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### RESEARCH ARTICLE

#### EFFECT OF HIP ABDUCTORS VERSUS KNEE EXTENSOR STRENGTHENING ON PAIN, FUNCTION AND QUADRICEPS ISOMETRIC STRENGTH IN KNEE OSTEOARTHRITIS : PROTOCOL FOR A RANDOMIZED CLINICAL TRIAL

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#### Abstract

**Background:** Thigh muscle strengthening is important in knee osteoarthritis patients, this study will investigate if hip abductors strengthening can improve knee pain, function and quadriceps isometric strength comparable to knee extensor strengthening.

**Methods/Design:** A pretest- posttest two groups study design will be applied in Faculty of Physical Therapy, Cairo University. 70 patients with knee osteoarthritis will be recruited with age ranges from 50-70. They will be randomized into 2 groups; hip abductors strengthening (HAS) group a will receive hip abductors strengthening exercises (Hip abduction standing-Clamshell-lateral leg raise-pelvic lift training-stretching Hamstrings) and knee extensor strengthening (KES) group will receive (Isometric quadriceps setting-Knee extensions from sitting with knee bend to 90° -Terminal knee extension from sitting- stretching Hamstrings), the treatment for 6 weeks, baseline and 6 weeks assessment of knee function will be done using ArWOMAC index, Timed Up and Go test and Quadriceps muscle strength assessment using Hand held Dynamometer.

**Sample size:** 70 patients based on power analysis using G\*power software.

**Conclusion:** Strengthening hip abductors only offer significant effects ; reaching same target with less risk of knee OA progression from knee extensor strengthening.

**Trial Registration:** [Clinicaltrial.gov](http://Clinicaltrial.gov), NCT04503304 (Effect of Hip Abductors Versus Knee extensor Strengthening in Knee Osteoarthritis), Registration date 6/8/2020.

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#### Introduction:-

Knee osteoarthritis (OA) is a common disabling condition that affects more than one-third of persons older than 65 years [1]. It is characterized by erosion of the articular cartilage, hypertrophy of bone at the margins (i.e., osteophytes), and subchondral sclerosis [2]. Despite its widespread prevalence, however, the precise etiology, pathogenesis and progression of osteoarthritis are unknown [1].

Thigh muscle weakness has been commonly observed in individuals with knee osteoarthritis (OA)[3]. Muscle loss and fat gain contribute to the disability, pain and morbidity associated with knee osteoarthritis and thigh muscle weakness is an independent and modifiable risk factor for Knee OA[4].

Based on the importance of thigh muscle strengthening in patients with knee OA, several authors [5]included strengthening of thigh muscles as an integral component of the treatment program of these patients. Further, hip muscles strengthening had been suggested to aid clinical improvement in patients with Knee OA in combination with knee extensors strengthening [6].

However, to the best of this study's investigators knowledge, no previous studies reported the effect of hip muscles strengthening, apart from knee muscles strengthening, in treating patients suffering from Knee OA. Therefore, investigators of the current study will conduct this study aiming to examine the effect of hip muscles strengthening versus knee extensor strengthening in managing pain, function and enhancing knee extensors isometric strength in patients with knee OA.

#### **Purpose of the study:**

To investigate whether hip abductors strengthening is capable of improving knee pain, function, and knee extensors isometric strength comparable to knee extensor strengthening.

#### **Significance of the study**

Knee OA as a highly prevalent musculoskeletal disorder [7]invites a large number of researches for reaching alternative treatment solutions. Strengthening of thigh muscles, being an integral component in the treatment of knee OA, have been widely investigated, and commonly advised in literature) [7].

Despite the clear importance of quadriceps strengthening in cases of knee OA, higher quadriceps strength entail a possibility of increasing progressing the condition of knee OA in some patients [8].

Since strengthening of hip abductors with patients, suffering Knee OA had been reported in previous studies when conducted in combination with knee muscles strengthening [6].It is likely that strengthening of hip abductors hold similar effects when applied without combination with knee extensors strengthening. Thus, reaching same target with less possible risk of knee OA progression from knee extensors strengthening.

If this suggested outcome is met at the end of this study, it will have an important clinical implication. This is because it would present an alternative means to achieve clinical outcomes comparable to those achieved through strengthening of knee extensors in those who complain, or who are susceptible to adverse effects with strengthening knee extensors.

#### **Hypotheses**

1. There will be no significant difference in pain subscale score of ArWOMAC index between the two groups; Knee extensor strengthening (KES) group , hip abductors Strengthening (HAS) group.
2. There will be no significant difference in stiffness subscale score of ArWOMAC index between the two groups; Knee extensor strengthening (KES) group , hip abductors Strengthening (HAS) group.
3. There will be no significant difference in physical function subscale score of ArWOMAC index between the two groups; Knee extensor strengthening (KES) group , hip abductors Strengthening (HAS) group.
4. There will be no significant difference in total ArWOMAC index score between the two groups; Knee extensor strengthening (KES) group , hip abductors Strengthening (HAS) group
5. There will be no significant difference in The Timed Up & Go Test (TUG) score between the between the two groups; Knee extensor strengthening (KES) group , hip abductors Strengthening (HAS) group.
6. There will be no significant difference in quadriceps isometric strength between between the two groups; Knee extensor strengthening (KES) group , hip abductors Strengthening (HAS) group.

#### **Methods:-**

This study will be pretest- posttest two groups study designed to study if strengthening hip abductors improve pain and function, and knee extensor isometric strength in patients with knee. The study will be applied in Faculty of Physical Therapy ,Cairo University.

**Patients:**

A total of 70 patients with knee OA will be recruited. All patients who will participate in the study will be referred by orthopedists. Patients with knee osteoarthritis will be included with age ranges from 50-70. They will be randomized into 2 groups; hip abductors strengthening (HAS) group will receive hip abductors strengthening exercises, and knee extensor strengthening (KES) group will receive quadriceps strengthening exercise.

All patients who will meet the study criteria will get a complete knowledge of the objectives and procedures of the study. Patients who will agree to participate will confirm participation by signing an informed consent form (Appendix I).

**Inclusion criteria:**

1. Patients with knee OA grade II- III Kellgren- Lawrence scores
2. Their age is 50-70 [6].
3. Body mass index (BMI) 25-30.

**Exclusion criteria:**

1. Patients who had surgical intervention in the knee and/or hip.
2. Fracture in the lower limbs.
3. Malignancy
4. Any associated ligamentous injuries in knee or ankle.
5. Spinal Cord Injury.
6. Hormonal imbalance or on hormonal therapy
7. Knee injection within the last 6 months prior to the study.

**Sample size:**

Sample size of 70 patients in the 2 experimental groups is based on power analysis done calculating effect size from the outcomes of a previous study [6]. Power analysis was done using G\*power software. Power set to (0.80), significance (0.05).

**Randomization**

A random number generator (Random.org) will be used to generate 2 sequences of numbers (2 sets), between 1-70 without repetition. Each set of numbers will be assigned to one of the study groups using a blind draw of group names from 2 opaque envelopes in a dark container. Then, 70 opaque envelopes will be prepared, each containing one number from 1-70. After recruitment patient initially agree to participate will be asked to pull an opaque envelope from a dark container. Patient will then be allocated to the study group to which the number he/she draws in envelope is related.

**Assessment Procedures:**

Assessment will be carried out using the same procedures for both experimental groups. Assessment will be done at baseline and after a day from the end of the last treatment session. Weight and height of all participants will be measured prior to assessment. Body mass index (BMI) will be calculated in accordance. All data will be recorded in a data collection sheet (Appendix III).

**Knee Function assessment:****Measuring lower limb functional disability using The Arabic version of reduced WOMAC (ArWOMAC) index (Appendix II):**

In this study, each patient will have ArWOMAC index sheet. Patient will be asked to mark the appropriate description for each category in the questionnaire & feels free to ask any question for more clarification, will be assured; the scores are summed for items in each subscale, with possible ranges as follows: pain=0-20, stiffness=0-8, physical function=0-68, Total Score: \_\_\_\_\_ / 96 = \_\_\_\_\_ % [9]. All the 3 subscales together with the total score will be used in analysis as outcomes.

**Measuring function using The Timed Up & Go Test (TUG):**

The TUG test measures the time required for an individual to rise from a chair (height 42 cm, depth 26 cm), walk 3 meters at a self-determined speed, turn around, walk back to the chair, and sit down [10]. Timed up & go test (TUG)

was developed to assess parameters of physical mobility, translated agility, speed and balance[11]. It is considered a valid and reliable tool for assessment of knee osteoarthritis[12]

In the test procedure the therapist will measure the time using mobile stopwatch. The patient will be seated on a chair (height 42 cm, depth 26 cm), put a cone at 3 meter distance on a level surface. The distance from the chair will be measured using tape measurement. A mark at the 3- meters end will be marked a then the cone will be placed for testing. Patient will be asked to stand up and walk to the cone return to the chair& sit down& will be written in a sheet &calculate the time the patient takes to walk& return to the chair& sit down& will be written in a sheet, three trials will be done and the average will be taken.

**Quadriceps Muscle Strength assessment using Hand held Dynamometer**

In this test procedure, Each patient will be asked to sit with hips & knees 90 degrees in flexion, legs dangling outside the bed, stabilizing themselves by holding onto the sides of the bed also stabilizing the thigh with straps and tighten it to the bed; This starting position was chosen for its applicability and comfort; moreover it has been used in previous studies assessing isometric strength in KOA [13].

The tested leg of the patient will be fixed to the HHD with a strap and a little pillow between the strap and the leg to avoid harming the patient& accurate results, the other end of the strap will be fastened to the bed's leg; The HHD will be kept just 2cm proximal to the lateral malleolus, perpendicular to the test leg, keeping the knee in 90 ° flexion, the patient will be asked to perform four 5-second isometric maximum voluntary contractions knee extension against the HHD with a 30-second rest between each contraction; To encourage the participants to do their best, the examiner will use the standardized cue “push ... hold, hold, hold and relax.” Till hearing the beep of the device, before the actual test, the participant will be asked to perform a submaximal test and 1 maximum voluntary contraction to ensure that the test procedure was understood; the examination will be converted from Kg to N using the leg length of the participant measured as the distance from the lateral joint line of the knee to the lateral malleolus, where force equals the HHD reading converted to Newtons and distance is the length between where the force is applied and the joint being tested in meters.

**Newtons conversions:**

1 kilogram = 9.81 Newtons, Data will be normalized to body weight [14]Using body weight to scale muscle force was the most effective anthropometric parameter for normalizing strength values based on the group of statistical measures of variability[15].

In the statistical analysis, the highest of the 4 consecutive examinations and the mean of the 3 highest examinations for knee extension will be used according to [16].

**Treatment Procedure:**

Treatment procedures will be done using a special protocol of strengthening for each group. KES group protocol will emphasize knee extensor strengthening, while HAS group protocol will emphasize in hip abduction strengthening. Hamstrings stretching will be a common component in both groups.

Both programs will be carried out over 6 weeks, (for 2 sessions/ week). Strengthening exercises resistance will be determined and progressed weekly using 1- repetition maximum (1-RM) [17]

Patients in the KES group will receive the treatment according to the following protocol:

1. Isometric quadriceps setting
2. Knee extensions from sitting with knee bend to 90<sup>0</sup>
3. Terminal knee extension from sitting.
4. Stretching Hamstrings

Number of sets = 3, Repetitions =10 repetitions for each set [18].

Patients in the HAS group will perform the following exercises

1. Hip abduction –standing[18].
2. Sidelying hip abduction(clamshell)[19].

3. lateral leg raise: in brief, the patients lie down on bed on the unaffected side, with the resistance band positioned around the distal thigh of the affected limb.;later, they raise the above lower limbs upwards for about 30 degrees, stay for 5– 10 s and slowly lay down[5].
4. pelvic lift training, specifically, patients stand single-leg off the side at a 10-cm step. Later, they begin with the other limb that is lower than the step level, and contract the stance-limb hip abductor to raise the free leg to the step level while keeping the stance knee extended[5].
5. Stretching Hamstrings [20].

Number of sets = 3, Repetitions =10 repetitions for each set [18].

### **Statistical Analysis**

Data analysis will be carried out using SPSS v.24. Descriptive data will be reported as means and standard deviations. Demographic data reported from patient in both groups will be compared using unpaired t- test. Outcome parameters including ArWOMAC total score and 3 subscales, TUG score, and knee extensor strength will be compared using mixed model ANOVA for each outcome parameter (within, between model).Statistical significance will be set to  $P < 0.05$

### **Discussion:-**

This study compared the effects of hip abductor strengthening exercises and quadriceps strengthening exercises on knee pain, physical function and quadriceps isometric strength in knee osteoarthritis patients.

Previous studies have shown that individuals with knee osteoarthritis have decreased function in their hip muscles, especially hip abductor strength [21,22].

Patients with severe knee OA walk with decreased gait speed, reduced stride length and increased time in double limb support [23]. These factors combined with reduced activity may result in lowered activation and diminished strength of the hip abductors over a period of time [24]. There has been a small quantity of research with promising findings that targeted hip strengthening programs in patients with end stage knee OA may lead to improvement in symptoms and quality of life [25].

A previous published study protocol pointed out that lower limb strengthening, especially the quadriceps training, is of much necessity for patients with knee OA [5].According totheirreview, previous studies suggest that strengthening of the hip muscles, especially the hip abductor can potentially relieve the knee OA-associated symptoms.

[5] recruited 80 KOA patients with the Kellgren-Lawrence grade (K-L grade) for KOA of II-IV in single-blind randomized controlled trial, in which patients with KOA will be randomly divided into quadriceps-plus-hip abductor-strengthening group and quadriceps-strengthening group;they mentioned that strength of the hip muscles, especially the hip abductor, may be altered in KOA patients.

[26] stated that the isokinetic strength of hip abductor in KOA group is remarkably lower than that in control group. Another study shows that the explosive force and endurance, as well as the isokinetic strength of the hip abductor in KOA group are lower than those in control group[21]

[27] reported that the addition of the hip muscles strengthening exercises resulted in better improvements in pain and function than did a knee-focused rehabilitation program in 4 weeks in females with patellofemoral pain syndrome (PFPS).

[28] conducted a randomized controlled trial to examine the effectiveness of isolated hip abductor and external rotator strengthening on pain, health status, and hip strength in females with patellofemoral pain (PFP).

An 8-week program of isolated hip abductor and external rotator strengthening was effective in improving pain and health status in females with PFP, as compared to a no-exercise control group;the observed improvements in the exercise group were maintained at a 6-month follow-up[28].

Hip abductor strength contributes to physical function such as turning whilst walking and rising from a chair in people with unilateral TKA[29].

There is a correlation between stronger hip abductor muscles and faster times for TUG and stair climb tests [30]. Unless rehabilitation programs specifically include hip abductor strengthening exercises, it is unlikely that the hip abductors will return to normal levels of strength, contributing to ongoing difficulties in activities of daily living such as walking and stair climbing[29].

A recent study [31] also supported the finding that higher baseline hip abductor strength was associated with reduced risks of worsening medial patellofemoral and lateral tibiofemoral cartilage damage from baseline to two years, as well as poor function outcomes from baseline to five years.

[6] concluded that Hip abductor strength-based exercises could display a clinically and statistically significant effect on improving functional activities in women with knee osteoarthritis also the effect of hip abductor strength-based exercises on pain was not clinically significant, although the effect was statistically significant.

On the contrary [32] assessed at baseline and at followup visits; knee pain was assessed using a visual analog scale and physical function was assessed using the Western Ontario and McMaster Universities Osteoarthritis Index.

They conclude that ,in men and women with symptomatic knee OA, no association was found between quadriceps strength and cartilage loss at the tibiofemoral joint, including in malaligned knees.

[33] referred that this is first study to look at longitudinal changes of isometric muscle strength before an interval of radiographic (structural) progression; Although they found that women with progression tended to have lower, and men with progression greater thigh isometric muscle strength prior to the interval of radiographic progression than those without progression, the variation between subjects and the overlap between progressors and non-progressors was large; this trend was somewhat stronger in KLG 0/1 than in KLG 2/3 knees, but was not significant in either group;the opposite trend was observed in men, particularly in those with definite radiographic KOA (KLG2/3).

However,[33] failed to detect strong evidence that (changes in) isometric muscle strength precedes or is associated with structural (radiographic) progression of KOA.

A 5-year longitudinal cohort study done by [34] in multicenter Osteoarthritis Study (MOST) of 50–79-year old adults with knee osteoarthritis (OA) or known risk factors for knee OA ; they examined longitudinal relationship between quadriceps weakness and worsening knee pain in men and women with or at increased risk for knee OA. [34] found that baseline quadriceps weakness was associated with worsening knee pain at 60-month follow-up in women but not men in the MOST cohort.

A study by [35], they couldn't provide evidence that early unilateral radiographic changes, i.e. presence of osteophytes, are associated with cross-sectional or longitudinal differences in quadriceps muscle status compared with contralateral knees without Radiographic KOA

The results by [36]Multicenter Knee Osteoarthritis (MOST) study participants(519 men (948 knees) and 784 women (1453 knees)) found that thigh muscle mass does not appear to confer protection against incident or worsening knee OA and future studies of risk for knee OA should focus on the roles of knee extensor neuromuscular activation and muscle physiology, rather than the muscle mass.

Men and women with knee osteoarthritis employ different gait strategies[37,38]. Women tend to use a hip strategy to minimize loading[37].and were more subject to weaker hip abductor strength[37,38].

It seemed that hip abductor strength had a greater impact on functional activities in women[6]. Therefore, [6] hypothesized that women would be more responsive to the hip abductor strength-based exercise, males may also benefit from these exercises, although additional research is needed to prove it across the knee

**Declaration:**

**Ethical approval** number was 012/002753 ,Board Name: ethical committee faculty of physical therapy Cairo University, **consent form** appendix I.

**Availability of data and materials**

Not applicable

**Competing interests**

the authors declare that they have no competing interests

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