to the ethical principles for human clinical research outlined in the Declaration of Helsinki. Additionally, it complied with personal data protection regulations per current legislation (Organic Law 3/2018 and Regulation (EU) 2016/679). It was approved by the Physiotherapy and Occupational Therapy Unit of Hospital Universitario del Henares (Coslada, Spain) and received approval from the Research Ethics Committee for Medicines of the hospital, accredited by the Health Department of the Community of Madrid (Spain).

Participants

The study was conducted in the basic health area of the University Hospital of Henares, focusing on patients diagnosed with chronic low back pain. From the rehabilitation waiting list in the Physiotherapy and Occupational Therapy Unit, a sample of 30 patients was selected (an adequate sample to conduct the study considering the hospital's staff capacity and resources). The selection was randomly performed by the Administration and Management staff using the software "IBM.SPSS.Statistics.v20.Multilingual". Selected patients provided consent after reading the Information Sheet about the proposed treatment.

The 30 randomly selected patients were assigned to the experimental treatment of the study. In contrast, others were scheduled for treatment on the next call from the waiting list or offered other physiotherapy treatments appropriate to their pathologies in the hospital. It is crucial to mention that the researchers did not have access to the distribution sequence generated by the software, thus ensuring impartiality and avoiding selection bias. Of the patients who started the three-month program, 24 completed it, and six did not attend the sessions.

The demographic characteristics and body mass index (BMI) of the patients, presented in Table 1, showed that the mean age was 57.33 years. Men had a mean age of 54.67 years, and women had a mean age of 58.22 years. Most participants were women, representing 75% of the total sample. The average BMI indicated overweight with a value of 25.78, which is slightly higher in women (25.89) than in men (25.45).

Table 1.
Patient Characteristics.

		Patient Characteristics							
		95% Confidence Interval				Median	SD	Minimum	Maximum
		N	Mean	Lower	Upper				
AGE	Total	24	57.33	52.74	61.9	57.00	10.89	32	74
	Male	6	54.67	39.36	70.0	57.00	14.58	32	74
	Female	18	58.22	53.39	63.1	57.00	9.72	40	72
ROLAND PRETREATMENT	Total	24	8.63	7.13	10.1	8.50	3.54	3	18
	Male	6	7.17	3.39	10.9	7.00	3.60	3	11
	Female	18	9.11	7.38	10.8	8.50	3.48	5	18
BMI (Body mass index)	Total	24	25.78	24.78	26.8	25.50	2.37	22.6	31.2
	Male	6	25.45	23.57	27.3	25.30	1.79	22.9	28.2
	Female	18	25.89	24.61	27.2	25.75	2.57	22.6	31.2

The study included participants over 18 years of age on the waiting list for treatment at the University Hospital of Henares, presenting with chronic lower back pain that had been present for more than 3 months. Additionally, these participants had not previously received other physiotherapy treatment.

Patients under 18 years of age, those whose lumbar pathology had less than 3 months of evolution, and those who had undergone surgery directly related to low back pain were excluded from the study. Patients with acute or chronic infectious diseases, uncontrolled metabolic diseases such as diabetes, hypertension, anorexia, and hyperlipidemia, and those with Class 2 obesity (BMI 35-39.9) or morbid obesity (BMI 40 or higher) were also excluded. Additionally, patients with diseases that could cause asthenia, muscle fatigue, balance disturbance or vertigo, cardiopulmonary problems, and those receiving medical or physiotherapy treatments that could alter the study results were

excluded. Patients with pre-existing medical conditions such as heart, kidney, liver, lung, and adrenal diseases were also excluded, as well as those with high levels of pain or disability that prevented them from adequately performing the exercise protocol.

Therapeutic Exercise Protocol

Six physiotherapists from the Physiotherapy and Occupational Therapy Unit, conducted the sessions twice a week for three months. Patients were organized into three groups, each composed of eight to nine participants. Each session, lasting 60 minutes, included an active kinesiotherapy program adapted to low back pain. Two physiotherapists were present in each group: one supervised and individually advised each patient, while the other coordinated and led group exercises.

Protocol of Adapted Active Kinesiotherapy Exercises for Lumbar Spine Stabilization in Patients with Chronic

Low Back Pain

This study proposes an active kinesiotherapy exercise protocol specifically designed to improve lumbar spine stabilization and mobility in patients with chronic low back pain. The protocol includes a combination of muscle strengthening exercises, stretches, balance exercises, mobility exercises, neuromuscular exercises, and motor control, detailed below.

The protocol will be carried out for 12 weeks, with exercise sessions three times a week. Each session will last 60 minutes and will be divided into the following phases:

1. Warm-up (5 minutes)

Gentle aerobic exercises to increase blood circulation and prepare the muscles for exercise.

2. Muscle Strengthening (15 minutes)

Bridges: Perform lumbar bridges, lifting the pelvis while contracting the glutes and abdominal muscles, 2 sets of 10 repetitions.

Lower Abdominals: Lie on your back with legs extended and raise both legs keeping them straight, 2 sets of 10 repetitions.

Prone Trunk Extension: Lie face down and lift the chest off the ground while keeping the feet and legs in contact with the ground, 2 sets of 10 repetitions.

Supine Knee Flexion: Lie on your back with knees bent and feet on the ground. Bring one knee to the chest while keeping the other leg bent and supported, alternate legs, 2 sets of 5 repetitions per leg.

3. Stretching (10 minutes)

Lumbosacral Stretch: Lie on your back and bring knees to the chest, gently hugging them to stretch the lumbar area, hold for 30 seconds. 1 set of 5 repetitions.

Hamstring Stretch: Lie on your back and lift one leg straight towards the ceiling, keeping the other leg bent, use a towel to gently pull the raised leg towards the body, hold for 30 seconds per leg. 1 set of 5 repetitions.

Psoas Stretch: Lie on your side with one leg extended and the other bent. Gently pull the bent leg back to stretch the psoas muscle, and hold for 30 seconds per side. 1 set of 5 repetitions.

4. Balance Exercises (5 minutes)

Lying Balance Exercise on One Leg: Lie on your side and lift the upper leg, maintaining trunk balance and stability, 2 sets of 15 repetitions per leg.

5. Mobility and Flexibility of the Spine (10 minutes)

Spine Rotations: Lie on your back with knees bent and feet on the ground. Let knees drop to one side while turning the head to the opposite side, 2 sets of 10 repetitions per side.

Spine Flexion and Extension: Lie on your back and perform flexion movements (bring knees to chest) and extension movements (stretch legs and arms out), 1 set of 10 repetitions.

"Cat" Exercise: In a quadruped position, alternate between arching the back upwards (cat) and downwards (cow), coordinating with breathing to improve mobility and relieve tension in the spine. 2 sets of 10 repetitions.

6. Neuromuscular Exercise and Motor Control (15 minutes)

Motor Control Exercises: Specific movements designed to improve coordination between the nervous system and spinal muscles, such as opposite leg and arm lifts in quadruped position, 2 sets of 10 repetitions per side.

Upper Abdominals: Lie on your back with knees bent and hands behind your head, lift the torso towards the knees, 2 sets of 10 repetitions.

Cross Upper Abdominals: Lie on your back with knees bent and hands behind your head, bring the right elbow towards the left knee and vice versa, 2 sets of 10 repetitions per side.

To help patients learn to manage and prevent back pain themselves (self-management of prevention and pain), at the end of the three-month study, information was provided on the anatomy and biomechanics of the spine, as well as the importance of maintaining correct posture and adopting ergonomic habits in daily life. Physiotherapists taught prevention techniques and strategies to manage pain autonomously, providing detailed guidelines for patients to continue these exercises and healthy habits at home, and integrate them into their daily activities to prevent relapses.

Measurement Outcomes

1. Roland Morris Questionnaire

The Roland-Morris Scale (RMQ) is an effective and reliable tool for assessing disability associated with chronic low back pain. In its Spanish version, it has demonstrated high internal consistency, with a Cronbach's alpha of 0.8375 on the first day and 0.9140 on day 15, and an intraclass correlation coefficient of 0.874 with a 95% concordance limit of 0.340 +/- 4.81 (Kovacs et al., 2002).

This questionnaire, consisting of 24 statements, assigns 1 point for each marked statement and 0 for each unmarked statement, resulting in a total score ranging from 0 to 24, where 0 indicates no disability and 24 indicates the maximum level of disability (González, 2020). It is self-administered and evaluates current disability in patients, addressing daily activities and limitations caused by pain (Kovacs, 2005). It does not measure pain intensity, as pain and disability correlate poorly. A score below 4 indicates very mild disability, with a clinically relevant variation of 2 or more points, and an optimal threshold between 3 and 4. Improvements of less than 2.5 points on the questionnaire and 1.5 points on a pain scale are not considered minimally clinically important differences, and the magnitude of improvement depends on the initial intensity of symptoms, being clinically relevant when they are greater than 30% of the initial level (Kovacs et al., 2007). The clinical use of the Roland Morris questionnaire is free (Kovacs, 2005).

Other studies indicate that the magnitude of improvement considered clinically relevant varies between 2 to 8 points, depending on the initial level of disability, with a minimum clinically relevant change between 2 and 3 points. Considering that the consideration of change depends on the level of disability before treatment, 30% is regarded as

a minimally clinically important difference (mean differences between pre-and post-treatment scores perceived by the patient as "much worse" or "much better"). In the case of considering improvements starting from "slightly improved," a 15% difference would be regarded as a minimally clinically significant difference (mean differences between pre-and post-treatment scores perceived by the patient as "a little worse" or "a little better," i.e., the point at which improvement or worsening begins) (Bombardier et al., 2001; Braten et al., 2022; Ostelo et al., 2008; Stratford et al., 1998).

Statistical Analysis

Descriptive statistics (mean \pm standard deviation) were calculated for the different variables. Related-sample t-tests were performed to analyze the differences between pre-treatment and post-treatment disability levels, assessed with the Roland Morris questionnaire. The normality of data distribution was verified using the Kolmogorov-Smirnov test, confirming a normal distribution of variables. Additionally, effect sizes were calculated and interpreted according to previously established ranges: <0.2 = insignificant; $0.2-0.6$ = small; $0.6-1.2$ = moderate; $1.2-2.0$ = large; $2.0-4.0$ = very large; >4.0 = extremely large (Hopkins et al., 2009).

Minimal clinical differences are defined as changes in a clinical outcome that a patient perceives as beneficial or harmful, justifying the implementation of treatment in patient management. These differences are crucial as they allow determining whether a treatment has a significant impact from the patient's perspective, beyond mere statistical significance. They are classified into three levels established by the percentage of improvement achieved in the patient after adapted kinesiotherapy for low back pain (Bombardier et al., 2001; Braten et al., 2022; Farrar et al., 2001; Ostelo et al., 2008; Kovacs et al., 2007; Salaffi et al., 2004; Tubach et al., 2012):

- "Clinically important difference" for percentages equal to or greater than 30%. Patients feel "much better," a threshold of significant improvement produced by treatment.
- "Clinically significant difference notably better" for percentages between 25% and 29%: This reflects a notable improvement that is more significant than a "clinically significant difference slightly better" (15%), but still does

not reach the threshold of "clinically important difference much better" ($\geq 30\%$).

- "Clinically significant difference" for percentages between 15% and 24%. Patients feel "slightly better," a threshold for the onset of improvement produced by treatment.

A scatter plot was created, and the linear regression equation was calculated to model the relationship between the variables "% improvement between pre-and post-treatment" and "score difference between post- and pre-treatment," to determine thresholds for clinical changes.

Results

In this study, 24 patients were evaluated with an average age of 57.33 years (SD = 10.89), with a 95% confidence interval between 52.74 and 61.90 years. The mean Roland Morris score in the pretreatment phase was 8.63 (SD = 3.54), with a 95% confidence interval between 7.13 and 10.10. The average body mass index (BMI) was 25.78 (SD = 2.37), with a 95% confidence interval between 24.6 and 27.2 (Table 1).

When data were broken down by gender, it was found that the average age of men (N = 6) was 54.7 years (SD = 14.58), with a 95% confidence interval between 39.4 and 70.0 years. For women (N = 18), the average age was 58.2 years (SD = 9.72), with a 95% confidence interval between 53.4 and 63.1 years (Table 1).

Regarding BMI, men had an average of 25.4 (SD = 1.79), with a 95% confidence interval between 23.6 and 27.3, while women had an average BMI of 25.9 (SD = 2.57), with a 95% confidence interval between 24.6 and 27.2, placing both genders in the overweight range according to the World Health Organization classification (Table 1).

Results of the paired samples t-test show a significant difference in Roland Morris scores before and after treatment ($t(23) = 6.09$, $p < 0.001$). The mean difference is 1.67 with a 95% confidence interval of 1.1 to 2.23 and a large effect size (Cohen's $d = 1.24$), indicating a significant moderate impact of the treatment (Hopkins et al., 2009). The Kolmogorov-Smirnov normality test ($p = 0.386$) suggests that the data follow a normal distribution, validating the use of the t-test (Table 2).

Table 2.

Paired Samples T-Test for Roland Morris pre-treatment - post-treatment for the entire sample $n=24$.

Paired Samples T-Test for Roland Morris pre-treatment - post-treatment for the entire sample $n=24$.									
95% Confidence Interval									
	statistic	gl	p	Mean difference	difference error	Lower	Upper	Effect Size	
T de Student	6,09	23	< ,001	1,67	0,274	1,1	2,23	Cohen's d	1,24
Tests of Normal									
	statistic	p							
Kolmogorov-Smirnov	0.185	0.386							

Regarding the pretreatment Roland score, men had a mean of 7.17 (SD = 3.60), with a 95% confidence interval between 3.39 and 10.90, while women had a mean of 9.11

(SD = 3.48), with a 95% confidence interval between 7.38 and 10.80 (Table 1). The results reveal that 37.5% of patients did not experience clinically significant improvements, while

12.50% showed clinically significant improvements of "somewhat better," and 50% achieved notable and significant improvements of "much better" (Table 3).

Table 3. Percentage of improvement in Roland Morris scores between post and pre-treatment by percentage improvement range.

PERCENTAGE IMPROVEMENT IN ROLAND MORRIS QUESTIONNAIRE SCORES BETWEEN POST AND PRE-TREATMENT BY CATEGORY	N	Mean	Median	SD	Minimum	Maximum	% of Patients
% improvement between pre- and post-treatment for the total sample n=24	24	17.20	19.50	13.20	0.00	38.00	100
% improvement between pre- and post-treatment by improvement category							
No improvement occurs	9	2.22	0.00	4.44	0.00	11.00	37.50
Improvement between 15 and 25%. Clinically significant difference "somewhat better"	3	17.33	17.00	2.52	15.00	20.00	12.50
Improvement between 25 and 29%. Clinically significant difference "noticeably better"	8	25.50	25.00	3.51	19.00	29.00	33.34
Improvement >= 30%. Minimally important difference "much better"	4	34.25	33.00	2.50	33.00	38.00	16.66

Discrepancies between pre-and post-treatment results were analyzed, dividing participants according to the degree of improvement observed. Of the 24 patients studied, 9 did not show clinically significant improvements, recording a mean difference of -0.222 (SD = 0.441) between pre-and post-treatment scores, with an average improvement of 2.22% (SD = 4.44). On the other hand, 4 patients showed a significant clinical improvement, classified as "much better," with a mean difference of -3.250 (SD = 0.500) and an

average improvement of 34.25% (SD = 2.50), while 8 showed a notable clinical improvement, presenting a mean difference of -2.500 (SD = 0.756) and an average improvement of 25.50% (SD = 3.51). Regarding patients with moderately clinically significant improvements, 3 exhibited a mean difference of -1.667 (SD = 0.577) and an average improvement of 17.33% (SD = 2.52) (Table 4, Figure 1).

Table 4. The difference in Roland Morris questionnaire scores between post and pre-treatment by percentage improvement range.

DIFFERENCE IN ROLAND MORRIS QUESTIONNAIRE SCORES BETWEEN POST AND PRE-TREATMENT BY PERCENTAGE IMPROVEMENT SEGMENT	N	Mean	Median	SD	Minimum	Maximum	% of Patients
% improvement between pre- and post-treatment for the total sample n=24	24	-1.67	-2.00	1.34	-4.00	0.00	100
% improvement between pre- and post-treatment by improvement category							
No improvement occurs	9	-0.22	0.00	0.44	-1.00	0.00	37.50
Improvement between 15 and 25%. Clinically significant difference "somewhat better"	3	-1.67	-2.00	0.58	-2.00	-1.00	12.50
Improvement between 25 and 29%. Clinically significant difference "noticeably better"	8	-2.50	-2.00	0.76	-4.00	-2.00	33.34
Improvement >= 30%. Minimally important difference "much better"	4	-3.25	-3.00	0.50	-4.00	-3.00	16.66



Figure 1. Percentage improvement and difference in Roland Morris questionnaire scores between post- and pre-treatment by percentage improvement range

Results by pre-treatment Roland Morris disability level range, classifying participants according to the observed disability level range. In the first range, where the disability level was equal to or less than 6, a total of 7 patients were found, with a mean difference of -0.143 (SD = 0.378) between pre-and post-treatment scores, and an average percentage improvement of 2.429% (SD = 6.425), with a range of improvement between 0% and 17%. In the following range, with disability levels greater than 6 but equal to or less than 10, 9 patients were identified, with a mean difference of -2.000 (SD = 1.000), and an average percentage improvement of 25.222% (SD = 12.070), with a range of improvement between 0% and 38%. Finally, in the range where the disability level exceeded 10, 8 patients were located, with a mean difference of -2.625 (SD = 1.061), and an average percentage improvement of 21.125% (SD = 7.220), with a range of improvement between 9% and 33% (Table 5).

Table 5.
The difference in Roland Morris questionnaire scores between post and pre-treatment by disability level range.

Roland Morris handicap section in T0	Difference between post-pretreatment		95% Confidence Interval					
	N	Mean	Lower	Upper	Median	SD	Minimum	Maximum
=<6	7	-0,143	-0,492	0,207	0	0,378	-1	0
> 6 y =<10	9	-2.000	-2.769	-1.231	-2	1.000	-3	0
>10	8	-2.625	-3.512	-1.738	-2,5	1.061	-4	-1

Results of the paired samples t-test for the sample without patients with mild disability (equal to or less than 6) show a significant difference in Roland Morris scores before and after treatment ($t(16) = 11.08, p < 0.001$). The mean difference is 2.53 with a 95% confidence interval of 2.07 to

3.00 and a large effect size (Cohen's $d = 3.04$), indicating a significant large impact of the treatment (Hopkins et al., 2009). The Kolmogorov-Smirnov normality test ($p = 0.217$) suggests that the data follow a normal distribution, validating the use of the t-test (Table 6).

Table 6.
Paired Samples T-Test for Roland Morris pre-treatment - post-treatment of the sample without patients with mild disability n=17

	statistic	gl	p	Mean difference	difference error	Lower	Upper	Effect Size
T de Student	11.8	16.0	< .001	2.53	0.215	2.07	3.00	Cohen's d 3.04
Tests of Normal	statistic	p						
Kolmogorov-Smirnov	0.272	0.217						

Before treatment, according to the Roland Morris disability scale, 29.2% of patients had a mild disability level, while 70.8% had moderate to high disability levels.

Results for notable and significant clinical improvements, in relation to the percentage of patients who did not improve by range, indicate the following: in the first range, with a disability level equal to or less than 6, 85.72% of patients did not achieve clinical improvements, while the rest

of the patients in that range showed moderate clinically significant improvements ("somewhat better"). However, in the other two ranges, with disability levels greater than 6 but equal to or less than 10, and greater than 10, the percentage of patients who did not improve is less than 25%. In both groups, more than 72% of patients achieved notable or significant clinical improvements ("much better") (Table 7).

Table 7.
Improvement was obtained by patients by disability level in pre-treatment and % of patients in relation to their range.

Roland Morris disability section in T0	percentage section of improvement	number of patients	% of patients in relation to their section
=<6	no improvement occurs	6	85.72%
	improvement => 30%. Minimally important difference "much better"	0	0%
	improvement between 15 and 25. Clinically significant difference "somewhat better"	1	14.28%
> 6 y =<10	improvement between 25 and 29%. Clinically significant difference "noticeably better"	0	0%
	no improvement occurs	2	22.23%
	improvement => 30%. Minimally important difference "much better"	3	33.33%
	improvement between 15 and 25. Clinically significant difference "somewhat better"	0	0%
>10	improvement between 25 and 29%. Clinically significant difference "noticeably better"	4	44.44%
	no improvement occurs	1	12.5%
	improvement => 30%. Minimally important difference "much better"	1	12.5%
	improvement between 15 and 25. Clinically significant difference "somewhat better"	2	25%
	improvement between 25 and 29%. Clinically significant difference "noticeably better"	4	50%

Considering the variables "% improvement between pre-and post-treatment" and "difference in score between post- and pre-treatment," a linear regression equation was obtained to model the relationship between the variables X and Y, obtaining $Y = 2.423 + 8.871X$. Therefore, the values of X are approximately 3.11, 2.54, and 1.42 when Y is 30%, 25%, and 15%, respectively. For our sample, an average improvement starting from 1.42 points on the Roland Morris questionnaire would indicate the onset of a clinically significant difference, with patients feeling "somewhat better," which is the threshold for the beginning of improvement produced by the treatment. From 2.54 points, changes begin to be notable, and from 3.11 points they start to be clinically important, with patients feeling "much better," marking the threshold of significant improvement produced by the treatment (Figure 2).

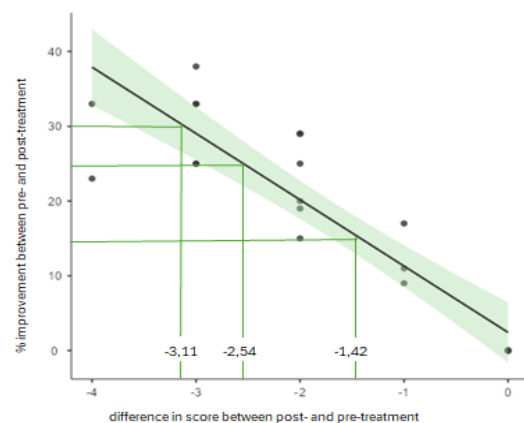


Figure 2. Scatter plot of the linear regression equation to model the relationship between the variables "% improvement between pre- and post-treatment" and "difference in score between post- and pre-treatment."

Discussion

The average improvement of 1.67 points in the Roland Morris score suggests a clinically significant impact of the treatment. However, the overall sample showed an average improvement of 17%, indicating initial clinical improvement but falling short of the 25-30% threshold considered clinically relevant. Of the total patients, 37.5% did not experience clinically significant improvements, with 67% of them starting with low disability levels. Nevertheless, upon subgroup analysis of achieved improvement percentages, 82.5% of patients demonstrated clinically relevant improvements: 12.5% showed improvements categorized as "somewhat better," and 50% as "much better." According to the study's linear regression, a 3.11-point difference in the Roland Morris score indicates "much better" improvement, while a 1.42-point difference indicates "somewhat better" improvement. These findings underscore the moderate effectiveness of tailored active physiotherapy for chronic low back pain in a significant proportion of patients.

Compared to previous studies on the effectiveness of exercise programs for managing chronic low back pain, our results show both consistencies and differences in the improvements of disability scores evaluated using the Roland-Morris questionnaire. Our study, with 24 patients averaging 57.33 years of age, reported a decrease of 1.67 points in the Roland-Morris score after 12 weeks of treatment with two weekly sessions. This result aligns with studies such as Albaladejo et al. (2010), who, in their trial with 348 patients, showed improvements of 2 points in the active management group and 2.2 points in the postural education plus physiotherapy group at 6 months. In terms of percentages of improvement, 62% of our patients showed significant improvement, similar to the 56.85% reported by Chumillas et al. (2003) in a study with 419 patients. Additionally, improvements in disability measured with the Roland Morris questionnaire were similar in a sample of 17 office workers aged 30 to 40 years, after 20 exercise sessions, with a significant improvement of 2.3 points, increasing to 3.4 points at 6 months (Alfonso Mora et al., 2017). Other studies reported slightly superior improvements to ours, such as Kovacs et al. (2007), where a 3-point improvement was observed at 180 days in a group of 661 subjects with a higher average age (79.9-81.2 years), Costa et al. (2009), which reported a 3.7-point improvement at 2 months and 2.8 points at 6 months in 154 patients with an average age of 54.6 years, and the study by Plata et al. (2023) with 90 patients reporting a decrease of 2.7 points in the first month and 4.1 points at three months in the exercise group, and 3 points in the first month and 4.7 at three months in the NSAIDs group. Despite the lower average age (38.5 years) and higher percentage of women, the superior improvements highlighted the possible influence of age and pharmacological intervention. Other studies have shown significant improvements in functional disability, as obtained in the study by Pakbaz et al. (2019), which also reported a significant decrease in disability with an educational and exercise

intervention. However, their population had a lower average age (38.9 years in the intervention group).

A recent study conducted in the Physiotherapy Department of the Hospital of Guadarrama, Spain, obtained results similar to ours. The patients, mostly women (78.5%) with an average age of 60 years, had characteristics very similar to our sample. The exercise protocol was carried out in the hospital's Physiotherapy Department in small groups attended by hospital physiotherapists. Unlike our study, disability was assessed using the Oswestry Low Back Disability Scale, revealing statistically significant differences. There was a mean difference of 8 points between the pre-treatment and post-treatment assessments (minimally detectable changes). Although this difference does not reach the 11 points required to be considered clinically relevant, it was achieved with only 10 sessions of approximately 30 minutes each over 2 weeks. The percentage improvement in disability in this study was 30.7%, very similar to the results obtained in our study (Cuenca et al., 2023).

Other studies indicate results higher than those obtained in our study, such as Cairns et al. (2006), who found significant improvements in the Roland-Morris in both groups of their study (conventional physiotherapy and stabilization exercises), with decreases of 5.1 and 5.4 points at 12 months, and Cecchi et al. (2010) with 210 patients, reported decreases of 3.7 and 4.4 points in back exercises and individual physiotherapy groups, respectively. The greater intensity, longer follow-up duration, different exercise program approaches for improving spine stability and mobility, and session frequency may have contributed to more significant improvements than our study.

More recent trials, such as Hernandez-Lucas et al. (2023), demonstrated significant improvements in the Roland-Morris with 8-week back exercise programs. Although the duration of their intervention was shorter, the observed improvements suggest that different durations and program structures can be effective in reducing disability in patients with chronic low back pain. The trial by Costantino and Romiti (2014) showed that both back exercises and hydrotherapy significantly improved Roland-Morris scores in older individuals with chronic low back pain, with decreases of 3.26 and 4.96 points, respectively.

Our results are consistent with the existing literature regarding the significant effectiveness of exercise programs for improving functional disability in patients with chronic low back pain. The improvement of 1.67 points in the Roland Morris score and the moderate effect size (Cohen's $d = 1.24$) indicate a clinically significant impact. However, it is essential to consider that, at the level of comparison of the entire sample, the differences produced by the treatment do not acquire clinically important benefits, achieving an average percentage of the whole sample of 17%, which, although significant and at the threshold of the beginning of disability improvement, is far from the estimated 30% to be clinically important "much better".

However, following the recommendations to increase the utility of clinical studies, it is crucial that reports on

chronic low back pain provide more specific and relevant data, detailing the mean differences, as well as analyzing the variables and their relationship with the magnitudes considered as minimally clinically relevant differences. Additionally, it is important to report the proportion of patients who improved or worsened beyond pre-established thresholds of minimal clinically relevant variation and the standardized mean difference (Froud et al., 2011). The results should be interpreted considering their relevance beyond statistical significance, being fundamental to take into account the minimal clinically important difference to provide a perspective on the benefits obtained by patients, integrating them into the decision-making process (Salas et al., 2021).

In our study, the majority of patients with disability due to chronic low back pain present moderate to severe physical limitation (70.8%), consistent with findings from other studies (Santiago et al., 2018).

The groups that showed significant clinical improvements ($\geq 30\%$ and 25% - 29%) presented the greatest differences in pre- and post-treatment scores, as well as the highest percentages of improvement. In contrast, the nine patients who showed no improvement had the most minor differences and, in general, lower levels of disability at the beginning of the study. These results may indicate that patients with mild disability, scores equal to or less than 6, affected by chronic low back pain tend to experience slight improvements in their functional capacity. Although physical interventions and rehabilitation can offer some improvement, these advances are usually modest due to the persistent and complex nature of the condition (comorbidities related to aging, overweight or obesity, and other clinical conditions that complicate full recovery).

These findings suggest that while some participants experienced notable improvements, others did not show significant changes in their post-treatment scores. This fact highlights that although the comparison of paired samples of all participants shows significant differences that are not considered clinically important, when the analysis is performed by subgroups, important considerations are obtained for clinical practice.

Analyzing the different levels of Roland Morris disability in pre-treatment, it is observed that patients with an initial disability level of 6 or less show minimal improvement in absolute terms, with a mean difference close to zero between pre-and post-treatment scores. Additionally, this group's average percentage of improvement is relatively low, suggesting that these patients experienced minimal improvement in their conditions. On the other hand, patients whose initial disability level exceeded 10 show more significant clinical improvements compared to different groups. Both the mean differences and the percentages of improvement are higher in this group, suggesting that these patients experienced the greatest clinical improvements in response to treatment. These findings highlight the importance of considering the initial level of disability when designing and evaluating interventions for the treatment of this condition.

The relationship between pre-and post-treatment differences and percentages of improvement confirms that higher percentages of improvement are associated with higher levels of pre-treatment disability. Although 37.5% of the patients did not experience significant clinical improvements (of which 67% had low pre-treatment disability levels), it is important to note that.

82.50% achieved relevant clinical improvements. Of these, 12.50% showed clinically significant improvements categorized as "somewhat better," and 50% achieved notable and significant improvements categorized as "much better."

According to the linear regression equation obtained in our study, for samples with characteristics similar to ours, a difference of 3.11 (improvements equal to or greater than 30%) is clinically important, indicating "much better," and a difference of 1.42 (improvements equal to or greater than 15%) indicates the onset of a clinically significant difference, with patients feeling "somewhat better," which marks the threshold for the beginning of improvement produced by the treatment. These results are similar to other studies in the scientific literature on thresholds of minimal clinically significant differences measured with the Roland Morris questionnaire in patients with chronic low back pain (Bombardier et al., 2001; Kovacs et al., 2007; Ostelo et al., 2008; Stratford et al., 1998; Braten et al., 2022).

The research conducted at Hospital Universitario del Henares had certain limitations. These included the inability to increase the number of weekly sessions or expand the sample size due to restrictions on available facilities and human resources. Concerns about inappropriate practices and possible injuries to patients under the physiotherapist's supervision also influenced this decision. Additionally, due to the limited availability of human resources and time, conducting physical condition tests or clinical evaluations related to functionality was not feasible. Although the study was conducted without an equivalent control group, a highlighted strength was its application in a real rehabilitation context. This provided an authentic perspective applied to patients' actual conditions, allowing for a better understanding of the applicability and potential benefits of treating of specific conditions.

Conclusions

A therapeutic exercise protocol of adapted active kinesiotherapy for chronic low back pain shows a clinically significant impact with beneficial effects and moderate efficacy on disability in patients with chronic low back pain. Despite an initial clinical improvement observed in the overall sample, the clinically relevant threshold of 25-30% improvement is not reached. However, subgroup analysis indicates that 82.5% of patients demonstrated clinically relevant improvements: 12.5% showed improvements categorized as "somewhat better" and 50% as "much better". Its inclusion could be considered as a disability management program for

patients with chronic low back pain in primary and secondary healthcare settings.

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Datos de los/as autores/as y traductor/a:

Mario Manuel López Mesa
Javier J. Cabrerizo Fernández
Yolanda Robledo do Nascimento

mariomlopezm@gmail.com
javier.cabrerizof@salud.madrid.org
yolandarobledo.uem@salud.madrid.org

Autor/a – Traductor/a
Autor/a
Autor/a