

STUDY PROTOCOL

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Quadriceps combined with hip abductor strengthening versus quadriceps strengthening in treating knee osteoarthritis: a study protocol for a randomized controlled trial

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Abstract

Background: Lower limb strengthening, especially the quadriceps training, is of much necessity for patients with knee osteoarthritis (KOA). Previous studies suggest that strengthening of the hip muscles, especially the hip abductor, can potentially relieve the KOA-associated symptoms. Nevertheless, the effects of quadriceps combined with hip abductor strengthening remain unclear. Therefore, the current randomized controlled trial is designed aiming to observe whether quadriceps in combination with hip abductor strengthening can better improve the function and reduce pain in KOA patients than quadriceps training alone.

Methods: A total of 80 subjects with symptomatic KOA will be recruited from the communities and hospital outpatient, and will be randomly assigned to the experiment group (Quadriceps-plus-hip-abductor-strengthening) or the control group (Quadriceps-strengthening). Specifically, participants in the experiment group will complete 4 exercises to train the quadriceps and hip abductor twice a day for 6 weeks at home, while those in the control group will only perform 2 exercises to strengthen the quadriceps. Besides, all patients will also receive usual care management, including health education and physical agent therapy when necessary. Knee pain will be measured using the Visual Analogue Scale (VAS) at baseline, in every week during the course of treatment, as well as 8 and 12 weeks after randomization. Furthermore, knee function will be measured using the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) scale, and the quality of life will be measured using the MOS Item Short-form Health Survey (SF-36). In this study, several simple tests will be applied to assess the objective function. All the assessments except for VAS will be carried out at baseline, and in the 6th, 8th and 12th weeks respectively.

Discussion: Our findings will provide more evidence for the effects of hip abductor strengthening on relieving pain and improving function in KOA patients. Hip abductor strengthening can be added into the muscle training program for KOA patients as a supplementary content if it is proved to be effective.

Trial registration: The current study has been registered with the Chinese Clinical Trials Registry (the registration number is [ChiCTR-IOC-15007590](https://www.clinicaltrials.gov/ct2/show/study?term=ChiCTR-IOC-15007590), 3rd December, 2015).

Keywords: Hip abductor, Quadriceps, Strengthening, Knee osteoarthritis

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Background

Knee osteoarthritis (KOA) is one of the most common chronic progressive, degenerative and debilitating diseases among the elderly [1]. KOA patients mostly suffer from progressive stiffness and knee pain. Gradually, they have some difficulties in performing daily activities, such as walking, squatting, climbing and doing housework, as the disease progresses [2]. Moreover, the KOA-induced pain and disability will impair their independence and remarkably reduce their quality of life, thus posing a heavy burden on both the families and the society [3]. Generally, the high prevalence, disability rate and medical expenses of KOA have gradually attracted extensive attention from the public [4].

KOA is a chronic progressive and debilitating disease; however, effective fundamental treatments are lacking at present. The existing clinical treatment strategies for KOA aim to relieve pain and symptoms, as well as to delay disease progression, including pharmacological strategies (such as analgesics, non-steroidal anti-inflammatory drugs, corticosteroids and cartilage protecting agents), non-pharmacological strategies (physiotherapies like ultrasonic treatment, acupuncture, patient education, weight loss, exercises and sports support) [5, 6], and surgical strategies (such as replacement of knee for end-stage KOA) [7]. Certainly, these treatments are helpful; nonetheless, some of them may be associated with many potential side effects and are uneconomical. In addition, some of them may be inconvenient for patients requiring frequent hospital visits, which will inevitably add to additional costs. It is noteworthy that, the latest guidelines for KOA have paid ample attention to some non-pharmacological strategies in disease management [5, 6, 8], particularly exercise rehabilitation and sports support.

A variety of exercises have been proposed in literature to treat KOA, including aerobic exercises such as cycling or walking, as well as some targeted exercises like strengthening of particular muscles, and some exercises targeting flexibility. To the best of our knowledge, studies investigating the effects of muscle strengthening on KOA patients mostly focus on the quadriceps [9]. Meanwhile, studies also find that quadriceps strengthening contributes to relieving pain, improving body function as well as quality of life of patients, and delaying disease progression. Furthermore, it is also characteristic of its safety and economical efficiency, which are extremely important for patients. Therefore, such treatment is unanimously recommended in various guidelines.

However, the lower limb represents a whole chain of motion, and changes in the biomechanical environment of the hip, such as in the muscle strength around the hip, may also affect the knee joint. As is discovered in recent studies, some knee diseases, such as patellofemoral pain syndrome [10, 11], iliotibial band syndrome

[12], and noncontact anterior cruciate ligament injuries, are related to the strength of muscles around the hip. Notably, the mechanical and kinematic parameters of hip movement in KOA patients are quite different from those in the normal control group [13–15]. In the meantime, some latest studies also propose that, KOA patients are suffering from decreasing hip abductor muscle strength [16, 17]. Specifically, results from a recent cohort study suggest that, people having a smaller external hip adduction moment (in other words, a weaker hip abductor) are undergoing a faster KOA progression [18]. Moreover, a few studies find that, hip abductor strengthening may potentially alleviate pain and improve the overall functions of these patients [19–21]. However, it can hardly decrease the knee load, as is measured by the knee adduction moment [20]. Nonetheless, the efficacy of hip abductor strengthening has not been fully confirmed by original studies yet, which has prevented the routine prescription of such exercises for KOA patients.

Given that hip abductor strength may potentially affect knee load, it is supposed in the current study that quadriceps combined with hip abductor strengthening may be superior to quadriceps strengthening alone for KOA patients. Thus, the current study is thereby designed on this basis, aiming to determine whether patients receiving quadriceps combined with hip abductor strengthening can attain more functional improvement, more pain relief and higher quality of life than those undergoing quadriceps strengthening alone.

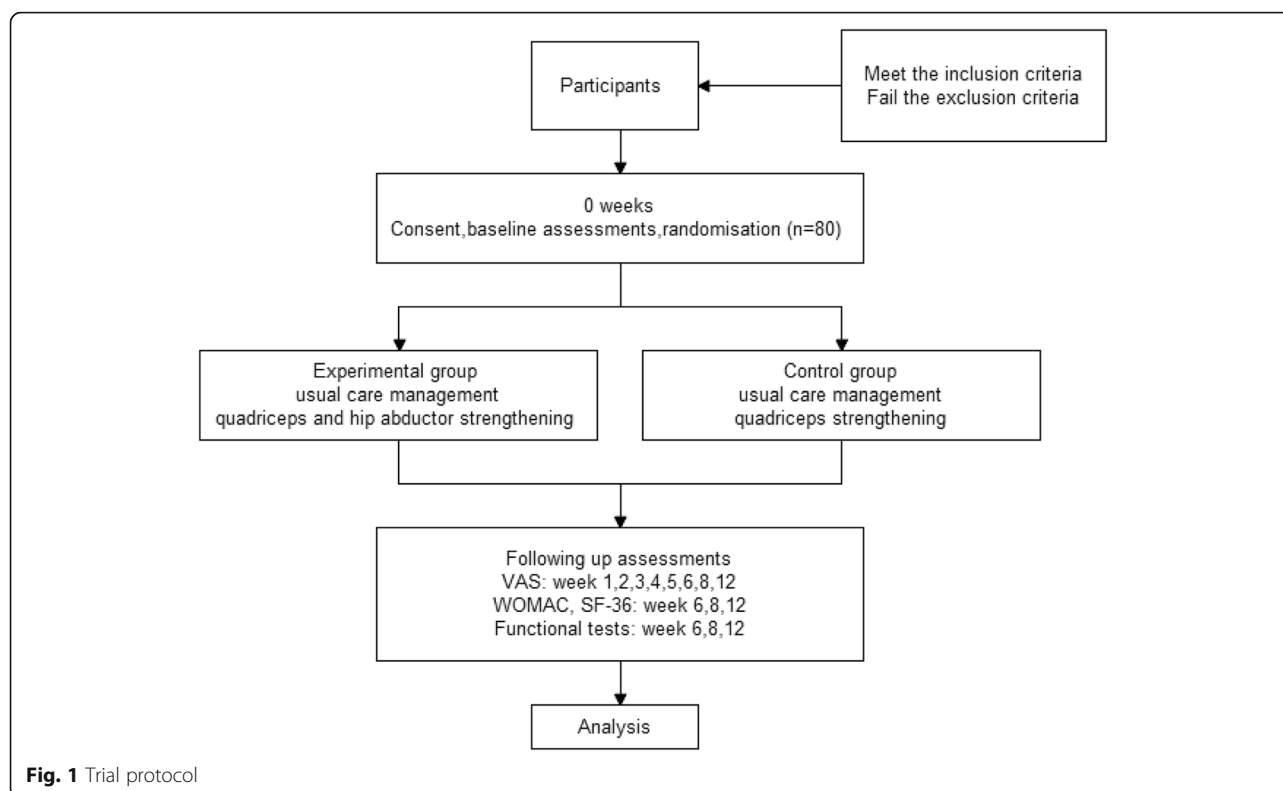
Methods

Design

The current study is a 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 (Fig.1). Importantly, physicians carrying out the assessments will not be informed of the group situation.

Study population and allocation

A total of 80 KOA patients will be recruited from the outpatient of the Affiliated Hospital of Southwest Medical University, as well as from some communities in the city by means of advertisements. The inclusion criteria are as follows: those with osteoarthritis in at least one knee according to the American College of Rheumatology Classification Criteria established in 1995 [22]; those aged over 50 years; those with the self-reported average knee pain > 2.0 and < 7.0 measured by the Visual Analogue Scale (VAS) for most days in the month; and those with the Kellgren-Lawrence grade (K-L grade) for KOA of II-IV. KOA will be confirmed through physical examinations and radiography. For participants with bilateral KOA, the more seriously affected side (as identified by K-L grade of



KOA and the pain intensity) would be selected as the affected leg.

In the meantime, the exclusion criteria are shown as follows: patients with the age of ≥ 70 years; those undergoing hip or knee muscle training in the past 4 weeks; those with obvious knee varus or valgus deformity; those who have taken oral corticosteroid within the last 4 weeks or intraarticular corticosteroid injection within the last 3 months; those with systemic arthritic conditions; those who had undergone tibial osteotomy, hip or knee joint replacement, or other surgeries of knee or hip joint; and those with any other neurological, muscular or joint diseases that may affect the lower limb function.

Patients will be recruited in strict accordance with the inclusion and exclusion criteria, and will be subsequently assigned randomly into the Quadriceps-plus-hip-abductor-strengthening group (experimental group) and the Quadriceps-strengthening group (control group) at the ratio of 1:1. Specifically, the randomization sequence will be obtained by an independent researcher not taking part in the treatment or assessments using the random number function in Excel. Allocation will be hidden in serial number, with opaque envelopes placed in the central location. In addition, another researcher participating in the study will then open the envelopes in sequence after patient recruitment and baseline assessment.

Interventions

All participants will receive routine care management for KOA, including health education and physical agent therapy when necessary.

As some guidelines suggested, all KOA participants in both groups will undergo the Quadriceps-strengthening training composed of 2 exercises designed to strengthen the quadriceps. The first exercise is straight leg raise, to be specific, patients lie in supine position, and keep their legs straight with a resistance band placed just proximal to the ankle of the affected limb. Afterwards, they raise the affected leg to the heel 25–30 cm away from the bed, stay in this position for 5–10 s based on their own abilities, and then slowly lay down. The second exercise is multi-angle static exercise. Briefly, patients sit on their seats with a resistance band positioned proximal to the ankle, and contract their quadriceps isometrically for 5–10 s when their knees are flexed at the angles of 0°, 30°, 60°, 90° and 120°, respectively.

Correspondingly, the experimental group will receive Quadriceps-plus-hip-abductor-strengthening training, which is constituted by 2 more exercises simultaneously to strengthen the hip abductor. One is 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. The other exercise is pelvic

1.5 m apart will be recorded [28]. Patients will be asked to stand in the middle of the 2 cones initially before they walk in a continuous figure-of-8 pattern around the cones. Finally, they will be asked to stop at the location where they begin, and the time spent will be recorded.

Moreover, the adverse effects, medication and other therapies in each participant over the course of trial will be recorded by themselves.

Sample size

The sample size is calculated with reference to relevant previous studies. Notably, a change in VAS of knee pain is estimated to be 2.0 between two groups after the strengthening program, which suggests clinically important change. Meanwhile, the standard deviation (SD) between the experiment and the control groups is estimated to be 2.5 based on relevant previous publications [20]. Moreover, the sample size required for each group is about 33 when a two-tailed test with the power of 90% and the significance level of 5% (α error) is applied. Eventually, the total sample size is calculated to be 80 after taking into consideration a 1:1 allocation ratio and a dropout rate of 20%.

Statistical analysis

Statistical analyses will be performed following the per-protocol (PP) analysis and intention-to-treat (ITT) analysis. Typically, PP analysis would be conducted if no participants have dropped out of the trial for any reason. In addition, the rule of last-observation-carried-forward will be applied for the missing data when performing ITT analysis. Additionally, baseline data will be analyzed and adjusted using the covariance analysis if no statistically significant differences between two groups and a possibility of covariance of baseline data are found. Categorical data, such as gender or those expressed as frequencies (%) will be analyzed using chi-square test or Fisher's exact test. Non-parametric statistical tests will be applied for data not conforming to normal distribution. In addition, statistically significant differences in intra-group and intergroup data will be analyzed by repeated measure analysis of variance. All statistical analyses will be performed using the SPSS 19.0 statistical software by a statistician blinded to the allocation. The significance level is set at 5%.

Safety

All exercises adopted in this study are very safe and harmless, especially under the guidance of physiotherapists. However, all expected or unexpected adverse events deriving from this study, such as muscle strain or ache, will be recorded and monitored. Moreover, patients subjected to harm from this study will receive free treatment, and any differences in safety between the two

groups will be reported by researchers as a part of the results.

Discussion

A single-blind randomized controlled trial is designed in the current study to examine whether quadriceps combined with hip abductor strengthening is superior to quadriceps strengthening alone in alleviating pain and improving physical function as well as the quality of life of KOA patients.

Researchers and clinicians have attached growing importance to lower limb muscle strengthening, which can be attributed to its effectiveness in reducing knee pain and improving physical function. Moreover, such a phenomenon is also linked to the economical efficiency of lower limb muscle strengthening and the possibility to be widely promoted among patients, especially those in communities. The lower extremities have formed a whole kinematic chain, which makes it impossible for the hip, knee or ankle joints to work completely independent from each other. Instead, they may affect each other.

As is noted in some studies, strength of the hip muscles, especially the hip abductor, may be altered in KOA patients. For instance, a research finds that the isokinetic strength of hip abductor in KOA group is remarkably lower than that in control group [19]. 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 [17]. Similarly, it is also found that the hip abductor in KOA patients is reduced by 24% compared with that in normal controls. Meanwhile, the hip abductor muscle strength is negatively correlated with the severity on KOA imaging findings, indicating that the more severe KOA imaging findings are related to the weaker hip abductor strength [16]. Not only the isokinetic strength, but also the isometric strength of hip abductor in KOA patients are smaller than normal, but the difference between two groups is not statistically significant [29]. Typically, the hip abductor plays an important role in stabilizing the trunk and pelvis in gait cycle. Therefore, weakness of hip muscle may lead to changes in the position of body center, resulting in contralateral movement of the pelvis or lateral leaning of the trunk over the standing limb. This would thus increase the magnitude of knee adduction moment, which is an indicator of disease progression. Consequently, it seems that hip abductor appears to have certain impact on knee joint load, which may also play a potential role in the symptoms and progression of disease.

Importantly, limited studies have pointed out that, hip abductor strengthening exercises may be helpful to improve the physical function and alleviate pain in KOA patients.

It was observed that the muscle strength of hip abductor is markedly enhanced, while the WOMAC-pain of knee and FTSST score are distinctly different before and after an 8-week home strengthening program for the hip abductor in 40 KOA patients [19]. Nonetheless, in that study, the patricians in control group are normal persons without KOA. Moreover, a study aiming at KOA patients discovers that, compared with the control group, hip muscle strength, WOMAC- pain, scores of the step test and the stair ascent/descent task are markedly improved in the training group receiving a 12-week hip muscle strength training [20]. It is also found that hip abductor training combined with the quadriceps femoris and hamstring muscle strength training can decrease the WOMAC-pain score in KOA patients by 78% [21]. However, the sample size is as small as 6, and no control group is set up [21]. Moreover, for patients undergoing total knee replacement, the muscle strength of hip abductor is also related to the functional activities (the Figure-of-8 Walk Test, the stair ascent/descent task, and FTSST) in addition to the quadriceps femoris [28]. Those studies have indicated that hip abductor muscle strength training may be beneficial to KOA patients. Therefore, we hypothesize that quadriceps combined with hip abductor strengthening may be superior to quadriceps strengthening alone for KOA patients, and the current study is thereby designed on this account.

Furthermore, the clinical changes in KOA-associated symptoms resulted from hip abductor strengthening intervention will be confirmed using the self-reported pain, as well as subjective measures of function and quality of life. Typically, the common and most widely used tools, including VAS, WOMAC and SF-36, are employed in the current study to measure the changes in symptoms and quality of life in KOA patients.

Besides, four simple tests that can be easily completed in the clinical hospital are selected as the objective measures of function, which have focused on different aspects, including the balance, walking ability, and flexibility. Therefore, the effects of hip abductor strengthening on the improvements of symptoms and quality of life in KOA patients can be evaluated in this study.

Abbreviations

FTSST: Five times sit-to-stand test; KOA: Knee osteoarthritis; SF-36: MOS item short form health survey; VAS: Visual analogue scale; WOMAC: Western Ontario and McMaster Universities Osteoarthritis Index

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Authors' contributions

YX, CZ and JW have designed this trial protocol and drafted the manuscript. LX, SG and FX have procured the project funding and provided consultation during the research. GP, RC and JY are physical therapists who train patients

in muscle strengthening. HT and JH are responsible for the assessment at baseline and following-up. WJ is a research assistant on the project who is responsible for the data collection and analysis. All authors have read and approved the final manuscript.

Ethics approval and consent to participate

This research is approved by the Ethics Committee of Affiliated Hospital of Luzhou Medical University (The approval number is ky2015017). In addition, the research protocol has been registered in the ClinicalTrials.gov (Identifier: ChiCTR-IOC-15007590, 3rd December, 2015). All participants will sign the written informed consent to participate in the study.

Competing interests

The authors declare that they have no competing interests.

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