QUADRICEPS STRENGTHENING EXERCISES ARE EFFECTIVE IN IMPROVING PAIN, FUNCTION AND QUALITY OF LIFE IN PATIENTS WITH OSTEOARTHRITIS OF THE KNEE

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ABSTRACT
Objective: The purpose of this research was to verify the effectiveness of an eight-week quadriceps strengthening program on pain, function and quality of life of patients with knee osteoarthritis. Methods: A hundred patients were randomized into two groups: 1- Exercise Group (ExG) and 2- Orientation Group. The Timed Up and Go (TUG) test, the Numerical Rating Scale (NRS) and the Short Form-36 were used for the assessment. Results: Eighty-one patients completed the survey. According to the intention to treat (ITT) analysis, there was statistically significant difference in ExG compared to OG in all the variables assessed. Conclusion: The program quadriceps strengthening exercises applied in this randomized clinical trial was effective in improving pain, function and quality of life of patients with knee osteoarthritis.

Level of Evidence I, Randomized Clinical Trial.

Keywords: Knee. Exercise therapy. Osteoarthritis/rehabilitation.

INTRODUCTION
Osteoarthritis (OA) is a chronic disease, located in the joints, affecting one third of adults and presenting a tendency to increase with age.1 Knee OA can be associated with symptoms of pain, instability, reduction of range of motion (ROM) and consequently, deterioration in quality of life and function. This functional limitation results in an increase of the risk of morbidity and mortality.2,3 Authors report that patients with knee OA present less quadriceps muscle strength in comparison to the control group. As the quadriceps muscle plays the role of shock absorber, a weakness of this muscle decreases the joint protection, resulting in greater stress and overload on the knee.4 Quadriceps strengthening exercises performed over eight weeks proved just as effective in function improvement as the use of non-hormonal anti-inflammatory drugs in patients with OA of the knee.5 Moreover, moderate-intensity exercises showed themselves to be a good form of treatment not only for the improvement of symptoms, but also in the increase of the glycosaminoglycan content.6 Fransen and McConnell7 carried out a systematic review of the effectiveness of exercises in patients with knee OA. The authors verified that these have a beneficial effect on pain and function. However, there was accentuated variability in terms of the type of exercise evaluated and particularly in relation to the methodological aspects. Besides the physical benefits, the exercises also had a beneficial effect on the mental health of patients with knee OA. Thus, due to the fact that reduced mobility is one of the main factors responsible for limitation of functionality and deterioration of quality of life in patients with knee OA, it is extremely important to conduct research on interventions based on an appropriate methodology, targeting the improvement of the functionality and quality of life of these patients.4 The objective of this randomized clinical trial was to verify the effect of an open kinetic chain quadriceps strengthening exercise program on the pain, function and quality of patients with knee OA.

METHODS
The rheumatologists of the Department of Rheumatology of the Ambulatório de Especialidades de Interlagos (Specialty Outpatient Clinic) referred the patients included in the present study. A statistician performed the allocation of the patients...
using a computer program. Aiming to avoid selection bias, a third person numbered and sealed the opaque envelopes. All the patients signed a consent term upon joining the group for participation in the study. The patients involved in the survey are registered with the Department of Rheumatology of the Ambulatório de Especialidades de Interlagos - São Paulo, Brazil. The study was conducted over the period between April 2007 and April 2009.

Approval by the Ethics Committee
The Institutional Reasearch Board of Universidade Federal de São Paulo approved this study under the following registration number: CEP 0141/07.

Sample Size
It was estimated that a sample of 40 patients would be able to detect a minimum clinical difference of 1 minute ± 3 seconds in the Timed Up and Go (TUG) test, with the power of 80%.8 10 We employed a paired comparison between the three groups with significance level of 0.05 (Student’s T-test), using a covariance analysis (ANCOVA). The present study followed the gold standard of evidence in rheumatology, allocating 50 patients in each group.10

Participants
One hundred patients were selected according to the inclusion and exclusion criteria established previously. The patients were allocated in two groups:
1) Exercise Group (ExG) (n = 50)
2) Orientation Group (OG) (n = 50).

The inclusion criteria were: age between 50 and 75 years, diagnosis of knee OA according to the criteria of the American College of Rheumatology (ACR) based on history, physical examination and radiographic findings (pain in the knee and one of the following items – over 50 years of age, less than 30 min of morning stiffness and crepituation in active movement and osteophytes), knee x-ray in the last 12 months and grade 2 or above in the Kellgren and Lawrence radiographic classification. Patients with a diagnosis of fibromyalgia, unstable heart condition, physical activity more often than twice a week, inability to pedal a stationary bicycle and previous knee arthroplasty were not included. The occurrence of adverse events was considered an exclusion criterion.

Medication
The patients’ medications were standardized and remained the same during the intervention period. Paracetamol was the drug prescribed for analgesia while diacerein and chloroquine diphosphate were used for control of OA.

Orientation Group (OG)
Patient orientation can be defined as “any educational activity planned with the objective of improving the patient’s state of health”.11 The patients from the Orientation group received an explanation about the manual after the initial evaluation. The orientation manual (Figure 1) consisted of a description of knee OA, as well as the possible signs and symptoms presented by the patients, and pointed them in the direction of a better way of dealing with the functional difficulties.

Over a period of eight weeks, the patients received two phone calls as a means of encouragement to follow the orientations.

Exercise Group (ExG)
The patients from the ExG group took part in group sessions lasting from 30 to 40 minutes, with a weekly frequency of twice a week.

The load used for muscle strengthening was based on the 10 maximum repetitions test.12 After estimating 100% of the load, 50-60% of this load was established for use in the strengthening of the patients from the study. The exercise protocol used by us consisted of 10 minutes of warm-up on a stationary bicycle, ischiotibial stretching exercises and three series of 15 repetitions of knee extension exercises, aiming to strengthen the quadriceps muscle. The interval between series was from 30 to 45 seconds. The load used in the exercise was increased according to tolerance. The patient’s positioning for the exercise was: seated in a chair, with 90 degrees of knee and hip flexion. The patients from the ExG also received the orientation manual given to the OG group. (Figure 1)

ASSESSMENT
The pre and post-intervention assessments were carried out by a physiotherapist blinded to the patient’s group. The following items were evaluated:

Functional performance by means of the TUG test: TUG is a low cost test with a simple method that was developed to assess the patient’s functional mobility in everyday activities. This test involves the following sequence of movements: getting out of the chair, walking three meters, turning around and sitting down on the chair again. The time that the patient takes to perform the movement sequence is recorded for comparison before and after treatment.8 In our study, the patients had a chance to become familiar with the test before the collection time was recorded. The best time recorded from three attempts was used. The level of pain was measured using the Numerical Rating Scale from 0 to 10.13 (Figure 2)

Quality of life – we used the SF-36 questionnaire,14 which contains 36 items that assess functional capacity, physical aspects, pain, general state of health, vitality, social aspects, emotional aspects and mental health. The scoring of each item of the questionnaire ranges from 0 to 100, where zero corresponds to the worst general state of health and 100 to the best state of health.14

Statistical Analysis
The paired t-test was used for the assessment between the pre and post-intervention times. Alpha=5% was used in all the tests, and tests with p<0.05 were considered statistically significant. For the intention to treat (ITT) analysis, which includes all the patients who were randomized, we used mixed model variance analysis (ANOVA) with repeated measurements, with measurements of occasion as intragroup factor and intervention as intergroup factor. The relations between observations were analyzed as an unstructured covariance matrix. There was no data input in the ITT to evaluate the pre and post differences between the three groups evaluated, since Chakraborty and Gu15 showed that the mixed model of analysis, without data input, always provides power greater than or equal to the analyses that use the mixed model, with lost data input. In both analyses, the effect size was computed as the difference between the

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It is a disease that promotes the wear and tear of the articular cartilage. The cartilage layers become damaged and as time passes cease to facilitate smooth contact between the bone surfaces of the joint. Pain is provoked by the friction of one bone rubbing against the other, in the absence or deterioration of the articular cartilage. What is osteoarthritis?

What are the signs and symptoms?
A patient with osteoarthritis may have pain, especially when about to start moving, which we call morning stiffness or after immobilization. Over time the pain may intensify and be present on a permanent basis. Crepitus upon knee movement is a frequent occurrence.

Which are the difficulties that I might experience in my daily routine?
Everyday difficulties vary according to patients’ symptoms. But difficulty and pain generally occur in bearing the body weight on the affected knee, going up and down stairs or walking.

What should I do if I feel pain?
Osteoarthritis has treatment and this should be supervised by a physician. But a simple way of improving your pain is to apply a hot water bottle, with temperature ranging from warm to hot, on the knee joint (be careful not to burn the skin. Use protection and test the temperature of the water beforehand) And what if I have swelling?
To cope with the swelling, you can combine rest with an icepack, and keep your knee raised above the level of your heart. The ice should be applied on the knee joint for 20min.

Which other precautions should I take?
- If you are overweight, losing a few kilos will reduce the stress on the joint.
- Use comfortable, flat shoes with a rubber sole.
- In relation to pain when walking, use a cane as a walking aid.
- Try to get plenty of sleep

CONTINUATION

EIGHT WEEKS AFTER RECEIVING THIS MANUAL, (___/___/____), YOU SHOULD PAY US A RETURN VISIT TO VERIFY YOUR PROGRESS DURING THIS PERIOD.
### Table 1. Demographic characteristics of the patients and baseline value means.

| Variable         | OG    | ExG   | p-value |
|------------------|-------|-------|---------|
| Sex              | 94.00 | 90.00 | 0.76    |
| Woman            | 6.00  | 10.00 |         |
| Man              |       |       |         |
| Side treated     | 34.00 | 22.00 | 0.35    |
| Right            | 41.67 | 25.00 |         |
| Left             | 22.92 | 29.17 |         |
| Age              | 58.78 | 61.50 | 0.23    |
| BMI              | 30.00 | 29.72 | 0.95    |
| KL Grade         | 0.83  |       |         |
| 2                | 91.18 | 92.88 |         |
| 3                | 5.88  | 4.88  |         |
| 4                | 2.94  | 2.44  |         |
| Pain (NRS)       | 6.92  | 7.43  | 0.09    |
| TUG              | 5.74  | 4.27  | 0.07    |
| SF-36            | 5.89  | 4.89  | 0.08    |
| Functional Capacity | 6.14  | 16.40 | 0.00    |
| Physical Aspects | 6.14  | 16.40 | 0.00    |
| Pain             | 6.14  | 16.40 | 0.00    |
| General State of Health | 6.14  | 16.40 | 0.00    |
| Vitality         | 5.17  | 5.17  | 0.56    |
| Social Aspects   | 5.17  | 5.17  | 0.56    |
| Emotional Aspects| 5.17  | 5.17  | 0.56    |
| Mental Health    | 5.17  | 5.17  | 0.56    |

Caption: OG – Orientation Group; ExG – Exercise Group; BMI – Body Mass Index; NRS – Numerical Rating Scale; SF-36 – Short Form-36 TUG - Timed Up and Go Test; CI – Confidence Interval; * - Values presented as mean (SD); + - Values presented as percentage.

### Table 2. Results between the pre and post-intervention times.

| Variable         | Groups | Pre    | Post   | Mean difference (CI of 95%) | p-value |
|------------------|--------|--------|--------|----------------------------|---------|
| Pain (NRS)       | OG     | 6.92 ±2.60 | 5.74 ±3.14 | -0.88 (-1.92;0.15) | 0.09    |
|                  | ExG    | 7.43 ±2.01 | 4.27 ±2.45 | -3.17 (-4.23;-2.10) | <.0001* |
| TUG              | OG     | 10.08 ±2.96 | 9.22 ±3.31 | -0.57(-1.20;0.06)  | 0.07    |
|                  | ExG    | 9.34 ±2.47 | 7.42 ±1.70 | -2.00(-2.54;-1.46) | <.0001* |
| SF-36            | OG     | 34.53 ±24.76 | 41.55 ±26.66 | 6.96(-0.46;14.39) | 0.06    |
|                  | ExG    | 31 ±19.59 | 49.38 ±23.94 | 20.28(12.68;27.88) | <.0001* |

Caption: OG – Orientation Group; ExG – Exercise Group; NRS – Numerical Rating Scale; CI – Confidence Interval; *Statistically significant result, p≤0.05.
DISCUSSION

The present study showed the effectiveness of an exercise protocol for quadriceps strengthening through the evaluation of pain, TUG test and quality of life. It is worth emphasizing that Outcome Measures in Rheumatology recommends the measurement of pain and function as a prerequisite for the assessment of patients with knee, hand and hip OA. The rehabilitation protocol applied by us lasted for 8 weeks, in twice-weekly sessions. The quality of life aspects that presented a statistically significant improvement were: functional capacity, physical aspects, pain, vitality and general state of health. Our study is consistent with Aglamis et al. who observed a statistically significant pre and post-intervention improvement in the exercise group in the following aspects of SF-36: functional capacity, pain and general state of health. In the study by Foley et al., the only statistical significant improvement brought about by the strengthening exercises was in the mental aspect of the SF-12 questionnaire, with no statistically significant difference in the score related to physical aspects. The main difference between the study by Foley et al. and the present study was the shorter duration of the intervention, which consisted of six weeks. However, both studies performed a rehabilitation protocol that involved 12 or more sessions. According to Fransen and McConnell, exercise programs that include more than 12 sessions are associated with an improvement in relation to pain and function. The focus of the orientation program used in this survey was to advise the patients on how to adjust their daily activities to decrease overload on the knee. The patients were provided with verbal and written guidance, based on the orientation manual distributed to the patients from both groups, which consisted of a brief description of knee OA, as well as the signs, symptoms and possible functional limitations. Moreover, the manual instructed the patients to apply a hot water bottle with the temperature ranging from warm to hot in case of pain with absence of signs of inflammation and use of an ice pack to improve pain when accompanied by swelling. It is worth emphasizing that such guidelines were reinforced during the sessions. The main goal of an orientation program is to maintain or improve health or, in some cases, to decrease the deterioration of the clinical state. However, the orientation group did not present statistically significant improvement in any of the aspects of SF-36 or in the evaluation of pain by means of the numerical rating scale. Nunez et al. observed a statistically significant improvement in a group that received guidance in the aspects pain and functional capacity of the SF-36 questionnaire. The main difference between the orientation program of this study and that used by Nunes is the fact that we did not include the exercise instruction as this was not the objective of the present survey. Thomas et al. verified that the patients who received only telephone calls as a means of contact intended as guidance and to monitor the symptoms of the patients with knee OA did not present statistically significant reduction in the pain level. On the other hand, the patients who performed exercises at home presented a statistically significant reduction in the pain level. Furthermore, the patients who performed exercises at home presented a statistically significant increase in the functional capacity of the SF-36 questionnaire. 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Table 3. Comparison between groups.

| Variable                     | Comparison between groups | Difference between the means - CI (95%) | Effect size CI (95 %) | p-value |
|------------------------------|---------------------------|----------------------------------------|-----------------------|---------|
| Pain (NRS)                   | OG x ExG                  | 2.09 (0.71 ; 3.46)                     | 0.72 (0.24 ; 1.18)    | 0.00*   |
| TUG                          | OG x ExG                  | 1.29 (0.54 ; 2.04)                     | 0.81 (0.33 ; 1.28)    | 0.00*   |
| SF-36                        |                           |                                        |                       |         |
| Functional Capacity          | OG x ExG                  | -12.39 (-23.44; -1.33)                 | 0.72 (0.24; 1.18)     | 0.02*   |
| Physical Aspects             | OG x ExG                  | -12.16 (-36.69; 12.37)                 | -0.23 (-0.68; 0.23)   | 0.32    |
| Pain                         | OG x ExG                  | -4.71 (-21.49; 12.05)                  | -0.16 (-0.61; 0.30)   | 0.49    |
| General State of Health      | OG x ExG                  | -1.66 (-11.46; 8.14)                   | -0.08 (-0.53; 0.38)   | 0.73    |
| Vitality                     | OG x ExG                  | -6.03 (-17.29; 5.22)                   | -0.24 (-0.70; 0.21)   | 0.29    |
| Social Aspects               | OG x ExG                  | -6.52 (-21.09; 8.05)                   | -0.20 (-0.59; 0.31)   | 0.37    |
| Emotional Aspects            | OG x ExG                  | -3.55 (-30.44; 23.35)                  | -0.07 (-0.52; 0.39)   | 0.79    |
| Mental Health                | OG x ExG                  | -1.46 (-12.09; 9.17)                   | -0.06 (-0.52; 0.39)   | 0.78    |

Caption: OG – Orientation Group; ExG – Exercise Group; NRS – Numerical Rating Scale; TUG – Timed Up and Go Test; CI – Confidence Interval; * The comparison presented statistically significant difference, p < 0.05.

the aspects functional capacity (p<0.001), pain (p=0.00), physical aspects (p=0.00), general state of health (p=0.02) and vitality (p=0.01). (Table 2) There was no statistically significant change in the scores of emotional aspects, mental health and social aspects. (Table 2) The assessments of the patients from OG did not show statistically significant pre and post-intervention difference in the evaluation of the aspects of the SF-36 quality of life questionnaire. In the intergroup comparison, only the functional capacity aspect presented statistically significant difference in ExG when compared to OG (p=0.02). (Table 3)
CONCLUSION

Quadriceps strengthening exercises included in a rehabilitation program are effective in the improvement of pain, function and quality of life aspects of patients with knee osteoarthritis.

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