Comparison of Closed Kinetic Chain Quadriceps and Gluteal Strength Training with Open Kinetic Chain Quadriceps and Gluteal Strength Training on Pain in Runners with Patellofemoral Knee Osteoarthritis: A Randomized Controlled Trial

Final Project

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Barcelona, 13th of December

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ACKNOWLEDGEMENTS

First of all, I would like to thank my parents, who have always supported me throughout my studies, both morally and financially. Without them, this project would never have seen the light of day.

I would also like to thank my sister and my stepbrother, who are role models for me in their profession, and who have also been there for me throughout my studies.

This project as it is would not have been possible without the invaluable help and support of my girlfriend, who followed the development of this work from start to finish, and who always supported and helped me gain self-confidence when I needed it most.

Nor can I fail to thank my two loyal team-mates, Ben and Elora, who have supported me throughout these 4 years and without whom everything would have been so different.

I would also like to thank Jules, Maé, Marie, Elouen, Léonie and Léo for everything they have given me.

And finally, I would like to thank my mentor, Tony Donegan, for his invaluable advice and exchanges.

ABSTRACT AND KEY WORDS

INTRODUCTION: Quadriceps and gluteal strength training is considered one of the main treatments for improving symptoms in patients suffering from knee osteoarthritis (KOA). This type of intervention appears to be of interest to runners suffering from this pathology, in view of the benefits of strength training in their discipline, particularly with its emphasis on eccentric work. However, most studies have focused on the effects of open kinetic chain (OKC) strength training on non-athletic subjects and on patients suffering from tibiofemoral KOA (TF KOA). The aim of this study is to compare the effects of two quadriceps and gluteal strength trainings, one in OKC and the other in closed kinetic chain (CKC), on pain, quadriceps and gluteal strength, function and running biomechanics in runners with patellofemoral KOA (PF KOA).

METHODS: This study will be a randomized, controlled, multi-centre, single blind (assessors) trial with repeated assessment at baseline, week 12 and week 25. To be included in the study, subjects (males or females) must be aged between 30 and 50, have a running training volume between 50 and 100 kilometres, present a PF KOA of at least grade 2 on the Kellgren-Lawrence scale and already have at least one session of lower-limb strength training per week in the gym. Each subject will be allocated to one of the two study groups and will perform, on their side, CKC or OKC quadriceps and gluteal training for 12 weeks, with 2 sessions per week in addition to their running training.
Pain, using the Brief Pain Inventory Short Form (BPISF), will be assessed as a primary outcome. Quadriceps and gluteal strength with the BiodexSystem 4 dynamometer, function with the Knee Injury and Osteoarthritis Outcome Score (KOOS) questionnaire and running biomechanics with the RunScribe wearable device will be evaluated as secondary outcomes.
Statistical analysis will be performed with repeated measures ANOVA and statistical significance at 0.05.

DISCUSSION: The expected results are that CKC quadriceps and gluteal strength training will result in greater improvement on pain, quadriceps and gluteal strength, function and running biomechanics compared to OCK quadriceps and gluteal strength training in runners with PF KOA.

KEY WORDS: Open Kinetic Chain strength training, Closed Kinetic Chain strength training, patellofemoral knee osteoarthritis, pain, runners.

I. INTRODUCTION :

Osteoarthritis (OA) is a chronic degenerative disease that is widespread throughout the world and is associated with a high health burden (1,2). Osteoarthritis affects the joints and surrounding tissue structures through degradation of the articular cartilage, which can lead to deterioration of the subchondral bone (1). Various joints can be affected by this pathology, particularly the knee.

Knee osteoarthritis (KOA) is one of the main reason for disability worldwide (3). KOA is characterized by anatomical and physiological degradation leading to bone tissue deterioration, osteophyte formation, synovial membrane inflammation and loss of normal knee range of motion (ROM) (3). There are 2 types of KOA. Tibiofemoral (TF) osteoarthritis, involving the tibia and femur and the various structures located between them, and patellofemoral (PF) osteoarthritis, involving the patella and femur, as well as the structures located between them (4). KOA leads to joint stiffness, knee pain, lower limb muscles imbalances and decrease range of motion (ROM) that reduce patients' quality of life (1,3).

KOA affects many people worldwide. Several epidemiological studies have shown a high prevalence in different countries: 14.6% in China, 15.4% in southern Sweden and 10.5% in Canada (5). Regarding PF OA, studies have also shown a high overall prevalence of 35% (6). However, a number of studies have shown that KOA can also affect athletes, and runners in particular, despite the fact that running may have a protective effect against knee pain (1,7).

The main risk factors for KOA are age, genetic predisposition and obesity (1). But other risks directly linked to physical and neuromuscular factors also come into play and can have a real impact on the progression of pathology, the pain and the reduction of knee functionality. Poor muscular control of the lower limb, poor dynamic stability of the knee, or low muscle strength in the quadriceps and hip abductors, combined with muscular imbalance in the lower limbs, can all have a deleterious impact on the consequences of KOA (2,8–12).

The aim of KOA treatment is to reduce pain, improve function, knee ROM and quadriceps strength. To achieve this, conventional physiotherapy strategies may include isometric contractions of the quadriceps, interferential therapy or stretching of the lower limb (3). Other

techniques include aqua therapy, pilates and mulligan mobilizations (3). However, these types of treatment do not appear to be particularly suitable or specific for amateur runners with a certain level of training. Indeed, the lack of time in the week due to a high volume of training may present a limit to the implementation of this type of treatment for KOA. It would seem interesting to be able to incorporate a treatment protocol that would not only improve the symptoms of KOA but also improve runners' performance.

Lower-limb strength training could be a good alternative (13,14). Indeed, loaded strength training appear in recent study to be very helpful for patient with KOA, particularly focusing on quadriceps and hip (abductors) strength. Firstly, it has been shown that short term high intensity strength training is safe and well tolerated in subjects with KOA (15). There is a positive impact of this kind of training on the KOA. In fact, strength training of the quadriceps and hip joints helps to protect the knee cartilage by absorbing more of the load on the joint (8). Quadriceps and hip strength training improves function and reduce pain intensity and stiffness in the knee (9). Some studies show that resistance exercises can reduce KOA pain severity and intensity similarly to traditional analgesic agents (11). It helps to slow the progression of pathology. It also increases strength in the hip and quadriceps muscles, since low muscle strength in these areas is one of the main risk factors (2,8,9,11).
The literature also describes other benefits of strength training specific to KOA. Indeed, strength training also increases the viscosity of joint fluid and hyaluronic acid within the joint capsule, helping to improve KOA symptoms (2). This type of training also increases the dynamic stability of the knee and hip and improves shock absorption during running (2,16). Finally, it improves postural stability and motor control in KOA patients (2).

Most strength training protocols for KOA often involve isotonic exercises with the emphasis mainly on the concentric phase. However, the eccentric phase of concentric-eccentric exercises should not be neglected. Indeed, eccentric training appears to be beneficial for KOA improvement (3), particularly for runners. It appears to be practice-specific during the mechanical stress absorption phase. It has been shown to improve strength and reduce pain in KOA patients (11). It has also been shown that quadriceps eccentric strength compared to concentric strength is lower in persons with focal cartilage lesions (17), hence the interest in working on the muscular strength of this muscle in this mode of contraction. Furthermore, eccentric training is well tolerated and safe in KOA patients (11).

Despite this, it should be noted that most of the studies that have shown the effectiveness of eccentric quadriceps training on KOA have demonstrated it using open kinetic chains (OKC) exercises. OKC can be defined as an exercise during which the distal body segment is not fixed and can move freely (18). As far as the lower limbs are concerned, we can give the example of leg extension. OKC enables better isolation of an individual muscle group. In addition, it generates more distraction and rotation force and is often used through the concentric contraction mode (19). However, this type of exercise does not appear to be functional for running activity, unlike the Closed Kinetic Chain (CKC) exercises (19). Indeed, during the CKC exercises, the distal segment of body parts remains stationary on the ground (18). CKC exercises are more functional because it represents a weight bearing pattern activity (20). In addition, it has been proved that CKC exercise produce superior eccentric contraction and co-contraction of muscles (19). However, researchers have shown that CKC increases the axial loading on the joint and therefore increases progressive stress on the joint and cartilage in particular (20).

Even though studies show equal improvement on pain, strength on quadriceps and quality of life in patients with KOA between OKC and CKC exercises, all the previous studies have been made on subjects who do not practise sport and not on athletes. It might therefore be more interesting to study these effects on a population of runners.
With all the elements mentioned above, CKC exercises, focusing on knee and hip muscles, appear to be a good strategy for KOA treatment for runners and according to their functionality and specificity in relation to the running activity. In addition, CKC exercises of the lower limbs are polyarticular. It allows to work on different muscles and joints like the knee and the hip and to improve dynamic stability and motor control, in addition to muscular strength. These exercises enables both eccentric and concentric work, as well unilateral which again seems to be even more specific for runners.

Despite all this, most studies showed the effectiveness of specific strength training in KOA patients have been carried out on TF KOA patients or without specifying the KOA type and very few on PF KOA patients.
The purpose of this randomized controlled trial is to evaluate the benefits of a CKC quadriceps and gluteal strength training compared to an OKC quadriceps and gluteal strength training on functional pain, quadriceps and gluteus strength, function and running biomechanics in runners with PF KOA.

1. Hypothesis :

The null hypothesis (H0) is there will be no difference on functional pain between the CKC quadriceps and gluteal strength training and the OCK quadriceps and gluteal strength training in runners with PF KOA.

The alternative hypothesis (H1) is the CKC quadriceps and gluteal strength training will result in greater improvement on functional pain compared to OCK quadriceps and gluteal strength training in runners with PF KOA.

2. Objectives :

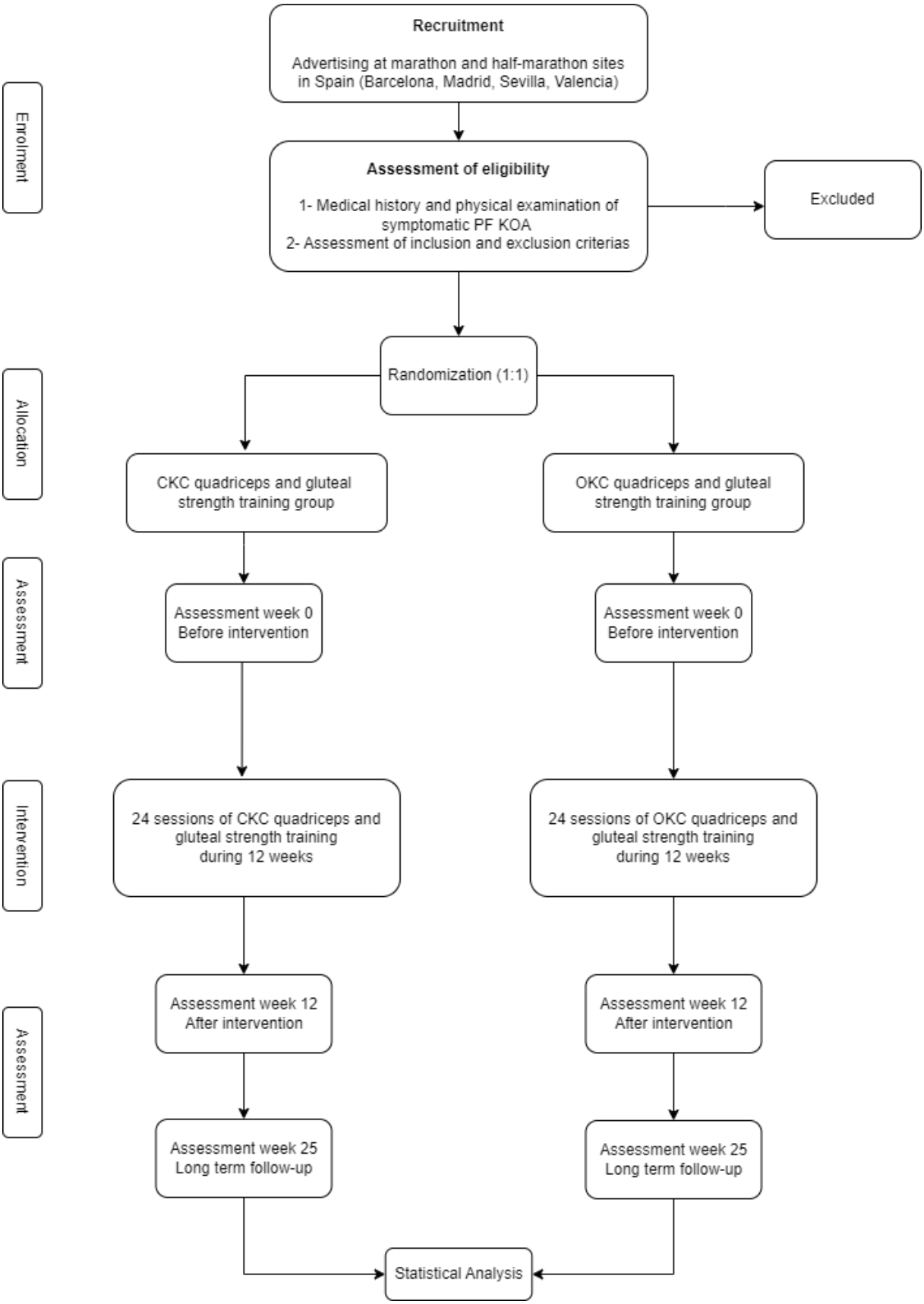
The primary objective of the study is to determine the effect of CKC quadriceps and gluteal strength training compared to OKC quadriceps and gluteal strength training on functional pain in runners with PF KOA.
The secondary objectives are multiple.
Firstly, the goal is to determine the effect of CKC quadriceps and gluteal strength training compared to OKC quadriceps and gluteal strength training on quadriceps and gluteus strength in runners with PF KOA.
Secondly, the goal is to determine the effect of CKC quadriceps and gluteal strength training compared to OKC quadriceps and gluteal strength training on function in runners with PF KOA.
The third objective is to determine the effect of CKC quadriceps and gluteal strength training compared to OKC quadriceps and gluteal strength training on running biomechanics in runners with PF KOA.

II. METHODS :

1. Study Design :

In order to determine the effects of CKC quadriceps and gluteal strength training compared to the OKC quadriceps and gluteal strength training on functional pain and then on quadriceps and gluteal muscle strength, function and running biomechanics in runners with PF KOA, a randomized controlled trial will be conducted. Two groups will therefore be compared and followed up for 12 weeks. The CKC group will perform strength training of quadriceps and gluteus composed by 4 exercises in CKC and the OKC group will perform strength training of quadriceps and gluteus composed by 4 exercises in OKC. This study is a multi-centre because it will involve runners from different geographical regions in Spain, making it impossible to group all the subjects taking part of it. In order to reduce the possible influence of bias, this randomized controlled trial will follow the CONSORT statement.

2. Flow diagram of the study Design :


Enrolment
Recruitment
Advertising at marathon and half-marathon sites in Spain (Barcelona, Madrid, Sevilla, Valencia)
Assessment of eligibility
1- Medical history and physical examination of symptomatic PF KOA
2- Assessment of inclusion and exclusion criterias
Excluded
Allocation
Randomization (1:1)
CKC quadriceps and gluteal strength training group
OKC quadriceps and gluteal strength training group
Assessment
Assessment week 0
Before intervention
Assessment week 0
Before intervention
Intervention
24 sessions of CKC quadriceps and gluteal strength training during 12 weeks
24 sessions of OKC quadriceps and gluteal strength training during 12 weeks
Assessment
Assessment week 12
After intervention
Assessment week 12
After intervention
Assessment week 25
Long term follow-up
Assessment week 25
Long term follow-up
Statistical Analysis

3. Eligibility criteria :

In order to participate in the study, subjects must meet the following inclusion and exclusion criteria.

a. Inclusion Criteria :

- Females and males from Spain
- Ages between 30 and 50 years old
- Recreational runners with a weekly running volume of 50 to 100 kilometres per week
- Only one knee affected by grade 2 or above PF KOA evaluated by the Kellgren-Lawrence scale (21) and present a self-reported alteration on pain, strength and function. PF KOA should be confirmed with a x-ray (21)
- No contraindications to the study protocols
- Practising load strength training at least once a week in a gym linked to their running activity for performance purposes

b. Exclusion Criteria :

- Knee prothesis
- Pathological TF KOA
- Cardiovascular and pulmonary pathologies that could reduce performance during the sessions
- Any comorbidity that could have an impact on pain, lower limb strength or subject function
- Uncooperative patients at the start of the study.

4. Sample Size :

The primary outcome of this study is pain related to PF KOA, which will be assessed using the Brief Pain Inventory Short Form (BPISF). After 12 weeks of the CKC quadriceps and gluteal strength training protocol, a reduction of the pain will be expected. The minimal clinically important difference for the BPISF has been set at 1 point on a scale of 0 to 10, according to the literature (22).

5. Outcomes :

a. Primary Outcome :

In this study, pain will be used as the primary outcome and more specifically the pain caused by PF KOA. Pain will be evaluated before and directly after our intervention but also 25 weeks after as long-term follow-up with the use of the "Brief Pain Inventory Short Form (BPISF)" (ANNEX 1). The BPISF is a short, self-administered questionnaire. It includes two items: the pain severity score and the pain interference score. This questionnaire of nine questions uses a numerical rating scale from 0 (no pain) to 10 (most severe pain imaginable) for each question. The pain severity score is calculated with the pain experienced by the patient in the last 24 hours and the current pain of the subject (23). These two scores together form the BPISF total score. This scale presents a good validity and sensitivity in patients with osteoarthritis and more specifically in those with KOA (23,24).

b. Secondary Outcomes :

As secondary outcome, quadriceps and gluteus strength which will be evaluated before and directly after our intervention but also 25 weeks after as long-term follow-up with the use of an isokinetic dynamometer system, the Biodex System 4 (ANNEX 2) which measure the strength in Newton meters (Nm) (25). This strength assessment tool is reliable and valid to test the knee extension but also the hip abduction (25).

For this assessment, all subjects will be asked to wear shorts and a sports shirt. Participants will be free to stop the assessment if they feel pain or fear. After a specific warm-up composed by five minutes on a cycle ergometer of 25 watts, all the subjects will be asked to test the device and to perform each movement three times at the velocity to become familiar with the apparatus (25,26). The movements used during the test will be knee extension, hip flexion and hip abduction in this order. The position and set-up for each movement are detailed in the following table (TABLE 1), according to the study of Van Tittelboom et al. (2022) (25).

Concentric isokinetic strength assessment		
Assessment	**Setup**	**Positioning**
Knee extension	- Dynamometer orientation: 90° - Dynamometer tilt: 0° - Seat orientation: 90° - Seatback tilt: 85° - Axis of rotation: lateral femoral condyle (sagittal plane) - Attachment: proximal to medial malleoli - Ready position: full knee flexion - End position: full knee extension	- Good alignment upper body, pelvis and lower legs - Tested leg fixed above the knee - Stabilization: pelvis, chest and thigh straps with arms across the chest to avoid compensatory movements
Hip extension	- Dynamometer orientation: 0° - Dynamometer tilt: 0° - Seat orientation: 0° - Seatback tilt: fully reclined - Axis of rotation: superior and anterior to greater trochanter (when limb in neutral position) - Ready position: full hip flexion - End position: full hip extension	- Good alignment upper body, pelvis and lower legs - Non-tested leg fixed on chair - Stabilization: straps around chest and arms crossed to avoid compensatory movements
Hip abduction	- Dynamometer orientation: 0° - Dynamometer tilt: 0° - Seat orientation: 0° - Seatback tilt: fully reclined - Axis of rotation: superior and medial to greater trochanter - Hip attachment: proximal to the knee - Ready position: full adduction - End position: full abduction	- Good alignment upper body, pelvis and lower legs - Non-tested leg fixed on chair - Stabilization: arms crossed to avoid compensatory movements

(TABLE 1 : Position and setup isokinetic strength assessment)

The angular velocity used to assess the strength will be 30°/s for each of the 3 movements (26). During the test procedure, participants will be required to perform three consecutive maximal repetitions for each tested muscle group (25) with 30 seconds rest between each repetition (26). Between each tested movement, participants will allow to rest for two minutes. The assessors will give standardized verbal feedback to encourage the subjects to perform the assessment at maximal strength (25). Peak torque (PT in Nm) and mean PT (MPT in Nm) will be measured as markers of muscle strength for each assessment. Peak torque is defined as the highest strength output during the repetition and the MPT is the average of the peak torque obtained during the

repetition (25). For each movement, the values of three consecutive isokinetic contractions will be used for statistical analyses (25).

The function will be evaluated before and directly after our intervention but also 25 weeks after as long-term follow-up with the use of the Knee Injury and Osteoarthritis Outcome Score (KOOS) questionnaire (ANNEX 3). This questionnaire presents five subscales with different items which are assessed on a scale from 0 (extreme knee problems) to 100 (no knee problem) (27). The KOOS has demonstrated a good validity, consistency, test-retest reliability and responsiveness (27).

The running biomechanics will be evaluated before and directly after our intervention but also 25 weeks after as long-term follow-up with the use of the RunScribe wearable device (ANNEX 4). This tool is a small wearable device inertial measurement unit made for analyse running gait biomechanics by wearing it directly on the runner's shoe. This device captures kinematic, kinetic, and spatiotemporal data (28). We will use this tool to evaluate the contact time (milliseconds), the cycle time (milliseconds) and the stride length (meters) of each subject on a treadmill. This assessment consists of a five-minute warm-up on a treadmill at an intensity of 60% of your Maximal Aerobic Velocity (VMA), known by each participant. Then an analysis of the parameters studied over 15 minutes of running at 75% of the VMA of each subject on a treadmill. Studies show a good validity of this tool to measure contact time and cycle time (28,29).

6. Assessment :

Subjects will be assessed several times during the study. The first assessment will take place at baseline, in order to obtain the first values for our different outcomes. The second assessment will be realized at 12 weeks later, directly when the treatment protocol has been fully implemented. Finally, the third and last assessment will take place at week 25, meaning 13 weeks after the end of the protocol in order to observe the long-term effects of the various interventions. For each subject, the three assessments will be conducted on the same day of the week and at the same time of day, to minimize bias. Each assessment will take place in four sports clinics, each located at four different places in Spain: Barcelona, Madrid, Valencia and Sevilla. One physiotherapist is responsible of the assessments for each clinic.

7. Ethics :

The conducted study aims to respect the fourth basic principles of research: respect for the people, beneficence, non-maleficence and justice. To ensure this, this randomized controlled trial will be evaluated by the Ethics Committee of the Spanish National Research Council (CSIC). The development of the study will follow the rules of good clinical practice, the principles set in the Helsinki Declaration (World Medical Association, 1989). In addition, participants will be informed of the study procedure by receiving an informed consent form, which will be requested for all study participants (ANNEX 5).

8. Recruitment :

Participants in the study will be recruited using advertisements set up during half-marathons and marathons at four different locations in Spain (Barcelona, Madrid, Sevilla, Valencia) during the year of 2025. At these events, runners will be able to access information about the study via a dedicated stand and the distribution of flyers, with the option of contacting the study team to take part, depending on their eligibility criteria. If subjects feel they meet the eligibility criteria, they can contact the study organization to make an appointment for a medical assessment by the investigator and the physiotherapist in the subject's city. This will determine whether the subject can take part in the study.

9. Randomization :

To ensure that the study has as little bias as possible and that the participants in the two study groups are similar, each subject will be randomly assigned by an external person who will be the study coordinator. Firstly, a random allocation sequence will be produced using the randomization software REDCap (Research Electronic Data Capture) to generate random numbers with a 1:1 ratio. Then, each allocation will be concealed by sealed and opaque envelopes containing the group assignment of each participant. Finally, the random allocation sequence will be implemented.

10. Blinding :

Given the design of this RCT, it is not possible to blind patients or therapists. Only the assessors will be blinded. This project is therefore a single-blinded study.

11. Intervention :

As previously mentioned, two groups are included in this RCT. Firstly, the study group, which mean the group that will perform CKC strength protocol. Secondly, the standard group, which will perform OCK strength protocol.

a. Study Group :

As study group, each subject of this group will perform CKC quadriceps and gluteal strength protocol for 12 weeks composed of two sessions of this strength training per week (24 sessions in total). Each session will be made up for 10 minutes of articular and muscular warm-up (ANNEX 6), 40 minutes of strength training protocol and 10 minutes of cool down with some slight stretching and parasympathetic breathing (ANNEX 7). Each session will last one hour in total. During the 12 weeks, the first session will be performed on Tuesday at 6.30 pm and the second one on Saturday at 6.30 pm.

The CKC strength training protocol will be composed of four exercises: Patrick Step Up (each leg), ½ Back Squat, Reverse Lunges (each leg), Trap Bar Deadlift (ANNEX 8). The exact programming and planification for each exercise is detailed in (TABLE 2). In order to monitor the sessions, each subject will have to find his or her 1RM for each exercise. The extrapolation of the 1RM will then be made. To do this, each subject will be asked to find the load corresponding to the 3RM for each exercise, which corresponds to 93% of the 1RM. The use of the Berger's table to extrapolate this load to the 1RM will be used. This procedure will be carried out in the same week as the baseline assessment, at week 0 (the baseline assessment took place on Tuesday and the 1RM extrapolation on Saturday). Olympic bar and trap bar with discs of various weights, squat rack and one step will be used as material to perform the strength protocol by the study group. The mode of delivery of this intervention will be individual. Each subject will carry out the protocol individually in their respective gym, after receiving details

of the sessions and instructions on their phone. Each subject will also be able to contact a member of the study team at any time if they have any questions about the protocol.

Week	Exercises	Volume (Set + Repetitions)	Inter-sets rest period	Inter-exercises rest period	TEMPO	Load (% 1RM)
1 and 2	- Patrick Step Up - 1/2 Back Squat - Reverse Lunges - Trap bar Deadlfit	3 x 8	2'	2'30	3121	75% 1RM
3 and 4	- Patrick Step Up - 1/2 Back Squat - Reverse Lunges - Trap bar Deadlfit	3 x 8	2'	2'30	3121	80% 1RM
5 and 6	- Patrick Step Up - 1/2 Back Squat - Reverse Lunges - Trap bar Deadlfit	3 x 6	2'30	3'	3121	85% 1RM
7 and 8	- Patrick Step Up - 1/2 Back Squat - Reverse Lunges - Trap bar Deadlfit	3 x 4	3'30	4'	3121	90% 1RM
9 and 10	- Patrick Step Up - 1/2 Back Squat - Reverse Lunges - Trap bar Deadlfit	3 x 4	3'30	4'	3121	90% 1RM
11 and 12	- Patrick Step Up - 1/2 Back Squat - Reverse Lunges - Trap bar Deadlfit	3 x 2	4'	4'30	3121	95% 1RM

(TABLE 2 : Study Group Protocol)

b. Standard Group :

As standard group, each subject of this group will perform OKC quadriceps and gluteal strength protocol for 12 weeks composed of two sessions of this strength training per week (24 sessions in total). Each session will be made up of 10 minutes of articular and muscular warm-up (ANNEX 6), 40 minutes of strength training protocol and 10 minutes of cool down with some slight stretching and parasympathetic breathing (ANNEX 7). Each session will last one hour in total. During the 12 weeks, the first session will be performed on Tuesday at 6.30 pm and the second one on Saturday at 6.30 pm.

The OKC strength training protocol will be composed of four exercises, all performed on guided weight machines: Sled Leg press, Leg Extension, Hip Abduction Machine, Cable Hip

Extension (each leg) on the bench (ANNEX 9). The exact programming and planning for each exercise is detailed in (TABLE 3). For each exercise, the same procedure than the study group to find the 1RM of each subject will be used. The corresponding guided weight machines will be used as material to perform the strength protocol by the experimental group. The mode of delivery of this intervention will be individual. Each subject will carry out the protocol individually in their respective gym, after receiving details of the sessions and instructions on their phone. Each subject will also be able to contact a member of the study team at any time if they have any questions about the protocol.

Week	Exercises	Volume (Set + Repetitions)	Inter-sets rest period	Inter-exercises rest period	TEMPO	Load (% 1RM)
1 and 2	- Sled leg press - Leg extension - Hip abduction machine - Cable hip extension on bench	3 x 8	2'	2'30	3121	75% 1RM
3 and 4	- Sled leg press - Leg extension - Hip abduction machine - Cable hip extension on bench	3 x 8	2'	2'30	3121	80% 1RM
5 and 6	- Sled leg press - Leg extension - Hip abduction machine - Cable hip extension on bench	3 x 6	2'30	3'	3121	85% 1RM
7 and 8	- Sled leg press - Leg extension - Hip abduction machine - Cable hip extension on bench	3 x 4	3'30	4'	3121	90% 1RM
9 and 10	- Sled leg press - Leg extension - Hip abduction machine - Cable hip extension on bench	3 x 4	3'30	4'	3121	90% 1RM
11 and 12	- Sled leg press - Leg extension - Hip abduction machine - Cable hip extension on bench	3 x 2	4'	4'30	3121	95% 1RM

(TABLE 3 : Standard Group Protocol)

12. Data Analysis :

As a reminder, the study will be composed of a primary outcome, which is pain, and three secondary outcomes, which are quadriceps and gluteal strength, function and running biomechanics. All these outcomes correspond to the dependant variables, while the protocol

administered to each patient (group assignment) and the time of assessment correspond to the independent variables. The classification of each variable is as follows :

Dependant variables :

- Pain (primary outcome) : quantitative discrete
- Quadriceps and gluteal strength (secondary outcome) : quantitative continuous
- Function (secondary outcome) : quantitative discrete
- Running biomechanics (secondary outcome) : quantitative continuous

Independent variables :

- The protocol administered to patients (the group assignment) : qualitative nominal
- The time of assessment : qualitative nominal

The two groups will be assessed at three different times (baseline, 12 weeks and 25 weeks), meaning that we analyse three quantitative variables (pain, strength, function and running biomechanics) and three nominal variables (before intervention, 12 weeks and 25 weeks after intervention). The aim of the statistical analysis is to determine the between-group comparison during the three different assessments, as well as the within-group comparison over the time. Thus, the most appropriate test to analyse the results should be repeated measures ANOVA (mean comparison in more than two groups).
Statistical significance is set at 0.05.

13. Calendar :

	Study Period						
	Enrollment	**Allocation**	**Baseline**	**12 weeks Intervention Period**		**Follow-up (Week 12)**	**Follow-up (Week 25)**
TIMEPOINT	T1	T2	T3	T4	T5	T6	T7
ENROLLMENT							
Eligibility screen	x						
Informed consent	x						
Allocation		x	x				
INTERVENTIONS							
Group 1: CKC quadriceps and gluteal strength training				—	—		
Group 2: OKC quadriceps and gluteal strength training				—	—		
ASSESSMENTS							
Pain (BPISF)			x			x	x
Strength (Biodex System 4)			x			x	x
Function (KOOS)			X			X	X
Running biomechanics (RunScribe)			X			X	X

14. Role of the Investigators :

Several professionals will take part in this RCT, each with a different role.
One researcher will be in charge of patient recruitment and randomization, assigning each patient to one of two groups. One researcher will be in charge of statistical analysis. An investigator and a physiotherapist will be responsible for studying the inclusion and exclusion criteria in each city to select subjects for the study. Four physiotherapists will carry out the assessments in one of the four cities in the sport clinics where the assessments will take place (Barcelona, Madrid, Valencia, Seville). Finally, a physiotherapist and a strength and conditioning coach will be responsible for drawing up the strength protocols for the two groups involved in the study.

15. Resources :

Several fungible and non-fungible resources will be used in this study.

- Non-Fungible materials: Olympic bars, trap bars, squat racks, disc of various weight, steps, sled leg press machines, leg extension machines, hip abduction machines, cable machines, benches, treadmill, isokinetic dynamometer Biodex System 4, inertial RunScribe device, tables, KOOS questionnaire, Brief Pain Inventory Short Form, Biodex4, pens, papers, recruitment flyers, inform consent.

- Fungible materials: Participants and investigators.

III. LIMITATIONS :

In this RCT, we can point out a few limitations. First, the difficulty of finding subjects corresponding to our study population. Indeed, there is a low prevalence of marathon and half-marathon runners with PF KOA. This will make it more difficult to find eligible subjects with the age range and training volume required for this RCT, which probably will complicate the feasibility of the study.

Secondly, the strength training protocol, for both CKC and OKC groups, will be carried out individually and without professional supervision, which may lead to a bias in the execution of training protocols. This choice will be made for logistical and practical reasons.

The third point concerns the evaluation of quadriceps and gluteal strength. This evaluation will be carried out on an open-chain isokinetic dynamometer, which is very similar to the strength protocol used by the OKC training group. This protocol will be more specific to the conditions for evaluating quadriceps and gluteal strength than the CKC strength protocol. As a result, the OKC group will be likely to have an advantage in the evaluation which can leads to better results.

Finally, the lack of a non-intervention control group will be also a limitation of this study. Without this type of group, we cannot observe the natural evolution of the different outcomes, meaning without external intervention.

IV. REFERENCES :

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V. ANNEXES :

ANNEX 1 : Brief Pain Inventory Short Form (BPISF)

1903

Date: (month) / (day) / (year)

Subject's Initials : _____

Study Subject #:

PLEASE USE BLACK INK PEN

Study Name: _____

Protocol #: _____

PI: _____

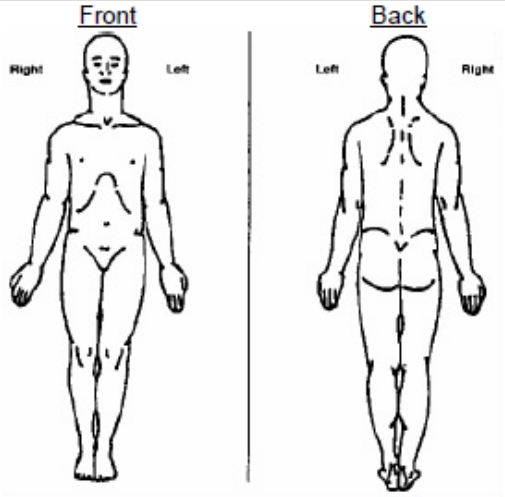
Revision: 07/01/05

Brief Pain Inventory (Short Form)

1. Throughout our lives, most of us have had pain from time to time (such as minor headaches, sprains, and toothaches). Have you had pain other than these everyday kinds of pain today?

☐ Yes ☐ No

2. On the diagram, shade in the areas where you feel pain. Put an X on the area that hurts the most.



3. Please rate your pain by marking the box beside the number that best describes your pain at its worst in the last 24 hours.

☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10

No Pain — Pain As Bad As You Can Imagine

4. Please rate your pain by marking the box beside the number that best describes your pain at its least in the last 24 hours.

☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10

No Pain — Pain As Bad As You Can Imagine

5. Please rate your pain by marking the box beside the number that best describes your pain on the average.

☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10

No Pain — Pain As Bad As You Can Imagine

6. Please rate your pain by marking the box beside the number that tells how much pain you have right now.

☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10

No Pain — Pain As Bad As You Can Imagine

Page 1 of 2

1903

Date: ____ / ____ / ____
(month) (day) (year)

Subject's Initials : _____

Study Subject #: _____

PLEASE USE BLACK INK PEN

Study Name: _____

Protocol #: _____

PI: _____

Revision: 07/01/05

7. What treatments or medications are you receiving for your pain?

8. In the last 24 hours, how much relief have pain treatments or medications provided? Please mark the box below the percentage that most shows how much relief you have received.

0%	10%	20%	30%	40%	50%	60%	70%	80%	90%	100%
☐ No Relief	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐ Complete Relief

9. Mark the box beside the number that describes how, during the past 24 hours, pain has interfered with your:

A. General Activity

☐ 0 Does Not Interfere ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10 Completely Interferes

B. Mood

☐ 0 Does Not Interfere ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10 Completely Interferes

C. Walking ability

☐ 0 Does Not Interfere ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10 Completely Interferes

D. Normal Work (includes both work outside the home and housework)

☐ 0 Does Not Interfere ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10 Completely Interferes

E. Relations with other people

☐ 0 Does Not Interfere ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10 Completely Interferes

F. Sleep

☐ 0 Does Not Interfere ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10 Completely Interferes

G. Enjoyment of life

☐ 0 Does Not Interfere ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10 Completely Interferes

ANNEX 2 : Biodex System 4

(https://biodexrehab.com)

ANNEX 3 : Knee Injury and Osteoarthritis Outcome Score (KOOS) questionnaire

Knee Injury and Osteoarthritis Outcome Score (KOOS)

Pain

P1 How often is your knee painful?	☐ Never	☐ Monthly	☐ Weekly	☐ Daily	☐ Always

What degree of pain have you experienced the last week when…?

P2 Twisting/pivoting on your knee	☐ None	☐ Mild	☐ Moderate	☐ Severe	☐ Extreme
P3 Straightening knee fully	☐ None	☐ Mild	☐ Moderate	☐ Severe	☐ Extreme
P4 Bending knee fully	☐ None	☐ Mild	☐ Moderate	☐ Severe	☐ Extreme
P5 Walking on flat surface	☐ None	☐ Mild	☐ Moderate	☐ Severe	☐ Extreme
P6 Going up or down stairs	☐ None	☐ Mild	☐ Moderate	☐ Severe	☐ Extreme
P7 At night while in bed	☐ None	☐ Mild	☐ Moderate	☐ Severe	☐ Extreme
P8 Sitting or lying	☐ None	☐ Mild	☐ Moderate	☐ Severe	☐ Extreme
P9 Standing upright	☐ None	☐ Mild	☐ Moderate	☐ Severe	☐ Extreme

Symptoms

Sy1 How severe is your knee stiffness after first wakening in the morning?	☐ None	☐ Mild	☐ Moderate	☐ Severe	☐ Extreme
Sy2 How severe is your knee stiffness after sitting, lying, or resting later in the day?	☐ None	☐ Mild	☐ Moderate	☐ Severe	☐ Extreme
Sy3 Do you have swelling in your knee?	☐ Never	☐ Rarely	☐ Sometimes	☐ Often	☐ Always
Sy4 Do you feel grinding, hear clicking or any other type of noise when your knee moves?	☐ Never	☐ Rarely	☐ Sometimes	☐ Often	☐ Always
Sy5 Does your knee catch or hang up when moving?	☐ Never	☐ Rarely	☐ Sometimes	☐ Often	☐ Always
Sy6 Can you straighten your knee fully?	☐ Always	☐ Often	☐ Sometimes	☐ Rarely	☐ Never
Sy7 Can you bend your knee fully?	☐ Always	☐ Often	☐ Sometimes	☐ Rarely	☐ Never

Activities of daily living

What difficulty have you experienced the last week…?

A1 Descending	☐ None	☐ Mild	☐ Moderate	☐ Severe	☐ Extreme
A2 Ascending stairs	☐ None	☐ Mild	☐ Moderate	☐ Severe	☐ Extreme
A3 Rising from sitting	☐ None	☐ Mild	☐ Moderate	☐ Severe	☐ Extreme
A4 Standing	☐ None	☐ Mild	☐ Moderate	☐ Severe	☐ Extreme
A5 Bending to floor/picking up an object	☐ None	☐ Mild	☐ Moderate	☐ Severe	☐ Extreme
A6 Walking on flat surface	☐ None	☐ Mild	☐ Moderate	☐ Severe	☐ Extreme
A7 Getting in/out of car	☐ None	☐ Mild	☐ Moderate	☐ Severe	☐ Extreme
A8 Going shopping	☐ None	☐ Mild	☐ Moderate	☐ Severe	☐ Extreme
A9 Putting on socks/stockings	☐ None	☐ Mild	☐ Moderate	☐ Severe	☐ Extreme
A10 Rising from bed	☐ None	☐ Mild	☐ Moderate	☐ Severe	☐ Extreme
A11 Taking off socks/stockings	☐ None	☐ Mild	☐ Moderate	☐ Severe	☐ Extreme
A12 Lying in bed (turning over, maintaining knee position)	☐ None	☐ Mild	☐ Moderate	☐ Severe	☐ Extreme
A13 Getting in/out of bath	☐ None	☐ Mild	☐ Moderate	☐ Severe	☐ Extreme
A14 Sitting	☐ None	☐ Mild	☐ Moderate	☐ Severe	☐ Extreme
A15 Getting on/off toilet	☐ None	☐ Mild	☐ Moderate	☐ Severe	☐ Extreme
A16 Heavy domestic duties (shovelling, scrubbing floors, etc)	☐ None	☐ Mild	☐ Moderate	☐ Severe	☐ Extreme
A17 Light domestic duties (cooking, dusting, etc)	☐ None	☐ Mild	☐ Moderate	☐ Severe	☐ Extreme

Sport and recreation function

What difficulty have you experienced the last week…?

Sp1 Squatting	☐ None	☐ Mild	☐ Moderate	☐ Severe	☐ Extreme
Sp2 Running	☐ None	☐ Mild	☐ Moderate	☐ Severe	☐ Extreme
Sp3 Jumping	☐ None	☐ Mild	☐ Moderate	☐ Severe	☐ Extreme
Sp4 Turning/twisting on your injured knee	☐ None	☐ Mild	☐ Moderate	☐ Severe	☐ Extreme
Sp5 Kneeling	☐ None	☐ Mild	☐ Moderate	☐ Severe	☐ Extreme

Knee-related quality of life

Q1 How often are you aware of your knee problems?	☐ Never	☐ Monthly	☐ Weekly	☐ Daily	☐ Always
Q2 Have you modified your lifestyle to avoid potentially damaging activities to your knee?	☐ Not at all	☐ Mildly	☐ Moderately	☐ Severely	☐ Totally
Q3 How troubled are you with lack of confidence in your knee?	☐ Not at all	☐ Mildly	☐ Moderately	☐ Severely	☐ Totally
Q4 In general, how much difficulty do you have with your knee?	☐ None	☐ Mild	☐ Moderate	☐ Severe	☐ Extreme

ANNEX 4 : RunScribe wearable device

(https://runscribe.com/)

ANNEX 5 : INFORMED CONSENT FORM

Title of the Study : Comparison of Close Kinetic Chain Quadriceps and Gluteal Strength Training with Open Kinetic Chain Quadriceps and Gluteal Strength Training on Pain in Runners with Patellofemoral Knee Osteoarthritis: A Randomized Controlled Trial

Principal Investigator : Baptiste Patyk

Purpose of the Study :

You are invited to participate in a research study investigating the effectiveness of a close kinetic chain quadriceps and gluteus strength training versus an open kinetic chain quadriceps and gluteus strength training for managing knee osteoarthritis. Your participation is entirely voluntary, and this form will help you to understand why the research is being done, what your participation will involve, and what risks and benefits may be associated with your participation.

Procedures :

If you agree to participate, we will ask you to:

- Complete baseline questionnaires and assessments related to your patellofemoral knee osteoarthritis.
- Be randomly assigned to one of two groups: the study group (Close kinetic chain muscle strength training) or the standard group (Open kinetic chain muscle strength training)
- Participate in the designated intervention sessions, which will involve strength training sessions.
- Undergo the two post-intervention assessments (at week 12 and week 25) similar to the baseline assessments.
- Allow the research team to collect and analyse data related to your knee osteoarthritis and the effects of the intervention.

Duration of Participation :

Your participation in this study will last 12 weeks. This period includes the initial assessments, intervention period, and the two post-intervention assessments.

Risks and Benefits :

There are several potential risks and benefits associated with participating in this study. The risks include muscle soreness, fatigue, pain, decrease function during daily living and during running. The benefits may include decrease of pain, increase of lower limbs muscle strength, improve function during daily living and during running.

Confidentiality :

All information collected during the study will be kept confidential to the extent allowed by law. Your identity will be protected, and your data will be anonymized before analysis. Only authorized personnel will have access to your data.

Voluntary Participation :

Your participation in this study is entirely voluntary. You are free to withdraw from the study at any time. If you choose to withdraw, there will be no negative consequences. If you wish to withdraw from the study, please contact by telephone:

Baptiste Patyk, +33654869618

Contact Information :

If you have any questions or concerns about the study, please contact:

Baptiste Patyk

+33654869618

baptiste.patyk@gmail.com

If you have any questions or concerns about your rights as a research participant, please contact:

The Ethics Committee of the Spanish National Research Council (CSIC).

Consent :

I, _____, have read and understood the information provided in this consent form. I have had the opportunity to ask questions and have received satisfactory answers. I voluntarily consent to participate in this research study.

Participant's Signature : _____ Date : _____

Witness's Acknowledgment :

I, _____, have witnessed the participant reading and understanding the information provided in this consent form. I am satisfied that the participant has been fully informed about the nature of the study and has had the opportunity to ask questions.

Witness's Signature : _____ Date : _____

Statement by the researcher taking consent:

I, _____, have presented the information in this consent form to the participant, answered any questions they had, and ensured that they fully understand the nature of the study.

Researcher's Signature : _____ Date : _____

ANNEX 6 : Warm-Up

WARM-UP **10'**	- Hip, knee, ankle articulaire warm-up - 2 x 30" chair isometric exercise (each leg) - 2 x 20 air squat (full amplitude) - 2 x 10 air lunges (full amplitude) - Gradual loading for each exercise

ANNEX 7 : Cool Down

COOL DOWN **10'**	- Slight stretch + automassage quadriceps and glutes - Parasympathetic breathing : cardiac coherence technique

ANNEX 8 : CKC photos

Back Lunges

½ Back Squat

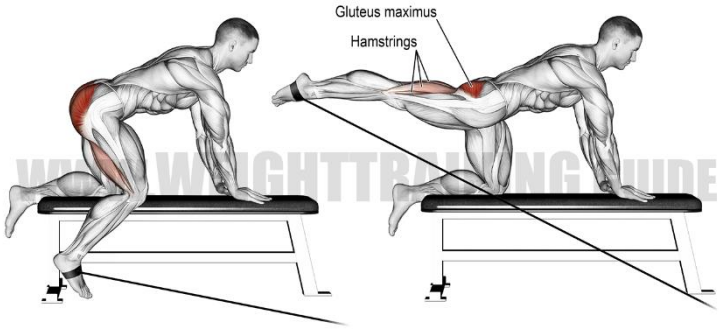
Patrick Step Up

Trap Bar Deadlift

(https://physiquedevelopment.com/trap-bar-deadlifts-variations/)

ANNEX 9 : OKC photos

Leg Extension



Cable Hip Extension on Bench

(https://weighttraining.guide/exercises/kneeling-cable-hip-extension/)

Hip Abduction machine

Sled Leg Press