Therapeutic Effect of Two Muscle Strengthening Programs in Patients with Patellofemoral Pain Syndrome from Bogota, Colombia. Experimental Study, Clinical Controlled Trial.

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PROCESSING AND DATA ANALYSIS.

For the classification and verification of the information, the database was refined by recoding and labeling the variables necessary for the analysis, in addition, the variables that required it were converted to alphanumeric format and the review of extreme non-plausible data was performed. For the continuous variables in which two attempts were made as balance and plate a new variable was generated with the average of the measurements and in this way obtain the final result for the analyzes.

Univariate Analysis

The report of absolute and relative frequencies was made; the qualitative variables were presented in proportions and 95% confidence intervals. The normality of the continuous variables was evaluated by scatter plots (histograms, Kernel density and Q-Norm) and the numerical test of Shapiro-Wilk, and according to their distribution they were reported as means and standard deviations, when they had a distribution normal, or on the contrary, as medians and interquartile ranges.

Bivariate Analysis

In the bivariate analysis, a comparison of each of the Kujala test domains was initially performed to assess pain in the baseline, assessing the differences between the intervention groups using the chi-square or Fisher's exact tests. Additionally, the Spearman correlation coefficient was used to evaluate the relationship between two continuous variables, such as the Q angle and the anterior knee pain, evaluating the correlation in a marginal and conditioned way to each of the treatment groups.

Later, to evaluate if there were differences between the groups of treatment after the intervention on the variables of interest, deltas were generated from the Kujala test, EVA, number of squats, Q angle, balance, physical activity and core strength. with iron and trunk extension, evaluating normality by means of graphic and numerical methods. For the analysis of the differences of medians between the groups, taking into account that the outcomes did not present a normal distribution, and assuming the assumption of independence of the variables, we proceeded to use the non-parametric Mann-Whitney U test. Finally, through the Wilcoxon test, intragroup differences were evaluated for strength, pain and physical activity components.

The hypothesis tests were presented in two tails with an alpha of 0.05 and all the analyzes were executed with the statistical program STATA version 14.0.

BASELINE:

Study population

Table 5 describes the general characteristics of the study population at baseline. There were no significant differences between the two intervention groups (A and B), which means that the randomization was adequate; however, in the total score of the Kujala test there was a difference of 12.5 points between the groups, with a lower score for group B (53.0), which indicates better core strength for these patients. Finally, the sex variable was defined as categorical and the rest of the variables as continuous, for which the medians and their respective interquartile range (IR) are reported, taking into account that the variables did not have a normal distribution.

Table 5: Baseline variables of the study population

Variables	Treatment A (n 20) Medium (RI)	Treatment B (n 20) Medium (RI)	Value p [a]
Sex * (Male, Ref)			
Female	90 (65.7-97.6) *	90.0 (65.7-97.6) *	1,000 [b]
Age	32.5 (25.5-38.0)	29.0 (25.0-36.5)	0,569
Initial weight (Kg)	64.6 (55.3-72.4)	62.7 (52.9-68.5)	0.379
Size (cm)	160 (156.5-167.0)	159.5 (154.0-163.0)	0.423
IMC	25.4 (21.5-27.9)	23.8 (22.3-25.2)	0.456
% of fat	35.4 (28.9-40.4)	35.4 (24.5-38.7)	0,714
% muscle	26.9 (24.5-28.9)	26.2 (24.6-29.0)	0.849
Visceral fat	6 (3.5-7.09)	5 (4.0-6.0)	0.433
IPAQ (minutes)	3003 (1116-4638)	1617 (944-6138)	0,588
Pain	7.5 (5.5-9.0)	7.0 (5.5-8.5)	0.764
Kujala total score	65.5 (42.5-72.5)	53.0 (44.5-71.5)	0,892
Q angle			
Straight	19.0 (15.0-20.0)	18.0 (15.0-20.0)	0,557
Left	18.0 (15.0-20.0)	18.0 (15.0-20.0)	0.944
Prone iron (seconds)	20.5 (12.0-32.0)	30.0 (13.5-33.5)	0.673
Side iron (seconds)			

Right	15.0 (10.0-21.0)	15.0 (9.5-20.0)	1,000
Left	12.5 (10.5-19.0)	18.0 (11.0-23.0)	0.356
Trunk extension (seconds)	13.5 (6.0-26.5)	13.5 (2.5-20.0)	0,586
Squats	10.0 (8.0-18.5)	12.5 (8.5-20.0)	0.673

* percentage (95% CI); a: U from Mann-Whitney; b: Chi square test

In **Table 6,** with a 95% confidence, the values are expected to oscillate in a narrow range: thus, a statistically significant difference was not found for the domains contemplated by the Kujala test for the two treatment groups, except for the squat domain with a p of 0, 028. However, it can be seen that within the thirteen domains contemplated by the Kujala test, it was found that these results agree with what was found for the total score of the test in the baseline, highlighting that in the pain domain, the "occasionally severe" response option was greater for group B; likewise, they were for the domains of "severe atrophy", "pain with the support of the limb", "going up and down stairs", "sitting with knees bent", especially if you have exercised before, as well as for the most painful movements of the patella with daily activities and severe pain always when running. The score was only greater in group A for the domains of inflammation every night and severe deficiency for knee flexion.

Kujala

Table 6: Distribution of the 13 domains of the Kujala Questionnaire by intervention group in the baseline.

Domain	**Treatment A (n = 20) % (95% CI)**	**Treatment B (n = 20) % (IC95%)**	**Value p ***
Pain			0.506 [a]
Constant and severe	20.0 (7.2-44.3)	20.0 (7.2-44.3)	
Occasionally severe	20.0 (7.2-44.3)	40.0 (20.5-63.2)	
Interferes with sleep	10.0 (2.31-34.2)	10.0 (2.31-34.2)	
Mild and occasional	50.0 (28.3-71.6)	30.0 (13.4-54.1)	
Inflammation			0.108 [b]

Permanently	10.0 (2.31-34.2)	20.0 (7.2-44.3)	
Every night	15.0 (4.5-39.2)	-	
With daily activities	30.0 (13.4-54.1)	10.0 (2.31-34.2)	
After great effort	30.0 (13.4-54.1)	30.0 (13.4-54.1)	
Do not	15.0 (4.5-39.2)	40.0 (20.5-63.2)	
Atrophy			0.451 [b]
Severe	-	5.0 (0.6-30.6)	
Mild	15.0 (4.5-39.2)	25.0 (10.2-49.3)	
Do not	85.0 (60.7-95.4)	70.0 (45.8-86.5)	
Limp			0.890 [a]
Constantly	10.0 (2.31-34.2)	10.0 (2.31-34.2)	
A little, sometimes	80.0 (55.6-92.7)	75.0 (50.6-89.7)	
Do not	10.0 (2.31-34.2)	15.0 (4.59-39.2)	
Limb support			0.347 [b]
Impossible to support	10.0 (2.31-34.2)	5.0 (0.6-30.6)	
Pain with support	55.0 (32.4-75.6)	80.0 (55.6-92.7)	
Completely painless	35.0 (16,9-58.7)	15.0 (4.59-39.2)	
Walk			1,000 [b]
Can not	5.0 (0.6-30.6)	5.0 (0.6-30.6)	
Between 1-2 Km	20.0 (7.2-44.3)	25.0 (10.2-49.3)	
More than 2 Km	45.0 (24.3-67.5)	45.0 (24.3-67.5)	
Unlimited	30.0 (13.4-54.1)	25.0 (10.2-49.3)	
Up and down stairs			0.050 [b]
Can not	5.0 (0.6-30.6)	-	

Pain when going up and down	50.0 (28.3-71.6)	75.0 (54.9-95.0)	
Slight pain when going down	45.0 (24.3-67.5)	15.0 (4.59-39.2)	
Without difficulty	-	10.0 (2.31-34.2)	
Squats			**0.028** [b]
Can not	20.0 (7.2-44.39)	-	
With help	5.0 (0.6-30.6)	15.0 (4.59-39.2)	
It is always painful	20.0 (7.26-44.3)	40.0 (20.5-63.2)	
Doing them quickly hurts	25.0 (10.2-49.3)	40.0 (20.5-63.2)	
Without difficulty	30.0 (13.4-54.1)	5.0 (0.6-30.6)	
Remain seated with knees bent	0.236 [b]		
Unable to do it	15.0 (4.59-39.2)	-	
Pain forces the knees to extend	65.0 (41.2-83.0)	70.0 (45.8-86.5)	
It is always painful	10.0 (2.31-34.2)	10.0 (2.31-34.2)	
There is only pain if you have exercised	5.0 (0.6-30.6)	20.0 (7.26-44.3)	
There is no problem	5.0 (0.06-30.6)	-	
Painful movements of the kneecap	0.303 [b]		
More than two dislocations	10.0 (2.31-34.2)	10.0 (2.31-34.2)	
Less than a confirmed dislocation	10.0 (2.31-34.2)	15.0 (4.59-39.2)	
Occasionally with everyday activities	20.0 (7.26-44.36)	40.0 (20.5-63.2)	
Occasionally with exercise	30.0 (13.4-54.1)	30.0 (13.4-54.1)	
Do not	30.0 (13.4-54.1)	5.0 (0.6-30.6)	
Deficiency for knee flexion	0,227 [b]		
Severe	20.0 (7.26-44.3)	5.0 (0.06-30.6)	
Mild	70.0 (45.8-86.5)	70.0 (45.8-86.5)	

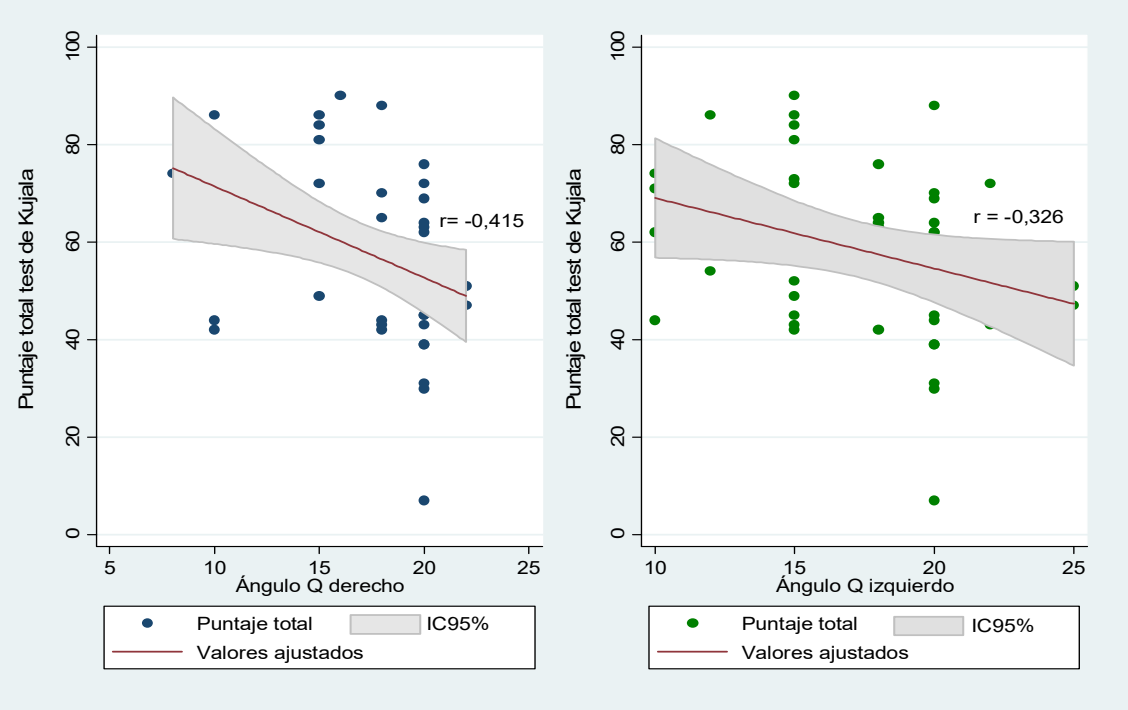
Do not	10.0 (2.31-34.2)	25.0 (10.2-49.3)	
Run			0.512 [b]
Be unable	25.0 (10.2-49.3)	15.0 (4.59-39.2)	
Severe pain always	-	15.0 (4.59-39.2)	
Mild pain from the start	25.0 (10.2-49.3)	25.0 (10.2-49.3)	
Pain after 2 Km	35.0 (16,9-58.7)	35.0 (16,9-58.7)	
Unlimited	15.0 (4.59-39.2)	10.0 (2.31-34.2)	
Skip			0.915 [b]
Be unable	25.0 (10.2-49.3)	30.0 (13.4-54.1)	
With permanent pain	15.0 (4.59-39.2)	20.0 (7.26-44.3)	
With slight difficulty	35.0 (16,9-58.7)	35.0 (16,9-58.7)	
Without difficulty	25.0 (10.2-49.3)	15.0 (4.59-39.2)	

* Statistical significance p <0.05; a: Chi square test; b: Fisher's exact test

Angle Q and Kujala

Graph 1 shows the correlation between the values of angle Q (right and left) and the total score of the test Kujala obtained in the initial population assessment (baseline), indicating that there is a negative correlation with a coefficient of Spearman's correlation r = -0.415 (moderate correlation) for the right Q angle and r = -0.326 (slight correlation) for the left Q angle, which means that when the values of the angle Q are greater, the total score in the Kujala test is lower.

Graph 1: Correlation of Q angle values on anterior knee pain with the Kujala test in the baseline.

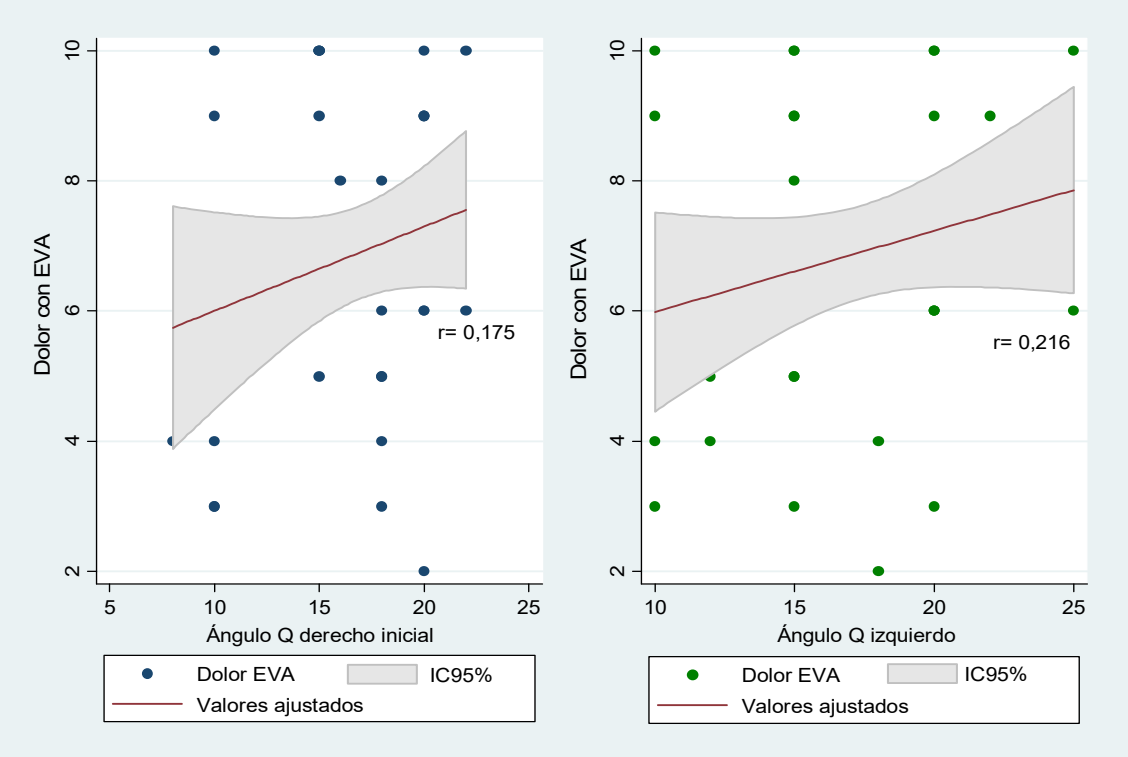


Source: Author.

Angle Q and EVA

In **Figure 2** a positive correlation, indicating that as the value of angle Q is greater, the score in the pain measured with a visual analog scale (VAS) is higher for both lower limbs, with a coefficient is observed of Spearman correlation of r = 0.175 for the right Q angle and r = 0.216 for the left Q angle. It should be noted that although the sample was small, there is a slight correlation.

Graph 2: Correlation of Q angle values on anterior knee pain with EVA in the baseline.

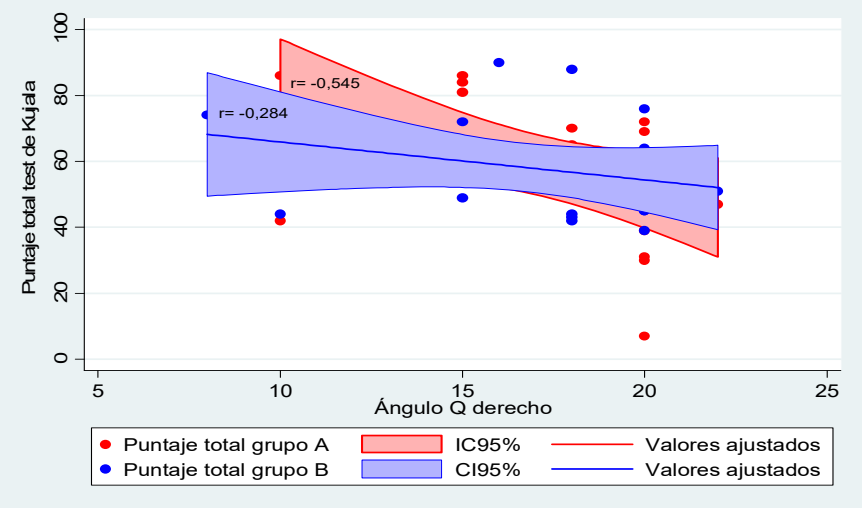


Source: Author.

Angle Q - Intervention Groups

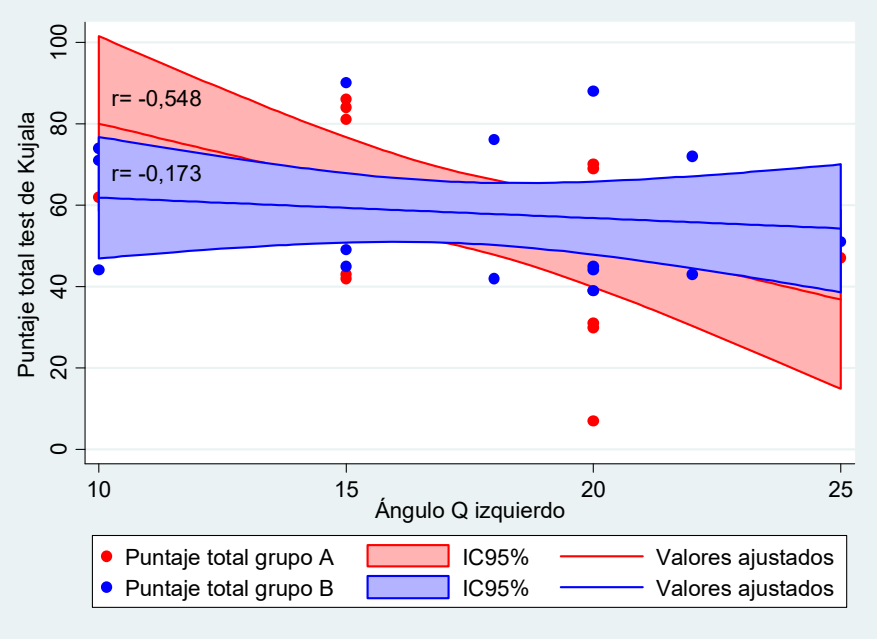
In **graphs 3 and 4**, a negative correlation is shown between the values of the angle Q of the right and left knee by treatment groups (A and B) measured at the beginning of the intervention, and the total score obtained in the Kujala test, which indicates that as the angle Q increases, the total Kujala score decreases, with a moderate correlation for group A (r = -0.545 right knee) and (r = -0.548 left knee) and mild for group B (r = -0.284 right knee and r = -0.173 left knee).

Graph 3: Correlation of the values of the angle Q on the anterior pain of the right knee in the baseline, by treatment groups.



Source: Author.

Graph 4: Correlation of Q angle values on left anterior knee pain in the baseline, by treatment groups.



Source: Author

Angle Q and Muscular Length

To determine the influence of muscle length (quadriceps, hamstrings, of tensioner of the fascia lata and gastrocnemius) on the alignment of the patella, in **Table 7,** the influence of muscle length on patellar alignment is observed, highlighting that the Right angle Q for people with a positive Ober

test (which evaluates the muscle length of tensioner of the fascia lata), obtained an average of 17.26 while for the left Q angle was 18.07 with one and one standard deviation of 3.88 and 4.11 respectively, indicating that those people with decreased muscle length, that is, a positive Ober test, had a higher Q angle compared to those who obtained a negative test. In the same way, a similar effect is observed in the 90-90 test which evaluates the muscle length of the hamstrings, because when the test is negative, that is, there is less muscle retraction, the angle Q is smaller, indicating lesser mal patellofemoral alignment.

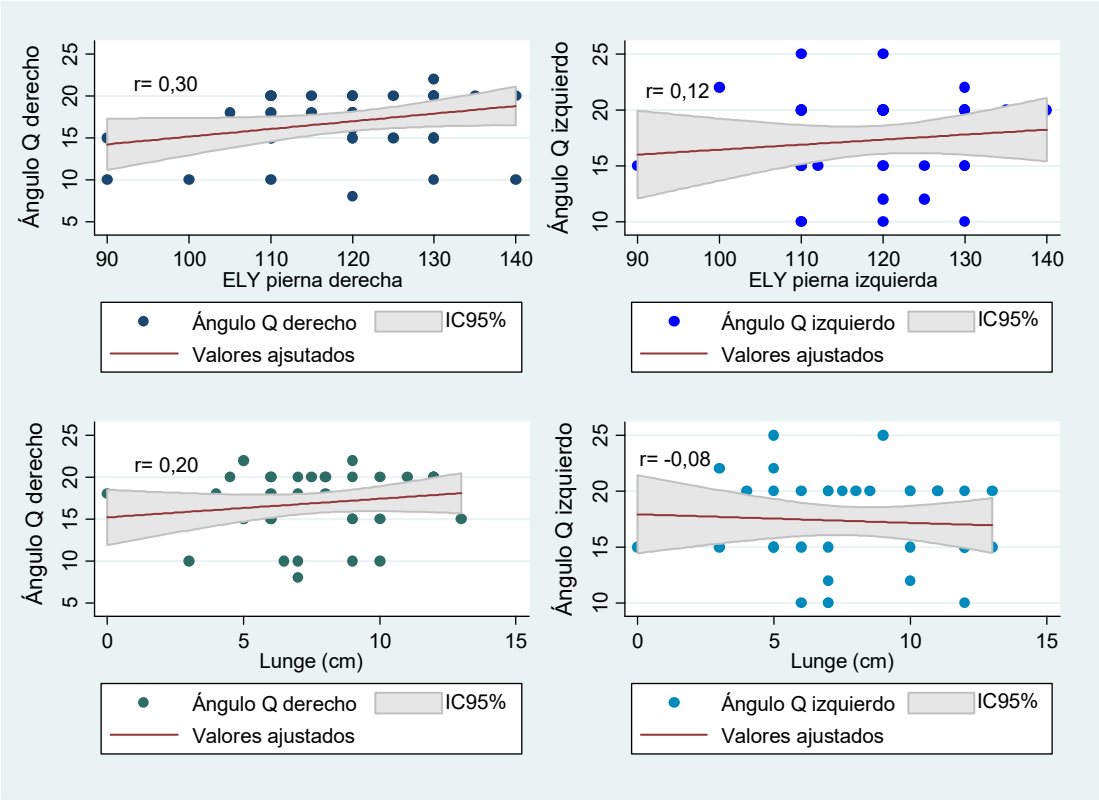
Table 7: Influence of muscle length on the alignment of the patella

Test	**Q angle**	
	Straight **Half of)**	**Left** **Half of)**
Ober		
Positive	17.26 (3.88)	18.07 (4.11)
Negative	16.28 (3.51)	16.96 (3.82)
90-90		
Positive	17,02 (3,81)	17,32 (3.90)
Negative	15.0 (0.00)	-
ELY [a]	0.30	0.12
Lunge [to]	0.20	-0.08

a: Spearman correlation coefficient

Now, **Figure 5** , highlights the relationship between the muscle length of the quadriceps and the gastrocnemius, measured in degrees and centimeters respectively, and the bilateral Q angle of knees, indicating that there is a positive correlation for both knees in the Ely test, and for the right knee in the Lunge test, this correlation being slight, which suggests that when the muscle length is greater, the angle Q is smaller, whereas for the left knee in the Lunge test, the correlation was negative (-0.08), classified as very mild.

Figure 5: Relationship of muscle length using the Ely and Lunge tests on the bilateral Q angle of the knees.



Source: Author.

Post-Intervention Results

To evaluate the effect of muscle strength on the alignment of the knees and analyze the effect of muscle strength on the unipodal balance, **Table 8** shows the deltas of the medians (changes or differences observed after the intervention) for each of the treatment groups and for each of the variables measured at the beginning and end of the intervention.

In this way, when they include or add exercises for the strengthening of the core, to the traditional treatment of SPF or anterior knee pain, the quality of life measured with the Kujala test in these patients increases, especially by the significant reduction of pain , highlighting for example, that for the total score of the Kujala test, there was a statistically significant difference (p = 0.025), with an increase of 5 points for group A (group A = 23.0, group B = 17.0), which indicates that the population of the study group improved their quality of life more after the intervention compared with the people of group B. A similar effect is observed in the increase of the strength of the core musculature for group A, especially in the oblique force evaluated with the side plate, with a difference of 30 seconds for group A, and only five seconds for group B on the left lateral plate, with a statistically significant p value (<0.001).

On the other hand, the differences for the total pain evaluated with EVA were -6 and -4 for group B, with an interquartile range (-10; -4) and (-7; -3) respectively. Although p was not statistically significant, these differences were clinically relevant. For the hip and knee muscle strength, measured with the squat test, there was no statistically significant difference in the median of the deltas between the treatment groups, but there was one in each group, which means that all of them increased strength muscle in hips and knees, as a result of strengthening for these muscle groups.

Table 8: Effect of muscle strengthening on pain, knee alignment, core, hip and knee strength and balance by treatment groups.

Variable	Treatment A			Treatment B			Value p *
	Initial Medium (RI)	**Final Medium (RI)**	**Delta Medium (RI)**	**Initial Medium (RI)**	**Final Medium (RI)**	**Delta Medium (RI)**	
Pain (EVA)	7.5 (5.5-9.0)	2 (0-2)	-6 (-10; -4)	7.0 (5.5-8.5)	2.0 (0-4)	-4 (-7; -3)	0.058
Kujala total test score	65.5 (42.5-72.5)	88.0 (81.0-95.0)	23.0 (16.0-37.0)	53.0 (44.5-71.5)	78.0 (64.0-88.0)	17,0 (8,0-24,0)	**0.025**
Squats	10.0 (8.0-18.5)	35.0 (30.0-38.0)	20.0 (18.0-25.0)	12.5 (8.5-20.0)	35.0 (29.0-38.0)	20.0 (15.0-24.0)	0.670
IPAQ (minutes)	3003 (1116-4638)	4275 (2587-6522)	1539 (807-2457)	1617 (944-6138)	4598 (2888-7344)	1977 (1191-2815)	0,492
Q angle							
Straight	19.0 (15.0-20.0)	18.0 (15.0-20.0)	0 (-2; 2)	18.0 (15.0-20.0)	18.0 (15.0-20.0)	0 (-2; 2)	0.819
Left	18.0 (15.0-20.0)	18.0 (16.0-20.0)	0 (-2; 2)	18.0 (15.0-20.0)	18.0 (15.0-20.0)	0 (-2; 2)	0.672

Balance with open eyes							
Straight	30.0 818.25-45.0)	45.0 (45.0-45.0)	11.5 (0-25.5)	40.0 (18.25-45.0)	45.0 (45.0-45.0)	7.5 (0-30.0)	0.916
Left	29.5 (15.75-44.0)	45.0 (45.0-45.0)	9.5 (0-21.5)	25.75 (14.5-45.0)	45.0 (45.0-45.0)	20.0 (0-30.0)	0.282
Balance with closed eyes							
Straight	4.5 (3.0-9.259	28.5 (21.0-35.0)	20.0 (14.0-27.5)	5.25 (3.0-7.25)	23.5 (16.5-31.5)	19.0 (9.5-24.0)	0.671
Left	5.0 (3.0-8.7)	30.0 (23.5-38.0)	24.5 (13.0-30.5)	4.25 (3.5-7.259	27.5 (14.0-34.5)	20.0 (10.5-30.5)	0.349
Griddle	20.5 (12.0-32.0)	60.0 (45.0-70.0)	37.0 (24.0-48.0)	30.0 (13.5-33.5)	35.0 (20.0-60.0)	10.0 (2.0-15.0)	**<0.001**
The t. Right	15.0 (10.0-21.0)	45.0 (38.0-51.0)	30.0 (19.0-36.0)	15.0 (9.5-20.0)	22.0 (16.0-38.0)	6.0 (2.0-12.0)	**<0.001**
The t. Left	12.5 (10.5-19.0)	45.0 (36.0-56.0)	30.0 (17.0-40.0)	18.0 (11.0-23.0)	21.0 (15.0-34.0)	5.0 (-2 - 10.0)	**<0.001**
Trunk extension	13.5 (6.0-26.5)	61.0 (50.0-75.0)	49.0 (30.0-55.0)	13.5 (2.5-20.0)	30.0 (15.0-60.0)	15.0 (7.0-34.0)	**0.001**

*** U of Mann-Whitney for the delta of the measurements between the groups.**

He was also interested in this research, to observe the intra-group differences of including hip and knee muscle strengthening exercises (conventional physiotherapeutic treatment) performed in the same way for both intervention groups, as mentioned in the description of the strengthening protocol.

Intragroup differences

In **Table 9,** differences in medians and interquartile ranges their entire study population at the beginning and end of treatment for muscle strength, pain and level of physical activity is. It can be seen that the gluteal and quadriceps muscle strength measured with the squat test at the end of the treatment was the same in both groups, with a statistically significant p value (<0.001), which means that the whole population increased strength in a significate way.

In the same way, a similar effect was observed in the median pain measured with the VAS at the end of the treatment, because they all reported a decrease in pain, this difference being statistically significant, with a p-value less than 0.001. However, in the measurement of physical activity level with the long IPAQ at the end of the treatment, it was observed that the study population in group B spent less time practicing physical activity at the beginning of treatment, but both groups increased in time similar this practice at the end of the treatment; however, this difference was not statistically significant.

Table 9: Difference of intragroup medians for muscle strength, pain and physical activity level.

Variable	**Treatment A**			**Treatment B**		
	Initial Medium (RI)	**Final Medium (RI)**	**Value p ***	**Initial Medium (RI)**	**Final Medium (RI)**	**Value p ***
Squats	10.0 (8.0-18.5)	35.0 (30.0-38.0)	**<0.001**	12.5 (8.5-20.0)	35.0 (29.0-38.0)	**<0.001**
IPAQ (minutes)	3003 (1116-4638)	4275 (2587-6522)	**0.029**	1617 (944-6138)	4598 (2888-7344)	**0.012**
Pain (EVA)	7.5 (5.5-9.0)	2.0 (0.0-2.0)	**<0.001**	7.0 (5.5-8.5)	2.0 (0-4)	**<0.001**

*** Wilcoxon nonparametric test**

Muscular Strength and Static Balance

In **Table 10**, the correlation between the muscle and gluteus muscle strength differences measured with the squat and unipodal balance test evaluated with the One Leg Stance test with open and closed eyes by treatment groups is shown, with which it is emphasized that, for both treatment groups, the unipodal balance improved clinically significant. However, for the study group (A), this correlation was greater (strong), especially in the variable with open eyes for both lower limbs, indicating that by increasing muscle strength (glutes and quadriceps in this case) it is improved the unipodal balance. Although there is an increase in the balance for both treatment groups, there is a stronger correlation when core exercises are included, which is what happens in group A.

Table 10: Correlation between differences in muscle strength and balance by treatment groups

Variable	**Squats**	
Balance	**Treatment A ***	**Treatment B ***
Right with open eyes	0,558	0.121
Left with open eyes	0,554	0.110
Right with closed eyes	0.390	0.009
Left with closed eyes	0.008	-0.244

*** Spearman correlation coefficient.**

With the previously stated results, the alternative hypothesis of this study is rejected, which means that adding core exercises to traditional hip and knee muscle strengthening for the treatment of anterior knee pain in patients diagnosed with SPF is more effective in reducing pain and improving the quality of life of these people, they do only hip and knee strengthening exercises.