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Design of a Clinical Trial Study to Evaluate the Effect of Dry Needling of Gluteus Medius Muscle on Pain and Function of Women with Patellofemoral Pain Syndrome: A Double-Blind Randomized Clinical Trial Protocol

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Original Article

Abstract

Introduction: The aim of this study is to design a double blind randomized clinical trial in order to investigate the effect of dry needling of gluteus medius muscle on pain and function of women with patellofemoral pain syndrome (PFPS).

Materials and Methods: In this clinical trial, 22 women with PFPS were randomly divided into the two treatment and control groups. Both groups received a conventional knee physiotherapy program that included two exercises for quadriceps muscle (15 minutes total) and high frequency transcutaneous electrical nerve stimulation (TENS) two times a week for three weeks. The treatment group also received dry needling once a week for three weeks with a fast-in and fast-out technique 10 times in the active trigger point of the gluteus medius muscle. The outcomes included pain and physical function, with the pain intensity and physical function measured using the visual analogue scale (VAS) and the Kujala questionnaire, respectively. The Shapiro-Wilk test was employed to check the distribution of data and based on the result of this test, the independent t-test was used if the data was of a normal distribution and the Mann-Whitney U test was used to compare the control and treatment groups if the data distribution was not normal.

Conclusion: Today, the use of dry needling technique in the treatment of musculoskeletal problems has a growing trend in physiotherapy clinics. Given the role of the gluteus medius muscle in PFPS, the results of this study may help plan treatment programs for these patients as part of their rehabilitation.

Keywords: Patellofemoral pain syndrome; Trigger point; Dry needling; Gluteus medius; Physical function

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Introduction

Patellofemoral pain syndrome (PFPS) is one of the most common knee problems, which accounts for about 25 to 40% of knee problems (1-3). PFPS is defined as the presence of anterior knee pain that is not due to other problems or pathologies of the knee (4). The prevalence of this syndrome is two to three times higher in women than men (2). Activities including walking, running, going up and down stairs, sitting cross-legged, as well as activities that are associated with prolonged sitting with the knee bent, cause or aggravate pain in these people (3,5). The cause of this syndrome is often unknown (6). The abductor muscles and external rotators of the hip, especially the gluteus medius, control the excessive internal rotational forces of the femur during daily activities that require the knee to bend in a closed chain (7,8). Weakness of the gluteal muscles,

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especially the gluteus medius muscle, which is often seen in these people, causes an additional and frequent internal rotational force to enter the femur, which increases the load on the patella and causes pain and functional disability in these people (8,9). Moreover, the presence of this frequent force creates a constant tensile force on the gluteus medius muscle, followed by the creation of trigger points (10). One of the physiotherapy treatments for trigger points is the use of dry needles that activate pain control mechanisms (11). The results of some studies have shown that using this method in some muscles involved in PFPS, pain and function are improved (11-13). So far, no study has been carried out on the effect of dry gluteus medius needle on pain and physical function in women with PFPS syndrome. Therefore, the aim of this study is to investigate the effect of dry needling of gluteus medius on pain and physical function in women with unilateral PFPS.

Materials and Methods

This study, which is a double-blind (analyst and examiner) clinical trial with a parallel design, was approved by the ethics committee of Isfahan University of Medical Sciences, Isfahan, Iran with the code IR.MUI.RESEARCH.REC.1398.229. The protocol of this project was registered on the Iranian Registry of Clinical Trials (IRCT) system with the code IRCT20160408027287N3. Additionally, the project was approved by the Iranian Research Institute for Information Science and Technology (IranDoc) with the number 398228 in 2019 and all its expenses were borne by Isfahan University of Medical Sciences.

The present study was conducted in 2020 in the School of Rehabilitation Sciences, Isfahan University of Medical Sciences. 22 non-athlete women with one-limb PFPS participated in the project. The women who were diagnosed with PFPS by an orthopedic or rheumatologist to receive physiotherapy treatment in public physiotherapy clinics and centers under the supervision of Isfahan University of Medical Sciences were talked with and if they met the inclusion criteria and were willing, entered the study project using the convenience sampling method. First, the physiotherapist, who was unaware of the grouping of participants, carefully recorded a complete and comprehensive history and clinical examination. The patient entered the study if she had the desired inclusion criteria and by completing the consent form. The inclusion criteria included reporting pain in the anterior area of the knee or around the patella of the affected side, pain in at least 3 activities of going up or down the stairs, squatting, running, kneeling, jumping, or hopping and sitting for a long time (14), positive patellar glide test (11), women with normal daily (non-athletic) activities with a one-sided involvement of this syndrome (11,15), age 17 to 40 years (15), symptoms for at least four weeks (14), full range of motion (ROM) in the knee joint and no history of knee injury (16), and the presence of an active trigger point (presence of local tenderness, touch of stiff tissue, presence of a point in the stiff tissue of the muscle that is more sensitive than other points, recurrent local or referral pain by touching the trigger point) in the gluteus medius muscle on the affected side (17,18).

The exclusion criteria included meniscus involvement and other intra-articular disorders, involvement of lateral and cruciate ligament of the knee, patellar tendon tenderness, iliotibial band, Pes anserinus muscle tendons, history of patellar dislocation, knee inflammation, previous patellofemoral joint surgery (16), fear of needles (19), pregnancy, cancer, knee arthritis, presence of various neurological symptoms with disturbances in sensation, movement or reflexes, as well as knee pain originating from the hip, lumbar, sacroiliac, or ankle joints (11).

The participants who met the criteria for participating in the study and signed the consent form were given a schedule to attend the Physiotherapy Clinic, School of Rehabilitation Sciences, Isfahan University of Medical Sciences. Before the first treatment session, the participants completed a demographic information form including details of contact, age, gender, employment status, level of education, weight, height, and body mass index (BMI). The researcher physiotherapist then trained the people the relevant exercises at the beginning of the session and made sure that the exercise was performed correctly. Eligible individuals were randomly divided into the control (conventional physiotherapy for the knee) and treatment groups (conventional physiotherapy for the knee and dry needle of the gluteus medius) using a random number table by the physiotherapist in the physiotherapy department (who was blind to the study).

The physiotherapist of the clinic of the school of rehabilitation sciences, who is unaware of the study process, was responsible for randomly dividing the individuals into the two groups and evaluating the participants and presenting the pain and performance questionnaires to the individuals. Pain was examined using visual analogue scale (VAS) and physical function using Kujala Patellofemoral Questionnaire

(KPQ), which is localized in Persian, by the physiotherapist of the clinic, once at the beginning of the first session and the second time at the end of the last session. The patients were then re-examined for pain and physical function one week after the last session. Each time, the measurement of pain score and physical function was measured only once, and the number used for the analysis was the value obtained in this measurement.

VAS: A scale that is available and free of cost and does not require special training that is widely used in the adult population and is completed by the participant in less than one minute (20). The scale is as a horizontal or vertical ruler that is often 10 cm (100 mm) long (Figure 1) and the pain intensity is graded from zero (no pain) to 10 cm (worst possible pain).

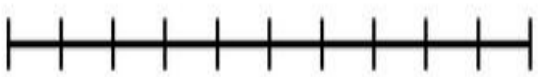

Figure 1. Visual Analog Scale (VAS)

VAS was printed on a piece of paper and how to answer it was explained to the person by the evaluator and the participant was asked to determine the intensity of the pain on the line using a pencil (21). This scale has high validity and reliability [Confidence interval (CI) = 0.74-0.92, Intraclass correlation coefficient (ICC) = 0.85-0.95] (20).

Anterior Knee Pain Scale (AKPS): A 13-item questionnaire that measures subjective function during various activities in individuals with PFPS. The questionnaire includes six activities "walking, running, jumping, climbing stairs, squatting, and sitting with a bent knee for a long time" that are accompanied by pain, particularly in PFPS. It also examines symptoms such as lameness, inability to bear weight on the affected limb, swelling, abnormal patellar movements, muscle atrophy, and limited knee flexion (22). The scale maximum score is 100 and a lower score indicates more pain and disability. Scoring is hierarchically and in different classifications including "no problem-disability" and "no pain-severe pain" and in some items is different from others (23). This scale is easy for the participant to understand and only takes a few minutes to complete (24). The AKPS has high validity and reliability for use in people with PFPS (ICC = 0.49-0.83) (20). Furthermore, the scale has been localized in Persian (25).

Patellar Glide Test: This test is used to check for patellofemoral disorders and, in fact, shows the centrality of the patella in the femoral trochlear groove (26). In the relaxed mode, the participant was placed on the bed in the supine position with a straight knee and the therapist placed both index fingers on either side of the femoral condyles, in which case the middle of the thumbs had to be placed in the center of the patella (Figure 2). A glide greater than 5 mm in the frontal plane was abnormal and indicated a positive test (26). This test has a high inter-rater reliability (0.90) (27).

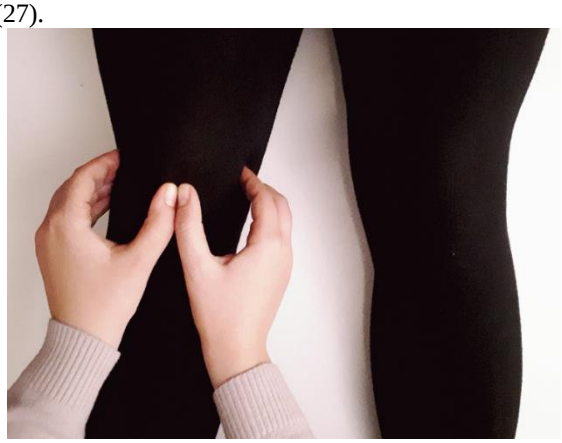

Figure 2. Patellar glide test

Interventions

The participants were randomly assigned to one of the two treatment or control groups through a random number table by the physiotherapist working in the physiotherapy department of the school of rehabilitation sciences who was blind to the study. Then, the researcher explained the steps to the subjects. The researcher physiotherapist, who was unaware of the grouping of the participants, performed only the conventional knee physiotherapy program for both the treatment and control groups. Besides, an experienced physiotherapist performed the dry needling. The total treatment time was about 30 minutes. The dry needling treatment was performed once a week for three weeks (13). Furthermore, the conventional physiotherapy was conducted for both groups twice a week for 3 weeks. The participants in both groups were instructed that during the four weeks of study (three weeks of intervention and one week of follow-up), the intensity, frequency, and duration of daily activities had to be such that they did not reach the onset of pain (28). The person responsible for dividing individuals into the control and treatment groups (physiotherapist in the physiotherapy department) measured pain intensity (using VAS) and physical

function (KPQ) once at the beginning of the first session, the second time at the end of the last session, and also at the end of the first week after stopping the treatment interventions (after the last session or the sixth session of treatment) as follow-up.

Dry Needle: An experienced and certified physiotherapist with at least five years of dry needling experience performed the dry needling intervention on the most painful trigger point active in the gluteus medius muscle on the involved side. For the gluteus medius, the person lay on their side on the bed and the knees and hip joints were slightly bent (Figure 3). The physiotherapist (observing health tips and wearing special gloves) cleaned the area with alcohol after a deep touch and finding the most painful trigger point.

Figure 3. Dry needling technique in the gluteus medius muscle

Then, they inserted a dry needle with a length of 75 mm and a diameter of 0.3 mm into the active trigger point with their dominant hand. The physiotherapist moved the needle in several directions (navigation) to create the first local twitch response. After the first local twitch response, the needle was inserted in and pulled out of the trigger point 10 times vertically in the same direction without rotation (Fast-in and fast-out technique). The approximate frequency of the needle movement was once per second for 10 seconds (29) and after the tenth time, the needle was removed from the muscle. The approximate time for this operation for the treatment group was 5 minutes.

The treatment group participants received a dry needling program once a week after the end of the conventional knee physiotherapy session.

Conventional physiotherapy program: This program for the knee included two exercises for the quadriceps muscle and then the use of 15 minutes of electric current, which were performed by the researcher physiotherapist, who was unaware of the groupings, for both groups. The exercises for strengthening the quadriceps muscle are as follows.

1. *Straight leg raise:* The participant slept in the supine position (Figure 4) and the knee of the non-involved side bent to prevent pressure on the waist. The lower limb on the affected side was then raised about 30 degrees from the hip joint with the knee perfectly straight and the ankle in the full dorsi-flexed state, and was held in this position for 10 seconds. The limb was then lowered and the person rested for 10 seconds (16). The training time was 7.5 minutes.

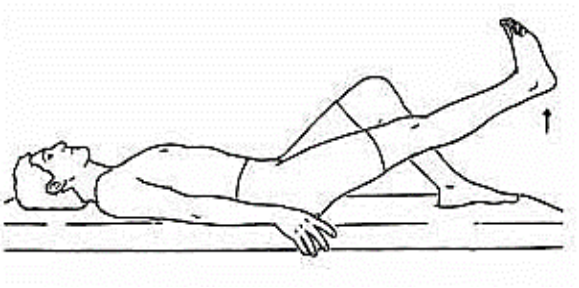

Figure 4. Straight leg raise exercise

2. *Single leg squats:* The participant stood on the involved leg; while the opposite limb was bent 90 degrees from the knee and 60 degrees from the thigh, with the arms facing the chest, and the participant bent the affected knee 30 degrees (Figure 5) and held it as far as he could, then rested as the same time. In other words, if a person performed this exercise in 10 seconds, they could rest for the same amount, i.e. 10 seconds (exercise to rest ratio 1: 1) (16). The training time was 7.5 minutes.

Figure 5. Single leg squats

3. *Transcutaneous electrical nerve stimulation (TENS) program:* After the exercises, each participant received sensory (high frequency) TENS for 15 minutes to reduce pain. The device used was a stimulator (MULTI STIM 735X, Novin, Iran) (Figure 6). Four electrodes were placed around the patella. The current frequency was set at 100 Hz and the duration at 150 milliseconds (16).

Randomization: The physiotherapist working in the physiotherapy clinic who was unaware of the study process randomly assigned the women with PFPS using a random number table. The participants were equally divided into the control and treatment groups.

Blinding strategy: Three physiotherapists were blinded during the study process:

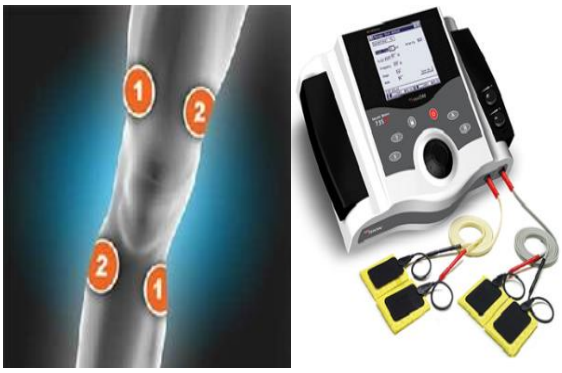

Figure 6. Transcutaneous electrical nerve stimulation (TENS) device and electrode sites around the patella

The researcher physiotherapist who was only responsible for performing the conventional physiotherapy for the knee and the necessary training for participants in both groups performed the same protocol for both groups. The researcher physiotherapist was unaware of grouping the subjects.

The physiotherapist of the center, who was responsible for randomly dividing the subjects into two groups, after conducting this task, submitted a form to the physiotherapist responsible for dry needling, which included the name of the participant and her group and the time of attending the physiotherapy clinic. This physiotherapist was also responsible for assessing the VAS and the KPQ questionnaire before, after, and one week after the sessions, and delivered the data on each participant's pain and performance to the researcher physiotherapist after coding, without name or profile.

A physiotherapist with at least 5 years of experience in the field of dry needling who was responsible for performing dry needling for the treatment group.

Upon completion of the data collection, the researcher physiotherapist delivered the data to the statistical analyst with the specified codes, and the statistical analyst, who was unaware of the groupings, performed the statistical analysis.

Pain and performance data, as well as coded participant profiles, were entered into SPSS software (version 24, IBM Corporation, Armonk, NY, USA). In order to describe the data and depending on the subject under study, the descriptive statistics indicators [median, mean, standard deviation (SD), percentage, frequency, range, and quartile] were used and statistical tests were applied to analyze the data. The Shapiro-Wilk test was used to check the data normal distribution. If the distribution of data was normal, the repeated measures analysis of variance (ANOVA) to compare the pain score and performance score before and after treatment sessions (immediately after the end of the sessions, and the last time one week after the end of the treatment sessions) in the treatment and control groups separately. In addition, independent t-test was used to compare the control and treatment groups, before and after the treatment sessions and one week after treatment. If the data distribution was not normal, the Mann-Whitney U test was utilized. Multivariate analysis was employed to investigate the effects of other variables on pain variables and performance scores, moreover, $P < 0.05$ was considered as the significant level.

The sample size was calculated using Equation 1 and considering the 95% confidence level and 80% test power. In this formula, Δ, the standardized difference of the mean score of knee pain intensity before and after the intervention, was considered to be 0.3 based on the previous studies (13).

Relation 1

$$n = \left(\frac{2\left(z_{1-\frac{\alpha}{2}} + z_{1-\beta}\right)^2}{\Delta^2} \right) + \frac{z^2_{1-\frac{\alpha}{2}}}{4}$$

$$\Delta = \frac{\mu_2 - \mu_1}{\sigma}$$

Finally, the sample size in each of the treatment and control groups was estimated to be 11 people, with the final sample size being 22 people.

The approval of the ethics committee of Isfahan University of Medical Sciences was issued in early August 2017. The announcement of participation in the study and arrangement with various orthopedic and rheumatology specialists were made in August and September. Furthermore, the participants' data were collected in October, November, and December.

Discussion

PFPS is a common disorder of the knee joint that is highly prevalent in both active and non-active women (30). Due to the multifactorial nature of this syndrome (6), its rehabilitation program should also be multifaceted and include a variety of approaches aimed at affecting each of the dimensions of this syndrome (31). Accordingly, the use of dry needling may be beneficial in patients with PFPS due to its effect on muscle function.

The current clinical trial was performed aiming to compare the effect of using the dry needling technic on gluteus medius with or without conventional knee physiotherapy. This study was also carried out to determine the effect of three dry needling sessions once a week on pain and function in women with PFPS. Given the role of the gluteus medius muscle in PFPS, the results may contribute to the success of rehabilitation treatment in these individuals. If dry needles are effective in reducing pain and improving the physical function of women with PFPS, it may be recommended as part of the physiotherapy process for these women.

Limitations

In this study, the effect of dry needles was investigated only in women. Therefore, the results will not be generalizable to the whole community.

Recommendations

It is suggested that in future research, the effect of dry needles on other muscles involved in this syndrome in both men and women be investigated.

Conclusion

The findings of the present study may play an important role in the treatment of women with PFPS, and if dry needles are effective in reducing pain and improving function, this intervention can be an effective treatment option along with a multifaceted physiotherapy program that includes exercise therapy and electrotherapy used in physiotherapy clinics for these patients.

Acknowledgments

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Authors' Contribution

Fereshteh Karamiani: study design and ideation, scientific and executive study services, providing study equipment and samples, data collection, manuscript preparation, responsibility for maintaining the integrity of the study process from the beginning to publication, and responding to referees' comments; Javid Mostamand: study design and ideation, attracting financial resources for the study, support and scientific services of the study, specialized evaluation of the manuscript in terms of scientific concepts, approval of the final manuscript to be sent to the journal office; Atefe Rahimi: executive and scientific services of the study, providing study equipment and samples, manuscript preparation, specialized evaluation of the manuscript in terms of scientific concepts, approval of the final manuscript to be sent to the journal office; Maryam Nasirian: analysis and interpretation of results, specialized statistical services, approval of the final manuscript to be sent to the journal office.

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The present study was based on the secondary analysis of some of the information extracted from the MSc thesis in physiotherapy with the number 8558358, ethics code IR.MUI.RESEARCH.REC.1398.229, and IRCT code IRCT20160408027287N3, approved by Isfahan University of Medical Sciences. Isfahan University of Medical Sciences has not commented on data collection, analysis, and reporting, manuscript preparation, and final approval of the article for publication.

Conflict of Interest

The authors declare no conflict of interest. Dr. Javid Mostamand attracted the budget for basic studies related to this study from Isfahan University of Medical Sciences and has been working as a faculty member of the Physiotherapy Department at this university since 1994. Fereshteh Karamiani has been an MSc student of Physiotherapy, School of Rehabilitation Sciences of Isfahan University of Medical Sciences since 2017.

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