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The effect of acupuncture at St34 on the patellar reflex – a prospective randomized, controlled clinical study

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DISSERTAÇÃO DE MESTRADO APRESENTADA
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The effect of acupuncture at St34 on the patellar reflex – a prospective randomized, controlled clinical study

Dissertação de Candidatura ao Grau de Mestre em Medicina Tradicional Chinesa submetida ao Instituto de Ciências Biomédicas Abel Salazar da Universidade do Porto.

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DEDICATION

To my son, who follows me on this adventure since the very beggining.

ACKNOWLEDGMENTS

To my wife and son, for all the times that I was not present and for all the support, patience and joy for beeing part of my life.

To my parents and brother for the future good ahead.

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To all the participants of this study, for making this study possible.

RESUMO

Introdução: A debilidade do músculo quadríceps pode ser um dos principais fatores de patologias do joelho, como a síndrome da dor patelo-femoral.
A condição, que geralmente tem início repentino, é caracterizada por uma dor difusa nas imediações da patela [39, 47, 53].
A incidência na população geral é relatada como sendo tão elevada como um em cada quatro indivíduos, com esta proporção aumentada na população atlética [39, 53].

O músculo quadríceps é o principal músculo extensor do reflexo patelar, desempenhando assim um papel importante na amplitude do movimento. Um aumento na força muscular traduz-se num aumento da amplitude e vice-versa.

O objetivo deste estudo foi verificar se a acupuntura produz um efeito no reflexo patelar de individuos saudáveis, de forma a inferir um aumento da potência muscular do quadriceps.

Metodologia:
Foi realizado um estudo clínico, prospectivo, randomizado e controlado com 45 indivíduos saudáveis com idades entre os 18 e 69 anos, de ambos os sexos (32 mulheres e 13 homens).
Os critérios de exclusão foram compostos por, prejuízo significativo motor, dor ciática, lombalgia, distúrbios dentro da prótese sacral-ilíaca ou ortopédicas (joelho ou pélvicas), gravidez, história de debilitante lesão nos últimos três meses, transtorno de artrite da coluna vertebral, e história de distúrbio no sistema nervoso periférico/central ou neuromuscular.

Os indivíduos foram aleatoriamente distribuídos por ordem de chegada em três grupos: controle (n = 15), experimental (n = 15) e sham (n = 15). Analisamos a amplitude movimento e o tempo de reacção do reflexo patelar, antes e depois da intervenção no ponto de acupuntura Monticulus Septi (St34) do conduto estômago.
Na análise dos dados, foram apenas considerados 41 registos, devido a dificuldades na análise dos mesmos. A distribuição final foi: controle (n=14), experimental (n=12) e Sham (n=15).

Resultados:

No grupo experimental houve um aumento de 30,71% na amplitude do movimento do joelho após a intervenção, mostrando um resultado estatisticamente significativo (P = 0,023).

No grupo de controlo (-2,87) e grupo sham (-2,30) não foram obtidas melhorias significativas (P = 0,768 e P = 0,838, respectivamente).

Relativamente ao tempo de reação, o grupo experimental, grupo de controlo e grupo sham não mostraram alterações significativas.

Conclusão:

Este trabalho sugere que o ponto de acupuntura St34 tem um efeito específico na amplitude do movimento do reflexo patelar, permitindo especular que houve um aumento da força muscular do músculo quadríceps devido a um maior número de unidades motoras recrutadas.

Palavras-chave: Anatomia do joelho, acupunctura, muscúlo quadriceps, patologias do joelho, reflexo patelar.

ABSTRACT

Background: Weakness of the quadriceps muscle may be one of the main factors of knee pathologies such as the patella-femoral pain syndrome.
The condition, which generally has sudden onset, is characterized by a diffuse ache in the vicinity of the patella [39, 47, 53].
The incidence in the general population is reported to be as high as one in four with this proportion increasing in the athletic population [39, 53].

The quadriceps muscle is the main extensor muscle in patellar reflex, thus playing a major role in the range of motion. An increase in muscle power translates into an increase of the amplitude and vice-versa.

The objective of this study was to determine whether acupuncture produces an effect on the patellar reflex of healthy individuals in order to deduce an increase in muscle strength of the quadriceps.

Metodology: We performed a prospective, randomized, controlled, clinical study with 45 healthy individuals aged between 18 to 69 years old, of both genders (32 women and 13 men).
The exclusion criteria were significant motor impairment, sciatic pain, lumbago, disorders within the sacral-iliac or orthopedic prosthesis (knee or pelvic), pregnancy, history of debilitating injury within the previous three months, spinal arthritic disorder, and history of a central/peripheral nervous system or neuromuscular disorder.

The individuals were distributed randomly in order of arrival in three groups: control (n=15), experimental (n=15) and sham (n=15). We analized the amplitude (range of motion) and reaction time of the patellar reflex, before and after the intervention in the acupunture point Monticulus Septi (St34) of the stomach conduit.
In the data analysis, were only considered 41 records, due to difficulties in analyzing the data collected. The final distribution was: control (n = 14), experimental (n = 12) and Sham (n=15).

Results:

In the experimental group there was an increase of 30,71% in the range of motion of the knee after intervention, showing a statistically significant result (p=0,023).
In the control group (-2,87) and sham group (-2,30) no statistically significant improvements were obtained (p=0,768 and p=0,838 respectively).
For time of reaction, none of the groups showed significant changes.

Conclusion: This work suggests that the acupuncture point St34 has a specific effect on increasing the range of motion of the patellar reflex, thereby we may speculate that it improve the recruitment of motor units promoting that way the increase of the muscular power of the quadriceps muscle.

Keywords: Knee anatomy, acupunture, quadriceps muscle, knee patologies, patellar reflex.

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Part III

Introduction

The patella-femoral pain syndrom affects one in four individuals in the general population. There are several factors that may be at the source, including the abnormal mechanics of the lower limbs, improper physical activity and weakness of the quadriceps in particular the oblique medial vast. This condition develops gradually and is characterized by diffuse pain in the area of the patella. Pain is a significant factor as it will change the functions and inhibit muscle activity.

Chondromalacia is an example of this syndrome, characterized by a softening of the articular cartilage. Is a degenerative process, probably by traumatic origin, most frequently of the patella first described in 1924 by Aleman.[1]

Is characterized by pain, swelling and retropatellar crackling described as an uncomfortable creaking sensation, as well as an increase in local sensitivity that is associated with functional imbalance of the quadríceps, especially with atrophy of the vastus medialis and the shortening of the iliotibial tract [45,4,71,59,74,78].

The chondromalacia patella often affects athletes and sedentary population, specially females, being young women the most affected (due to women to have wider hips, the femur rotates internally causing lateralization of the patella), constituting 25% of the lesions that compromise the knee and 5% of all sports injuries, representing a common complaint in 20% of the population. [4,6,11,13].

The knee extensor muscles, holds an important role on the patella working in four forces, two vertical up of the rectus femoris and vastus intermediate, an oblique left up the vastus lateralis and another oblique right up represented by oblique medial vast. The combined pull of these muscles allows the patella to slide properly on the intercondylar notch or trochlear groove.

In order to evaluate possible changes in muscle strength of the quadriceps muscle, we analyzed the patellar reflex of 45 healthy individuals to verify changes in range of motion and reaction time between the percussion with the reflex hammer and the onset of reflex movement, before and after the intervention of acupuncture.

Since the quadriceps muscle is the main extensor muscle in patellar reflex, it plays a major role in the amplitude of the motion. An increase in muscle power translates into an increase of the amplitude and vice-versa.

Acupuncture in the West, particularly in Europe arises in the second half of the last century, and despite some resistance because it was an alternative to the existing medicine and reduced scientific evidence, its success is recognized by the World Health Organization (WHO). Due to efforts of the scientific community worldwide over the last three decades of continuous and extensive, to prove the effectiveness of acupuncture, WHO has published several reviews and bibliographic analysis, editing a list of diseases, symptoms and health conditions that present fine results with acupuncture treatment. [77]

Acupuncture has shown to increase muscular power [28,30,54,79,81], to improve microcirculation [37], to release endogenous endorphins [31], to inhibit spinal and supra spinal nociceptive transmission [32]. Therefore, from a theoretical standpoint, acupuncture might be a low-cost, quick and low-risk treatment strategy for patelo-femoral syndrome pain treatment by improving the muscular power of the quadriceps muscle.

At the sporting level, for example, there has been an increasing use of acupuncture, as well as its credibility and acceptance by athletes, coaches and health professionals. It was primarily used for the treatment of sports injuries or conditions responsible for a reduction of the athlete's performance, such as chronic pain [77], osteoarthritis of the knee [12, 13], back pain [14] and anterior knee [15], more common in jumping sports such as volleyball.

In addition to the treatment of traumatic injury or overload, acupuncture also demonstrated its effectiveness in controlling or promoting a rapid relief of signs and symptoms related to fatigue [16] and muscle soreness induced by exercise enabling the athlete to rapid recovery and at the same time, restore its peak faster performance [64, 33].

The objective of this study was to verify whether acupuncture point St34 promotes a change in muscle power of the quadriceps muscle.
In the first part, a background is made covering the anatomy and biomechanics of the knee, the knee jerk, the main muscles responsible for the patellar reflex extension movement and also an aproach to the Heidelberg Model of Tradicional Chinese Medicine.
Part two consists in explaining the methodological procedures and acupuncture intervention, followed by the analysis of the results.
In the third part is presented the discussion of the results and final conclusions.

Part I

1. Knee anatomy and biomecanics

The knee joint plays a critical role in the anatomical and functional integrity of the organism. As part of the support of osteo-articular system, this joint is located at the ends of two important lever arms: the femur and the tibia [2].
The knee joint is known as a condyloid and middle joint of the lower limb, which works essentially in compression by gravity [25,35,62]. Plays the role of supporting the weight of the body and transmitting the forces from the ground, thus regulating the distance of the body in relation to the same in addition to allowing a high amount of movement between the femur and tibia.

When flexed (unstable position), the knee is more prone to meniscus and ligament injuries. In extension is more vulnerable to articular fractures and ligament ruptures.

The knee joint is comprised of the distal femur, proximal tibia and the patella, being divided in three compartments: medial tibiofemoral, lateral tibiofemoral and anterior patellofemoral.
The medial and lateral tibiofemoral, are the places where the medial and lateral femoral condyles make contact through an intermediary cartilage with the upper extremity of the tibia.
The femoral condyles appear as asymmetric prominences of the distal femur, projected less on the front and more sharply on the back of the bone shaft.
The lateral condyle, is flattened and tightly curved, having a largest area in the anterior surface and is aligned with the femur, thereby maintaining the patella in place. The medial condyle is more projected over the longitudinal and medial side being further longer anteroposterior and adopt an angle out of the femur being aligned with the tibia.

The articulation with the patella occurs through a special groove formed by the front part of the two femoral condyles that takes the name of trochlea.
The condyles lie on the tibial plateau (medial and lateral surface separated by a bony prominence) [63,25,66].
This bony prominence is called intercondylar eminence. In addition to being a place of insertion of ligaments, also serves the function of centering the articulation and stabilize the bone during weight bearing.

The medial surface of the tibial plateau has an oval shape and is longer in the anteroposterior direction and concave to accept the convex femoral condyle. The medial tibia and femur fit in effortlessly, yet, the lateral tibia and the femur does not fit because both surfaces are convex. This structural difference determines in part the rotation, since the lateral condyle has more excursion during flexion and extension of the knee [25].

The tibial tuberosity, that is the insertion point of the patellar ligament in the tibia, lies usually in the midline to the side, but occasionally may be located toward the lateral side, which causes the increase of the quadriceps angle (angle Q), contributing to a lateral rotation of the patella [73].

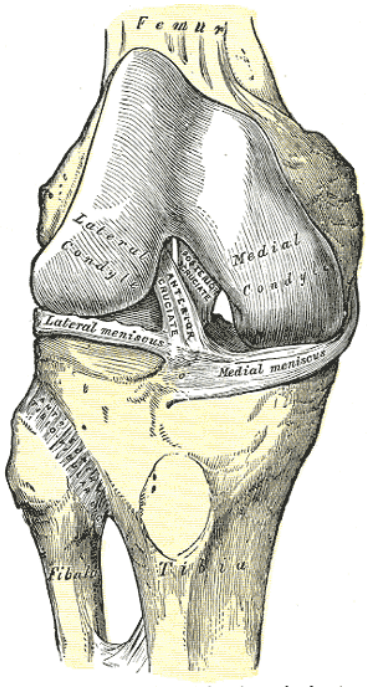


Fig. 1 - Knee anatomy [20]

Biomechanically, the knee-joint movement is measured around the three axes. The full extent of motion (0 °) to full flexion is approximately 140 °. The knee motion in the transverse plane, typically follows the flexion and extension and is referred to as the medial and lateral tibial rotation. No rotation is allowed when the knee is fully extended, however, up to 45 ° lateral rotation and 30º medial rotation 30 ° is possible when the knee is flexed to 90 °. At full extension, the rotation is restricted by the architecture of the bone joint, whereas beyond 90 ° of flexion the movement is limited by the soft tissue stretched around the joint [63].

1.1. Menisci

The menisci are fibrocartilaginous discs in the shape of crescent located between the femoral condyles and tibial plateaus.

The menisci are composed of three faces which Kapandji [35] comprise at: concave top which is in contact with the condyles; cylindrical peripheral, on which is fixed the capsule

for its deep and almost flat form, located in the outskirts of the internal and external glenoid.

As shown by Prentice et al. [62], these structures act to enhance knee stability, increase the absorption of impact and distribute the weight over a larger surface area, while protecting articular cartilage and underlying subchondral bone. The medial meniscus in particular, helps to stabilize the knee when a bending of 90 °.

The menisci transmit half of the contact force in the medial compartment and an even higher percentage contact load in the lateral compartment, and the loss of its function results in significant effects on the subchondral bone.

Biomechanically, the menisci limit the movement between the tibia and femur. In flexion and extension, the menisci move with the femoral condyles. As it gives the flexing of the legs, the menisci move later due to the rolling of the femur and to the muscular action of the popliteal and semimembranosus muscles. At the end of flexion, the menisci fill the posterior portion of the joint acting as a buffer. The opposite movement takes place to the extent where the quadriceps and the patella assist in moving the meniscus forward over the surface. Furthermore, the menisci follows the tibia during rotational movements [63,25].

1.2. Patella

The patella is a sesamoid bone, which is characterized by its development within a tendon, in this case from the quadriceps muscle. The patella protects the anterior side of the knee joint and acts as a type of pulley, changing the ligament insertion angle of the patella on the tibial tuberosity, increasing the mechanical advantage of the quadriceps [63].

The patella has as its most important function the facilitation of the knee extension, increasing the distance from the extender unit in relation to the axis of flexion and extension of the knee. The hyaline cartilage, with its firmness and hardly modifiable coefficient of friction is indispensable for the transmission of quadriceps strength around the distal femur and tibia.

It acts as a guide to the quadriceps tendon, by centralizing the divergent forces of the four muscles and send them to the patellar tendon, reducing the compression forces harmful to the quadriceps tendon during knee flexion. This reduces the possibility of dislocation of the extensor apparatus and controls the tension capsular knee.

The patella articulates with the anterior and distal surfaces in the form of a saddle and also protects the cartilage from the trochlea as well the condyles thus acting as a bone cover [69,18].

Distally, the patella is anchored in the tibial tuberosity by the patellar tendon where fibrous retinacula and muscles anchor the patella on each side. Laterally, it is stabilized by superficial and deep retinacula, the iliotibial tract and the vastus lateralis muscle.
The patella femoral ligament extends from the medial epicondyle of the femur to the medial superior border of the patella and is considered a static stabilizer of the patella, which resists lateral translation of the patella to prevent total subluxations or luxations.
During the full extent, the patella is slightly lateral and next to the trochlea. At 20 ° of knee flexion, the tibial rotation occurs and the patella moves into the trochlea. At 30 ° the patella is maximally prominent. From 30 °, the patella moves deeper into the the trochlea. At 90 ° the patella is positioned again laterally. When the knee flexion reaches 135 °, the patella moves laterally in relation to the trochlea.
Regarding movements, the patella moves up and down, occurring also inclinations and rotation, so that there is this major contact between the internal surface of the patella and the femur [62,45].

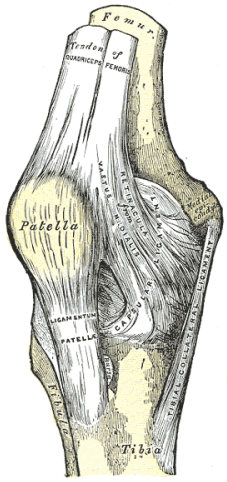


Fig. 2: Knee anatomy [20]

1.3. Muscles involved in the knee bio-mecanic

In order for the knee to perform its function properly, a number of muscles, total 12, must work together with all these highly complex bone structures, ligaments and capsular structures.

The knee flexion is performed by the biceps femoris, semitendinosus, semimembranosus, gracilis, sartorius, gastrocnemius, popliteal and plant, which are classified as hamstring group.

In addition, semitendinosus and semimembranosus medially rotate the tibia when the knee is flexed partly because the gastrocnemius muscles and plant, although acting in flexion, are potentially used by the ankle joint.

The extent and also medial rotation of the tibia (secondarily, because of its medial insertion) is performed by the quadriceps, comprising the vast medial, lateral and intermediate and rectus femoris, which is the only muscle of the four which operates in more than one joint.

Biomechanically, the knee-joint movement is measured around the three axes. The full extent of motion (0 °) to full flexion is approximately 140 °. The knee motion in the transverse plane, typically follows the flexion and extension and is referred to as the medial and lateral tibial rotation.

1.4. Tendon reflexes

The control of the posture and movement is performed, according Ghez, C. [19], by adjusting the contraction of skeletal muscles, which in turn requires that the motor system receives information from the periphery continuously.

The integration of this information, collected by the sensory receptors, access to different levels of the central nervous system according to their increasing complexity, in order to provide the most appropriate response to each type of stimulus.

According Bizzi et al. [5], the muscles, the organs responsible for motor response, act as if they were "elastic springs" adjustable, in which the power of the work done is directly related to the degree of stretch with the intensity of neuronal stimulation.

Thus, taking into account that the muscles are divided under the functional point of view and in relation to the joints, for agonists and antagonists, Bizzi et al. [5], consider that the balance between these two muscle groups, is dependent on factors such as the stimulation performed by motoneurons that innervate both muscle groups (agonists and

antagonists), the stretch-strain and the elastic properties of the muscle fibers comprising these muscles and the extrinsic forces that they exert on.

In this type of motor response, action potentials in sensory receptors are originated by the action of a specific stimulus and conducted through the sensory pathways, the motor nerve cells found in the anterior horns of the spinal cord. The motor neurons are activated to produce new action potential capable of stimulate the muscle cells, causing in turn the respective response.

These motor neurons, leading up to the effector organ, constitute the final common pathway. The assembly formed by the motor neuron and the fibers innervated by it is referred to as motor unit.

1.5. Neuronal circuit of the patellar reflex

Like in other tendon reflexes, the spinal cord is the integration center of the patellar reflex.
Sensory signals sent by muscle spindles, access the spinal cord mainly through the sensory posterior roots.
These signals follow the direction of the anterior horn through the neuronal circuit established between the inter-neurons and anterior motor neurons that constitute the preceding nerve roots, giving rise to a new signal into the muscle where was originated the signal sent by the muscle spindle.
This monosynaptic circuit allows the reflex signal emitted, during the excitement of the muscle spindle, return to the muscle where it was originated in the shortest period of time.

1.6. Muscle Spindles and Golgi tendon organs

The muscle spindles contain a variable number of intrafusal muscle fibers that can be of two types: in bag or nuclear chain.
The fibers in nuclear bag have in its non-contractile part (central part), void-spiral terminations formed by winding of the IA fibers.
The fibers in nuclear chain have endings in range of fibers II.
The IA and type II fibers are the dual sensory innervation of muscle spindles.
The IA-type fibers are rapid conduction fibers and they are responsible for the transport of information on muscle length changes, especially the information about the speed in those changes sended by the nuclear chain fibers. This type of fiber, due to their connections to the motoneuron, are an integral part of myotatic reflection and return path.

The Golgi receptors are sensitive to the degree of tension which is exerted by the muscles over the tendon. Its sensory innervation consists of the IB fibers, through its connections with the motoneurons (alpha), performing a proprioceptive reflex arc inhibitor of the contraction, called reverse myotatic reflex. [24]

1.7. Patellar reflex

The percussion of the patellar tendon with a reflex hammer causes the stretch of the quadriceps tendon, stimulating this way proprioceptive sensory receptors that in turn send an afferent impulse via an afferent sensory nerve fiber from the femoral nerve toward the lumbar region of the spinal cord.
Here, this impulse is received by sensory neurons, which through synapses, communicate with motor neurons, resulting in an efferent impulse toward the quadriceps muscle ordering him to contract, causing a dynamic stretch reflex, where the sudden contraction and subsequent relaxation of muscles (hamstrings) flexor antagonist, causes the leg extension.

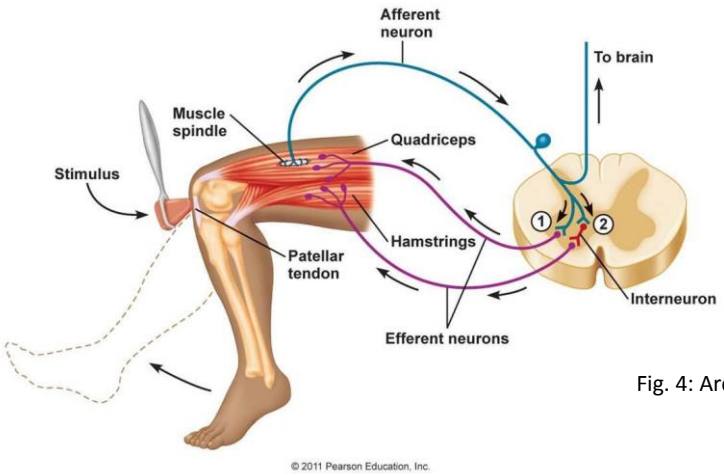


Fig. 4: Arc reflex

This reflex helps to maintain posture and balance, allowing the individual to walk without having to be thinking consciously about each step.

1.8. Clinical aplication of patellar reflex

In clinical practice, the knee jerk is a low cost and fast way to analyze the degree of facilitation of spinal cord centers.
The analysis of the patellar reflex, allows to obtain relevant information about how much basal excitation is being sent to the spinal cord by the brain.
When exaggerated reflexes are found, it can mean that large amounts of facilitating pulses from upper central nervous system regions are being sent to the spinal cord, and in turn when these reflexes are reduced or even absent, the number of facilitators impulse is reduced [24].

2. Heidelberg Model of Tradicional Chinese Medicine

Currently, several models integrate the fundamental principles of classical Tradicional Chinese Medicine (TCM) in contemporary anatomical and physiological knowledge, like for example the Heidelberg Model of TCM.

According to the Heidelberg model, TCM is described as "a system of sensations and findings, which establish the functional vegetative state of the body and can be treated with acupuncture, Qigong, Tuina, Chinese Herbal Medicine, PTTCM and Dietetics". [23]

The Heidelberg Model of TCM, developed by Prof. Henry Greten, allows an interpretation of the classics concepts of TCM such as Yin and Yang and stages, in vegetative functional terms.
This model can be understood as a modern approach of TCM, integrating the fundamental principles of Western classical TCM on current knowledge of human anatomy and physiology.

Heidelberg Model of TCM focuses on the neurovegetative activity in order to systematize the diagnosis and treatment through the creation of a cybernetic model applied to biological systems. [23]
Based on a holistic conception of the human being, this model aims to facilitate the integration of TCM in health and western research system, combining the classic concepts of TCM and the current scientific knowledge.
The effectiveness of this model was demonstrated in a recent study, double and triple blinded. It was found that acupuncture based on the reconstruction of the classical theory is almost twice as effective as current Western acupuncture (standardized) taught in most societies of medical acupuncture. The results were obtained in a wide range of

pathologies: polyneuropathy; chronic heart failure; Pain after tonsillectomy and sternotomy; cardiothoracic surgery; breath after thoracic surgery; walk distance in peripheral arterial disease [23,22].

2.1. Acupuncture

While the knowledge of the mechanisms of action of acupuncture remain limited, the latest research, demonstrates a relation between acupunture points with the peripheral nerves [38]. The action mechanisms may be explained by neural and humoral factors [11,34,38], present at several cenarios [34]:

- Through neural reflexes, regulatory effects of acupuncture act instantly in the functions of tissues or organs;
- Directly through the autonomous nerve centers and indirectly via the endocrine system of the regular glandular secretions and various visceral functions;
- Through adjustment of various humoral factors, mainly in two different ways. The first suggests that the effects of hormones released by acupuncture act directly in the related organs. The second suggests that acupuncture works in the target organs, thanks to a control by feedback of the released hormone;
- The regulation of the functions of various organs can also be achieved by acupuncture via its regulatory action at the the cerebral cortex level, and in turn the cortical centers or endocrine system.

Thus, acupuncture can be seen as a method for regulating endogenous mechanisms through the peripheral nervous system and the mechanical stimulation.
In general, the action of acupuncture is checked in several systems, including the immune system, nervous, inflammatory, endocrine and circulatory [49].

2.2. Yin Yang

As in classical TCM, the Heidelberg model, covers the yin and yang concepts. In classical terms this binomial is the qualitative basis of all Chinese science, including medicine, expressing all the fundamental premise of Chinese thought.

The yin and yang terms can be interpreted as the "dark side of the mountain" and "light side of the mountain", respectively. While describing opposite phenomena, they describe a basic concept, in which everything in the universe changes cyclically. For example, the

day (yang) gives place at night (yin) and vice versa [52]. Porkert et al [60] refers that in Chinese medicine is important to understand the yin as the "structure" and yang as the "activity".

2.3. Phases

According Heidelberg Model, a phase may be described as a cybernetic term, part of a circular process that relative to man can be understood as a a functional vegetative tendency whose expression is defined as an orb "group diagnostically relevant signals indicating the functional state of body part, also called body island, which correlates with the functional properties of a conduit. [23]

The Heidelberg Model of TCM, characterizes the internal regulation of the body as a technical process, making an analogy to a system controlled by a thermostat. In this analogy, when the heating element is activated and assuming that the reference point is 37º, the water temperature starts to raise starting Wood phase. When the potential (vegetative) maximum is reached, the heating element is disabled, thus beginning a downward phase, the fire phase, whose purpose is to put all this potential into action. When the temperature falls below 37º, the heating element activates again, initiating the metal and water phases corresponding to recovery and regeneration towards the reference point.

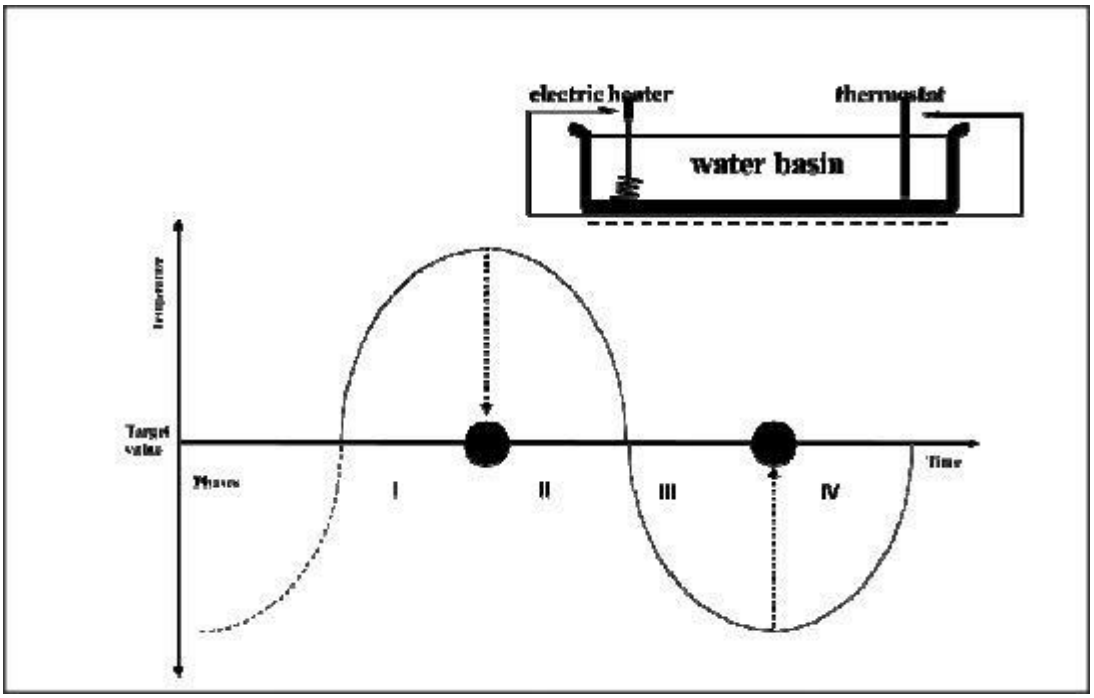


Fig. 5: Sinus wave water basin analogy [23]

Thus, we can verify that this symbol more accurately describes the regulation made by the earth (center) that initially exerts a downward adjustment in the first half movement and an upward adjustment in the second half of that motion.
Announced in the above illustration, we can still see that a higher activity (activity above the predicted value, Earth) represents the yang or repletion and low activity (activity below the expected value) is the yin or depletion.

In general, the sinusoidal curve describes the Chinese view that correlates with the activation and deactivation systems and transmission mechanisms according to the Western medicine.

The model of vegetative regulation consists of five phases: Wood, Fire, Earth, Metal and Water.

Phase	**Funtion of the phase (da fase)**	**Orb**	**Features of orb**
Wood	Creating potential	Hepatic	* Conflicting / explosive people * Hypertonic (muscles) * Loud voice (screaming) *”Bulging eyes"
Fire	Turn the potential into function	Cardial and Pericardiac	* Hyper-dynamic people * Bright eyes * Laughter voice * Talk and move hands simultaneously * People very busy * Yin deficiency * High Anxiety
Metal	Relaxation function	Pulmonar	* Hypotonic person * Mournful voice * Lowered shoulders *Lack of energy
Water	Regeneration Function	Renal	* Hypo-dynamics person * Weakly and emotionless * Hyper rationality

Chart. 1: Phases and functions

Being the earth phase the reference point (homeostasis), the internal regulation of the body is described not as static and stable, but describing a sinusoidal curve, where a fluctuation above this value, ie, Yang phases (Wood and Fire) are regulated by the sympathetic system, and below this value, the Yin phases (Metal and Water) are regulated by the parasympathetic system.

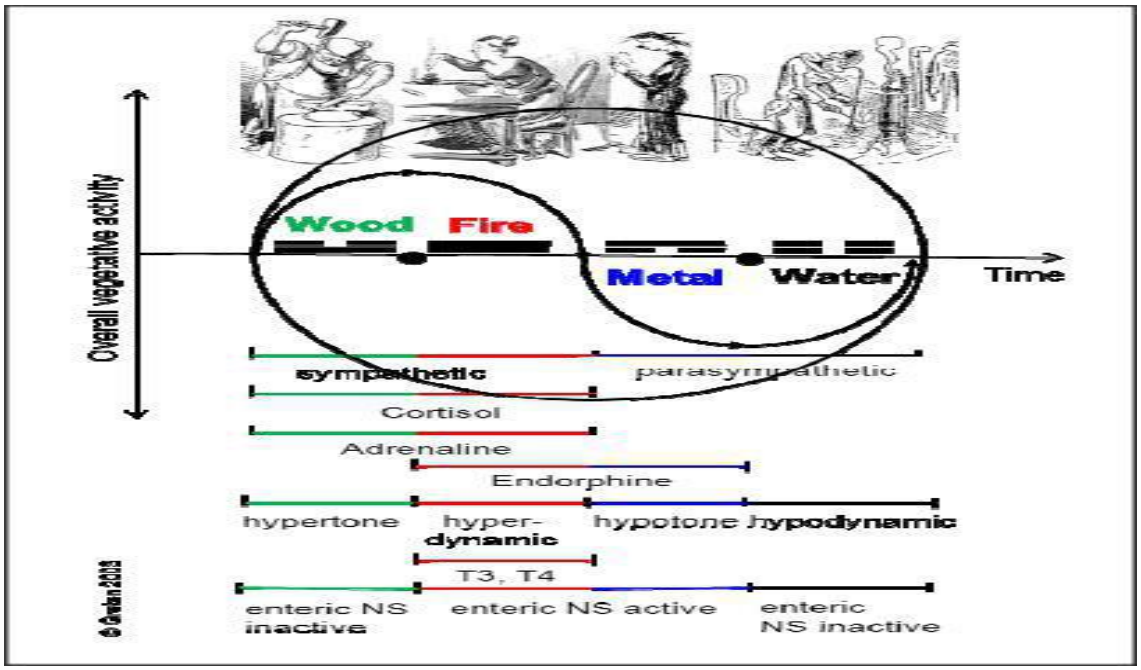


Fig. 6: Representation of the phases with their yin yang bigrams and the sinus wave [23]

In a state of health there is a harmonious balance between the ascending and descending vectors of the internal regulation, however, a change of this balance can lead to physiological events or sensations in certain areas (orbs) in the body. A system deregulation can be caused by several factors: external (weather conditions, biological agents, nutrition, etc.) and internal (emotions, etc).

"TCM, as with other medicines, relies primarily on a system to describe functional abnormalities through analysis of signs and symptoms from the vegetative activity. These signs, symptoms and feelings of patients do not appear by chance but by body tissue dysfunctions and it is through an overview of the symptoms that can be presented a picture of the dysfunctions [21]

2.4. Conduits

There are 12 cardinal conduits that extend in a duplicate and symmetric way, between the left and right side of the body, connected to a corresponding orb. Each yin conduit is connected to a yin orb, as well each yang conduit is connected to a yang orb. Each yin conduit finds its complementary yang pair in the tips of the fingers or toes. The yin \ yang and intimate \ extima polarity is evident in the layout of the complex system of conduits. The yin conduits are presented in the anterior or abdominal region, and the inner side of members. For yang conduits, these show in the posterior region, head and back, and on the outer side of the members. [60]

2.5. Stomach conduit and acupuncture point Stomach 34 (St34)

The stomach conduit, together with the spleen conduit, represents respectively the Yang (action) and Yin (structure) aspects of Phase earth, whose purpose is to regulate and align all other orbs.

The stomach conduit represents a connection of 45 points on the body surface. Starts on the face, following the torso 4 cun the center line, and 2 cun when it reaches the abdomen. Follows the outside of the quadriceps muscle, knee and musculus tibialis anterior, ending on the second toe, thus presenting a downward direction like the orb of the stomach.

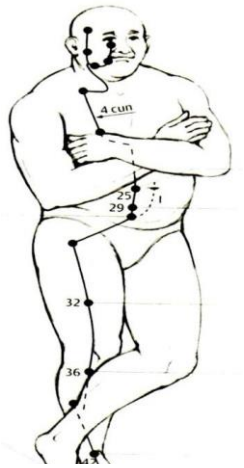


Fig 7: The stomachal conduit [23]

Regarding the present study, the acupoint St34, plays an important role since the intervention consists in the manipulation of this point.

St34 is located in the thigh, on a line between the lateral border of the patella and of the anterior superior iliac spine, a depression situated 2 cun proximal to the upper border of the patella.

This point, is the rimicum point of the stomach conduit and is the only one of rimicums points of the twelve primary channels that is located proximal to the knee or elbow. It is an important adjacent point to treat knee disorders, painful obstruction and Algor (lack of microcirculation).

The rimicum points are the points where the qi and blood, which flow relatively superficially along the channels, gather and plunge more deeply. The rimicum points in general are indicated in the treatment of acute conditions and pain. [60, 65].

The point S34 plays an important role, particularly in pain management throughout the conduit [23]. Beyond the local analgesic effect (mainly in disorders to knee level) and

distal (in the canal path) this point is still traditionally used in muscle weakness and neurological disorders in the lower limbs [26]. It is also indicated in the presence of algor patterns (decreased functional microcirculation), cold lower extremities and affections of the digestive tract, such as: pain, convulsions or spasms of the stomach, gastritis and diarrhea [60,27] and for stimulation metabolic functions [27,3].

2.6. Qi

Qi is one of the fundamental concepts of TCM, usually translated as energy, life force or vital energy as the basis of everything, an immaterial way that promotes dynamism and activity of the living.

According to the model of Heidelberg, Qi is "the vegetative functioning capacity of a tissue or organ that can cause the sensation of pressure, tear or stream [23]. Porkert, defines qi as "an immaterial power with a qualification and direction." [60]

In Chinese medicine, Qi has two fundamental aspects. It designates the essence (Jing), which has the function of constructing the body and the mind (Shen). Also, it indicates the complex functional activities to maintain both.

The states of health and disease are related to qi and its movement. Therefore, processing and correcting the direction of movement of qi is the basis for the motion of xue (Blood) transformation of essence (Jing), movement of body fluids, food digestion, nutrient absorption, excretion, hydrating the skin and increasing resistance to external pathogenic factors [23].

2.7. Xue

Despite having in Western medicine a concept similar to blood, Xue, according to the model of Heidelberg, can be understood as a form of functional capacity (energy), associated with body fluids, assuming various functions such as: heating, wetting, creation of qi and nutrition of a tissue. [23]

According to Porkert et al [60] Xue ("blood") is defined as a "moveable structure".

It circulates in the conduit system driven by Qi, thus showing a dual nature. On one side is structure (Yin), but also at the same time a form of energy (Yang).

From the point of view of the western medical sciences, clinical effects of Xue can be compared with the effects of blood and microcirculation including functional relationships, components of blood cells, plasma, parenchyma and endothelium [23].

2.8. Traditional Chinese unit of measurement (Cun)

Cun Chinese unit is a measure used to find and locate the acupuncture points on the human body. The width of the patient's thumb is considered a Cun, three fingers 2 Cun Cun three and four fingers

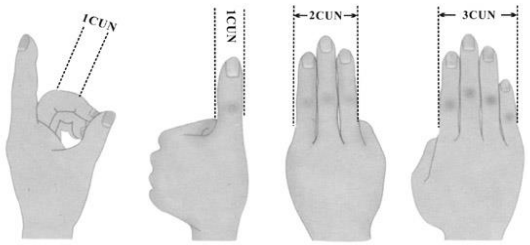


Fig. 8: Cun - Chinese measurement unit

2.9. Leopard Spot Technique

Letting out blood is among the most ancient acupuncture techniques.

Leopard spot technique is one of five puncture techniques described in the classic TCM literature, consisting of rapid skin penetration in a particular acupuncture point. [26,50]

It is speculated that acupuncture began as a method of poking boils, and then expanded to letting go the "bad blood" generated by injury or fevers and finally allowing invisible evil spirits and atmospheric perverse "Qi "(most notably “ventus") escape from the body. [40]

Bleeding is recommended for syndromes characterized by excess, because it allows to drain excess, thus relieving congestion and stagnation of Qi and Xue, and allowing the removel of pathogenic agents. The function of this therapy is to drain heat or quicken the Xue and Qi and relieve local congestion". [75]

While standard acupuncture therapy is depicted as being effective, in part by releasing various transmitter substances (i.e., endorphins), by stimulating local blood flow (i.e., by dilating vessels), and by producing changes in the brain that may have both systemic and highly specific effects, letting out a small amount of blood (usually just a few drops) remains without a suitable explanation for the potent effects claimed. The technique used to let out the blood is one of quick and light pricking to pierce the skin and vein. The Leopard Spot technique has four major therapeutic aims that are useful in the clinical arena [68]: 1. It can invigorate the smooth flow of “Qi” and “Xue”, thereby picking up and facilitating its flow when the “Qi” and “Xue” need invigoration. An example of this scenario occurs when a patient presents with a wiry pulse and mild feelings of stagnation that indicate “Qi” stagnation. Improving circulation and preventing “Xue” from remaining

stagnated; 2. It disperses “Qi” and “Xue” stasis, as in cases of backache or spider veins; 3. It can drain excess, *calor* and *ardor*. Such excess includes pathogenic factors as in an invasion of *Calor-Venti* in the Pulmonary conduit that produces a fever and extremely sore throat; 4. Finally, bleeding can bring down Yang rising, as in the varieties of high blood pressure due to Hepatic Yang rising.

Part II

3. Clinical research methodology

3.1. Main investigator

Bruno Pacheco

Master's student in Traditional Chinese Medicine – ICBAS-UP.

3.2. Research supervisors

Main supervisor

Prof. Doutor Henry Johannes Greten. Director of the TCM Master Program – ICBAS-UP. Head of the Heidelberg School of Traditional Chinese Medicine, Germany.

Co-supervisors

Prof. Doutor Jorge Pereira Machado – Director of Physiology Laboratory and Co-director of TCM Master Program, ICBAS-UP.

Maria João Rodrigues Ferreira Rocha dos Santos - Master in Traditional Chinese Medicine at Abel Salazar Institute for Biomedical Sciences – ICBAS-UP; TCM professional at HSCM, School of Health and Science – Oporto Clinic; Invited Lecturer at ICBAS-UP.

Statistical analysis technician

Bruno Ramos - Technical Assistant at Abel Salazar Institute for Biomedical Sciences – ICBAS-UP - Specialist in Microbiology – AESBUC, BSc Aquatic Environment Ciences student.

3.3. Objective of the study and Study hypothesis

The aim of this study was to verify if the bleeding from acupuncture point s34, produces an effect on amplitude and reaction time of the patellar reflex in healthy adults.

– Hypothesis 1: Improved amplitude and time of reaction of the knee jerk after intervention in experimental group, in comparison with the other groups, in healthy adults
– Hypothesis 2: Improved amplitude and time of reaction of the knee jerk after intervention in experimental group, in comparison with control group but similar in group sham group.
– Hypothesis 3: No significante diference between groups.

3.4. Methods

Study design

A prospective, randomized, controlled clinical study.

Participants

This study focused on population of ICBAS-UP, without any pathological symptoms or complaints.

Took part in this study forty-five subjects (n = 45), divided equally by three different groups: Control Group (CG), Experimental group (EG) and Sham Group (SG). Participants were distributed by the various groups in order of arrival.

The exclusion criteria included all participantes with any significant motor impairment, sciatic pain, lumbago, disorders within the sacral-iliac or orthopedic prosthesis (knee or pelvic), pregnancy, history of debilitating injury within the previous three months, spinal arthritic disorder, lumbar nerve root compression, and history of a central/peripheral nervous system or neuromuscular disorder.

Recruitment procedures

The participants were addressed in ICBAS facilities by the main investigator and invited to participate in the study if they fulfilled the inclusion criteria, ie, not demonstrate any pathological symptoms or complaints.

Ethical considerations

All participants in the sample were fully informed of the procedures used, the study's objectives and the possible risks inherent in the acupuncture treatment.

They were also properly informed of the right to refuse participation in any time of the study in question and for any reason without therefore suffer any consequences or reprisals. In the end, after all the relevant information supplied, it was delivered to each participant a statement of consent, according to the ethical standards of the Declaration of Helsinki.

All data collected were properly stored and reviewed only by the researcher, ensuring confidentiality and anonymity. The data presented were not used for any purpose other than the data analysis by the researcher and his organization.

Randomization of groups

The selected 45 participants were distributed at random by the several groups by order of arrival. The first participant was then inserted in CG, EG for the second and SG in last.

Pilot study

A pilot study was conducted before making the experimental study itself, by using three participants who did not belong to the sample but with the same characteristics. This had as purpose to give acess to familiarization with the tools to be used by the investigators, as well as create an estimate of the time required for data collection. It allowed us to identify methodological errors and amend it.

3.5. Material

For this research, the following material was used:

- Biopac® Student Lab System: Data Collection Unit (MP36) and software BSL 4.

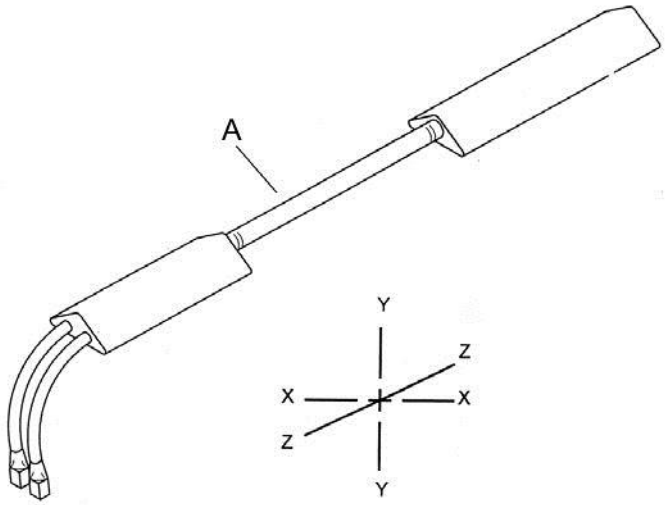
The data collection unit MP36 receives the input data, in this case, transmitted by the goniometer and the reflex hammer and converts them into digital signals to thereby be processed with the aid of a computer using the BSL 4 software.

- Reflex hammer (SS36L)

Based on a reflex hammer Taylor model, it has an attached transducer allowing to communicate with the collecting unit MP36 in order to register the time and intensity of the hit. It is necessary to produce a stroke to generate a signal, i.e., only shake the hammer in the air does not produce any kind of registration.

- Two-axis Goniometer (SS21L)

The goniometer is designed to measure the angular movement of a limb. The goniometer turns the angle position into a proportional electrical signal using measuring elements (A) which measure bending over or around an axis, thereby measuring the angular rotation about two orthogonal planes simultaneously.



We also used the following materials:

- Desk
- Computer Asus X550C
- Surgical tape
- Needles (BD *Micro- Fine*®, 0.25mm [31G] × 8mm)

3.6. Range of motion and reaction time measurements

In the three groups, reaction time was measured with the reflex hammer SS36L and the range of motion was measured with the goniometer SS21L.

Reaction time is the time (ms) difference between the impact of the hammer head and the onset of the reflex movement.

Range of motion is the peak-to-peak amplitude of the EMG response in each tap.

This was calculated for each repetition with BIOPAC Student Lab software (Biopac Systems Inc.)

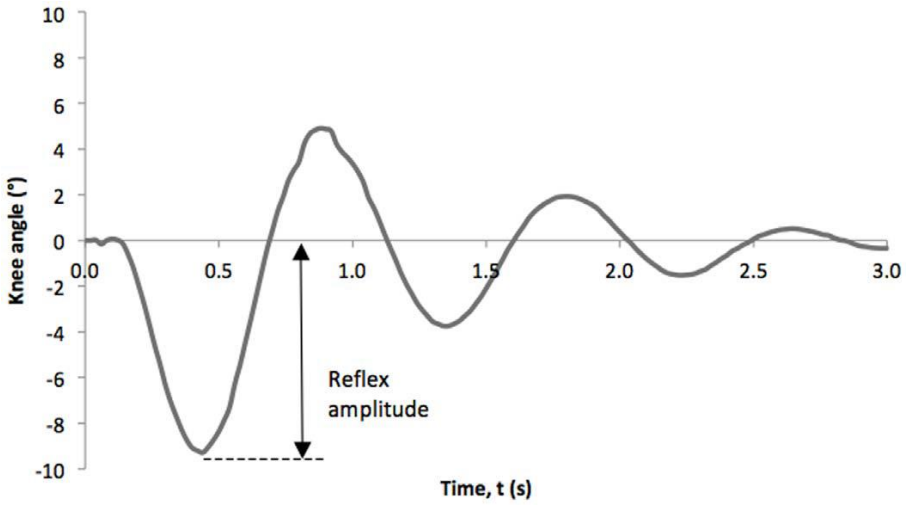


Fig. 9: Reflex amplitude

3.7. Procedures

The data was gathered in two phases, before and after acupuncture intervention (only in the experimental group and sham group).

After having been explained to each participant the central purpose of the investigation, we carried out the placement of the goniometer on the participant in order to carry out the data collection.

For this purpose we used surgical tape to hold the goniometer in place. Section A of the goniometer was placed at the side of the inner thigh and the B section in the inner lateral zone, below the knee, whereupon the midpoint of Section C (measuring element) at the same level as the kneecap as shown in figure. Participants were then asked to seat on a table, with their hips and knees in 90° of flexion, at a height where their feet could not touch the ground.

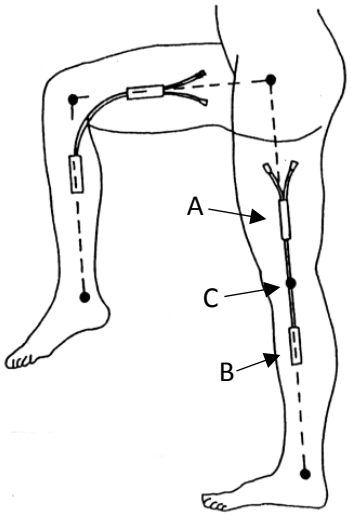


Fig. 10: Goniometer position

As already mentioned, for this study three groups were created, and the formation of the groups was made by order of arrival.

With the leg swinging freely, a series of taps where elicited in order to locate the optimal reflex strike point, following the next steps:

-first, locate the midline ridge on the knee cap,

- feel below the ridge, less than an inch below the tip of the patella.

- using the reflex hammer, several taps were made at areas around this location in order to the spot that gives the strongest response.

After finding the spot with the strongest response, it was used yellow color tape to mark the place.

3.8. Biopac® system configuration

When starting the software BIOPAC Student Lab, in which will be recorded the data gathered, and after entering the participant's identifying data, it is requested to proceed with the calibration of BIOPAC system.

Calibration establishes the hardware's internal parameters (such as gain, offset, and scaling) and is critical for optimum performance.

The calibrations consists in the following steps: first is requested to the participant that fully extend the leg, and in the next step is requested to return to the initial position, ie, 90º, starting then the system calibration that lasts 12 sec.
The data collection menu appears aftern calibration is finish.

After the calibration is complete we started recording in order to collect data regarding the amplitude and reation time of the patellar reflex.
Each participant has carried out two data collections, ie, an initial data collection was made and subsequently after the intervention, a new data collection was made. Only the EG and SG were subject to an intervention. In the CG, we only collected the data, however, like in the other groups, this data collection was done twice.

3.9. Acupuncture intervention

After the first data collection, the Leopard Spot technique was used in experimental group and sham group, however in the first the acupunture intervention was taken in the acuponture point St34 (Figure 11) of the Stomach conduit and in the sham group was used a sham point (point with no therapeutical evidence and not associated with any conduit), situated one cun below and one cun to the lateral side of point St34.
Therefore, after identifying the location of points we applied the technique mentioned above, which consists of five rapid penetration of the skin [26,50], in the selected points (Sham and St34). The depth was controlled by the own shape and length of the needle [26].
After the intervention, a two minutes wait was made, giving then start to a new data collection.

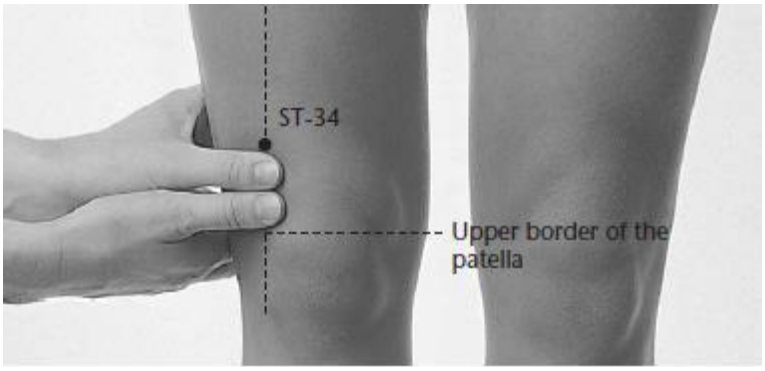


Fig. 11: St34 location

4. Data analysis

We used the version 22 of SPSS and Excel 2013.
For the statistical analysis, we used a 95% confidence interval.
It was considered a normal distribution, the variables that in the Kolmogorov-Smirnov test obtained a value of p> 0.05. The ANOVA - Tukey test was used for comparison between groups.
To compare the evolution of each group by the result of normality, we used the T test for paired samples when P> 0.050 and the Wilcoxon test when P <0.050.

4.1. Patellar reflex amplitude before and after intervention

- Control Group

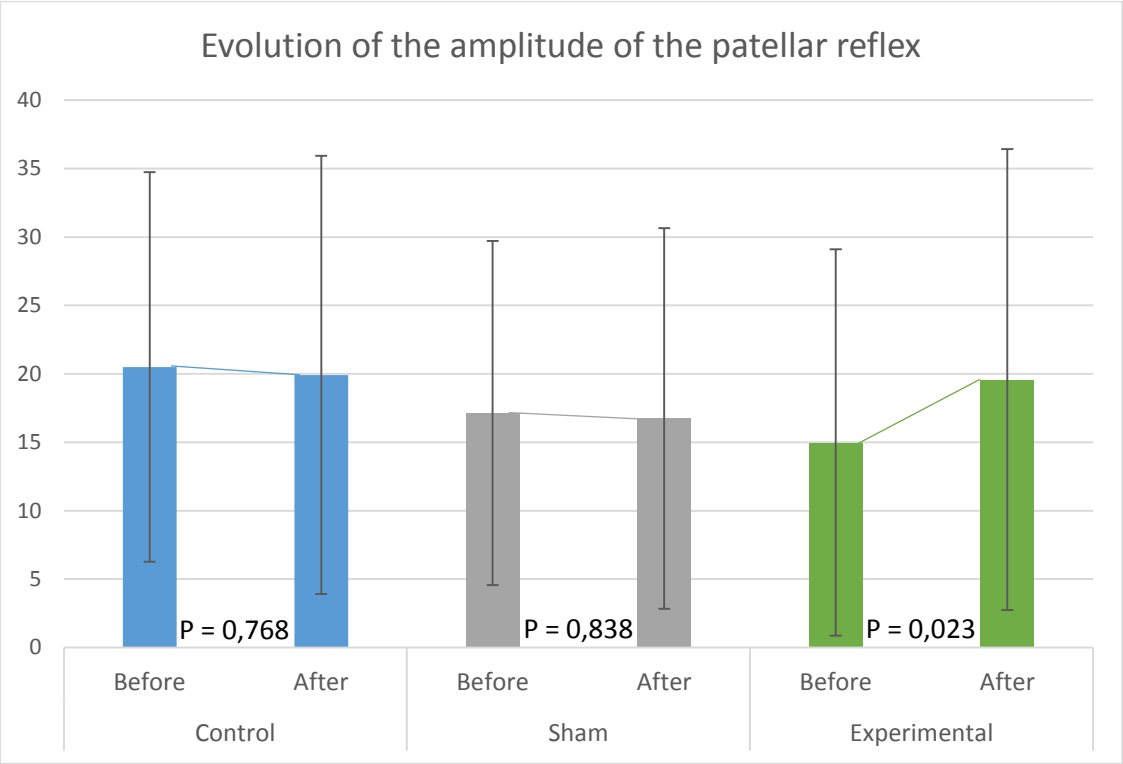
The results obtained in the control group were not statistically significant (p=0,768), showing a reduction in the average patellar reflex of 2,87%.

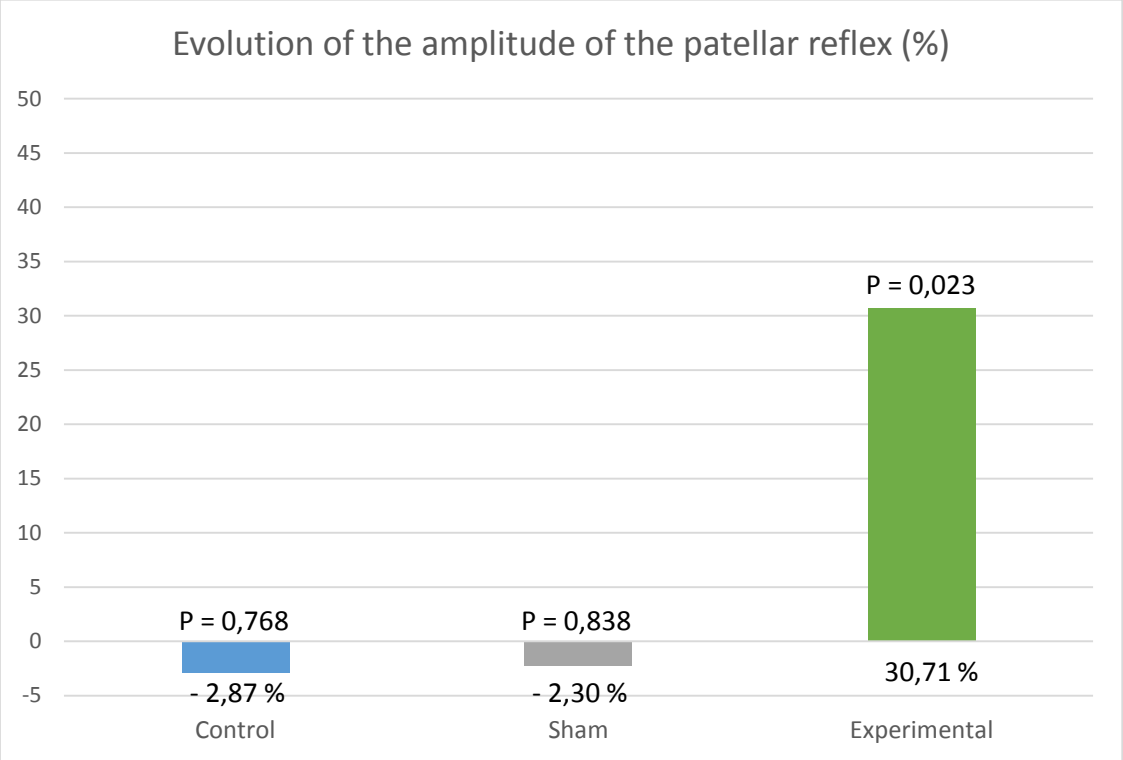
- Sham group

Also in this group there was a reduction in the average patellar reflex of 2.30% and has not been seen statistically significant results (p = 0.838)

- Experimental Group

The experimental group had statistically significant result (P = 0.023) and was found an increase in the average of the patellar reflex of 30.71%.


Evolution of the amplitude of the patellar reflex
40
35
30
25
20
15
10
5
0
P = 0,768
P = 0,838
P = 0,023
Before
After
Before
After
Before
After
Control
Sham
Experimental


Evolution of the amplitude of the patellar reflex (%)
50
45
40
35
30
25
20
15
10
5
0
-5
P = 0,768
P = 0,838
P = 0,023
- 2,87 %
- 2,30 %
30,71 %
Control
Sham
Experimental

4.2. Reaction time, before and after intervention

- Control Group

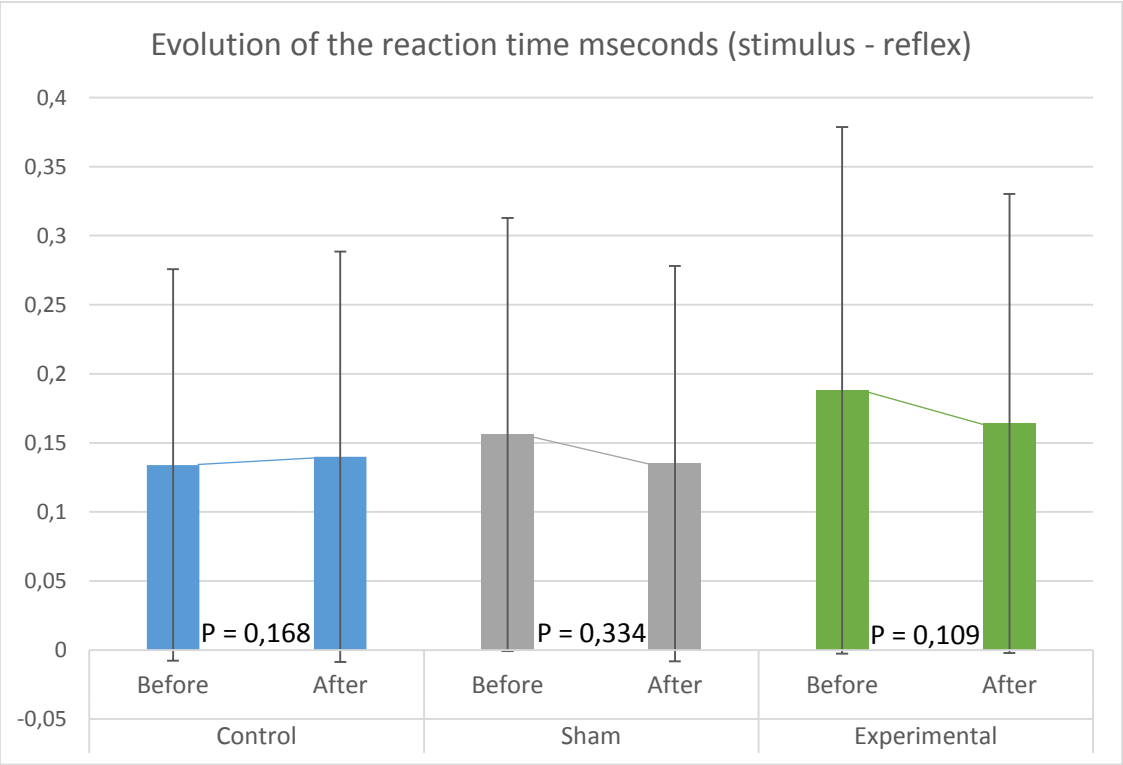
In this group was not obtained a significant statistical result (p = 0.168) and was found an increased average reaction time of 4.97%.

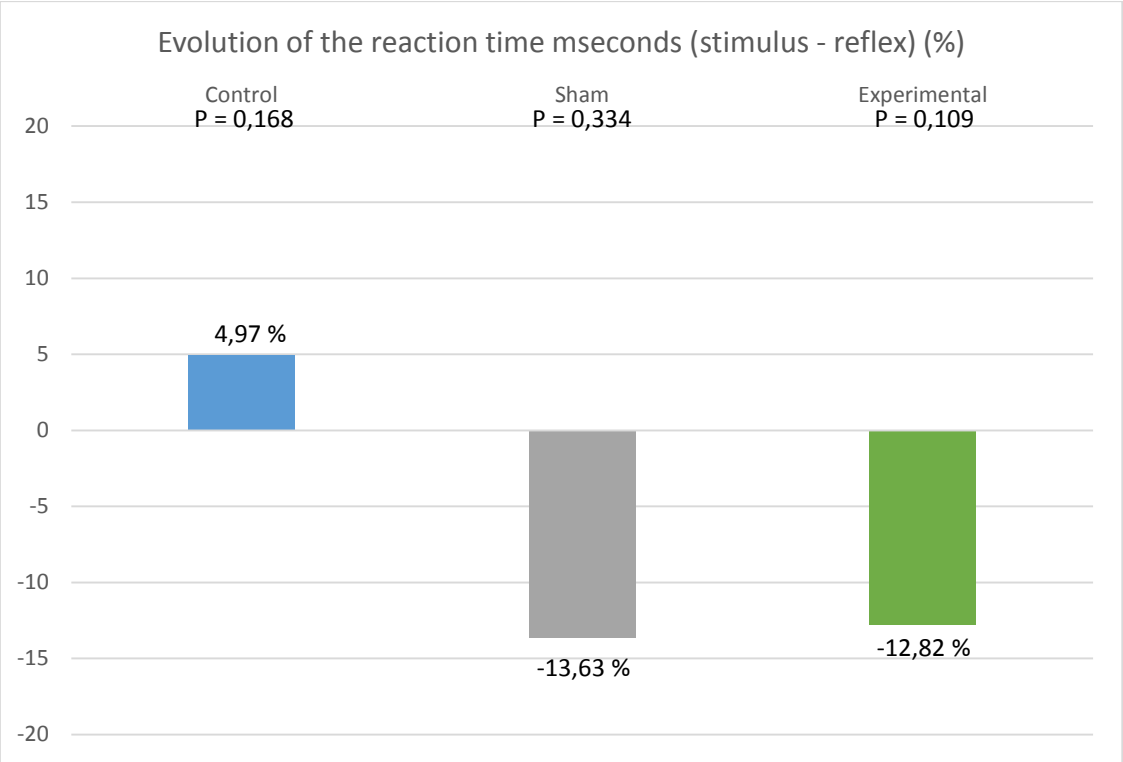
- Sham Group

Also in this group was not obtained a significant statistically result (p = 0.334), but there was an average reduction of 13.63% of the reaction time.

- Experimental group

Although it also has not obtained a significant statistical result (p = 0.109), the value is close to a significance. Increasing the sample size, could have a positive impact on this result. In this case has also been found a reduction of reaction time averaged 12.82%.





Control	Ampl_A	Ampl_B	%	Rt_A	Rt_B	%
MEAN	20,50	19,92	-2,87	0,134	0,140	4,97
STDEV	14,23	16,01	P=0,768	0,142	0,149	P=0,168
Sham	Ampl_A	Ampl_B	%	Rt_A	Rt_B	%
MEAN	17,14	16,74	-2,30	0,156	0,135	-13,63
STDEV	12,57	13,90	P=0,838	0,157	0,143	P=0,334
Experimental	Ampl_A	Ampl_B	%	Rt_A	Rt_B	%
MEAN	14,98	19,58	30,71	0,188	0,164	-12,82
STDEV	14,11	16,85	P=0,023	0,191	0,166	P=0,109

Part III

5. Discussion

Based on the results obtained in this study, we can infer that, in the control group and sham group there were no statistically significant differences ($p > 0.05$) of the amplitude and the reaction time of the patellar reflex in the two moments, but in the experimental group, despite not having checked a change in the level of the reaction time, in relation to the amplitude, we note that the same has increased.

The CG and SG had as its objective, to eliminate possible placebo effect research and check if the point s34 causes a specifies change in the patellar reflex.
Lin et al. [41] inferred that the CG should be carefully selected according to the type of study and the therapeutic acupuncture effects that are being examined, as well as all the elements of the CG and SG should experience the same placebo effect EG, remaining blind relative to the group to which they belong.
The Sham selected point was used by Hauer et al. [26] in the CG, in order to determine the influence of "leopard spot" in S34 technical point on walking performance in geriatric patients and has demonstrated its effectiveness remain inert with respect to the neurophysiological effects of acupuncture.

From the results obtained in this study in relation to GS, it was found that after the intervention, unlike the observed in CG and SG, the St34 acupuncture point has a direct influence in increasing the amplitude of the reflection patellar reflex, showing a statistically difference significant ($p < 0.05$) between the two data collection when compared to the other groups, thus minimizing possible placebo effect.

In the literature many studies are shown that demonstrate the efficacy of acupuncture in increasing muscle strength [81,30].
Yang et al. [78] in a study of 150 athletes divided into GC and GE, presents results similar to those obtained in this study. In this study, the authors aimed to search for a method to increase the explosive power of athletes. They used electro-acupuncture, techniques and points of acupuncture, similars to those used in our study, and found an improvement of performance and muscle power tested by isokinetic in in a 30 meters sprint race and long jump.
Also Zhou et al. [8] developed an experimental study in order to determine the effect of unilateral manual acupuncture on the strength of dorsiflexors in both lower limbs. After 4 weeks of intervention, they obtained an increase in isometric muscle strength of 21.3% and 15.2% on the ipsilateral and contralateral member, respectively, demonstrating the

ability of acupuncture in improving anaerobic work of muscles. The same results were obtained in a study by Ozerkan et al. [54], where it was investigated the acute effects of an acupuncture point isolated and without anatomical relationship with the muscles tested in the isokinetic force of extensors and flexors of the knee in 24 soccer players, getting a statistically significant increase in strength muscle in those muscle groups.

In another study [43], forty-two sportsmen were examined in an isometric strength test on an isokinetic system linked up with electromyography were 14 persons received true acupuncture. After tonifying stimulation of two acupuncture points of the stomach conduit (St 32 and St 36), the quadriceps femoris muscle showed a significant increase in EMG amplitude (on average 29%) and maximum strength (10%) values in the retest. A second group received placebo acupuncture. The CG received no treatment. Both of these groups showed no improvement in the retest. According the autor, acupuncture appeared to produce better excitability in tonifying muscle function and enabled the quadriceps muscles to produce a higher performance. In this study however, the statistical analysis was poorly described and baseline differences between the groups were in some instances larger than differences before and after acupuncture.

Some studies however, demonstrate results where the authors were unable to verify the increase in muscle strength.
In a study [10], the autors found that the chosen points, did not induce an increase of isokinetic strength in the tibialis anterior muscle, stressing the importance of specificity in the selection of acupuncture points.
Also Banzer et al. [3], in a study of twelve students of physical education, in order to test the acute effects of acupuncture on physical performance, no significant changes in results after an acupuncture session having the same results were checked by Hubscher et al. [30] in a similar study.
In these above mentioned studies [30,3] both used an identical protocol acupuncture, using the same acupuncture points. With this in mind, we can infer that the selection of acupuncture points according to their specificity takes a leading role to achieve the desired results [8,57].

In addition to the positive result in increasing the amplitude of the patellar reflex which allows to speculate an increase in muscle strength of the quadriceps, acupuncture technique "Leopard spot" in S34 point has other advantages. It is a technique of quick and easy implementation, cost-effective, virtually painless and no adverse effects with the exception of a small bleeding in some cases but without specific treatment.

Note that the technique and point used in this study were selected according to the TCM theory however, the sample was not created based on a TCM diagnosis in which is determined the neuro-vegetative state of the individual, which studies indicate can boost or drastically maximize the effects of acupuncture [61,23,56]. So the results of this study may represent only a small sample of the effectiveness of acupuncture in improving muscle strength.

The increase in the amplitude of the patellar reflex obtained in this study, according to the TCM, probably is due to the favoring of the balance between yin and yang, as the St34 point belong to the stomach conduit (earth phase), characterized by harmonizing and regulate the functions of all other orbs, thus contributing to the homeostasis.

By using the Leopard Spot technique, the action of the acupuncture point is emphasized by enhancing the flow of qi and xue in the conduit, thus favoring muscle contraction and making it more efficient.

Given that in addition to other factors, muscle strength is directly linked to the number of recruited motor units [36] and considering that acupuncture is a reflex therapy involving local mechanisms, central and vegetative, there are in the literature some studies [7,14] who report conflicting results on the effects of acupuncture on the excitability of motoneurons, among which are the alpha motor neurons.

In this sense, the increase in the stimulation of the alpha motor neurons in the quadriceps can result in higher excitability and recruitment of motor units fibers, which could justify the increase in amplitude of the reflection patellar movement.

Another mechanism that may additionally have contributed to the results, was the increase in microcirculation and oxygen supply to different tissues induced by acupuncture [65, 12, 80].

Zheng et al [80], in a study on the effect of acupuncture in blood perfusion through the achieved results, suggests that stimulation of a single point in the stomach conduit can increase the subcutaneous microcirculation into adjacent points along the conduit.

We can not avoid mentioning the anatomical location of the S34 point located on the side of the quadriceps muscle vast. Other contemporary techniques include that the manipulation of this point, results in an improvement of the dynamic balance of the knee promoting better muscle performance [44].

The physiological mechanisms of the acupuncture benefits in increased muscle strength are still unexplained and the type of study in this paper does not allow us to deepen the mechanisms responsible for improving the amplitude of the patellar reflex evidenced in our results.

5.1. Study Limitations

As several study indicate [72], the reflex assessments should follow a guideline to insure the best optimal results, since there are several factors that can affect the reflex response such as the tapping force and the direction and location of the impact.

5.2. Conclusion

Taking into account the results of this study, we can conclude that the acupuncture blood technique performed in St34 point can influence the amplitude of the patellar reflex, which may occur due to improved local blood flow, and higher number of motor units recruited, thereby promoting an increase in the power of the quadriceps muscle, the main responsible for extension of the leg in the patellar reflex.

Further studies should be taken into account the creation of a sample based on the diagnosis of TCM in order to increase the efficacy of acupuncture, as evidenced by several studies.

In future studies, should also be examined the contraction of the quadriceps muscle through electromyography, thus reinforcing the theory of a greater number of motor units recruited by this technique.

The duration of the results obtained in order to check the long-term efficacy has yet to be studied.

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Annexes

Comissão de Ética U.PORTO
INSTITUTO DE CIÊNCIAS BIOMÉDICAS ABEL SALAZAR
UNIVERSIDADE DO PORTO

Parecer da Comissão de Ética do ICBAS-UP

PROJETO Nº 120/2015

Título: *Influência da acupuntura no reflexo patelar*
Investigador Responsável: Bruno Filipe da Silva Pacheco
Orientador: Prof. Henry Greten
Coorientador: Prof. Jorge Machado e Mestre Maria João Santos
Duração do Projeto: até janeiro de 2016

A Comissão de Ética (CETI) do ICBAS-UP reuniu dia 03 de novembro de 2015 no edifício do ICBAS - Sala de reuniões do Departamento de Ciências do Comportamento, na presença de Liliana de Sousa, Manuel Vilanova, Margarida Araújo e Paulo Maia. Considerando o acompanhamento próximo de todo o projeto pelo orientador e coorientador, decidiu a CETI emitir parecer favorável à realização do projeto supracitado, por unanimidade. O investigador responsável deverá manter em arquivo os "consentimentos informados" assinados pelos participantes.

Com os melhores cumprimentos,

Pela Comissão de Ética do ICBAS-UP,

Prof. Doutora Liliana de Sousa (presidente)

The above project is in accordance with the Portuguese law and the ICBAS-UP Ethics Committee criteria.

CONSENTIMENTO INFORMADO, LIVRE E ESCLARECIDO PARA PARTICIPAÇÃO EM PROJETOS DE DOCÊNCIA E/OU INVESTIGAÇÃO

de acordo com a Declaração de Helsínquia[1] e a Convenção de Oviedo[2]

Por favor, leia com atenção a seguinte informação. Se achar que algo está incorreto ou que não está claro, não hesite em solicitar mais informações. Se concorda com a proposta que lhe foi feita, queira assinar este documento.

Título do estudo: "A influência da acupuntura no reflexo patelar"

Enquadramento: O estudo será realizado no ICBAS-UP. No âmbito do projeto de Mestrado de Medicina Tradicional Chinesa do Instituto de Ciências Biomédicas Abel Salazar da Universidade do Porto, orientado pelo Professor Doutor Henry Johannes Greten, e supervisionado pelo Professor Doutor Jorge Machado e pela Mestre Maria João.

Explicação do estudo: Com este estudo pretende-se verificar a influência da acupuntura ao nível do reflexo patelar. Será realizada uma recolha dos dados quantitativos a avaliar antes da intervenção e nova recolha de dados após 2 minutos da intervenção a três grupos distintos: grupo de controlo, grupo experimental e grupo sham, sendo a formação dos mesmos feita pela ordem de chegada dos participantes. Na intervenção de acupuntura, será utilizada a "Leopard Spot Tecnique", que consiste em aplicar 4 a 5 punções em determinados pontos, dependendo do grupo em questão. A profundidade da inserção da agulha será controlada pelo comprimento e forma da agulha utilizada. Os riscos associados a acupunctura são mínimos. Todas as agulhas de acupuntura são esterilizadas e descartáveis, de uso único. Antes da inserção das agulhas, a pele será desinfetada com uma solução antisséptica alcoólica.
Poderá contudo sentir algum grau de dor ou desconforto e "formigueiro" no local das picadas com as agulhas de acupunctura. Mais raramente, poderá sentir tonturas, ansiedade ou náuseas. É possível que após o tratamento possam surgir ligeiros sangramentos, em particular se estiver a tomar a tomar medicamentos anti-agregantes (ex.: ácido acetilsalicílico) ou anticoagulantes (ex.: varfarina) e/ou aparecerem ligeiros hematomas no local onde foram inseridas as agulhas que se resolverão espontaneamente. Caso esteja a tomar a medicação acima referida (ou outra) deverá informar a equipa de investigação."

Condições e financiamento: O presente estudo será realizado sem qualquer custo para o paciente ou para a escola em questão. Todos os custos serão suportados pelo Instituto de Ciências Biomédicas Abel Salazar da Universidade do Porto (ICBAS-UP). Sendo a sua participação voluntária terá o que tempo que necessitar para ponderar sobre a sua participação neste estudo. É livre de consultar a opinião dos seus familiares ou amigos. Caso decida aceitar, poderá posteriormente a qualquer momento recusar continuar no estudo, sem quaisquer tipos de

[1] http://portal.arsnorte.min-saude.pt/portal/page/portal/ARSNorte/Comiss%C3%A3o%20de%20%C3%89tica/Ficheiros/Declaracao_Helsinquia_2008.pdf

[2] http://dre.pt/pdf1sdip/2001/01/002A00/00140036.pdf

prejuízos assistenciais ou outros, caso não queira continuar a participar. Este documento é elaborado em duplicado, sendo uma via para o participante e outra para o investigador.

A responsabilidade de eventuais danos ocorridos durante o estudo, será da inteira responsabilidade da Heidelberg School of Chinese medicine, sito na Karlsruher Str. 12, 69126 Heidelberg, Germany, e cujo contacto telefónico é +49 (0) 6221 37 45 46.

Este estudo mereceu o parecer favorável da Comissão de Ética do ICBAS-UP.

Confidencialidade e anonimato: Todos os dados recolhidos para o presente estudo asseguram uma total confidencialidade e anonimato dos participantes, os seus nomes nunca serão tornados públicos. Todos os resultados obtidos serão devidamente codificados; os dados serão apenas do conhecimento do investigador principal e dos orientadores do estudo.

Agradecendo desde já a colaboração e ajuda, para qualquer esclarecimento poderá entrar em contacto com o Mestrando Bruno Pacheco, pelo telemóvel 936000583.

Eu, abaixo-assinado,

_____BI/CC:_____

_____

Declaro ter lido e compreendido este documento, bem como as informações que me foram fornecidas pela pessoa que acima assina e que considero suficientes. Foi-me garantida a possibilidade de, em qualquer altura, me retirar da participação neste estudo sem qualquer tipo de consequências. Desta forma, aceito a participação neste estudo e permito a utilização dos dados que de forma voluntária forneço, confiando em que apenas serão utilizados para esta investigação e nas garantias de confidencialidade e anonimato que me são dadas pelo investigador.

Porto, ____ de _____ de 2016

Assinatura do Participante

_____

_____

Assinatura do investigador: