

## **Proprioceptive Neuromuscular Facilitation compared to usual resistance exercise therapy in individuals with knee osteoarthritis: a randomized clinical trial protocol**

**Facilitação Neuromuscular Proprioceptiva comparada à exercícios resistidos em indivíduos com osteoartrite de joelho: um protocolo de ensaio clínico controlado**

**Facilitación neuromuscular propioceptiva en comparación con la terapia habitual de ejercicios de fuerza en personas con osteoartritis de rodilla: un protocolo de ensayo clínico aleatorizado**

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### **Abstract**

**Background/Aims:** Knee osteoarthritis (KOA) is characterized by functional impairment in performing of daily life activities. Proprioceptive Neuromuscular Facilitation (PNF) is a treatment concept that recommends performing exercises within a context of functionality. To develop a protocol to evaluate the efficacy of (PNF) compared to conventional physiotherapy (CPT group) on pain reduction and improvement in physical functioning and quality of life in individuals with KOA. **Methods:** A protocol for a randomized controlled trial was proposed to evaluate the effectiveness of the PNF protocol in pain reduction, improvement physical functioning, quality of life and evaluation of adverse effects, according Consolidated Standards of Reporting Trials. Participants will be randomly assigned (1:1) to PNF or CPT group and twelve weekly sessions will be carried out for three months. To assess primary outcome measures are knee pain severity (Numeric Rating Scale) and physical functioning (The Western Ontario and McMaster Universities questionnaire). The outcomes will be performed at baseline, 12th session (6 weeks), 24th session (12 weeks) and three-month follow-up. Intention-to-treat will be performed. **Results:** A PNF protocol was developed for KOA, consisting of seven illustrated exercises. Biomechanical objectives, observations, positions of individuals and therapists, load progression, PNF principles, procedures and techniques have been described. **Conclusion:** The detailed elaboration of a physical therapy treatment protocol based on the PNF-concept allows a

treatment approach based on the principles of learning and motor control, favoring the mitigating and improving physical functioning and quality of life of the individuals with KOA.

**Keywords:** Functional capacity performance; Osteoarthritis; Arthralgia; Muscle stretching exercise.

### Resumo

**Introdução/Objetivos:** A osteoartrite de joelho (OAJ) é caracterizada por comprometimento funcional na realização das atividades de vida diária. A Facilitação Neuromuscular Proprioceptiva (FNP) é um conceito de tratamento que recomenda a realização de exercícios dentro de um contexto de funcionalidade. Desenvolver um protocolo para avaliar a eficácia do FNP comparado à fisioterapia convencional (grupo CPT) na redução da dor e melhora da funcionalidade e qualidade de vida em indivíduos com OAJ. **Métodos:** Foi proposto um protocolo para um ensaio clínico randomizado para avaliar a eficácia do protocolo FNP na redução da dor, melhora do funcionamento físico qualidade de vida e avaliação de efeitos adversos. Os participantes serão distribuídos aleatoriamente (1:1) para o grupo PNF ou CPT e serão realizadas doze sessões semanais durante três meses. Para avaliar as medidas de resultados primários são a gravidade da dor no joelho (escala de classificação numérica) e o funcionamento físico (o questionário Western Ontario e McMaster Universities). Os resultados serão realizados na linha de base, 12ª sessão (6 semanas), 24ª sessão (12 semanas) e três meses de acompanhamento. A intenção de tratar será realizada. **Resultados:** Foi desenvolvido um protocolo de FNP para OAJ, com carga, princípios, procedimentos e técnicas de FNP foram descritos. **Conclusão:** A elaboração detalhada de um protocolo de tratamento fisioterapêutico baseado no conceito PNF permite uma abordagem de tratamento baseada nos princípios de aprendizagem e controle motor, favorecendo a atenuação e melhora da funcionalidade física e qualidade de vida dos indivíduos com OAJ.

**Palavras-chave:** Desempenho físico funcional; Osteoartrite; Artralgia; Exercícios de alongamento muscular.

### Resumen

**Antecedentes/Objetivos:** La osteoartritis de rodilla (OR) se caracteriza por un deterioro funcional en el desempeño de las actividades de la vida diaria. La Facilitación Neuromuscular Propioceptiva (FNP) es un concepto de tratamiento que recomienda realizar ejercicios dentro de un contexto de funcionalidad. Desarrollar un protocolo para evaluar la eficacia de FNP en comparación con la fisioterapia convencional (grupo CPT) en la reducción del dolor y la mejora en el funcionamiento físico y la calidad de vida en personas con OR. **Métodos:** Se propuso un protocolo para un ensayo controlado aleatorizado para evaluar la efectividad del protocolo PNF en la reducción del dolor, mejora del funcionamiento físico, calidad de vida y evaluación de efectos adversos, según Consolidated Normas de Informes de Ensayos. Los participantes serán asignados aleatoriamente (1:1) al grupo PNF o CPT y se realizarán doce sesiones semanales durante tres meses. Para evaluar las medidas de resultado primarias son la gravedad del dolor de rodilla (escala de calificación numérica) y el funcionamiento físico (cuestionario de las universidades de Western Ontario y McMaster). Los resultados se realizarán al inicio, 12.ª sesión (6 semanas), 24.ª sesión (12 semanas) y seguimiento a los tres meses. Se realizará intención de tratar. **Resultados:** Se desarrolló un protocolo FNP para OR, que consta de siete ejercicios. Se han descrito los objetivos biomecánicos, las observaciones, las posiciones de los individuos y los terapeutas, la progresión de la carga, los principios, los procedimientos y las técnicas de la FNP. **Conclusión:** La elaboración detallada de un protocolo de tratamiento basado en el concepto PNF permite un abordaje del tratamiento basado en los principios de aprendizaje y control motor, favoreciendo la mitigación y mejora del funcionamiento físico y la calidad de vida de los individuos con OR.

**Palabras clave:** Rendimiento físico funcional; Osteoartritis; Artralgia; Ejercicios de estiramiento muscular.

## 1. Introduction

Knee osteoarthritis (KOA) is a disease characterized by whole joint degeneration causing important functional repercussions (Brandt & Dieppe, 2009). The presence of functional impairment in performing activities of daily and professional life (Rosis et al., 2010) is due to a clinical disorder characterized by pain, stiffness and crepitation in movement (Michael et al., 2010). Due to the presence of pain, individuals with KOA often avoid activities which may trigger it, thereby predisposing them to lack of physical fitness and muscle weakness (Rosis et al., 2010).

Thus, there are several treatment methods studied in this population aimed at reducing pain, delaying degeneration progression and improving functionality (Michael et al., 2010). Among conservative treatments, resistance exercise is recommended by osteoarthritis clinical guidelines (Hochber et al., 2012; Bennel et al., 2012). However, there is still no consensus on the physical therapy intervention programs in the literature in relation to the modality and prescription of the exercises to be performed (Bennell et al., 2012).

Training using a combination of concentric and eccentric contractions appears to increase the functional capacity of individuals with KOA when compared to solely training using concentric contractions (Gür et al., 2002). These findings were observed in 23 individuals allocated to concentric training and concentric-eccentric training groups, and a group performing no intervention. The concentric-eccentric contraction training group showed improvement in functional capacity in daily living activities such as going up and down stairs (Gür et al., 2002).

The importance of the functional performance of individuals with KOA corroborates the need for a physiotherapeutic approach, showing the components of activities and participation in the different environments in which individuals are inserted, and not only at the structural level, as recommended by the Classification of Functioning, Disability and Health (ICF).

In this context, PNF emerges as a treatment concept which recommends performing exercises within a context of functionality that has been applied in several types of musculoskeletal disorders, with efficacy and safety, and in ICF (Adler et al., 2014; Guiu-Tula et al., 2017; Kim et al., 2019).

In performing the PNF combination of isotonic technique, it is possible to perform concentric, isometric and eccentric muscle contractions, promoting increased muscle strength and functional eccentric control of movement. The rhythmic initiation technique enables the individual to teach each movement, progressing from passive to free active exercises, facilitating motor initiation, coordination and sensation of movement (Adler et al., 2014).

PNF is based (Adler et al., 2014; Smedes et al., 2016) on control and motor learning principles, enabling functional activity retention learned through repetition and movement progression, which enables creating and recreating efficient functional movement strategies (Bertichamp, 2012). Moreover, it is known that the way practice is structured determines learning consolidation (Kantak et al., 2010). Based on these precepts, using treatment based on the PNF concept can enable functionality in individuals with neuromusculoskeletal disorders to be addressed from multiple perspectives, not only at the body structure level, but also at the activity and participation levels.

Despite the above information, only two studies (Weng et al., 2009; Chow et al., 2010) were identified using the PNF-concept in individuals with KOA. However, the PNF technique used in these protocols was contract-relax with its action being aimed at gaining flexibility. Thus, no studies using PNF techniques which are capable of teaching movement control have been identified so far, which can potentially generate benefits in important individual outcomes such as increased functional capacity and improved quality of life.

The present study aimed to develop a protocol to evaluate the efficacy of (PNF) compared to conventional physiotherapy (CPT group) on pain reduction and improvement in physical functioning, quality of life and adverse effects in individuals with knee osteoarthritis (KOA).

## **2. Methodology**

### **Trial design**

This is a controlled and randomized study protocol, including the elaboration of an intervention protocol based on the PNF-concept approved by the Ethics Committee in Human Research of the Health Sciences Center (Opinion number - 2.232.156). The study was registered in the Clinical trials digital platform (NCT02919020) according to recommendations of CONSORT (Moher et al., 2010).

The participants will be allocated into two groups: 1) PNF Group (intervention): submitted to a protocol composed of lower limb muscle strengthening exercises based on the principles of the PNF-concept; 2) conventional physiotherapy (CPT group): submitted to a protocol of lower limb muscle strengthening exercises described in the literature (Bennell et al.,

2014). The load progression will occur every three weeks, according to the Table 1. The study period is 12 weeks, with measurements at baseline (t0), 12th session - six weeks (t1), 24th session -12 weeks (t2) and three-month follow-up (t3).

**Table 1:** Protocol prescription.

<b>Variables</b>	<b>Prescription PNF</b>	<b>Prescription Control</b>
Frequency	2 times per week	<b>2 times per week</b>
Training Time	12 weeks	<b>12 weeks</b>
Number of sessions	24 sessions	<b>24 sessions</b>
Load Progression / Training volume	1st to 3rd weeks: 2 series of 3 repetitions	1st to 3rd weeks: 3 sets of 8 repetitions, intensity: 75% of 1RM
	4th to 6th weeks: 2 series of 4 repetitions	4th to 6th weeks: 3 sets of 8 repetitions, intensity: 80% of 1RM
	7th to 9th weeks: 2 series of 5 repetitions	7th to 9th weeks: sets of 6 repetitions, intensity: 85% of 1RM
	10th to 12th weeks: 2 series of 6 repetitions	10th to 12th weeks: 3 sets of 4 repetitions, intensity: 90% of 1RM
Interval between one series to the next	30 seconds	30 seconds
Interval between one exercise to the next	60 to 90 seconds	60 to 90 seconds
Session time	50 minutes	50 minutes
Follow-up	12 months	12 months

Legends: 1 RM= 1 Repetition Maximun. Source: Authors.

## Participants

Participants will be recruited from specialized out individual clinics. Inclusion criteria: (1) Age between 40 to 80 years old, men and women, with KOA, ICD-10: M17; (2) clinical diagnosis and confirmed by an radiography and/or Magnetic Resonance; (3) knee pain persisting for at least 3 months with pain severity during walking  $\geq 2/10$  on a Numeric Rating Scale; (4) not engaged in physical activity or other physical therapy treatment modalities during the protocol period including follow up; and (5) who has knee flexion range of motion (ROM) of at least 90°. Exclusion criteria: (1) Diagnosis of other associated rheumatologic diseases and/or diagnosis of neurological diseases.

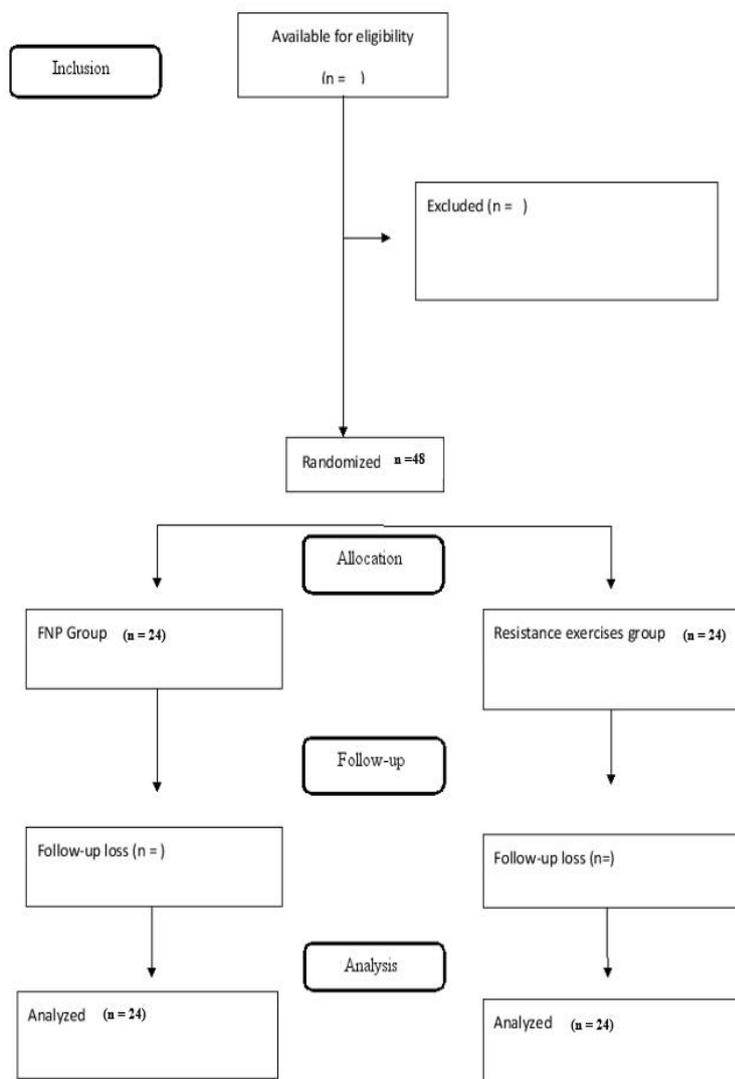
## Recruitment

Participants' recruitment will be consecutive and carried out by one researcher (A), who will collect clinical and sociodemographic data.

## Randomization and allocation concealment

Participants who meet the eligible criteria will be randomized, after the initial assessment, into two groups: PNF-concept (PNF group) or conventional physical therapy (CPT group) through a random sequence generated in the website randomization.com, with an allocation rate of 1:1. The block randomization will be carried out by a research assistant (B) without involvement in the study. The cards will be stored in identical, opaque and sealed envelopes. The group allocation number will be kept confidential and open on the day of the intervention by the physiotherapist responsible for this procedure. The sample capture flowchart is shown in Figure 1.

**Figure 1:** Flowchart of sample capture.



Source: Authors.

## Blinding

Both participants and researcher (A) will be masked in relation to the allocation of treatment. The blinding of the participants will be guaranteed if they carry out the sessions at individualized times, since both groups will be submitted to exercises. However, due to the nature of the intervention, the physiotherapist responsible for the treatment (C) cannot be blind. In addition, all statistical analyzes will be carried out by researcher (D), blind to the allocation of groups.

## Interventions

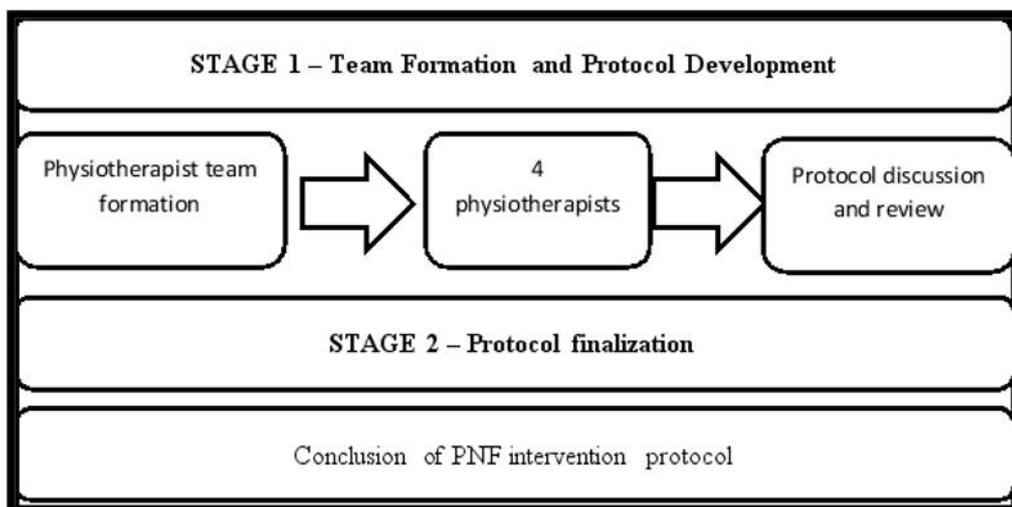
Two weekly sessions will be carried out over a 12 weeks period in both groups, by researcher (C) who should present with the required expertise for conducting the interventions. Each session has approximately a 50-min duration (Table 1).

## PNF Group

The elaboration of the protocol (Figure 2) based on the PNF-concept was performed by researchers from the Department of Physical Therapy at the Federal University of Pernambuco and the Federal University of Rio de Janeiro,

Brazil. The protocol complies with the recommendations of the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) (Chan et al., 2013).

**Figure 2:** Main stages of the PNF protocol structuring.



Source: Authors.

A team of four PNF-trained physiotherapists was formed to develop the PNF-concept based rehabilitation protocol for KOA individuals; Two of them are conceptual PNF instructors, one being an advanced instructor, both certified by the International Proprioceptive Neuromuscular Facilitation Association, and all have experience in rehabilitation of individuals with musculoskeletal disorders.

The research team met six times for discussion, review, and conclusion of the protocol before (Figure 2). The exercise protocol recommends performing movements which work the same muscle groups and perform similar activities to those described by Bennel et al, 2014 adapted to the PNF principles, procedures, and techniques.

Thus, manual contacts were made at specific points in the joints and auditory and visual stimuli in order to direct movement implementing a functional approach. Thus, protocol based on the PNF-concept consists of seven exercises which are described in the Table 3.

**Table 3:** Intervention protocol with proprioceptive neuromuscular facilitation (PNF).

<b>Neuromuscular Facilitation Protocol for Osteoarthritis</b>			
<b>Exercise 1</b>	<b>BRIDGE</b>		
<b>Volunteer positioning</b>	<b>Therapist positioning and action</b>	<b>Load progression</b>	<b>Images</b>
<p>Lying supine with hips and knees bent and feet flat on the mat. Wear an elastic band around the knee to maintain femoral alignment</p>	<p>The physiotherapist stands beside patient and maintains manual contact on iliac crest, stabilizing pelvis with resistance to upward movement.</p> <p>In the rhythmic initiation technique, the patient is asked:</p> <p><i>“Help me bring your hips up and relax on the return”; “Push my hand bringing your hip up and relax on the return”; “Bring your hips up by yourself, and relax on the return”</i></p> <p>Repeat each phase 3 to 4 times.</p> <p>In the combination of isotonic technique, the patient is asked:</p> <p><i>“Raise your hip, support and allow me to push you down without relaxing”.</i></p>	<p><b>1<sup>st</sup> session:</b> Use rhythmic initiation technique (progress from assisted active to free active movement)</p> <p><b>2<sup>nd</sup> to 24<sup>th</sup> session:</b> Combination of isotonic technique.</p> <p><b>1<sup>st</sup> to 3<sup>rd</sup> weeks:</b> 2 series of 3 repetitions</p> <p><b>4<sup>th</sup> to 6<sup>th</sup> weeks:</b> 2 series of 4 repetitions</p> <p><b>7<sup>th</sup> to 9<sup>th</sup> weeks:</b> 2 series of 5 repetitions</p> <p><b>10<sup>th</sup> to 12<sup>th</sup> weeks:</b> 2 series of 6 repetitions</p>	

<b>Exercise 2</b>	<b>SIDE DECUBITUS</b>
<p><b>Biomechanical Proposal:</b> Work lower limb musculature, prioritizing hip extensors and abductors; knee extensors and plantar flexors, facilitating the use of the lower limb for extensor activities.</p>	
<p><b>Caution:</b> Therapist should be mindful of patient's body alignment.</p>	

Volunteer positioning	Therapist positioning and action	Load progression	Images
<p>dorsiflexion and ankle inversion.</p>	<p>In the rhythmic initiation technique, the patient is asked: <i>“Let me bring your leg and your foot up”</i>; <i>“Help me bring your leg and your foot up and relax on the return”</i>; <i>“Push my hand bringing your leg and your foot up and relax on the return”</i>; <i>“Bring your leg and foot up by yourself, and relax on the return”</i> Repeat each phase 3 to 4 times.</p> <p>In the combination of isotonic technique, the patient is asked: <i>“Put your toe down, bring the heel up, extend your knee and leg. Raise your leg, maintain the contraction, and let me take your leg down in control”</i></p>	<p><b>2<sup>nd</sup> to 24<sup>th</sup> session:</b> Combination of isotonic technique.</p> <p><b>1<sup>st</sup> to 3<sup>rd</sup> weeks:</b> 2 series of 3 repetitions <b>4<sup>th</sup> to 6<sup>th</sup> weeks:</b> 2 series of 4 repetitions <b>7<sup>th</sup> to 9<sup>th</sup> weeks:</b> 2 series of 5 repetitions <b>10<sup>th</sup> to 12<sup>th</sup> weeks:</b> 2 series of 6 repetitions</p>	<div style="text-align: center;">  <p>Initial position</p> </div> <div style="text-align: center;">  <p>Final position</p> </div>

Exercise 3		SURAL TRICEPS	
<p><b>Biomechanical Proposal:</b> Strengthen lower limbs and optimize balance in standing position, making it easier for them to perform daily life activities such as getting up to grab something and walking.</p>			
<p><b>Caution:</b> Perform the exercise with the patient leaning on a firm and safe surface, preventing fall occurrences.</p>			
Volunteer positioning	Therapist positioning and action	Load progression	Images
<p>In front of the backrest, standing upright with both legs flat on the floor</p>	<p>Therapist positions their hands above the patient's iliac crests and prompts them to stand up and then the patient goes down without touching their heel to the floor.</p> <p>In the rhythmic initiation technique, the patient is asked: "Let me help you me get up and be on your tip-toes and relax on the return"; "Get up on your tip- toes against my resistance and relax on the return"; "Get up on your tip-toes alone and relax on the return" Repeat each phase 3 to 4 times.</p> <p>In the combination of isotonic technique, the patient is asked: "Get up on your tip-toes, hold on, let me pull you down slowly".</p>	<p><b>1<sup>st</sup> session:</b> Use rhythmic initiation technique (progress from passive to free active movement)</p> <p><b>2<sup>nd</sup> to 24<sup>th</sup> session:</b> Combination of isotonic technique.</p> <p><b>1<sup>st</sup> to 3<sup>rd</sup> weeks:</b> 2 series of 3 repetitions <b>4<sup>th</sup> to 6<sup>th</sup> weeks:</b> 2 series of 4 repetitions <b>7<sup>th</sup> to 9<sup>th</sup> weeks:</b> 2 series of 5 repetitions <b>10<sup>th</sup> to 12<sup>th</sup> weeks:</b> 2 series of 6 repetitions</p>	

<b>Exercise 4</b>	<b>SITTING AND STANDING FROM A CHAIR</b>
<p><b>Biomechanical Proposal:</b> Prepare hip and lower limb extensor muscles to promote strength, balance and coordination for patients in the progressive development of functional activities such as sitting and standing from a chair until gait is performed.</p>	
<p><b>Caution:</b> Do not allow the volunteer's toes to move off the floor during the lifting movement.</p>	

Volunteer positioning	Therapist positioning and action	Load progression	Images
<p>In sitting position, upright spine, feet flat on the floor, 90 ° hip flexion and knee flexion varying 90 ° - 100 °. Put an elastic band around the legs to prevent medial collapse of the knee.</p>	<p>Therapist with manual contact above the iliac crests, resists the patient's pelvis in retroversion and tilts the trunk forward.</p> <p>In the rhythmic initiation technique, the patient is asked: "My help to get up and relax on the return"; "Stand up against my resistance and relax on the return"; "Get up alone and relax on the return" Repeat each phase 3 to 4 times.</p> <p>In the combination of isotonic technique, the patient is asked: <i>"Incline your trunk forward and get up, hold, incline your trunk forward and go down in a controlled manner, without sitting in the chair"</i>.</p>	<p><b>1<sup>st</sup> session:</b> Use rhythmic initiation technique (progress from passive to free active movement)</p> <p><b>2<sup>nd</sup> to 24<sup>th</sup> session:</b> Combination of isotonic technique.</p> <p><b>1<sup>st</sup> to 3<sup>rd</sup> weeks:</b> 2 series of 3 repetitions <b>4<sup>th</sup> to 6<sup>th</sup> weeks:</b> 2 series of 4 repetitions <b>7<sup>th</sup> to 9<sup>th</sup> weeks:</b> 2 series of 5 repetitions <b>10<sup>th</sup> to 12<sup>th</sup> weeks:</b> 2 series of 6 repetitions</p>	

<b>Exercise 5</b>	<b>LATERAL WALK</b>
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<p><b>Biomechanical Proposal:</b> Improving joint proprioception and strengthening hip abductor muscles, allowing greater balance in standing position and improving gait performance.</p> <p><b>Cautions:</b> Do not allow the patient to attempt to compensate for movement by tilting their trunk to the contralateral side or flexing their hip.</p>
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Volunteer positioning	Therapist positioning and action	Load progression	Images
<p>In standing position with support of upper limbs on the wall (can use the backrest or parallel bars)</p>	<p>Therapist stands beside patient resisting contralateral leg abduction.</p> <p>In the rhythmic initiation technique, the patient is asked: <i>“Let me bring you to my side and relax on the return”</i>; <i>“Help me to bring you to my side and relax on the return”</i>; <i>“Come to my side against my resistance and relax on the return”</i>; <i>“Come to my side and relax on the return”</i>                      Repeat each phase 3 to 4 times.</p> <p>In the combination of isotonic technique, the patient is asked: <i>“Hold, let me push you, hold, push me”</i></p>	<p><b>1st session:</b> Use rhythmic initiation technique (progress from passive to free active movement)</p> <p><b>2<sup>nd</sup> to 24<sup>th</sup> session:</b> Combination of isotonic technique.</p> <p><b>1<sup>st</sup> to 3<sup>rd</sup> weeks:</b> 2 series of 3 repetitions</p> <p><b>4<sup>th</sup> to 6<sup>th</sup> weeks:</b> 2 series of 4 repetitions</p> <p><b>7<sup>th</sup> to 9<sup>th</sup> weeks:</b> 2 series of 5 repetitions</p> <p><b>10<sup>th</sup> to 12<sup>th</sup> weeks:</b> 2 series of 6 repetitions</p>	

<b>Exercise 6</b>	<b>GOING UP AND DOWN STAIRS</b>
<p><b>Biomechanical Proposal:</b> Improve knee joint coaptation and lower limb muscle strengthening, increase joint proprioception and prepare the individual for the progression of functional activities (i.e.: up and down stairs, up and down sidewalks, walking).</p>	
<p><b>Caution:</b> Avoid leaning the trunk forward to compensate for movement during the step-up movement.</p>	

Volunteer positioning	Therapist positioning and action	Load progression	Images
<p>The volunteer stands in an upright position facing a step, with one foot resting on the step and one foot in contact with the ground. It is recommended to use a step with a handrail.</p>	<p>The physiotherapist stands behind patient with hands above the iliac crests and prompts them to raise their leg on the ground toward the next step.</p> <p>In the rhythmic initiation technique, the patient is asked: <i>“Come up with me and relax on the return”</i>; <i>“Step up against my resistance and relax on the return”</i>; <i>“Step up alone and relax on the return”</i> Repeat each phase 3 to 4 times.</p> <p>In the combination of isotonic technique, the patient is asked: <i>“Get on the step, hold it, let me bring you down without touching your foot, hold it”</i></p>	<p><b>1<sup>st</sup> session:</b> Use rhythmic initiation technique (progress from passive to free active movement)</p> <p><b>2<sup>nd</sup> to 24<sup>th</sup> session:</b> Combination of isotonic technique.</p> <p><b>1<sup>st</sup> to 3<sup>rd</sup> weeks:</b> 2 series of 3 repetitions <b>4<sup>th</sup> to 6<sup>th</sup> weeks:</b> 2 series of 4 repetitions <b>7<sup>th</sup> to 9<sup>th</sup> weeks:</b> 2 series of 5 repetitions <b>10<sup>th</sup> to 12<sup>th</sup> weeks:</b> 2 series of 6 repetitions</p>	

<b>Exercise 7</b>	<b>SQUATTING</b>
<p><b>Biomechanical Proposal:</b> Strengthen the hip and lower limb muscles, improve joint stability and enhance performance in performing activities of daily living (e.g., sitting, standing and walking).</p>	
<p><b>Cautions:</b> If the patient feels insecure and has difficulty maintaining balance while moving, he/she can maintain support on the handrail.</p>	

Volunteer positioning	Therapist positioning and action	Load progression	Images
<p>In orthostatic posture with legs wrapped around an elastic band to maintain femur alignment.</p>	<p>The physiotherapist is in a half kneeling position behind the patient and maintaining manual contact above the iliac crests and asks the patient to ascend.</p> <p>In the rhythmic initiation technique, the patient is asked: <i>“Come up with me and relax on the return”</i>; <i>“Come up against my resistance and relax on the return”</i>; <i>“Go up alone and relax on the return”</i>                      Repeat each phase 3 to 4 times.</p> <p>In the combination of isotonic technique, the patient is asked: <i>“Hold, let me bring you down controlled, hold, go up”</i></p>	<p><b>1<sup>st</sup> session:</b> Use rhythmic initiation technique (progress from assisted active to free active movement)</p> <p><b>2<sup>nd</sup> to 24<sup>th</sup> session:</b> Combination of isotonic technique.</p> <p><b>1<sup>st</sup> to 3<sup>rd</sup> weeks:</b> 2 series of 3 repetitions <b>4<sup>th</sup> to 6<sup>th</sup> weeks:</b> 2 series of 4 repetitions <b>7<sup>th</sup> to 9<sup>th</sup> weeks:</b> 2 series of 5 repetitions <b>10<sup>th</sup> to 12<sup>th</sup> weeks:</b> 2 series of 6 repetitions</p>	

Source: Authors.

The PNF techniques chosen to be performed in the protocol were rhythmic initiation and combination of isotonic. The first session of the protocol was instituted so that the rhythmic initiation technique was exclusively performed given the difficulty for some individuals in understanding and coordinating the movement, since it advocates a progression of movements through passive until free active movement, thus facilitating the motor initiative and movement coordination, teaching and directing the correct performance of the activity to the individual (Adler et al., 2014).

The technique implemented in the other sessions was a combination of isotonic, consisting of concentric-eccentric contractions interspersed with isometric contractions, increasing coordination and active movement control (Adler et al., 2014; Smedes et al., 2016) thus favoring functional eccentric control which is essential for performing daily life activities such as sitting and getting up from a chair, crouching and walking.

Considering the heterogeneity of rehabilitation programs for people with KOA in relation to exercise prescription (number of sessions, frequency, time, volume and intensity), we based our protocol on recommendations from articles or guidelines of societies in the musculoskeletal or related areas.

Regarding training frequency, the American Society of Geriatrics (2001) and the American College of Sports Medicine (2012) recommend that neuromotor exercise training be performed for two to three times a week. Thus, considering the socioeconomic profile of our population and the greater possibility of treatment adherence, we chose to perform a protocol which institutes a training of two times per week.

Results of a systematic review showed that a training time with resistance exercise during 12 weeks has significant effects (moderate effect size) on treating pain, function and stiffness in individuals with knee osteoarthritis, thus we adopted this training time period for our protocol application (Li et al., 2016).

Although the American College of Sports Medicine (2012) recommends that strength training take place with maximal repetition (1RM) load progression, our study institutes training progression based on increased repetitions of each exercise, since we only use manual resistance as a load in this protocol. Therefore, we followed a strength training study in arthritis individuals (Messier et al., 2013), wherein training progression occurs every three weeks.

Table 1 shows the progression of each exercise following the recommendations of the American Society of Geriatrics<sup>18</sup>, describing strength training (Messier et al., 2013) over twelve weeks (Li et al., 2016).

The protocol for the treatment of individuals with KOA based on the PNF concept is described in detail in steps in Table 3.

### **CPT group**

In the Control group, the physiotherapist is instructed to provide habitual exercise therapy to individuals with knee OA, as proposed by Bennel et al.<sup>5</sup> The prescription and exercise progression of individuals allocated to the control group are described in detail in Table 1. This protocol consists of eight lower limb exercises, such as: Sitting knee extension, Partial wall squats, Sit to stand, Standing hip abduction, Seated knee bending, Step Ups, Step Downs, Standing calf raises.

### **Criteria for study discontinuity**

During the period corresponding to the performance of the protocols (PNF group and CPT group), individuals are instructed not to seek other types of operations or treatments with physical exercises, in order to ensure comparability between groups. Those individuals who discontinue the study should be included in the intention to treat analysis.

#### Treatment Adherence

Some strategies will be listed in order to secure that individuals adhere to treatment. Among them we can highlight: (1) Keeping the patient and his family aware of the disease and the objectives of the proposed treatment, (2) Establishing regular communication with the individuals to carry out the scheduling of the sessions according to the individual availability of each participant, (3) Motivate the individual to participate actively and collaboratively during the intervention period.

#### Outcome assessment

The data collected and the instruments used are shown in the Table 4.

Measurements will be taken at baseline (t0), 12th session - 6 weeks (t1), 24th session - 12 weeks (t2) and 3 months of follow-up (t3). The outcomes will be evaluated by a physiotherapist (Researcher "B") who was unaware of the protocol performed by the participants.

#### Primary outcomes:

The "pain domain" from the Western Ontario and McMaster Universities Questionnaire (WOMAC) will be used to assess the referred knee pain intensity, which contains 5 questions scored from 0 to 4. Thus, the score can range from 0 to 20, in which a higher score corresponds to greater pain intensity. The questions evaluate the pain intensity in performing certain movements and/or functional activities (walking, climbing or descending stairs, sitting or lying down, standing) (Belamy et al., 1988).

The "physical function domain" from Western Ontario and McMaster Universities Questionnaire (WOMAC) will be used to assess physical knee function, which contains 17 questions scored from 0 to 4. Thus, the score can vary from 0 to 68, without a higher score corresponding to a worse knee function<sup>22</sup>. Furthermore, the physical function will be assessed using three tests which are recommended by the Osteoarthritis Research Society International (OARSI) (Dobson et al., 2013):

- i. Sitting and rising from a chair during 30 seconds: The volunteer will begin seated in a chair with their feet flat on the floor, and will start from the verbal command "go", get up from the chair, and then return to the sitting position, repeating this action for 30 seconds;
- ii. 40-meter walk test with quick steps: The individual will walk four laps with a distance of 10 meters between one cone and another with quick steps, resulting in a total of 40 meters. The evaluator will record the test time.
- iii. Climbing test: The volunteer will get up and down a four-step flight of stairs, and the examiner will record the time to perform the test.

#### Secondary outcome: Quality of life and evaluation of adverse effects.

Quality of life: The SF-36 is a self-administered questionnaire that aims to assess quality of life. It consists of 8 domains with a total of 36 questions. The score ranges from 0 to 100, where higher scores advanced a better health status.

Evaluation of adverse effects: The presence of adverse effects will be assessed by the following questions: "Did you feel muscle pain in your knee, thighs or legs after exercise?"; "Did you feel knee joint pain after exercise?"; "Was it necessary to use pain medication after performing the protocol activities?" The record will be made from medical records based on individual reports of the presence of pain or discomfort after and between each treatment session. Adverse effects

will be considered: knee joint pain and muscle pain (quadriceps femoris, hamstrings and triceps suralis).

At the end of the 12 weeks of evolution, a global assessment of the effects of the intervention will be carried out by respondent B, who will apply the Global Impression Scale for Patient Change in the Portuguese version (PGICVP), which has a validity of tall and negative construct ( $r = - 0.822$ ) (Domingues et al., 2014).

**Table 4:** Summary of Outcome.

Outcome	Outcome measurement	Timelane for Date
<b>Primary</b>		
Pain	The “pain domain” from the Western Ontario and McMaster Universities Questionnaire (WOMAC), which contains 5 questions scored from 0 to 4. Thus, the score can range from 0 to 20. (Bellamy, Buchanan, Goldsmith, Campbell e Stitt, 1988).	baseline (t0), 12th session - 6 weeks (t1), 24th session - 12 weeks (t2) and 3 months of follow-up (t3)
Physical functioning	Western Ontario and McMaster Universities Questionnaire (WOMAC) was used to assess physical knee function, which contains 17 questions scored from 0 to 4. Thus, the score can vary from 0 to 68. (Bellamy et al., 1988)  Sitting and rising from a chair during 30 seconds;  40-meter walk test with quick steps;  Climbing test. (Dobson et al., 2013)	baseline (t0), 12th session - 6 weeks (t1), 24th session - 12 weeks (t2) and 3 months of follow-up (t3)
<b>Secondary</b>		
Quality of life	Medical Outcomes Study 36 – Item Short – Form Health Survey (SF-36). It consists of a 36-item questionnaire divided into 8 domains: functional capacity, physical aspects, pain, general health, vitality, social aspects, emotional aspects and mental health. (CICONELLI et al., 1999).	baseline (t0), 12th session - 6 weeks (t1), 24th session - 12 weeks (t2) and 3 months of follow-up (t3)
Treatment satisfaction	Patient Global Impression of change scale – Portuguese Version – PGICVP) (1-7 score, where “1= no change or worse” and “7= a great deal better”	12 weeks
Treatment adherence	Number of absences and dropouts recorded by research C	12 weeks
Adverse events	Ocurrence of adverse events recorded by research C	Weekly

Source: Authors.

### Sample Size

The sample size was based on primary outcomes, knee pain and physical function, due to its relevance in reflecting the success of treatment in daily activities. Sample size was determined using G\*Power Software 3.1.9.4 (Düsseldorf, Germany), considering ANOVA for two groups, four repeated measurements, with significance level of 0.05, a power of 0.80

and an effect size of 0.49 (knee pain on 0-10 scale) and 0.52 (physical function on 0-100 scale) (Fransen et al., 2015). Based on these criteria, at least 48 participants (24 per group) will be needed.

### Statistical methods

Data will be analyzed using the SPSS version 20.0 program. A descriptive analysis will be performed by calculating the mean (M) of measurement variables and standard deviation (SD). The Kolmogorov-Smirnov test will be used for the normality test of the variables. The Mann-Whitney test will be used for the non-parametric variables, considering a significance level of  $p < 0.05$ . A mean difference will be calculated and a 95% confidence interval (95% CI) will be considered. Intention-to-treat will be performed.

### 3. Results and Discussion

The PNF aims to explore the individual's ability to access their highest level of capacity, through proprioceptive and exteroceptive stimuli, within a functional biomechanical context, facilitating isometric, concentric and eccentric muscle contractions (Adler et al., 2014). In this sense, rehabilitation through the performance of functional activities is paramount, since motor learning and restoration of functionality involve the reorganization of perception related to the activities and environments where they are performed (Shumway & Woolacott, 2012).

Although PNF has been used in physiotherapy to treat various muscle disorders (Feber et al., 2002; Kofotolis et al., 2006), there are few studies that evaluate its application in individuals with KOA (Weng et al., 2009; Chow et al., 2010). Furthermore, the protocols available in the literature do not provide information that is necessary for replication. This becomes especially worrying, considering the importance that the PNF has been showing a process of rehabilitation of disfunctions caused by musculoskeletal diseases. Despite this importance, studies that use PNF in individuals with KOA have low methodological rigor and evaluate only the range of motion, muscle strength and pain (Weng et al., 2009; Chow et al., 2010).

Thus, the present study aims to develop a protocol for the rehabilitation of individuals diagnosed with KOA, based on the philosophy of the PNF involving motor learning and control (Anastakis et al., 2008) and having as a guide a protocol available in the literature (Bennell et al., 2014) that works with movement that involves the same muscle groups.

Furthermore, the aim of this study is to describe the steps and methods of a randomized clinical trial designed to test the effectiveness of PNF treatment in individuals with knee osteoarthritis in the future. The intervention group receives treatment based on the concept of PNF and the control group receives treatment with conventional physiotherapy.

The literature shows that PNF increases the functional capacity of individuals with muscle disorders due to myoreceptor and exteroceptor stimuli that trigger neurophysiological changes, thus promoting memories of motor skills (Li et al., 2016).

This can also be explained by motor control and the learning process. This is because motor control allows the domain of movement to develop a specific activity and not just isolated movements, organizing the movement around objective-oriented functional behaviors (Greene, 1982). In addition, the internal processes associated with the experience promote changes in the ability to produce certain motor activities (Cano-de-la-Cuerda et al., 2015). Thus, what is learned is retained or stored in the brain, constituting memory (Correa et al., 2007).

Finally, we emphasize the applicability of this protocol, as there are few describing studies (Weng et al., 2009; Chow et al., 2010) describing the approach through PNF as a desired physical therapy treatment with knee osteoarthritis. This proposal of physical therapy intervention is of low cost, since there are no resources to apply the protocol. The description of the exercises is presented in a clear and organized way in a sequenced and illustrative layout. Furthermore, the individuality of each patient is considered in the prescription of exercise intensity, frequency, resistance and progression time.

As study limitations, we emphasize that to ensure a high performance of the intervention, it is advisable for the physical therapist to have experience with the use of PNF in practice. In addition, another limitation to be highlighted is the impossibility of blinding the physiotherapist, considering that the PNF is inherent to the knowledge of physiotherapy, however, an evaluation of the outcomes can be blinded by the evaluators.

#### **4. Conclusion**

The PNF protocol was described with details that allow easy applicability. The development of the randomized clinical trial protocol will produce evidence about PNF compared to usual resistance exercises, in reducing pain and improving physical function and quality of life according to KOA.

Thus, this protocol shows that it can be used in clinical practice and in future research with this population. It is suggested that further clinical trial studies be performed using this protocol, its practice in clinical practice.

#### **Implications for physiotherapy practice**

The rehabilitation of individuals with knee osteoarthritis must be based on the principles of learning and motor control in order to ensure functional recovery and improved quality of life. The therapeutic approach based on the PNF principles allows you to simulate activities of daily living. This protocol is feasible and can be used in physical therapy practice in future research with controlled and randomized clinical trials.

#### **Conflict of Interest**

The authors declare that there is no conflict of interest.

**Clinical Trials Registration Number:** NCT02919020

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