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IMPACT OF EXERCISE ON PAIN CONTROL, QUALITY OF LIFE AND MOTIVATION IN PATIENTS WITH KNEE ARTHRITIS

- RANDOMIZED CONTROLLED TRIAL -

MASTER IN SPORTS MEDICINE

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- RANDOMIZED CONTROLLED TRIAL -

Dissertação do Mestrado em Medicina Desportiva da Faculdade de Medicina da Universidade de Coimbra, Portugal

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ABBREVIATIONS LIST

AAOS – American Academy of Orthopaedic Surgeons

ACR – American College of Rheumatology (ACR)

BREQ-2 – Behavioral Regulation in Exercise Questionnaire 2

EQ-VAS – EQ-5D Visual Analogue Scale

ESM – EQ-5D Health Status at the Moment

OA – Osteoarthritis

OARSI – Osteoarthritis Research Society International

PACE – Patient-centered Assessment and Counseling for Exercise

WHOQOL-Group – World Health Organization Quality of Life

ABSTRACT

Introduction

Knee osteoarthrosis is among the most prevalent musculoskeletal disorders, especially in elderly and exercise is one of the most effective non-pharmacological treatment options, although its impact is not totally studied.

Objective

Evaluate the impact of physical exercise on knee pain, quality of life and exercise motivation in patients with knee osteoarthritis.

Methods

Non-pharmacological, randomized, controlled clinical trial with a sample composed by primary care patients with age over 50 years, with diagnosis of knee osteoarthritis randomly assigned to a intervention and a control group. Evaluations through biometric data and questionnaires before and after exercise plan compliance with for 8 weeks follow-up.

Results

Twenty seven patients were studied. The majority was male accounting for 51,9% (N=14) of the sample. The participants were between 59 and 85 years old with a mean age of 70,7 +/- 6,7 years, with no demographic or biometric differences between groups. The intervention group had a decrease in weight and BMI (p=0,009) and less and less pain intensity after the trial, compared to control group (p=0,178). Statistically significant differences between groups were found in abdominal perimeter (p=0,050), quality of life (p<0,001), motivation for exercise (p=0,002) and physical activity level (p<0,001) at the end of the trial.

Conclusion

A physical exercise 8 week program has a positive impact in abdominal perimeter, quality of life, motivation for exercise and physical activity level in patients in knee osteoarthritis.

Keywords: Exercise, Pain, Knee, Osteoarthritis, Motivation, Quality of Life

RESUMO

Introdução

A artrose do joelho está entre os distúrbios músculo-esqueléticos mais prevalentes, sobretudo em idades mais avançada e o exercício é das opções mais eficazes de tratamento não farmacológico, embora o seu impacto não esteja totalmente estudado.

Objetivo

Avaliar o impacto do exercício físico na gonalgia, motivação para o exercício físico e na qualidade de vida das pessoas com artrose do joelho no contexto de cuidados primários.

Métodos

Ensaio clínico não farmacológico, randomizado e controlado. Amostra composta por pacientes dos cuidados de saúde primários com idade superior a 50 anos e diagnóstico de artrose de joelho randomizada em grupos de intervenção e controlo. Avaliação através de dados biométricos e questionários antes e depois do cumprimento do plano de exercício com 8 semanas de seguimento.

Resultados

Vinte e sete pacientes foram estudados. A maioria era do sexo masculino, representando 51,9% da amostra. Os participantes tinham entre 59 e 85 anos, com idade média de 70,7 +/- 6,7 anos, sem diferenças biométricas ou demográficas entre os grupos. O grupo de intervenção teve uma diminuição no peso e IMC (p=0,009) e menor intensidade de dor depois do período experimental em relação ao grupo controlo (p = 0,178). Verificaram-se diferenças estatisticamente significativas entre os grupos no perímetro abdominal (p = 0,050), qualidade de vida (p <0,001), motivação para exercício (p = 0,002) e nível de atividade física (p <0,001) no final do período experimental.

Conclusão

Um programa de exercício físico de 8 semanas tem um impacto positivo no perímetro abdominal, qualidade de vida, motivação para o exercício e nível de atividade física em pacientes com artrose do joelho.

Palavras-chave**:** Exercício físico, Dor, Joelho, Artrose, Motivação, Qualidade de Vida

INTRODUCTION

Chronic musculoskeletal disorders are highly prevalent worldwide (1), with knee osteoarthritis (OA) being predominant among them (2) affecting approximately 250 million individuals (3), particularly the elderly (4). It affects approximately 12,4% of the Portuguese population, with higher prevalence in women (15,8%) (5). This is in line with the worldwide trend with higher prevalence in women than men, especially among those with 50 years and more (3).

The etiology of osteoarthritis is multifactorial and not fully understood (6). Age, gender, obesity, trauma, overuse, severe joint injury, chondrocalcinosis, neuromuscular dysfunction, occupational factors/labor, high-impact sports and genetic factors are considered risk factors (6-8). Facing an aging population and an obesity epidemic, it is expected that the prevalence of knee OA will reach 40% by 2025 (1).

Knee OA results from cartilage degeneration, followed by gradually changes in periarticular soft tissues and subchondral bone calcification. These processes lead a chronic inflammation through synovitis, osteophytosis, loss of joint space, bone remodeling and, finally, a severe and irreversible joint destruction (6, 9, 10).

Although patients with knee OA may present with swelling, stiffness, limited ambulation and declined balance function (11), pain is the main clinical concern (12). It is a major limiting factor for physical function (4) and impacts in mood, daily activities, labor relations, leisure, social life, sleep, fatigue, emotional status, stress and anxiety (12-14). Although quadriceps weakness and psychosocial factors are strongly associated with disability (15, 16), primary care management is manly focused on pain relief (17).

Despite all negative consequences of knee OA, the most important point is that quality of life is also affected (11, 18). Taking account the subjunctive of the term, the World Health Organization Quality of Life (WHOQOL-Group) defines quality of life as *individual´s perceptions of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns* (19). It is a primary objective of medical care, regardless of the improvement of the associated symptoms (1). Measuring health outcomes is essential for monitoring clinical practice, particularly when evaluating and comparing different medical interventions (20).

With disease progression, physical limitations, pain, and functional restriction worsen (14). A study showed a low perception of quality of life in functional capacity, functional limitation and pain in patients with osteoarthritis, especially in people with low educational levels (9).

Motivation is defined as the interest in initiating or maintaining a healthy behavioral

modification at the expense of harmful behavior (21). Some motivational factors influence exercise practice such as social support from friends, relatives, and physicians, exercise program related factors, exercising partner alongside and receiving rewards for exercise behavior (22).

Knee OA treatment aim is reduce join pain and improve function, resulting in a positive impact in quality of life. Thus, there is a growing interest in the investigation of non-pharmacological treatments, namely physical exercise. International recommendations advocate that physical activity is an integral part of knee osteoarthritis' treatment given the evidence of its efficacy, viability and safety (23). Other identities such as Osteoarthritis Research Society International (OARSI) (24), American Academy of Orthopaedic Surgeons (AAOS) (25), and American College of Rheumatology (ACR) (26) also consistently recommending exercise programs for individuals with knee OA as well as weight loss programs for overweight individuals with knee OA. It has some evidence of benefit but there are few studies that relate exercise programs and quality of life in patients with knee osteoarthritis and even less about motivation in these subjects (27).

The aim of this study was to evaluate the impact of physical exercise on knee pain, quality of life and exercise motivation in patients with knee osteoarthritis.

MATERIALS AND METHODS

Participant recruitment

We conducted a non-pharmacological, randomized, controlled clinical trial with a sample composed by primary care patients who were attended in primary care center USF Araceti (Coimbra, Portugal) from January to April 2018. Patients diagnosed with uni or bilateral knee osteoarthrosis were invited by doctors or nurses to participate in this study. It was an opportunistic recruitment in patients who, in that period, had a medical consultation.

Patients with age over 50 years, with diagnosis of knee osteoarthritis (with ICPC-2 L90 coding in informatic *SClínico* program) who came to a medical consultation in the defined period for recruitment and with knee pain for more than 6 months ago were analyzed to be included in this study.

Exclusion criteria were having another active osteoarticular pathology associated with the knee (N=3) - secondary osteoarthritis or ligament injury; knee with inflammatory signs (N=1) - acute pathology, knee effusion and increased temperature; deformities in the knee prior to arthritis (N=0); orthopedic intervention or intra-articular injection in the knee in the last 6 months (N=0); orthopedic intervention with a consequent decrease in performance in lower limbs (N=0); history of severe knee trauma (N=0); another uncontrolled medical condition that does not allow safe participation in the physical exercise program (N=14) such as: symptomatic heart or vascular disease (angina, peripheral vascular disease, congestive heart failure), severe hypertension, recent stroke, decompensated chronic obstructive pulmonary disease, severe insulin dependent diabetes mellitus, uncontrolled psychiatric illness, kidney disease, liver disease, active cancer disease and anemia; inability/improbability in being able to participate in the 8 weeks of study (N=17); inability to complete the protocol, in the opinion of the clinical team, due to the fragility, disease or other reasons (N=2); programed exercise practice (N=0). Also 7 patients were excluded for not having knee pain despite the diagnosis of knee osteoarthritis and 2 with bilateral knee replacement. From a total of 90 patients, 46 were excluded.

The patients who understood the research objectives and agreed to participate were included after signing the informed consent term in accordance with guidelines of the Faculty of Medicine of the University of Coimbra. The ethical committee of the Centre ARS approved this study.

At first contact, the first training session, the included patients that consented be in the study were weighed and abdominal perimeter was measured, BMI was calculated and a

questionnaire was filled out (Attachment I: Questionnaire). The general and clinical data were collected, such as age, gender, marital status, household, income, professional situation and usual medication for pain. Four other standardized instruments were also applied. Pain intensity was quantified through a numerical scale, which varies between 0 (absence of pain) and 10 (maximum pain) and 5 represents moderate pain. Quality of life was quantified through EuroQoL EQ-5D scale that allows generating an index representing the state value health of an individual. It is a multidimensional instrument, which includes five dimensions: Mobility, Personal cares, Habitual activities, Pain/malaise and Anxiety/Depression. It allows to describe a total of 243 states of health. In addition, there is a visual analogue scale (EQ-VAS), in which health status at the moment (ESM) is classified with scores between 0 (worst imaginable health) and 100 (the best health imaginable) and permits to compare current health status with health status a year ago (20). Portuguese calculation algorithm was used, with the Portuguese version author's consent. To measure the motivation for exercise, Behavioral Regulation in Exercise Questionnaire (BREQ-2**)** was used. It is composed by 19 items on a five-point Lickert-type scale measuring amotivated (questions 5, 9, 12 and 19), external (questions 1, 6, 11 and 16), introjected (questions1, 6, 11 and 16), identified (questions 3, 8, 14 and 17), and intrinsic (questions 4, 10, 15 and 18), regulation of exercise behavior. We used the validated Portuguese version (28). For the evaluation of the current level of physical activity was used the Patient-centered Assessment and Counseling for Exercise (PACE) instrument that divides the current activity and motivation in 8 stages (1-8) (29). It was applied by structured interview, with the questions being read by the researcher, seeking to obtain maximum responses.

Subsequently, participants were randomly divided with the use of random numbers generator into 2 groups, each one with 22 patients. A control group in which usual care was carried on and an intervention group that underwent an exercise plan for 2 months, 3 times a week. Six of the 22 people included in e intervention group did not start the training because of non-availability, although this issue was addressed when recruiting. So, a total of 38 individuals (*Figure I*).

After 8 weeks of training, all the participants filled out the questionnaires again and the biometric parameters were again evaluated. In the control group, 6 patients were unavailable o reach for the final evaluation. In the intervention group, 5 patients didn´t complete the training program. Two of them due to increased back pain, two others due to unavailability and another one because of personal reasons.

Eleven of 16 participants completed the 8-week progressive exercise program, a total of 23 training lessons. Of these ones, 2 completed 22 sessions of the training plan, 6 completed 21 sessions and 1 completed 18,19 and 20 sessions. All the participants studied participated in the minimum of 78% of the training sessions.

Training program

General advices were given to the subjects. They were recommended to stop exercise if any kind of pain was felt. In addition they were advised on the importance of wearing comfortable clothes, appropriate training shoes and drink water after exercise.

This training program had its focus on using large muscle groups with predominance of the lower limbs. The training program consisted of three sessions per week of 50 minutes each. A graded exercise program was created with weekly adjustments.

The training sessions were, alternately, taught by a doctor with sports degree and a nurse with rehabilitation degree.

First week

Six exercises were included. In this session's exercises were taught and demonstrated to subjects.

1. 10 minutes walking
2. Chair squat (2 series of 15 repetitions)
3. Knee extension exercise (siting in a chair knee extension at 90º and coming back, 2 series of 15 repetitions)
4. In supine position leg elevation at 45º with extended lower limb (2 series of 15 repetitions)
5. Hip extension exercise (lift the hips between the knees and shoulders, 2 series of 15 reps)
6. 8 minutes walking (fast pace)

Second to fourth week:

Another series were added to the previous exercises and were included resistance with elastic band.

1. 10 minutes walking
2. Chair squat (3 series of 15 repetitions)
3. Knee extension exercise (siting in a chair knee extension at 90º and coming back, 3 series of 15 repetitions)
4. Seated Hip Abduction with Resistance Band Exercise (3 series of 15 reps)
5. In supine position leg elevation at 45º with extended lower limb (3 series of 15 repetitions)
6. Hip extension exercise (lift the hips between the knees and shoulders, 2 series of 15 reps)
7. 8 minutes walking (fast pace)

Fifth to sixth week:

Two more exercises were added to improve resistance.

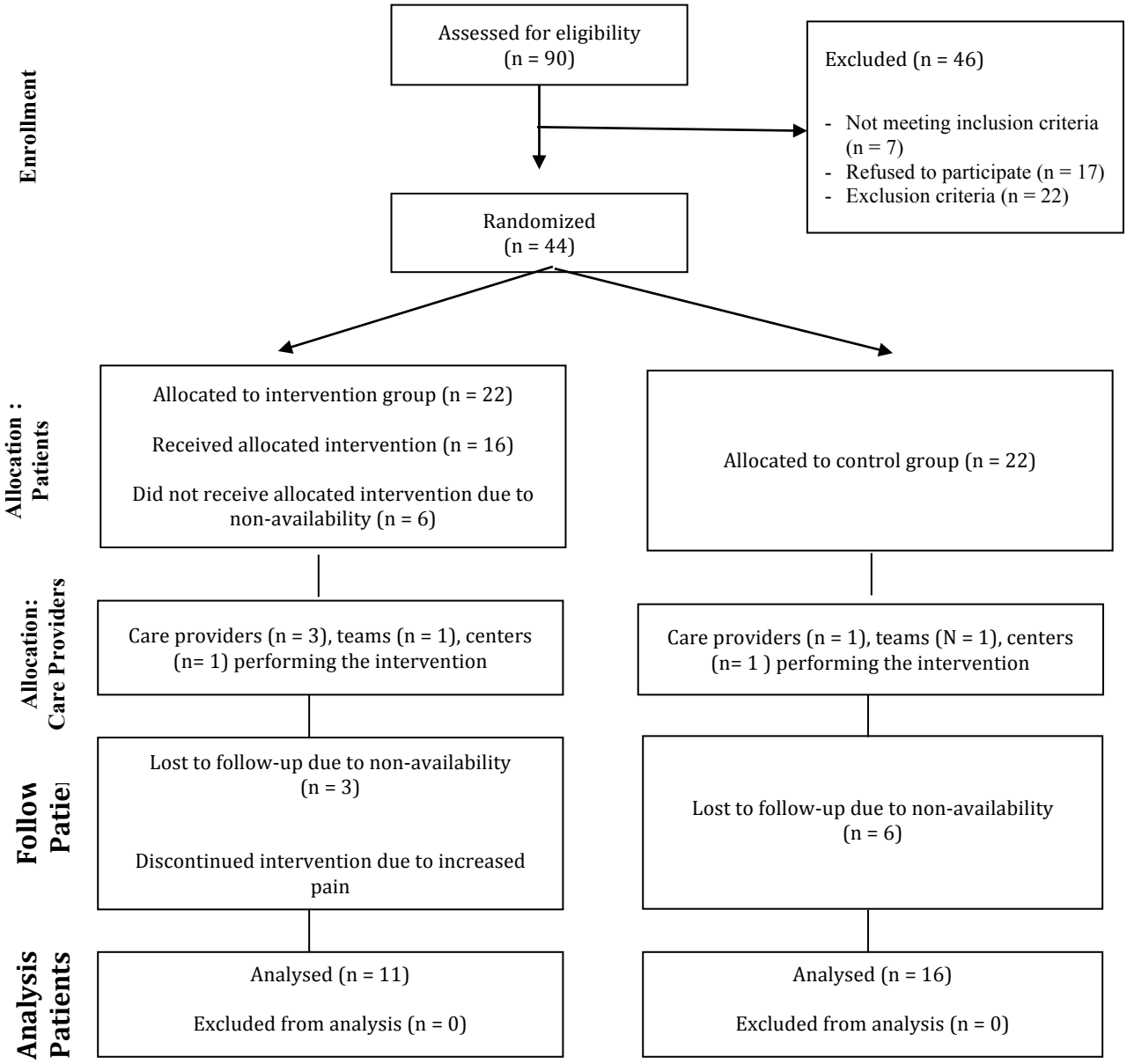
1. 10 minutes walking
2. Chair squat (3 series of 15 repetitions)
3. Dynamic stepping exercise (walking up and down one step, maximum reps in 1 minute)
4. Balance on support alternately
5. Knee extension exercise (siting in a chair knee extension at 90º and coming back, 3 series of 15 repetitions)
6. Seated hip abduction with resistance band exercise (3 series of 15 reps)
7. In supine position leg elevation at 45º with extended lower limb (3 series of 15 repetitions)
8. Hip extension exercise (lift the hips between the knees and shoulders, 2 series of 15 reps)
9. 8 minutes walking (fast pace)

Seventh to eight week:

In the last two weeks, the number of repetitions were increased to 20

Figure I presents the diagram of the study according to the CONSORT model (30).

Figure 1. Diagram of the study.



Statistical analysis

Statistical analysis were performed using Excell /IBM SPSS version 23.0 program.

Firstly, the variables were checked for normal distribution. It was found that not all of them followed a normal distribution and due to the small number of the sample, non-parametric tests were used. For the analysis, age, gender, marital status, household, income, professional situation and usual medication for pain were considered as independent variables. Inferential statistics was used to characterize the sample.

Mann-Whitney test was used for comparative study of the continuous variables between the two groups at each point of time and Qui-square test was used to compare nominal variables. To compare each group before and after the intervention, related samples Wilcoxon Rank was used. The level of statistical significance was set at $p<0.05$.

RESULTS

From the 44 individuals included, 38 were studied once 6 participants from the intervention group did not attend any evaluation session, and only 27 completed the follow-up (Figure 1). The intervention group consisted of 11 participants and the control group consisted of 16. The majority was male accounting for 51,9% (N=14) of the sample. The participants were between 59 to 85 years old with a mean age of 70,7 +/- 6,7 years. About marital status, 81,5% of the sample was married and only 18,5% of the participants live alone. More than half of individuals had an income below the minimum wage, accounting for 66,7% of the sample. These variables did not show significant differences between the groups (Table I).

Table I. Sample characteristics.
Legend: Control G – Control Group, Interv G – Intervention Group
* Mann-Whitney U test
** Qui-square test (Continuity correction when needed)
*** Fisher's exact test

CHARACTERISTICS		MEAN (YEARS) +/- SD			P
		SAMPLE	CONTROL G	INTERV G	
Age	Sample	70,7 +/- 6,7	71,2 +/- 7,6	69,9 +/- 5,4	0,827
	Female	68,4 +/- 5,3	69,4 +/- 6,6	66,8 +/- 1,6	0,524
	Male	72,8 +/- 7,4	73,0 +/- 8,6	72,5 +/- 6,1	1,000
CHARACTERISTICS		**NUMBER (%)**			**P**
		SAMPLE	**CONTROL G**	**INTERV G**	
Gender	Female	13 (48,1)	8 (50,0)	5 (45,5)	1,000**
	Male	14 (51,9)	8 (50,0)	6 (54,5)	
Marital status	Single	0 (0)	0 (0)	0 (0)	0,522**
	Married	22 (81,5)	12 (75,0)	10 (90,9)	
	Divorced	1 (3,7)	1 (6,3)	0 (0)	
	Widow	4 (14,8)	3 (18,8)	1 (9,1)	
	Other	0 (0)	0 (0)	0 (0)	
Household	Alone	5 (18,5)	4 (25,0)	1 (9,1)	0,618***
	Accompanied	22 (81,5)	12 (75,0)	10 (90,9)	
Income	≥ minimum wage	9 (33,3)	5 (31,3)	4 (36,4)	1,000***
	< minimum wage	18 (66,7)	11 (68,8)	7 (63,6)	
Occupation	Active	1 (3,7)	0 (0)	1 (9,1)	0,417**
	Retired	24 (88,9)	14 (87,5)	10 (90,9)	
	Unemployed	1 (3,7)	1 (6,3)	0 (0)	
	Student	0 (0)	0 (0)	0 (0)	
	Other	1 (3,7)	1 (6,3)	0 (0)	

The anthropometric variables, pain intensity, quality of life, physical activity practiced and motivation to practice it were not different between the two groups at the beginning of the trial.

There was an increase in weight and BMI in the control group and a decrease in the intervention group, with significant differences in the intervention group (p=0,009).

The mean abdominal perimeter significantly increased almost 3 cm in the control group and had a 4,41 cm decrease in the intervention group. Statistically differences were found between the two groups at the end (p=0,050),

There was a decrease in pain intensity, more pronounced in the intervention group. No statistically differences were found (p=0,178).

The assessment of quality of life through the EQ-5D scale revealed a decrease of quality of life in control group and an increase in intervention group with statistically significant differences between groups at the end (p<0,001).

The level of physical activity decreased in the control group and increased in the intervention group. Statistically significant differences were found between groups at the end of the trial (p<0,001). Also for motivation, after the trial, BREQ-2 scale results showed a statistically significant difference between groups (p=0,002), with greater motivation found in the intervention group.

Table II. Variation of studied variables.
*Related samples Wilcoson Ranked test
** Mann-Whitney U test
Leg: EQ-5D – Quality of life; PACE – Physical activity level; BREQ-2 – Exercise motivation.

VARIABLES		CONTROL G		INTERV G		P**
		MEAN +/- SD	P*	MEAN +/- SD	P*	
Weight	Initial	78,88 +/- 13,65	0,705	79,69 +/- 11,59	**0,009**	0,753
	Final	79,06 +/- 14,33		76,96 +/- 11,92		0,942
Abdominal Perimeter	Initial	104,07 +/- 9,92	**0,034**	104,73 +/- 6,50	0,074	0,563
	Final	106,88 +/- 10,24		100,32 +/- 9,55		**0,050**
BMI	Initial	31,47 +/- 4,97	0,064	30,86 +/- 4,99	**0,009**	0,680
	Final	31,49 +/- 5,01		29,56 +/- 5,76		0,212
Pain Intensity	Initial	6,94 +/- 2,29	0,277	6,09 +/- 2,43	0,291	0,451
	Final	6,44 +/- 2,10		5,36 +/- 0,81		0,178
EQ-5D	Initial	0,42 +/- 0,19	0,062	0,48 +/- 0,22	0,333	0,512
	Final	0,32 +/- 0,14		0,56 +/- 0,11		**<0,001**
PACE	Initial	2,13 +/- 1,09	0,084	2,64 +/- 1,57	0,070	0,481
	Final	1,56 +/- 0,81		3,27 +/- 0,90		**<0,001**
BREQ-2	Initial	32,94 +/- 12,37	0,641	38,91 +/- 15,92	0,350	0,368
	Final	34,69 +/- 8,32		45,09 +/- 7,49		**0,002**

As shows Table III, in initial evaluation, habitual use of **pain medication** was verified in 8 (29,6%) participants (Table III*).* In both groups, the majority of patients maintained the medication after the trial. Comparing with the intervention group, in the control group more medication was used initially and there was a greater increase, which was higher during the study period (18,2% in the intervention and 25% in the control group).

Table III. Evolution of medication needs.

MEDICATION		NUMBER (%)		
		SAMPLE	CONTROL G	INTERV G
Initial Evaluation	Daily	5 (18,5)	4 (25)	1 (9,1)
	2-3x / week	3 (11,1)	2 (12,5)	1 (9,1)
	2-3x / month	0	0	0
	Rarely	0	0	0
	No	19 (70,4)	10 (62,5)	9 (81,8)
	Total	27 (100)	16 (100)	11 (100)
Final Evaluation	Daily	3 (11,1)	3 (18,8)	0
	2-3x / week	5 (18,5)	2 (12,5)	3 (27,3)
	2-3x / month	0	0	0
	Rarely	3 (11,1)	1 (6,3)	2 (18,2)
	No	16 (59,3)	10 (62,5)	6 (54,5)
	Total	27 (100)	16 (100)	11 (100)
Evolution	Maintained	16 (59,3)	10 (62,5)	6 (54,5)
	Increased	5 (18,5)	4 (25)	2 (18,2)
	Decreased	6 (22,2)	2 (12,5)	3 (27,3)
	Total	27 (100)	16 (100)	11 (100)

DISCUSSION

As far as we know, this is the first study investigating the impact of an exercise program in patients with knee OA, knee pain, quality of life and motivation to exercise in Portugal. Our results revealed a positive impact of exercise in all these variables. Patients with knee OA undergoing an exercise plan have better quality of life, best level of physical activity, more motivation for exercise and a smaller abdominal perimeter when compared to the control group.

Weight, abdominal perimeter and BMI were lower in the intervention group at the end of the trial (p=0,942, p=0,050 and p=0,212, respectively). It is expected that exercise will cause weight reduction, especially in obese patients. Some studies have shown positive effects on symptoms after weight reduction (31, 32), so it was also expected to have pain reduction in this trial in the intervention group, what we actually found, although with no significant differences when compared to the control group. Maybe this could have happened because of a greater increase in pain medication in this last group (as part of the usual care). So, it is consistent with OARSI, AAOS, ACR, and EULAR recommendations of exercise programs for individuals with knee OA as well as weight loss programs for overweight individuals with knee OA (23-26).

In our study, knee OA patients that underwent the exercise program had an increase in quality of life with statistically significant differences between them and the control group (p<0,001). Following the natural history of OA of the knee, limitations to physical activity and pain tend to worsen with restriction of functionality. These effects have a negative impact on daily life activities with a consequent personal and social impact on the psychological and economic aspects, which results in an important decrease in quality of live. As we found here, also several studies indicate that regular physical activity has beneficial effects on quality of life, depression and functional capacity in patients with knee osteoarthritis (11, 13, 18, 33)

The level of physical activity increased substantially more in the intervention group (p<0,001). In fact, the patients who participated in this study started to have a higher level of physical activity. According to the patients themselves, participation in the training and the positive evolution they encountered made them participate in more sports activities at the time. As previous studies suggest, previous physical activity is the strongest predictor of future physical activity level (34). Consistent with this finding and rationale, is the one that motivation for exercise, evaluated by BREQ-2 scale, was higher at the end of the trial in intervention group whit a statistically significant difference when compared to control group (p=0,002). Also a previous study found that believing that exercise is practicable, safe and

positive outcome expectations seems to be motivational in older adults with knee pain carrying out and persevering with exercise, and this finding is independent of age, socioeconomic status, work status, comorbidities, and depression (35).

Ideally, knee OA treatments should decrease pain, improve physical functioning and increase the quality of life in a safe and durable manner. Therapeutic interventions for knee OA requires a thorough understanding of the impact of a treatment on a patient's physical, social and psychological status. This program seemed to be a good treatment option for this population with knee osteoarthritis.

The training plan was essentially based on the recommendations of the OARSI guidelines that describe the exercise of strength as an appropriate non-surgical treatment for patients with knee OA (24). Other articles refer advantages of strength and walking exercises in patients with OA of the knee (36, 37). We chose this type of plan as a systematic review that included 48 trials suggests that an exercise program should be supervised, carried out 3 times weekly and comprise at least 12 sessions (27), although there were no previous studies using this type of structure in Portuguese primary care.

Although there are sampling (semi-random patients that came to practice on the study enrollment dates) and sample size limitations, there are interesting results which provide relevant direction for future larger and longer studies. Also, the male gender was predominant in the sample, representing 51,9%. This data not coincides with published findings that shows that knee osteoarthritis is more prevalent in women, both in Portugal and worldwide (3, 5). In this studied population, the higher prevalence of men could be justified by the greater independence of men with regard to transportation, one of the most limiting factors referred by our patients to participate in the trial sessions. The impossibility of providing transportation to the participants was one of the causes of limitation in sampling since many of the patients did not have their own transportation. The fact that patients did not fill out the questionnaires alone may have influenced some of their answers because they could have feared some judgment by the investigator. The choice of a questionnaire with double negation (BREQ-2) made it difficult to interpret and fill out the questionnaire, which may have led to answers that did not fully correspond to the reality. There are some other factors that influence the quality of life and the motivation for the exercise that have not been studied and that can act as confounding factors, such as cultural beliefs, barriers to exercise in the perspective of the patient, self-efficacy for exercise and positive outcome expectations. The dropouts could be a cause of a bias in this study, however, in the initial sample as in the final sample, there were no statistically significant differences between the groups.

CONCLUSION

Physical exercise has a positive impact in abdominal perimeter, quality of live, level of physical activity and motivation for exercise in patients in knee osteoarthritis.

In the future, it would be important to evaluate larger random samples in order to reduce these limitations of the study and eliminate the possible effect of confounding factors. Since knee osteoarthrosis is more prevalent in the elderly, we believe that it would also be important to develop and validate simpler and more direct questionnaires appropriate to the literacy of these patients. Also, long time impact of exercise in OA and motivation role should also be assessed.

This study confirms that, in Portugal, it would be important to think about creating physical exercise programs for people with OA knee pain, in order to improve quality of life of these people and also the motivation to practice more physical activity, promoting positive changes.

CONFLICT OF INTEREST

No potential conflict of interest relevant to this article was reported.

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QUESTIONÁRIO

Código ☐

IMPACTO DO EXERCÍCIO FÍSICO NO CONTROLO DA DOR, QUALIDADE DE VIDA E MOTIVAÇÃO EM PESSOAS COM ARTROSE DO JOELHO

QUESTIONÁRIO SOCIODEMOGRÁFICO E CLÍNICO

Assinale, a resposta correspondente às seguintes questões com um ☒

A. Dados Pessoais

1. Idade _____ Anos

2. Sexo
   - Masculino ☐
   - Feminino ☐

3. Estado Civil
   - Solteiro ☐
   - Casado ☐
   - Divorciado ☐
   - Viúvo ☐
   - Outro ☐

4. Vive
   - Sozinho ☐
   - Acompanhado ☐

5. Rendimentos
   - Superior ou igual ao salário mínimo ☐
   - Inferior ao salário mínimo ☐

6. Estado profissional
   - Ativo ☐
   - Reformado ☐
   - Desempregado ☐
   - Estudante ☐
   - Outro ☐

B. Dados Clínicos

7. Pratica exercício físico programado (caminhadas, ginásio, desporto, exercícios de força ou alongamentos, etc.)

Sim ☐
Não ☐

7.1. Quanto tempo em média por dia?

Superior ou igual a 30 minutos por dia ☐
Inferior a 30 minutos por dia ☐

8. Medicação habitual para a dor
(que esteja a tomar todos os dias nas últimas 2 semanas)

Sim ☐
Não ☐

8.1. Se respondeu que sim, indique qual/quais:

Medicação	Princípio ativo	Dose	Frequência			
			Diária	2-3x Semana	2-3x Mês	Raramente

9. Classificação da dor

Faça uma cruz ou um traço perpendicular à linha que represente a intensidade da sua dor.

AVALIAÇÃO DE GANHOS EM SAÚDE - E Q - 5 D

Assinale com uma cruz (assim X), um quadrado de cada um dos seguintes grupos, indicando qual das afirmações descreve melhor o seu estado de saúde hoje.

- **Mobilidade**

Não tenho problemas em andar ..... □1
Tenho alguns problemas em andar ..... □2
Tenho de estar na cama ..... □3

- **Cuidados Pessoais**

Não tenho problemas em cuidar de mim ..... □1
Tenho alguns problemas a lavar-me ou vestir-me..... □2
Sou incapaz de me lavar ou vestir sozinho/a ..... □3

- **Actividades Habituais** *(ex. trabalho, estudos, actividades domésticas, actividades em família ou de lazer)*

Não tenho problemas em desempenhar as minhas actividades habituais ..... □1
Tenho alguns problemas em desempenhar as minhas actividades habituais ..... □2
Sou incapaz de desempenhar as minhas actividades habituais ..... □3

- **Dor / Mal Estar**

Não tenho dores ou mal estar..... □1
Tenho dores ou mal estar moderados ..... □2
Tenho dores ou mal estar extremos ..... □3

- **Ansiedade / Depressão**

Não estou ansioso/a ou deprimido/a ..... □1
Estou moderadamente ansioso/a ou deprimido/a ..... □2
Estou extremamente ansioso/a ou deprimido/a ..... □3

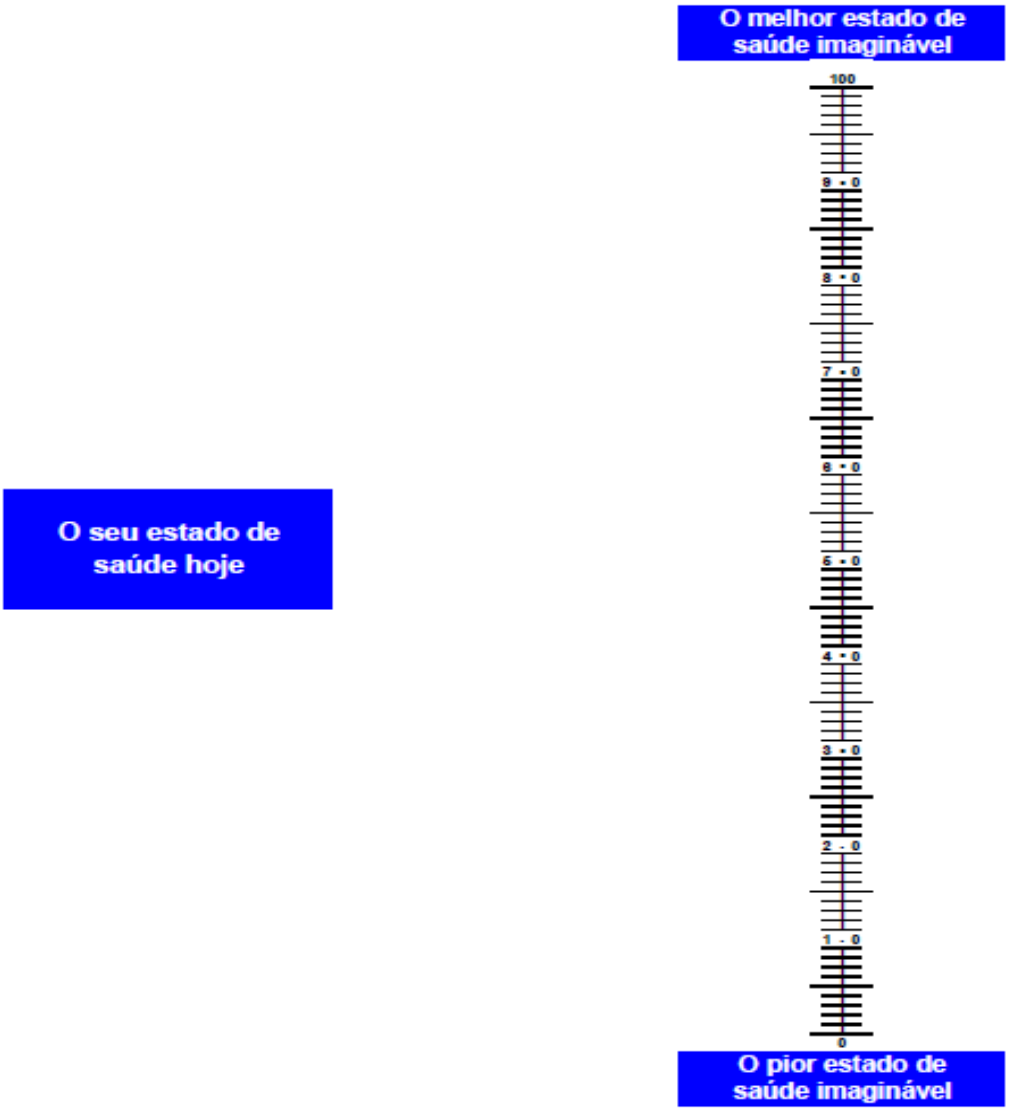
Comparado com o meu nível geral de saúde durante os últimos 12 meses, o meu estado de saúde hoje é:

Melhor ..... □1
O mesmo ..... □2
Pior ..... □3

ASSINALE O QUADRADO APROPRIADO

- Para ajudar as pessoas a classificarem o seu estado de saúde, desenhámos uma escala (semelhante a um termómetro) na qual o melhor estado de saúde que possa imaginar é marcado por 100 e o pior estado de saúde que possa imaginar é marcado por 0.

  Gostaríamos que indicasse nesta escala qual é hoje, na sua opinião, o seu estado de saúde. Por favor, desenhe uma linha a partir do rectângulo que se encontra à esquerda, até ao ponto da escala que melhor classifica o seu estado de saúde hoje.



Muito obrigado por ter preenchido este questionário.

Projecto
P A C E

NÍVEL ACTUAL DE ACTIVIDADE FÍSICA

Seleccione apenas um número

☐ 1. Não faço exercício nem caminhadas com regularidade, nem tenciono começar a fazê-lo num futuro próximo.

☐ 2. Não faço exercício nem caminhadas com regularidade, mas tenho pensado em começar.

☐ 3. Estou a tentar começar a fazer exercício ou caminhadas (ou) faço exercício ou caminhadas por vezes.

☐ 4. Faço exercício intenso menos que 3 vezes por semana (ou) faço exercício moderado menos que 5 vezes por semana.

☐ 5. Tenho feito exercício moderado 5 ou mais vezes por semana (ou mais do que 2 horas por semana) nos últimos 1-6 meses.

☐ 6. Tenho feito exercício moderado 5 ou mais vezes por semana (ou mais do que 2 horas por semana) nos últimos 7 meses ou mais.

☐ 7. Tenho feito exercício intenso 3-5 vezes por semana nos últimos 1 - 6 meses.

☐ 8. Tenho feito exercício intenso 3-5 vezes por semana nos últimos 7 meses ou mais.

E**xercício "intenso"** compreende actividades como correr, andar de bicicleta depressa, aulas de "aeróbica", natação e jogar ténis na modalidade de singulares. Deverá incluir qualquer actividade que faça o seu corpo trabalhar tanto como correr devagar e que dure pelo menos 20 minutos de cada vez. Este tipo de actividade aumenta o seu ritmo cardíaco, e fá-lo transpirar e por vezes ficar sem fôlego (não considere a musculação).

E**xercício "moderado"** inclui actividades como andar depressa, jardinar, andar de bicicleta lentamente, dançar, jogar ténis em pares ou qualquer trabalho exigente em casa. Deverá incluir qualquer actividade que faça o seu corpo trabalhar tanto como andar depressa e dure pelo menos 30 minutos de cada vez.

BREQ-2 – Versão Portuguesa
(Palmeira, A., Teixeira, P. Silva, M. & Markland, D., 2007)

Estamos interessados nas razões fundamentais das pessoas na decisão de se envolverem ou não envolverem no exercício físico. Usando a escala abaixo, por favor indique qual o nível mais verdadeiro para si. Relembramos que não há respostas certas ou erradas nem perguntas traiçoeiras. Queremos apenas saber como é que se sente em relação ao exercício.

Porque é que faz exercício?

Não é verdade para mim		Algumas vezes é verdade para mim		Muitas vezes é verdade para mim
0	1	2	3	4

1. Faço exercício porque outras pessoas dizem que devo fazer 0 1 2 3 4
2. Sinto-me culpado/a quando não faço exercício 0 1 2 3 4
3. Dou valor aos benefícios/vantagens do exercício 0 1 2 3 4
4. Faço exercício porque é divertido 0 1 2 3 4
5. Não vejo porque é que tenho de fazer exercício 0 1 2 3 4
6. Participo no exercício porque os meus amigos/família dizem que devo fazer 0 1 2 3 4
7. Sinto-me envergonhado/a quando falto a uma sessão de exercício 0 1 2 3 4
8. É importante para mim fazer exercício regularmente 0 1 2 3 4
9. Não percebo porque é que tenho de fazer exercício 0 1 2 3 4
10. Gosto das minhas sessões de exercício 0 1 2 3 4
11. Faço exercício porque os outros vão ficar insatisfeitos comigo se não fizer 0 1 2 3 4
12. Não percebo o objectivo de fazer exercício 0 1 2 3 4
13. Sinto-me fracassado/a quando não faço exercício durante algum tempo 0 1 2 3 4
14. Penso que é importante fazer um esforço por fazer exercício regularmente 0 1 2 3 4
15. Acho o exercício uma actividade agradável 0 1 2 3 4
16. Sinto-me pressionado/a pela minha família e amigos para fazer exercício 0 1 2 3 4
17. Sinto-me ansioso/a se não fizer exercício regularmente 0 1 2 3 4
18. Fico bem disposto e satisfeito por praticar exercício 0 1 2 3 4
19. Penso que o exercício é uma perda de tempo 0 1 2 3 4

(Página a preencher pelo médico(a))

1. Peso _____ Kg
2. Perímetro Abdominal _____ cm
3. IMC _____

4. Doenças Crónicas

Doença Crónica	Controlada	Não controlada

5. Critérios de inclusão/exclusão

	Presente	Ausente
Tem idade superior a 50A		
Dor no joelho há mais de 6M		
Diagnóstico de artrose do joelho (codificação L90 no SClínico) que veio a consulta no mês definido para recrutamento (abril de 2018)		
Apresentação de outra patologia osteoarticular ativa (osteoartrite secundária ou lesão ligamentar)		
Joelho com sinais Inflamatórios articulares (fase aguda, derrame do joelho, aumento da temperatura local)		
Deformidades do joelho prévias à artrose		
Intervenção ortopédica/Infiltrações articulares no joelho (nos últimos 6M)		
Intervenção ortopédica condicionante à capacidade dos membros inferiores		
História de traumatismo grave no(s) joelho(s)		
Condição médica não controlada que não permita uma participação segura no programa de exercício físico*		

6. O(A) paciente aparenta condições e capacidade para participar no programa contemplado por este estudo?

Sim	☐
Não	☐

7. É provável que o(a) paciente adira e seja capaz de manter as 8 semanas previstas pelo estudo?

Sim	☐
Não	☐

8. A participação no estudo será benéfica para este(a) paciente?

Sim	☐
Não	☐

CONSENTIMENTO INFORMADO

FORMULÁRIO DE INFORMAÇÃO E CONSENTIMENTO INFORMADO

TÍTULO DO PROJECTO DE INVESTIGAÇÃO: IMPACTO DO EXERCÍCIO FÍSICO NO CONTROLO DA DOR, QUALIDADE DE VIDA E MOTIVAÇÃO EM UTENTES COM ARTROSE DO JOELHO

CENTRO DE ESTUDO USF Araceti

INVESTIGADOR PRINCIPAL Joana Daniela de Oliveira Silva

MORADA Rua das Lavouras, Nº236, 4505-070 Argoncilhe

CONTACTO TELEFÓNICO 914250019

NOME DO DOENTE

(LETRA DE IMPRENSA) _____

É convidado(a) a participar voluntariamente neste estudo porque tem artrose do joelho com consequente sintomatologia que limita de alguma forma a sua qualidade de vida.

Este procedimento é chamado consentimento informado e descreve a finalidade do estudo, os procedimentos, os possíveis benefícios e riscos. A sua participação poderá contribuir para melhorar o conhecimento sobre sua patologia e uma das formas de atenuar a sintomatologia que apresenta consequente da mesma.

Receberá uma cópia deste Consentimento Informado para rever e solicitar aconselhamento de familiares e amigos. O Investigador ou outro membro da sua equipa irá esclarecer qualquer dúvida que tenha sobre o termo de consentimento e também alguma palavra ou informação que possa não entender.

Depois de compreender o estudo e de não ter qualquer dúvida acerca do mesmo, deverá tomar a decisão de participar ou não. Caso queira participar, ser-lhe-á solicitado que assine e date este formulário. Após a sua assinatura e a do Investigador, ser-lhe-á entregue uma cópia. Caso não queira participar, não haverá qualquer penalização nos cuidados que irá receber.

1. INFORMAÇÃO GERAL E OBJECTIVOS DO ESTUDO

Este estudo irá decorrer na USF Araceti, com o objectivo de avaliar o impacto do exercício físico na gonalgia, na qualidade de vida e motivação para o exercício nos indivíduos com artrose do joelho. Trata-se de um com intervenção mas não será feita nenhuma alteração na sua medicação.

Este estudo foi aprovado pela Comissão de Ética da Faculdade Medicina da Universidade de Coimbra (FMUC) de modo a garantir a protecção dos direitos, segurança e bem-estar de todos os doentes ou outros participantes incluídos e garantir prova pública dessa protecção.

Como participante neste estudo beneficiará da vigilância e apoio do seu médico, garantindo assim a sua segurança.

Este estudo tem por objectivo estudar o impacto do exercício físico na gonalgia e motivação para o exercício físico e, naturalmente, na qualidade de vida nos indivíduos com artrose do joelho seguidos em cuidados primários.

Serão incluídos 50 doentes.

2. PROCEDIMENTOS E CONDUÇÃO DO ESTUDO

2.1. Procedimentos

Um médico do estudo realizará uma revisão da sua história médica recente e registará a sua medicação para a dor.

Será pedido que responda a um questionário com dados sobre a sua idade e formação, qualidade de vida, motivação para fazer exercício e grau de dor e será medido o seu peso e altura.

As pessoas serão divididas em dois grupos: um deles com intervenção - submetido a um plano de exercício físico com acompanhamento – e o outro, controlo - sem qualquer intervenção além dos cuidados habituais de alívio de dor.

2.2. Calendário das visitas/ Duração (exemplo)

Após 8 semanas, serão novamente preenchidos os inquéritos após nova consulta médica.

O grupo escolhido para fazer exercício, virá durante essas 8 semanas a 3 treinos semanais.

2.3. Tratamento de dados/ Randomização

As pessoas serão divididas aleatoriamente (à sorte) em dois grupos.

Os dados serão registados e posteriormente trabalhados através de estatística descritiva e inferencial recorrendo a testes paramétricos e não-paramétricos de acordo com a normalidade ou não da distribuição das variáveis na população.

4. POTENCIAIS BENEFÍCIOS

Este estudo tem a vantagem de estudar a sua doença e permitir um melhor conhecimento de como fazer o tratamento da mesma. Além disso, a informação que será recolhida irá contribuir para uma melhor informação dos médicos de forma a melhorar os cuidados clínicos a prestar aos doentes com situações idênticas à sua.

5. NOVAS INFORMAÇÕES

Ser-lhe-á dado conhecimento de qualquer nova informação que possa ser relevante para a sua condição ou que possa influenciar a sua vontade de continuar a participar no estudo.

8. PARTICIPAÇÃO/ ABANDONO VOLUNTÁRIO

É inteiramente livre de aceitar ou recusar participar neste estudo. Pode retirar o seu consentimento em qualquer altura sem qualquer consequência para si, sem precisar de explicar as razões, sem qualquer penalidade ou perda de benefícios e sem comprometer a sua relação com o Investigador que lhe propõe a participação neste estudo. Ser-lhe-á pedido para informar o Investigador se decidir retirar o seu consentimento.

O Investigador do estudo pode decidir terminar a sua participação neste estudo se entender que não é do melhor interesse para a sua saúde continuar nele. A sua participação pode ser também terminada se não estiver a seguir o plano do estudo, por decisão administrativa ou decisão da Comissão de Ética. O médico do estudo notificá-lo-

á se surgir uma dessas circunstâncias, e falará consigo a respeito da mesma.

9. CONFIDENCIALIDADE

Sem violar as normas de confidencialidade, serão atribuídos a auditores e autoridades reguladoras acesso aos registos médicos para verificação dos procedimentos realizados e informação obtida no estudo, de acordo com as leis e regulamentos aplicáveis. Os seus registos manter-se-ão confidenciais e anonimizados de acordo com os regulamentos e leis aplicáveis. Se os resultados deste estudo forem publicados a sua identidade manter-se-á confidencial.

Ao assinar este Consentimento Informado autoriza este acesso condicionado e restrito.

Pode ainda em qualquer altura exercer o seu direito de acesso à informação. Pode ter também acesso à sua informação médica directamente ou através do seu médico neste estudo. Tem também o direito de se opor à transmissão de dados que sejam cobertos pela confidencialidade profissional.

Os registos médicos que o identificarem e o formulário de consentimento informado que assinar serão verificados para fins do estudo pelo promotor e/ou por representantes do promotor, e para fins regulamentares pelo promotor e/ou pelos representantes do promotor e agências reguladoras noutros países. A Comissão de Ética responsável pelo estudo pode solicitar o acesso aos seus registos médicos para assegurar-se que o estudo está a ser realizado de acordo com o protocolo. Não pode ser garantida confidencialidade absoluta devido à necessidade de passar a informação a essas partes.

Ao assinar este termo de consentimento informado, permite que as suas informações médicas neste estudo sejam verificadas, processadas e relatadas conforme for necessário para finalidades científicas legítimas.

Confidencialidade e tratamento de dados pessoais

Os dados pessoais dos participantes no estudo, incluindo a informação médica ou de saúde recolhida ou criada como parte do estudo, (tais como registos médicos ou resultados de testes), serão utilizados para condução do estudo, designadamente para fins de investigação científica e farmacológica relacionados com o medicamento ou com a patologia em estudo.

Ao dar o seu consentimento à participação no estudo, a informação a si respeitante, designadamente a informação clínica, será utilizada da seguinte forma:

1. Os investigadores e as outras pessoas envolvidas no estudo recolherão e utilizarão os seus dados pessoais para as finalidades acima descritas.
2. Os dados do estudo, associados às suas iniciais ou a outro código que não o (a) identifica directamente (e não ao seu nome) serão comunicados pelos investigadores e outras pessoas envolvidas no estudo ao investigador principal, que os utilizará para as finalidades acima descritas.
3. Os dados do estudo, associados às suas iniciais ou a outro código que não permita identificá-lo(a) directamente, poderão ser comunicados a autoridades de saúde nacionais e internacionais.
4. A sua identidade não será revelada em quaisquer relatórios ou publicações resultantes deste estudo.
5. Todas as pessoas ou entidades com acesso aos seus dados pessoais estão sujeitas a sigilo profissional.
6. Ao dar o seu consentimento para participar no estudo autoriza o promotor ou empresas de monitorização de estudos/estudos especificamente contratadas para o efeito e seus colaboradores e/ou autoridades de saúde, a aceder aos dados constantes do seu processo clínico, para conferir a informação recolhida e registada pelos investigadores, designadamente para assegurar o rigor dos dados que lhe dizem respeito e para garantir que o estudo se encontra a ser desenvolvido correctamente e que os dados obtidos são fiáveis.
7. Nos termos da lei, tem o direito de, através de um dos médicos envolvidos no estudo/estudo, solicitar o acesso aos dados que lhe digam respeito, bem como de solicitar a rectificação dos seus dados de identificação.
8. Tem ainda o direito de retirar este consentimento em qualquer altura através da notificação ao investigador, o que implicará que deixe de participar no estudo/estudo. No entanto, os dados recolhidos ou criados como parte do estudo até essa altura que não o(a) identifiquem poderão continuar a ser utilizados para o propósito de estudo/estudo, nomeadamente para manter a integridade científica do estudo, e a sua informação médica não será removida do arquivo do estudo.
9. Se não der o seu consentimento, assinando este documento, não poderá participar neste estudo. Se o consentimento agora prestado não for retirado e até que o faça, este será válido e manter-se-á em vigor.

10. COMPENSAÇÃO

Este estudo é da iniciativa do investigador e, por isso, se solicita a sua participação sem uma compensação financeira para a sua execução, tal como também acontece com os investigadores e o Centro de Estudo.

11. CONTACTOS

Se tiver perguntas relativas aos seus direitos como participante deste estudo, deve contactar:

Presidente da Comissão de Ética da FMUC,

Azinhaga de Santa Comba, Celas – 3000-548 Coimbra

Telefone: 239 857 707

e-mail: comissaoetica@fmed.uc.pt

Se tiver questões sobre este estudo deve contactar:

Joana Daniela de Oliveira Silva

Rua das Lavouras, Nº 236, 4505-070 Argoncilhe

E-mail: joana.oliveira.silva@gmail.com

Telemóvel: 914250019

NÃO ASSINE ESTE FORMULÁRIO DE CONSENTIMENTO INFORMADO A MENOS QUE TENHA TIDO A OPORTUNIDADE DE PERGUNTAR E TER RECEBIDO RESPOSTAS SATISFATÓRIAS A TODAS AS SUAS PERGUNTAS.

CONSENTIMENTO INFORMADO

De acordo com a Declaração de Helsínquia da Associação Médica Mundial e suas atualizações:

1. Declaro ter lido este formulário e aceito de forma voluntária participar neste estudo.
2. Fui devidamente informado(a) da natureza, objectivos, riscos, duração provável do estudo, bem como do que é esperado da minha parte.
3. Tive a oportunidade de fazer perguntas sobre o estudo e percebi as respostas e as informações que me foram dadas.

   A qualquer momento posso fazer mais perguntas ao médico responsável do estudo. Durante o estudo e sempre que quiser, posso receber informação sobre o seu desenvolvimento. O médico responsável dará toda a informação importante que surja durante o estudo que possa alterar a minha vontade de continuar a participar.
4. Aceito que utilizem a informação relativa à minha história clínica e os meus tratamentos no estrito respeito do segredo médico e anonimato. Os meus dados serão mantidos estritamente confidenciais. Autorizo a consulta dos meus dados apenas por pessoas designadas pelo promotor e por representantes das autoridades reguladoras.
5. Aceito seguir todas as instruções que me forem dadas durante o estudo. Aceito em colaborar com o médico e informá-lo(a) imediatamente das alterações do meu estado de saúde e bem-estar e de todos os sintomas inesperados e não usuais que ocorram.
6. Autorizo o uso dos resultados do estudo para fins exclusivamente científicos e, em particular, aceito que esses resultados sejam divulgados às autoridades sanitárias competentes.
7. Aceito que os dados gerados durante o estudo sejam informatizados pelo promotor ou outrem por si designado.

   Eu posso exercer o meu direito de rectificação e/ ou oposição.
8. Tenho conhecimento que sou livre de desistir do estudo a qualquer momento, sem ter de justificar a minha decisão e sem comprometer a qualidade dos meus cuidados médicos. Eu tenho conhecimento que o médico tem o direito de decidir

sobre a minha saída prematura do estudo e que me informará da causa da mesma.

9. Fui informado que o estudo pode ser interrompido por decisão do investigador, do promotor ou das autoridades reguladoras.

Nome do Participante**_____**

Assinatura : **_____** ***Data:*****_____/____/___**

Nome de Testemunha / Representante Legal:**_____**

Assinatura: **_____** ***Data:*****_____/____/___**

Confirmo que expliquei ao participante acima mencionado a natureza, os objectivos e os potenciais riscos do Estudo acima mencionado.

Nome do Investigador:**_____**

Assinatura: **_____** ***Data:*****_____/____/___**

CONSORT CHECKLIST

CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/ Topic	Item No	Checklist item	Reported on page No
		Title and abstract	
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	6
		Introduction	
Background and objectives	2a	Scientific background and explanation of rationale	8
	2b	Specific objectives or hypotheses	8
		Methods	
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	10
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	10
Participants	4a	Eligibility criteria for participants	10
	4b	Settings and locations where the data were collected	10
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	10-11
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	11
	6b	Any changes to trial outcomes after the trial commenced, with reasons	-----
Sample size	7a	How sample size was determined	10
	7b	When applicable, explanation of any interim analyses and stopping guidelines	-----
Randomisation: Sequence generation	8a	Method used to generate the random allocation sequence	11
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	11
Allocation concealm	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps	11

ent mec hani sm		taken to conceal the sequence until interventions were assigned	
Implement ation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	11
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	-----
	11b	If relevant, description of the similarity of interventions	-----
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	15
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	15
		Results	
Participant flow (a diagram is strongly recommen ded)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	16
	13b	For each group, losses and exclusions after randomisation, together with reasons	16
Recruitme nt	14a	Dates defining the periods of recruitment and follow-up	-----
	14b	Why the trial ended or was stopped	-----
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	16
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	16
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	16-18
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	-----
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	-----
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	-----
		Discussion	
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	20
Generalis ability	21	Generalisability (external validity, applicability) of the trial findings	19-20

Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	19-20
		Other information	
Registration	23	Registration number and name of trial registry	45
Protocol	24	Where the full trial protocol can be accessed, if available	45
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	-----

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

TRIAL REGISTRY

ClinicalTrials.gov PRS
Protocol Registration and Results System

ID: UCoimbra IMPACT OF EXERCISE IN PATIENTS WITH KNEE ARTHRITIS - RANDOMIZED CONTROLLED TRIAL - [NCT ID not yet assigned]

Protocol Registration Preview

This is a rough approximation of how the Protocol Registration will appear on the ClinicalTrials.gov public web site.

IMPACT OF EXERCISE IN PATIENTS WITH KNEE ARTHRITIS - RANDOMIZED CONTROLLED TRIAL -

⚠ The safety and scientific validity of this study is the responsibility of the study sponsor and investigators. Listing a study does not mean it has been evaluated by the U.S. Federal Government. Read our disclaimer for details.

ClinicalTrials.gov Identifier: [Not yet assigned]

Recruitment Status: Completed
First Posted: *
Last Update Posted: *

* Date not available in PRS

Sponsor:

University of Coimbra

Information provided by (Responsible Party):

Joana Daniela de Oliveira Silva, University of Coimbra

Study Description

Brief Summary:

Knee osteoarthrosis is among the most prevalent musculoskeletal disorders, especially in elderly and exercise is one of the most effective non-pharmacological treatment options, although its impact is not totally studied.

Evaluate the impact of physical exercise on knee pain, quality of life and exercise motivation in patients with knee osteoarthritis.

Non-pharmacological, randomized, controlled clinical trial with a sample composed by primary care patients with age over 50 years, with diagnosis of knee osteoarthritis randomly assigned to a intervention and a control group. Evaluations through biometric data and questionnaires before and after exercise plan compliance with for 8 weeks follow-up.

Twenty seven patients were studied. The majority was male accounting for 51,9% (N=14) of the sample. The participants were between 59 and 85 years old with a mean age of 70,7 +/- 6,7 years, with no demographic or biometric differences between groups. The intervention group had a decrease in weight and BMI (p=0,009) and less and less pain intensity after the trial, compared to control group (p=0,178). Statistically significant differences between groups were found in abdominal perimeter (p=0,050), quality of life (p<0,001), motivation for exercise (p=0,002) and physical activity level (p<0,001) at the end of the trial.

A physical exercise 8 week program has a positive impact in abdominal perimeter, quality of live, motivation for exercise and physical activity level in patients in knee osteoarthritis.

Condition or disease	Intervention/treatment
Knee Osteoarthritis	Exercise

Study Design

Study Type: Interventional
Actual Enrollment: 38 participants
Allocation: Randomized
Intervention Model: Parallel Assignment
Masking: None (Open Label)

Primary Purpose:	Treatment
Official Title:	IMPACT OF EXERCISE ON PAIN CONTROL, QUALITY OF LIFE AND MOTIVATION IN PATIENTS WITH KNEE ARTHRITIS - RANDOMIZED CONTROLLED TRIAL -
Actual Study Start Date:	January 3, 2018
Actual Primary Completion Date:	April 30, 2018
Actual Study Completion Date:	August 31, 2018

Arms and Interventions

Arm	Intervention/treatment
No Intervention: Control Group A control group in which usual care was carried on	
Experimental: Intervention Group An intervention group that underwent an exercise plan for 2 months, 3 times a week	Exercise 1º week 10 minutes walking Chair squat Knee extension exercise In supine position leg elevation at 45º with extended lower limb Hip extension exercise 8 minutes walking 2º to 4º week: 10 minutes walking Chair squat Knee extension exercise Seated Hip Abduction with Resistance Band Exercise In supine position leg elevation at 45º with extended lower limb Hip extension exercise 8 minutes walking 5º to 6º week: Two more exercises were added to improve resistance 10 minutes walking Chair squat Dynamic stepping exercise Balance on support alternately Knee extension exercise Seated hip abduction with resistance band exercise In supine position leg elevation at 45º with extended lower limb Hip extension exercise 8 minutes walking 7º to 8º week: Number of repetitions were increased to 20

Outcome Measures

Primary Outcome Measure:

1. Quality of life [Time Frame: Before and after exercise plan compliance with for 8 weeks follow-up]

Secondary Outcome Measures:

1. Pain [Time Frame: Before and after exercise plan compliance with for 8 weeks follow-up]

2. Exercise level [Time Frame: Before and after exercise plan compliance with for 8 weeks follow-up]

3. Motivation for exercise [Time Frame: Before and after exercise plan compliance with for 8 weeks follow-up]

Eligibility Criteria

Ages Eligible for Study: 50 Years and older
Sexes Eligible for Study: All
Gender Based: No
Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

- Patients with age over 50 years, with diagnosis of knee osteoarthritis (with ICPC-2 L90 coding in informatic SClinico program) who came to a medical consultation in the defined period for recruitment and with knee pain for more than 6 months ago

Exclusion Criteria:

- Exclusion criteria were having another active osteoarticular pathology associated with the knee (N=3) - secondary osteoarthritis or ligament injury; knee with inflammatory signs (N=1) - acute pathology, knee effusion and increased temperature; deformities in the knee prior to arthritis (N=0); orthopedic intervention or intra-articular injection in the knee in the last 6 months (N=0); orthopedic intervention with a consequent decrease in performance in lower limbs (N=0); history of severe knee trauma (N=0); another uncontrolled medical condition that does not allow safe participation in the physical exercise program (N=14) such as: symptomatic heart or vascular disease (angina, peripheral vascular disease, congestive heart failure), severe hypertension, recent stroke, decompensated chronic obstructive pulmonary disease, severe insulin dependent diabetes mellitus, uncontrolled psychiatric illness, kidney disease, liver disease, active cancer disease and anemia; inability/improbability in being able to participate in the 8 weeks of study (N=17); inability to complete the

protocol, in the opinion of the clinical team, due to the fragility, disease or other reasons (N=2); programed exercise practice (N=0). Also 7 patients were excluded for not having knee pain despite the diagnosis of knee osteoarthritis and 2 with bilateral knee replacement.

Contacts and Locations

Locations

Portugal

FACULTY OF MEDICINE, UNIVERSITY OF COIMBRA

Coimbra, Portugal, 3004-504

Investigators

Principal Investigator: Joana Silva, Dr University of Coimbra

More Information

Responsible Party:	Joana Daniela de Oliveira Silva, Joana Oliveira Silva, University of Coimbra
ClinicalTrials.gov Identifier:	
Other Study ID Numbers:	UCoimbra
Last Verified:	March 2018

Individual Participant Data (IPD) Sharing Statement:

Plan to Share IPD: No

Human Subjects Protection Review Board Status: Approved

Studies a U.S. FDA-regulated Drug Product: No

Studies a U.S. FDA-regulated Device Product: No