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# Effectiveness of back therapeutic exercises and Pilates on the clinical improvement of the intensity of chronic low back pain and determination of the minimal clinically important improvement threshold from treatments in a hospital setting

# Eficacia de los ejercicios terapéuticos de espalda y Pilates en la mejora clínica de la intensidad del dolor lumbar crónico y determinación del umbral mínimo de mejora clínicamente importante de los tratamientos en el ámbito hospitalario

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**Abstract.** The primary aim was to compare the effectiveness of therapeutic back exercises and Pilates in reducing chronic low back pain and to determine the threshold of improvement and the difference in pre- and post-treatment scores considered clinically relevant for patients. Methodology: A total of 53 patients with chronic low back pain were randomly assigned to two groups: one with 27 participants performing Pilates and another with 26 participants following a back exercise program. The treatment consisted of sessions twice a week for three months. Pain intensity was assessed before and after treatment using the Visual Analog Pain Scale. A clinically relevant threshold was defined as a sufficient reduction in pain score for patients to feel "very satisfied." A Receiver Operating Characteristic Curve analysis was used to determine the sensitivity and specificity of the improvement threshold. Additionally, a linear regression model was applied to analyze the relationship between score difference and the percentage of improvement. Results: Although both groups showed significant improvements in pain reduction after treatment, there were no statistically significant differences between them. The average reductions in both groups did not exceed two points (Back Exercise Group = 1.43 points, Pilates Group = 1.82 points), thus not reaching the two-point average improvement required to meet the clinically relevant improvement threshold. However, at an individual level, 45.83% of the Pilates group and 37.5% of the back exercise group achieved a clinically relevant improvement (≥30% improvement). The improvement threshold of 31.4%, equivalent to a two-point reduction, was correlated with greater clinical satisfaction (sensitivity 84%, specificity 87%). Conclusions: Both treatments produced beneficial effects in reducing chronic low back pain. However, the average improvement was not clinically relevant for the overall sample. At an individual level, a significant proportion of patients achieved clinically relevant improvement, particularly in the Pilates group. The 31.4% improvement threshold serves as an additional indicator for evaluating the clinical relevance of treatments.
**Keywords:** Therapeutic back exercises, Pilates, chronic low back pain, Visual Analog Scale for Pain, Minimal Clinically Important Change.

**Resumen.** La finalidad principal fue comparar la efectividad de ejercicios terapéuticos para la espalda y Pilates en la reducción del dolor lumbar crónico y determinar el umbral de mejora y la diferencia en las puntuaciones pre y postratamiento que se considera clínicamente relevante para los pacientes. Metodología: Se incluyeron 53 pacientes con dolor lumbar crónico, quienes fueron asignados aleatoriamente a dos grupos: uno con 27 participantes que realizó Pilates y otro con 26 que siguió un programa de ejercicios para la espalda. El tratamiento consistió en sesiones dos veces por semana durante tres meses. La intensidad del dolor se evaluó antes y después del tratamiento mediante la Escala Visual Analógica del Dolor. Se definió un umbral clínicamente relevante como una reducción suficiente en la puntuación de dolor para que los pacientes se sintieran "muy satisfechos". Un análisis de la Receiver Operating Characteristic Curve se utilizó para determinar la sensibilidad y especificidad del umbral de mejora. Además, se aplicó un modelo de regresión lineal para analizar la relación entre la diferencia en las puntuaciones y el porcentaje de mejora. Resultados Tras los tratamientos, aunque ambos grupos mostraron mejoras significativas en la reducción del dolor, no hubo diferencias estadísticamente significativas entre ellos. Las reducciones promedio de ambos grupos no superaron los dos puntos (Grupo ejercicios de espalda=1.43 puntos, Grupo Pilates=1.82 puntos) , por lo que no alcanzaron los dos puntos de promedio de mejora que marca el umbral de mejora clínicamente relevante. Sin embargo, a nivel individual, el 45,83% de los pacientes del grupo de Pilates y el 37,5% del grupo de ejercicios de espalda lograron una mejora clínicamente relevante (porcentaje de mejora≥30%). El umbral de mejora del 31,4%, equivalente a una reducción de dos puntos, se correlacionó con una mayor satisfacción clínica (sensibilidad 84%, especificidad 87%). Conclusiones: Ambos tratamientos produjeron efectos beneficiosos en la reducción del dolor lumbar crónico. Sin embargo, la mejora promedio no fue clínicamente relevante en la muestra total. A nivel individual, una proporción importante de pacientes alcanzó una mejora clínicamente relevante, especialmente en el grupo de Pilates. El umbral de mejora del 31,4% constituye un indicador adicional para evaluar la relevancia clínica de los tratamientos.
**Palabras claves**: Ejercicios terapéuticos para la espalda, Pilates, dolor lumbar crónico, Escala Visual Analógica del Dolor, Cambio Mínimo Clínicamente Importante.

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## Introduction

Chronic low back pain (CLBP) is a prevalent and complex condition that has been the subject of extensive research and revisions in its definition and classification. The International Association for the Study of Pain (IASP) defines pain as “an unpleasant sensory and emotional experience associated with, or resembling that associated with, actual or potential tissue damage,” emphasizing that even in the absence of an objective injury, pain must be acknowledged and validated as a real experience. This conceptualization highlights that chronic pain is not merely a symptom but can be regarded as a disease in itself, encompassing both cognitive and emotional aspects in its understanding (Vidal, 2020). The

World Health Organization (WHO), in its guidelines for the non-surgical management of chronic primary low back pain in adults within primary and community care settings, defines chronic primary low back pain as persistent or recurrent pain lasting more than three months, not reliably attributable to an underlying disease process or structural injury. The WHO recommends that management of this type of pain, especially in older adults, should include educational interventions and structured exercise programs, with an emphasis on implementation in primary and community care settings (World Health Organization, 2023).

CLBP, alongside neck pain, hip and knee osteoarthritis, and fibromyalgia, ranks among the most prevalent forms of chronic musculoskeletal pain. Research suggests that in patients with low back pain, with or without radiculopathy, exercise may provide mild to moderate pain reduction, with its effectiveness potentially enhanced when combined with pharmacological or more invasive treatments (Flynn, 2020).

Non-pharmacological treatments, such as therapeutic exercise for the back, multidisciplinary rehabilitation, and back school programs, have proven effective and are strongly recommended by various clinical guidelines and systematic reviews for the management of CLBP. Current evidence supports the use of these interventions due to their ability to improve pain and functionality, with minimal risk of side effects, making them safe and effective options for CLBP patients. Multiple systematic reviews and clinical guidelines reinforce the value of non-pharmacological treatments, such as therapeutic exercise for the back, multidisciplinary rehabilitation, and back school programs, in the management of chronic low back pain. These interventions are recommended for their efficacy in pain reduction, safety, and ability to enhance physical function and quality of life (Ángel et al., 2015).

The American College of Physicians (ACP) suggests that patients with CLBP should initially opt for non-pharmacological treatments, such as therapeutic exercise, multidisciplinary rehabilitation, acupuncture, and mindfulness-based stress reduction techniques, based on moderate-quality evidence supporting their use (Qaseem et al., 2017; Alcántara & González, 2019). In particular, therapeutic exercise for the back and multidisciplinary rehabilitation are highly recommended for their proven efficacy in reducing pain and improving physical function in patients with CLBP (Chou et al., 2017). Additionally, therapies such as yoga, tai chi, and motor control exercises have also shown benefits, albeit with lower-quality evidence (Qaseem et al., 2017).

Systematic reviews, such as the one conducted by Skelly et al. (2020), report moderate improvements in short- and medium-term pain outcomes with interventions like massage, mindfulness-based stress reduction, acupuncture, and multidisciplinary rehabilitation. These therapies are recognized for their positive impact on pain management, especially in contexts where pharmacological treatments are undesirable or present significant risks. Moreover, Chou et al. (2007) recommend that for patients with chronic or subacute low back pain who do not improve with self-care options, non-pharmacological therapies such as intensive interdisciplinary rehabilitation, exercise therapy, acupuncture, massage, yoga, and cognitive-behavioural therapy should be considered. These interventions are not only effective but also associated with pain reduction and improvements in patients' quality of life.

International guidelines, such as the Dutch Physiotherapy Guidelines (Bekkering et al., 2003), support these interventions, emphasizing the importance of exercise and patient education in managing CLBP. These guidelines consistently recommend therapeutic exercise for the back, not only for its effectiveness but also for its safety and low risk of adverse effects. Similarly, the guidelines from the American Pain Society and the ACP (Chou et al., 2007), as well as those from the Institute of Health Economics in Canada (2017), agree that therapeutic exercise for the back, multidisciplinary rehabilitation, and other non-pharmacological therapies should be the first-line treatments for chronic low back pain, reserving pharmacological interventions only for cases where non-pharmacological therapies prove ineffective. This approach aligns with the guidelines developed by Osakidetza and the Department of Health of the Basque Government (Pérez-Irazusta et al., 2007), which also emphasize the importance of non-pharmacological treatment in the early management of persistent low back pain, promoting strategies such as therapeutic exercise for the back and back school programs to prevent pain progression and improve patient quality of life.

Current clinical guidelines highlight the importance of self-care, educational guidance, back school programs, and therapeutic back exercises, along with a multidisciplinary approach and psychological support. In contrast, pharmacological and surgical interventions are given less prominence (Zhou et al., 2024).

Although research has been conducted on the effects of exercise and back school programs in patients with chronic low back pain, the results tend to focus on identifying statistically significant differences without providing sufficient information on the actual clinical improvements experienced by patients. Significance testing, as commonly used today, originated from the combination of two methods that assess the level of incompatibility of the data with a hypothesis, as well as decision-making between two hypotheses. It is evident that, in epidemiology and other fields, these tests have been overused, with statistically significant differences or associations being mistakenly interpreted as clinically relevant. The correct conclusion from a statistically significant result is that a difference or association distinct from zero has been detected; this does not necessarily imply that it is large, relevant, or clinically important, only that it is not equal to zero (Barrera, 2008).

This issue is particularly evident in the field of healthcare treatments, such as therapeutic exercises for the back and the Pilates method, where studies tend to use the p-value as

the primary criterion for assessing the efficacy of interventions. This practice can lead to confusion between statistical significance and clinical relevance, resulting in the erroneous interpretation that a statistically significant result is automatically clinically meaningful. However, it is crucial to distinguish between these concepts, as a result can be statistically significant but lack real clinical importance. Therefore, in addition to determining whether the observed differences are due to chance, it is essential to evaluate how many participants experience notable clinical improvements and what constitutes an acceptable magnitude of change between pre- and post-treatment scores in clinical practice (Barrera, 2008; Iraurgi, 2009; Iraurgi, 2010).

According to the NIH Task Force on Research Standards for Chronic Low Back Pain, developed by the National Institutes of Health (Deyo et al., 2015), in addition to reporting measures such as pain or function, along with mean scores and their variations, it is essential to provide information on the proportion of participants who achieve clinically significant thresholds. Researchers should include data on the percentage of participants who achieve a previously established minimum clinically important change as part of a treatment response analysis. Some experts have suggested that a 30% improvement in pain or function may be considered clinically significant, recommending that the proportion of participants reaching this level of improvement be reported. It is also possible to specify a particular number of points as the relevant change or the percentage of participants who reduce their pain below a threshold considered clinically relevant. Another useful strategy proposed by this expert group is to create graphs that show the proportion of patients at each percentage of improvement or scale score, highlighting those who experience clinically significant change. This involves calculating the percentage of patients who respond to each value on the outcome scale.

In the clinical hospital setting, this research aims to provide results that are valid and applicable, following the guidelines established by the NIH Task Force, as well as the recommendations of Barrera (2008) and Iraurgi (2009 and 2010). The primary purpose of this study is to evaluate the effectiveness of two treatment approaches (therapeutic back exercises and Pilates exercises) in reducing subjective pain intensity in patients with chronic low back pain in a real clinical setting. The trial will determine the threshold of improvement and the difference in pre- and post-treatment scores that is considered clinically relevant for the patient sample involved, in addition to assessing whether the differences between treatments are both statistically significant and clinically meaningful.

Among the specific objectives of the study is to offer a detailed presentation of the results, highlighting the number of patients who experience various levels of improvement and the percentage of those who achieve clinically significant improvements. Another goal is to identify meaningful differences between pre- and post-treatment scores that are useful for healthcare professionals. This aims to ensure the effectiveness of the evaluated treatments and support clinical decision-making to improve the quality of healthcare.

## Methodology

### *Study Design*

A randomized, controlled, and comparative clinical trial was conducted to evaluate the efficacy of two rehabilitation modalities in patients with chronic low back pain. The study compared the effects of therapeutic back exercises with Pilates exercises. Randomization was performed using statistical software, ensuring equitable and random assignment of participants to the treatment groups.

### *Participants and Sample Size*

The sample size calculation was performed using the JAMOVI 2.3 software. This calculation was based on an analysis comparing independent samples, considering an expected effect size between 0.373 and 0.618 (d), a statistical power of 80%, and a maximum alpha error rate of 0.1. The resulting sample size was 24 patients. Accounting for a 10% dropout rate, the final sample size was set at a minimum of 26 patients per treatment group.

Participant selection was carried out among patients on the waiting list for rehabilitation treatments at Hospital Universitario del Henares. Of the 102 patients on the list, 53 individuals with chronic low back pain met the inclusion criteria and provided consent to participate in the study.

To randomly assign participants to treatment groups, the IBM SPSS Statistics v20 program was used. Two groups were formed: Group A for the Pilates intervention, consisting of 27 patients, and Group B for back exercises, with 26 patients. Assignment was conducted by administrative staff not involved in the interventions, ensuring anonymity and impartiality. Of the 53 initially selected patients, five did not complete treatment (three from Group A and two from Group B) and were offered alternative physiotherapy rehabilitation treatments.

Eligible participants were adults over 18 years old with a diagnosis of chronic low back pain who had not previously received physiotherapy treatments. Exclusion criteria included individuals under 18, those with a history of low back pain lasting less than three months, individuals who had undergone lumbar surgery, and those with medical conditions that could interfere with exercise, such as infectious diseases, severe metabolic problems, significant obesity, or conditions affecting the ability to follow the intervention protocol.

The sample had a mean age of 58.75 years, with males averaging 56.86 years and females 59.07 years. The majority of participants were women, constituting 85.41% of the sample. The mean body mass index (BMI) was 25.11, with similar values between men (25.54) and women (25.03), indicating a prevalence of overweight in the study population (see Table 1).

Table 1.
Patient Characteristics

| Characteristic | n | X (Mean) | Standard Deviation (SD) |
|---|---|---|---|
| Age | 48 | 58.75 | 10.49 |
| - Male | 7 | 56.86 | 15.35 |
| - Female | 41 | 59.07 | 9.66 |
| Body Mass Index(BMI) | 48 | 25.11 | 3.06 |
| - Male | 7 | 25.54 | 2.48 |
| - Female | 41 | 25.03 | 3.17 |
| VAS pretreatment | 48 | 6.57 | 1.55 |
| - Male | 7 | 6.86 | 1.35 |
| - Female | 41 | 6.52 | 1.60 |
| VAS postreatment | 48 | 4.94 | 1.66 |
| - Male | 7 | 5.29 | 1.87 |
| - Female | 41 | 4.88 | 1.65 |

Note: X represents Mean, SD represents Standard Deviation.

***Intervention Procedures***

Both the Pilates Method exercise program and the therapeutic back exercise program were conducted over a 12-week period, with 60-minute sessions held three times a week. Each program was designed to address specific goals related to back health, such as enhancing stability, flexibility, and muscle strength. The sessions were led by a team of six physiotherapists from the Physiotherapy and Occupational Therapy Unit, ensuring consistency in intervention delivery. Each session involved groups of eight to nine patients, supervised by two physiotherapists: one provided personalized attention, while the other coordinated group exercises.

Pilates Method Exercise Program: The Pilates Method exercise program aimed to enhance pelvic stability and strengthen the abdominal muscles through a variety of targeted exercises. Each session was divided into several phases to ensure a comprehensive workout:

Warm-Up (4 minutes): Gentle mobility and breathing exercises to prepare the body.

Pause: 1 minute

Leg Circles (4 minutes): Making circles with one extended leg while lying supine.

Pause: 1 minute

Chest Lift (4 minutes): Lifting the head and torso with the hands crossed behind the head.

Pause: 1 minute

Hundred (4 minutes): Raising the head and hands while keeping the legs at a 45-degree angle to the floor.

Pause: 1 minute

Side Kick (4 minutes): Lateral lifting of the top leg while resting the head on the arm.

Pause: 1 minute

Quadruped (4 minutes): Performed on hands and knees, maintaining a neutral spine and pelvis.

Pause: 1 minute

Hip Flexion and Extension (4 minutes): Movements performed in the supine position to strengthen the hips.

Pause: 1 minute

Single Leg Stretch (4 minutes): Stretching one leg while contracting the abdomen, alternating legs.

Pause: 1 minute

Double Leg Stretch (4 minutes): Bringing the knees towards the chest while lying supine.

Pause: 1 minute

Swimming (4 minutes): A movement simulating swimming to strengthen and stretch the back.

Pause: 1 minute

Criss-Cross (4 minutes): An advanced exercise that involves trunk rotation to enhance flexibility.

Pause: 1 minute

Cool-Down and Final Stretch (4 minutes): Gentle exercises to relax the muscles and improve flexibility.

Pause: 1 minute

Therapeutic Back Exercise Program: The therapeutic back exercise program focused on enhancing lumbar stability and strengthening the core through a series of exercises. This program aimed to improve back strength, flexibility, and overall spinal health:

Warm-Up (4 minutes): Gentle aerobic exercises.

Pause: 1 minute

Muscle Strengthening (12 minutes): Includes lumbar bridges, lower abdominals, trunk extension in the prone position, and knee flexion in the supine position.

Pause: 3 minutes (1 minute after each 4-minute segment)

Stretching (8 minutes): Includes lumbosacral, hamstring, and psoas stretches.

Pause: 2 minutes (1 minute after each 4-minute segment)

Balance Exercises (4 minutes): Includes single-leg balance while lying down.

Pause: 1 minute

Spine Mobility and Flexibility (8 minutes): Involves spine rotations, flexion, extension, and the "cat" exercise.

Pause: 2 minutes (1 minute after each 4-minute segment)

Neuromuscular Exercise and Motor Control (8 minutes): Includes motor control exercises, upper abdominals, and crossed upper abdominals.

Pause: 2 minutes (1 minute after each 4-minute segment)

Cool-Down and Final Stretch (4 minutes): Gentle exercises to relax the muscles and improve flexibility.

Pause: 1 minute

At the end of the treatment period, patients in both groups were provided with information on spine anatomy and biomechanics, as well as the importance of maintaining proper posture and adopting ergonomic habits in daily life. Physiotherapists also instructed patients on prevention techniques and self-management of pain, with the goal of helping them integrate these exercises and healthy habits into their daily routine to prevent relapses.

***Measurement and Analysis***

Pain Measurement: Pain intensity was measured using the Visual Analog Scale (VAS) before and after the intervention, where patients indicated their pain level on a scale from 0 to 10.

Statistical Analysis: Data normality was assessed using the Shapiro-Wilk and Kolmogorov-Smirnov tests, and homogeneity of variances was verified with Levene's test. Independent samples t-tests were used to compare average scores between the two groups, and paired t-tests were employed to analyze within-group changes. Effect sizes were calculated using Cohen's d.

Determination of Clinically Important Change Threshold (MCIC): Following the criteria of Ostelo and de Vet (2005) for clinically important outcomes in low back pain, a Clinically Important Change (MCIC) in the VAS pain score was defined as the mean difference between pre- and post-treatment scores, where the patient reported pain improvement as "very satisfied."

A subjective improvement assessment was also performed by asking patients if they were "very satisfied" with the reduction in pain after treatment. This analysis identified the score and percentage of improvement considered clinically relevant by the patients. The question posed was, "Are you very satisfied with the reduction in low back pain intensity experienced as a result of the treatment received?" Participants answered by selecting either 'yes' or 'no.'

Linear Regression: A linear regression equation was developed to examine the relationship between the difference in VAS scores and the percentage of improvement between pre- and post-treatment measurements.

Receiver Operating Characteristic Curve (ROC) Analysis: A ROC curve analysis was performed to evaluate the effectiveness of the percentage of improvement in distinguishing between patients with and without clinically relevant improvement. Sensitivity, specificity, and the area under the curve (AUC) were calculated to assess the predictive accuracy of the model.

Evaluation of Treatment Effects: The percentage of patients in each group who achieved 18% and 30% improvements in VAS scores was analysed, comparing the effectiveness of both treatments based on these thresholds.

This methodological approach allowed for a rigorous and detailed evaluation of treatment efficacy, providing a solid foundation for interpreting the results and determining the clinical relevance of the interventions.

### *Ethical Approval*

The study adhered to fundamental ethical principles for human research, as outlined in the Declaration of Helsinki. Compliance with current data protection regulations was ensured, in line with Organic Law 3/2018 and Regulation (EU) 2016/679. The research was approved by the Ethics Committee of Hospital Universitario del Henares and was conducted under the supervision of the hospital's Physiotherapy and Occupational Therapy Unit. Ethical approval was obtained to ensure respect for participants' rights and the integrity of the study.

## Results

### *Comparison of the efficacy of back exercises and Pilates in treating back pain*

This study compared the effectiveness of therapeutic back exercises and Pilates exercises in patients with low back pain, using the Visual Analog Scale (VAS) as an outcome measure. A total of 24 patients were included in each group, assessing pain intensity before and after the interventions.

Before treatment, the average VAS score was 6.58 (SD = 1.24) in the back exercise group and 6.55 (SD = 1.84) in the Pilates group, indicating similar baseline pain levels with no statistically significant differences (p = 0.949). Post-treatment, the back exercise group showed a reduction in the average VAS score to 5.15 (SD = 1.76), while the Pilates group experienced a decrease to 4.73 (SD = 1.57). Although both groups exhibited a reduction in pain intensity, there were no statistically significant differences between them in the post-treatment evaluation (p = 0.382) (Table 2).

Intragroup analysis showed a significant decrease in VAS scores in both the back exercise and Pilates groups, with average reductions of 1.43 points (p = 0.001, Cohen's d = 0.99) and 1.82 points (p = 0.001, Cohen's d = 1.32), respectively. These results suggest substantial improvement in pain perception in both groups, with a moderate effect size in the back exercise group and a large effect size in the Pilates group (Table 2).

These findings indicated that both back exercises and Pilates resulted in significant reductions in low back pain, with a slight superiority in the magnitude of improvement in the Pilates group. However, no statistically significant differences were found between the two treatments, suggesting that both are equally viable as therapeutic interventions for managing low back pain in the studied population.

Table 2
Comparison of paired and independent samples

| | | Back exercises (n=24) | | Pilates (n=24) | | |
|---|---|---|---|---|---|---|
| | N | X | SD | X | SD | p-value* |
| VAS before treatment | 24 | 6.58 | 1.24 | 6.55 | 1.84 | 0.949 |
| VAS after treatment | 24 | 5.15 | 1.76 | 4.73 | 1.57 | 0.382 |
| | Average difference | 1.43 | | 1.82 | | |
| | † p value (within group intragroup) | 0.001 | | 0.001 | | |
| | Cohen's d | 0.99 | | 1.32 | | |

X: Mean / SD: Standard Deviation
† p-value obtained using Student's t-test for paired samples
* Student's t-test for independent samples
p-values ≤0.05 are considered significant (highlighted in bold)
Cohen's d: <0.2 = trivial; 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)

***Subjective perception of improvement and determination of clinically relevant improvement threshold***

Based on data analysis in Table 3, a value for the minimum clinically important change (MCIC) was established, representing the smallest change in pain measurement, as assessed by the VAS, that patients considered significant. This analysis used the subjective perception of patients regarding the relevance of their post-treatment improvement.

Table 3.
Average difference in points and percentage of improvement corresponding to all patients in the sample (n=48) who indicate that they obtain or do not obtain "much better" improvement.

| | | | | | | | | Percentiles | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | RIIP | n patients | X | Median | SD | Min. | Max. | 20th | 50th | 90th |
| VAS pre post treatment difference | RIIP – | 23 | 0.60 | 1.00 | 1.20 | -1.50 | 2.00 | -0.80 | 1.00 | 1.96 |
| | RIIP+ | 25 | 2.58 | 2.50 | 0.78 | 1.50 | 4.50 | 2.00 | 2.50 | 3.42 |
| VAS % improvement | RIIP - | 23 | 5.03 | 15.38 | 20.63 | -60.00 | 25.00 | -13.02 | 15.38 | 25.00 |
| | RIIP+ | 25 | 40.34 | 38.46 | 10.00 | 26.67 | 61.54 | 31.34 | 38.46 | 53.13 |

X: Mean / SD: Standard Deviation / Min: Minimum / Max: Maximum /RIIP: Relevant Improvement Indicated by the Patient / RIIP-: patients perceive much better improvement / RIIP+: patients do not perceive much better improvement

The results demonstrated a clear distinction in patients' subjective perception of improvement. Among those who reported clinically relevant improvement (RIIP+), 25 patients (53.09%) showed an average pre-to-post-treatment VAS score difference of 2.58 points (50th percentile = 2.50), with differences of 2.00 points at the 20th percentile and 3.42 points at the 90th percentile. In contrast, patients who did not perceive the improvement as relevant (RIIP-), totalling 23 (47.91%), showed an average VAS score difference of 0.60 points (50th percentile = 1.00), with a 20th percentile difference of -0.80 points and a 90th percentile difference of 1.96 points (Table 3, Figure 1).

These data indicated that a two-point difference in the post-treatment VAS score was associated with a clinically significant improvement. Specifically, 80% of patients who experienced relevant improvement (RIIP+) had a VAS difference of two points or more, while 90% of those who did not perceive a relevant improvement (RIIP-) had a difference of less than two points.

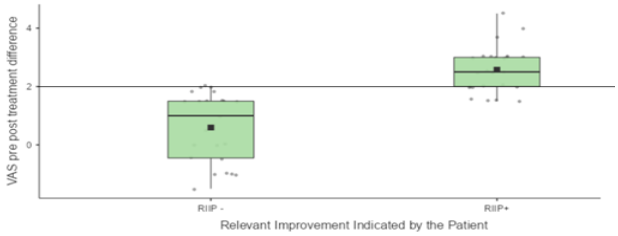


Figure 1. Comparative graph of average improvement points corresponding to all patients in the sample (n=48) who indicate that they obtain or do not obtain "much better" improvement

In terms of percentages, a 31.4% improvement threshold was considered significant, effectively distinguishing between patients who perceived clinically relevant improvement and those who did not (Figure 2).

Based on these results, for a sample with characteristics similar to this study, a two-point difference in the VAS can be considered a reference value for MCIC, as it effectively differentiates patients experiencing clinically relevant improvements from those who are not. Additionally, a 31.4% improvement percentage could be used as an additional indicator to assess the clinical relevance of treatments.

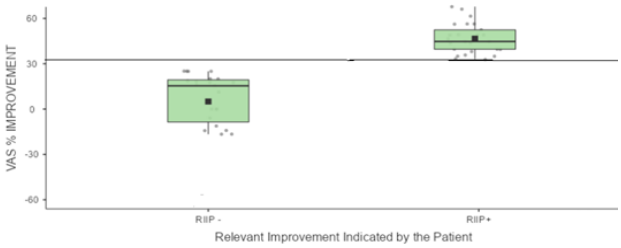


Figure 2. Comparative graph of average percentage of improvement corresponding to all patients in the sample (n=48) who indicate that they obtain or do not obtain "much better" improvement

***Results from the linear regression equation***

Considering the variables "percentage of improvement between pre- and post-treatment" and "difference in score between post- and pre-treatment," a linear regression equation was developed to model the relationship between variables X and Y, yielding the equation Y = 15.98X - 2.5826. Thus, when X corresponds to a two-point improvement, Y resulted in a value of 29.38%, representing the threshold for indicating a "much better" individual outcome three months after treatment. Post-treatment improvements of at least 29.38% relative to baseline values were associated with a clinically relevant change, considered "much better" (Figure 3).

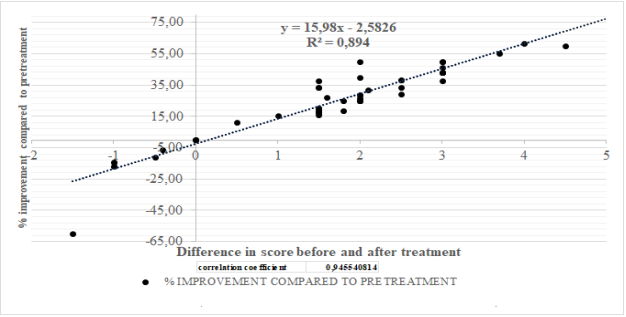


Figure 3. Linear regression graph of the variables "% improvement between pre- and post-treatment" and score difference between post- and pre-treatment, and the ROC curve

Research such as that carried out by Gallagher et al. (2001), Kelly (2001) and Sadovsky (2002) estimated that improvements of approximately 13 mm (1.3 points on a 0-

10 scale) on the Visual Analog Pain Scale reported a change of "slightly less pain." Although it is not a clinical improvement considered important, it is considered a possible threshold for the beginning of improvement. In this study, the threshold of onset of improvement, according to the linear regression equation, is estimated at 18%, which represents the threshold to indicate an individual result of "a little better" at three months after treatment

***Validation of clinically relevant threshold through subjective perception analysis and linear regression***

The results from the subjective perception analysis identified a clinically relevant threshold based on the VAS, where a two-point difference was considered significant by patients. This threshold corresponded to a 31.4% improvement, effectively separating patients who experienced relevant improvement from those who did not. These findings emphasize the importance of MCIC as a key value in interpreting the clinical relevance of treatments.

On the other hand, results derived from the linear regression equation, which modeled the relationship between "difference in score between post- and pre-treatment" and "percentage of improvement between pre- and post-treatment," showed that a two-point VAS improvement was associated with a 29.38% improvement. This percentage closely aligns with the previously identified 31.40% improvement threshold, reinforcing the validity of both approaches in determining the clinical relevance of post-treatment improvements.

The consistency between these approaches suggests that the 29.38% threshold identified through linear regression is not only coherent with the results obtained through subjective perception analysis but also confirms the robustness of the two-point VAS change as a solid reference for determining a clinically relevant change. Thus, the findings from the linear regression equation provide additional support for using these threshold values in clinical practice, consolidating their utility as indicators to assess treatment effectiveness based on patients' perceived improvement.

***Curve Analysis Results (ROC)***

The ROC curve analysis, performed to evaluate the percentage of clinical improvement, yielded significant results in terms of specificity, sensitivity, and AUC. The model's specificity was 0.87, indicating that it correctly identified 87% of patients who did not experience clinically relevant improvement. This level of specificity was crucial for minimizing false positives and ensuring that only patients requiring further intervention were detected (Figure 4).

The model's sensitivity reached 0.84, reflecting its ability to accurately detect 84% of patients who experienced clinically significant improvement. This sensitivity was essential to reduce false negatives and ensure that patients with notable improvements were properly identified and treated.

The area under the curve (AUC) was 0.94, highlighting the model's high discriminative capacity. An AUC close to 1 indicated excellent precision in distinguishing between patients with and without clinically relevant improvement.

The results of analysis of the subjective perception of improvement, linear regression equation and ROC method revealed that a minimum reduction of the initial VAS score (before treatment) by 31.4% (equal to an average reduction of 2 points in this group of patients) represented the threshold for indicating a "very satisfied" individual outcome at 3 months (MCIC). after treatment (sensitivity 84% and specificity 87%).

The results from the subjective perception analysis, linear regression equation, and ROC method revealed that a minimum reduction of 31.4% in the initial VAS score (equivalent to an average reduction of two points in this patient group) represented the threshold for indicating an individual result of "very satisfied" three months post-treatment (MCIC). These findings indicated that the model was robust and reliable for predicting clinical improvements, achieving a balanced sensitivity and specificity. The model's high discriminative capacity, reflected in the high AUC value, underscored its usefulness in clinical contexts where precision in identifying significant improvements is critical for therapeutic decision-making.

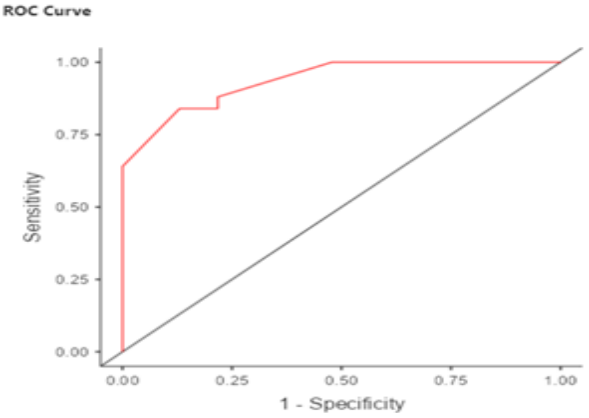


Figure 4. ROC curve of the model

***Results of the effects of treatments, therapeutic back exercises and Pilates, in the clinical improvement of pain in patients***

In the present study, the effects of two treatments, therapeutic back exercises and Pilates, were analysed in improving pain in patients, distributed in two independent groups of 24 people each. The results focused on two improvement thresholds: an improvement equal to or greater than 18% (threshold for the start of improvement) and an improvement equal to or greater than 30%, the latter considered clinically relevant according to the study criteria.

In the group that performed back exercises, it was observed that 17 of the 24 patients (70.83%) achieved an improvement equal to or greater than 18%, while in the Pilates group, 16 of the 24 patients (66.67%) achieved this level of improvement. Adding both groups, 33 of the 48 patients (68.75%) achieved at least 18% improvement in their pain.

It was also recorded that 29.16% of patients in the back exercise group and 33.34% in the Pilates group did not achieve an 18% improvement, representing a total of 31.25% of patients in both groups combined (Table 4).

Regarding clinically relevant improvement, defined as an improvement equal to or greater than 30%, it was documented that 9 of the 24 patients (37.50%) in the back exercise group and 11 of the 24 patients (45.83%) in the Pilates group reached this threshold. Overall, 20 of the 48 patients (41.67%) achieved clinically relevant improvement (Table 4, Figure 5).

Table 4.
Number and percentage of patients by improvement percentage ranges

| | Back exercises (n=24) | | Pilates (n=24) | | Both treatments (Back exercises and Pilates n=48) | |
|---|---|---|---|---|---|---|
| Pain Improvement Range | number of patients | % of Total | number of patients | % of Total | number of patients | % of Total |
| Less than 18% improvement | 7 | 29.16% | 8 | 33.34%% | 15 | 31.25% |
| 18% to less than 30% improvement | 8 | 33.34% | 5 | 20.83% | 13 | 27.08% |
| 30% or greater improvement | 9 | 37.50% | 11 | 45.83% | 20 | 41.67% |

These results indicated that the majority of patients treated with back exercises or Pilates experienced a significant initial improvement in pain reduction, with 68.75% of patients achieving an improvement equal to or greater than 18% and 41.67% achieving a clinically relevant improvement. It was observed that Pilates provided slightly greater improvements at the clinically relevant threshold: 45.83% of patients in the Pilates group achieved a clinically relevant improvement (equal to or greater than 30%), surpassing 37.5% in the back exercise group. Additionally, approximately one-third of patients in each group failed to achieve an 18% improvement. These findings underline the overall effectiveness of both treatments in reducing pain, with Pilates showing slight superiority in achieving clinically relevant improvements and the need to complement the treatments with other physical therapies and multidisciplinary rehabilitation.

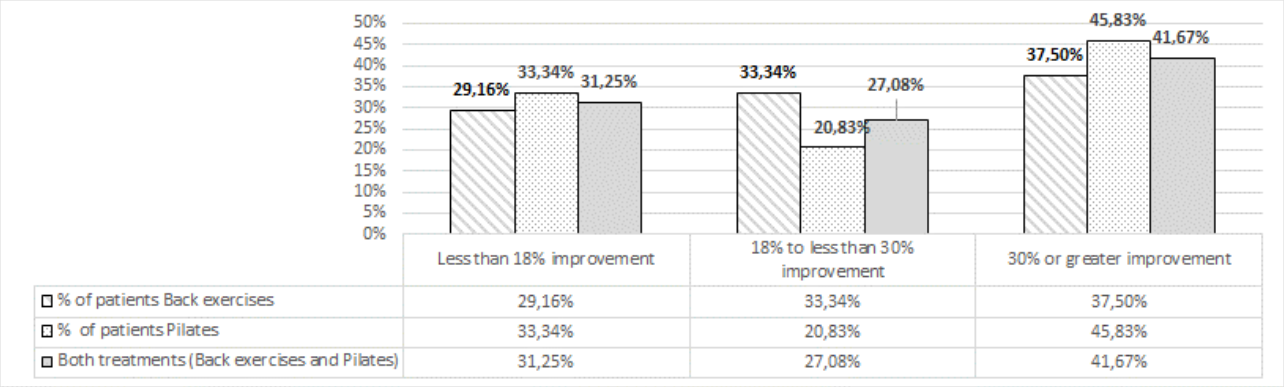


Figure 5. Graph of the percentage of patients by percentage improvement sections

## Discussion

The results from the therapeutic back exercise group in this study show a significant improvement of 1.43 points on the Visual Analog Scale (VAS) for pain ($p<0.001$) after a three-month back exercise program with two weekly sessions. These findings are consistent with previous studies, although there are differences in the magnitude of improvement and the methodology applied. Previous studies, such as those by Morone et al. (2011) and Donzelli, reported greater reductions, approximately two points on the VAS, with similar Back School programs. Additionally, Sadeghi-Abdollahi et al. (2012) observed an improvement of 2.75 points, while Shirado et al. (2005) reported a reduction of 3.5 points, suggesting that factors such as participant age and intervention frequency may influence the results. Other studies, such as Durmus et al. (2014) and Çakmak Başer et al. (2020), also showed significant improvements in low back pain, highlighting that higher session frequency and the use of additional modalities, such as electrotherapy, could explain the differences in the magnitude of improvement compared to the present study.

Regarding the Pilates group, pain improvement, as measured by the Visual Analog Scale (VAS), was 1.82 points, reflecting a moderate reduction in pain. Comparing these results with other studies, both similarities and differences were observed. Similar results were reported in the studies by Yang et al. (2021) and Miyamoto et al. (2013), while slightly greater improvements were observed in the studies by da Silva et al. (2018), da Luz et al. (2014), and Cruz-Díaz et al. (2017). On the other hand, research by Yıldırım et al. (2022), Stieglitz et al. (2016), Batibay et al. (2021), and Baskan et al. (2021) showed a greater reduction in pain. The variability in the results may be explained by factors such as the older age of the participants and the lower session frequency.

One of the main factors that could influence the differences observed is the age of the participants. In this study,

the mean age of the experimental group was 58.75 years, considerably older than in other studies. Most studies included younger participants, such as those by Yıldırım et al. (2022) and Stieglitz et al. (2016), with mean ages around 30 years, or Batibay et al. (2021), with a mean of approximately 50 years. This suggests that younger participants may have responded better to the Pilates intervention, resulting in a greater reduction in pain, possibly due to better physical capacity or less age-related wear and tear.

Another important factor is the duration of the treatment. In this study, treatment was administered with two sessions per week, similar to what was observed in the studies by Yıldırım et al. (2022) and Cruz-Díaz et al. (2017). However, studies that showed greater improvements in pain, such as those by Batibay et al. (2021) and Baskan et al. (2021), applied three sessions per week, suggesting that a higher frequency and intensity of treatment could be key to achieving better results in pain reduction.

The results of our study show that a 31.4% reduction in the initial Visual Analog Scale (VAS) score, equivalent to an average decrease of 2 points (or 20 mm on a 0-100 scale), is sufficient for patients to consider themselves "very satisfied" after three months of treatment. These findings align with and complement previous studies on the minimum clinically important change (MCIC), though they present some variations in thresholds and approaches.

Gallagher et al. (2001) identified an MCIC of 13 mm when patients reported a mild improvement in emergency services. This value is lower than the 20 mm found in our study, which could be due to Gallagher et al.'s focus on a more moderate improvement ("a little less pain"), while our assessment was based on a stricter criterion of significant satisfaction ("very satisfied"). This difference is also relevant when compared with Ostelo et al. (2005), who determined an MCIC of 20 mm in patients with subacute or chronic low back pain, coinciding with our results, highlighting that this change should reflect a noticeable improvement, not just a slight one. Similarly, it is comparable to the estimate in the Lumbar Pathology Protocol of the Castilla y León Health Department, which states that the minimum important change is 15 mm on a 100 mm scale and 2 points on a 0-10 scale on the VAS pain scale.

Kovacs et al. (2007) found that the MCIC varied between 1.5 and 4.3 points in subacute and chronic patients, depending on the initial pain score. These values are consistent with those observed in our study, identifying a significant clinical improvement around 2 points on the 0-10 scale. Similarly, van der Roer et al. (2006) reported MCIC values between 2.5 and 4.5 points in chronic patients, suggesting that the more severe the pain, the greater the change needed for patients to perceive a clinically significant improvement. This also reinforces the findings of Hägg et al. (2003), who observed a reduction of 18-19 mm in post-treatment back pain, results that approximate ours and highlight the consistency in research evaluating chronic pain.

The international consensus proposed by Ostelo et al. (2008) suggested that a 30% change from the initial pain value could be considered clinically relevant, which is notably similar to the 31.4% threshold found in our study. However, Ostelo et al. (2008) proposed an MCIC of 15 mm on the VAS, slightly lower than the 20 mm reported by us and other studies such as Hägg et al. (2003). This difference may be attributed to variations in methodology and clinical contexts between studies.

Considering previous studies on the MCIC in patients with chronic low back pain, our results align with the existing literature by identifying a reduction of 20 mm or 2 points on the VAS as a significant change for patients with pain, especially when patient satisfaction is the reference criterion. The specific differences observed between studies reflect the different populations and clinical contexts, but overall, there is consensus that a change of around 30% from the initial pain value is clinically relevant for most patients.

In the present study, the results indicate that most patients treated with back exercises or Pilates experience significant pain reduction, with 66.67% of patients achieving an improvement equal to or greater than 18%. Comparatively, Shirado et al. (2005) reported that 80.8% of patients improved, 15.4% showed no changes, and 3.8% experienced a worsening. Both studies demonstrate a high improvement rate, though with slight differences in the proportion of patients who do not improve or worsen. However, in the present study, it was observed that 29.16% of patients in the back exercise group and 33.34% in the Pilates group did not achieve an 18% improvement, representing a total of 31.25% of patients across both groups combined. This finding aligns with guidelines that suggest the need for implementing complementary physiotherapeutic treatments and multidisciplinary rehabilitation for those patients who do not achieve the expected improvements in their rehabilitation process.

In the intergroup comparison between Pilates and therapeutic back exercises in this study, no significant differences were found between the treatments ($p=0.382$). This result is consistent with the findings of Donzelli et al. (2006), who evaluated patients with nonspecific low back pain participating in Pilates or Back School programs. Their research showed that the Pilates method is equally effective as the Back School program, suggesting that Pilates represents a viable alternative for the treatment of low back pain.

The results of this study are consistent with the findings of the report titled "Efficacy and effectiveness of Pilates methods in selected clinical conditions. Technical report. AQuAS.", developed under the Health Protection Plan against Pseudo therapies, promoted by the Ministry of Health and the Ministry of Science and Innovation of Spain. This report concluded that "there is no evidence that the Pilates method is superior to other techniques or methods aimed at improving spinal pathologies" (Agència de Qualitat i Avaluació Sanitàries de Catalunya, 2022, p. 18). In our research, the average pain intensity improvement for the total sample ($n=24$) was less than 2 points (Pilates Group

= 1.82 points), which also aligns with the conclusion of the report that "the differences cannot be considered clinically relevant" (Agència de Qualitat i Avaluació Sanitàries de Catalunya, 2022, p. 19). However, it is important to highlight that, when analyzing the individual improvement of patients, it was observed that in the Pilates group, 45.83% achieved clinically relevant improvement, as did 41.67% of the back school group, representing significant proportions of clinical improvement in terms of the benefits provided by the treatments.

This study presents several limitations. The variation in the average age of the participants and the differences in treatment frequency could explain the discrepancies observed compared to other studies. In this study, the average age of the participants was 58.75 years, higher than the average age reported in similar research. Additionally, the Hospital Universitario del Henares faced limitations due to the need for the Rehabilitation and Physiotherapy service to maintain care for other patients with different pathologies, without compromising the quality and safety of services or affecting the usual healthcare provided in the hospital, which restricted the availability of resources and time for the study. The lack of personnel prevented increasing the number of weekly sessions and conducting additional physical condition tests and clinical functionality evaluations. The sample size was also affected by space and infrastructure restrictions, and it was decided to conduct the treatments in small groups to avoid inappropriate practices and potential injuries under the supervision of the physiotherapist. Nonetheless, a significant strength of the study was its conduct in a hospital rehabilitation setting, which allowed for results to be obtained in a real clinical context, providing a more accurate view of the applicability and potential benefits of the treatments investigated.

## Conclusions

Both treatments, therapeutic back exercises and the Pilates method, were shown to be effective in reducing chronic low back pain, with significant improvements in pain scores after three months of intervention.

No statistically significant differences were found between the groups, suggesting that both approaches are equally valid for managing chronic low back pain in general terms.

Data analysis revealed that, on an individual level, a larger proportion of patients in the Pilates group (45.83%) achieved clinically relevant improvement compared to the back exercise group (37.5%).

A total of 29.16% of patients in the back exercise group and 33.34% in the Pilates group did not achieve an 18% improvement, representing 31.25% of patients across both groups combined. This finding is in line with guidelines that suggest the need to implement complementary physiotherapeutic treatments and multidisciplinary rehabilitation for those patients who do not achieve the expected improvements in their rehabilitation process.

The analysis of the clinically relevant improvement threshold established that a reduction of 31.4%, equivalent to a decrease of 2 points on the Visual Analog Scale for pain, is correlated with greater clinical satisfaction among patients. This threshold could serve as a useful reference for evaluating clinical relevance in future studies and in clinical practice. This finding underscores the importance of defining clinical thresholds not only based on statistically significant improvements but also considering patients' perception of treatment effectiveness.

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