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Effects of Exercise Therapy Plus Quadriceps, Gluteus Medius and Quadratus Lumborum Muscles Self-myofascial Release on Pain, Function, and Balance in Patients with Patellofemoral Pain Syndrome through Telerehabilitation: A Study Protocol for a Randomized Clinical Trial

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ABSTRACT

Background: Patellofemoral pain syndrome (PFPS) is one of the most common knee pathologies that is highly prevalent in adolescents and adults. Patients who suffer from this syndrome usually experience weakness in the hip and knee muscles, as well as myofascial trigger points in the lumbopelvic- hip region, which can negatively impact their lower limb biomechanics. The purpose of this study is to evaluate the effectiveness of exercise therapy combined with self-myofascial release (SMFR) techniques for quadriceps, gluteus medius, and quadratus lumborum muscles on pain, function, and balance in these patients through telerehabilitation.

Methods: The study will be a prospective, single-blinded, randomized controlled clinical trial, involving 60 patients who will be randomly allocated to either an experimental group that will receive four weeks of exercise therapy with SMFR techniques through telerehabilitation or a control group that will receive four weeks of exercise therapy only in the same manner. The outcome measures will include pain, pressure pain threshold, function, and balance. Data will be collected at baseline, at the end of treatment and two weeks after treatment.

Results: Ultimately, the results of this study will provide evidence regarding the efficacy of exercise therapy combined with SMFR techniques for quadriceps, gluteus medius, and quadratus lumborum muscles on pain, function, and balance in patients with PFPS through telerehabilitation.

Trial Registration: IRCT20220628055300N1.

Introduction

Patellofemoral pain syndrome(PFPS), also referred to as runner's knee [1], is one of the most common musculoskeletal disorders in adolescents and adults under the age of 60 years [2]. Almost one in four people worldwide suffer from this disorder [3]. It appears that PFPS is more prevalent in females than males [4]. PFPS is characterized by insidious pain in the anterior, retropatellar, and/or peripatellar region of the knee [5] that intensifies during weight-bearing activities such as ascending/descending stairs, running, and squatting [6]. The exact etiology of PFPS, however, remains uncertain, although biomechanical factors such as femur or patella

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malalignment and lower limb muscle imbalance are primarily involved [7]. Weakness in the hip abductors, hip external rotators, and hip extensors is usually observed in individuals with PFPS [8], along with changes in knee proprioception and balance [9]. Several studies have demonstrated that different therapeutic approaches, such as exercise therapy and lumbopelvic manipulation, can lead to improved balance [10].

Myofascial trigger points (MTrPs) are characterized by hypersensitive spots located in the palpable taut bands of skeletal muscles [11]. Travell and Simon stated that palpation of MTrPs in quadriceps muscle can create peripatellar and anterior knee pain [12]. The motor activation of gluteus medius muscle may be altered due to its MTrPs [13], which can substantially change eccentric hip adduction and result in an increased valgus force at the knee as well as excessive movements in the frontal plane at the pelvic region. This raises the risk of PFPS [14]. If the gluteus medius muscle is not able to produce enough force or is not recruited correctly, two events may happen: A person may walk in an uncompensated Trendelenburg pattern or in a compensated Trendelenburg pattern in which the trunk bends toward the affected hip [15]. As a result, the quadratus lumborum muscle on the opposite side should eccentrically control the lateral movement of the trunk in the coronal plane [16]. This event can cause the formation of MTrPs in this muscle [13]. The literature demonstrates that the prevalence of MTrPs in lumbopelvic-hip muscles, especially in the quadriceps, gluteus medius and quadratus lumborum muscles, is higher in subjects with PFPS than in healthy people [17].

Conservative treatment is the initial therapeutic approach for individuals with PFPS; however, the best option remains unknown [18]. According to evidence, exercise therapy, particularly a combination of hip and knee exercises, is the keystone of PFPS management [19, 20]. Self myofascial release (SMFR) is a type of myofascial release carried out by subjects themselves, and it is one of the methods used to eliminate MTrPs [21]. In this approach, various tools can be used, such as foam rollers, lacrosse balls, and tennis balls [22]. The term "telerehabilitation," considered as a branch of telehealth, has been utilized in many contexts, particularly in the physiotherapy field. It refers to the delivery of rehabilitation through telecommunication technologies [23]. Its primary goal is to increase accessibility and improve continuity of care for those who live in rural or remote areas, have mobility issues, or have difficulty accessing traditional in-person services [24]. Different services, including assessment, intervention, monitoring and education may be provided through various forms of communication, such as email, phone, and videoconference [25]. The relatively low cost of connecting to the Internet along with the use of smart devices has eliminated obstacles associated with in-person rehabilitation such as the need to travel to a clinic, making it possible for a wide range of patients to benefit from remote rehabilitation [26]. In one review, it was found that telerehabilitation in physiotherapy for osteoarthritis, low-back pain, hip and knee replacement, multiple sclerosis, and also in the context of cardiac and pulmonary rehabilitation is comparable to or better than in-person rehabilitation [24]. Furthermore, a recent study suggested that telerehabilitation may be equally as effective as supervised rehabilitation in enhancing functional outcomes in female patients with PFPS [27]. In certain situations, such as during virus pandemics, remote treatments become more suitable for patients who are required to stay at home. Some treatments require direct supervision by a therapist, while others, like SMFR, can be taught by a therapist in a single session, allowing patients to benefit from the treatment's effects remotely through follow-up sessions. Therefore, the effectiveness of hip and knee exercise therapy plus SMFR of quadriceps, gluteus medius, and quadratus lumborum muscles through telerehabilitation on pain, function, and balance in patients with PFPS will be studied. To the best of our knowledge, no study has investigated the efficacy of SMFR or other techniques that eliminate MTrPs in all these muscles together in patients with PFPS. Only one article [28] was found to have investigated the impact of adding dry needling of the gluteus medius and quadratus lumborum muscles to regular exercise therapy in treating PFPS. However, dry needling is an invasive technique, whereas SMFR is a non-invasive, hands-off technique that individuals can perform themselves [29, 30].

Methods

Study Design

Our study will be a prospective, single-blinded, randomized controlled clinical trial. The flow chart is illustrated as Figure 1. A standard protocol items recommendations for interventional trials (SPIRIT) checklist is provided as Additional File 1. Formal written informed consent will be obtained from all eligible volunteers after the research procedure has been explained to them. The study will be conducted in accordance with the Declaration of Helsinki and was approved by the Ethics Committee in Research, SUMS (Approval ID: IR.SUMS.REHAB.REC.1401.016) on July 3, 2022. The trial was registered with the Iranian Registry of Clinical Trials (IRCT; https://www.irct.ir: IRCT20220628055300N1) on July 27, 2022.

Subjects

Participants with PFPS will be recruited through advertisements placed in hospitals and clinics covered by Shiraz University of Medical Science and physiotherapy clinics in Shiraz city. The inclusion criteria will be: 1)aged between 18 and 45 years; 2) onset of pain lasting for more than one month and exacerbated by at least two of the following activities: prolonged sitting, squatting, kneeling, running, ascending/descending stairs, jumping, and landing with a pain intensity of >= 3 on the visual analogue scale during movement; 3) unilateral pain in the anterior, peripatellar, or retropatellar that is reported as having a pain intensity of at least three on the visual analogue scale in the previous week (If the individual suffers from bilateral pain, the side with more pain will be considered); 4) a positive Clarke's sign; 5) a score equal to or less than

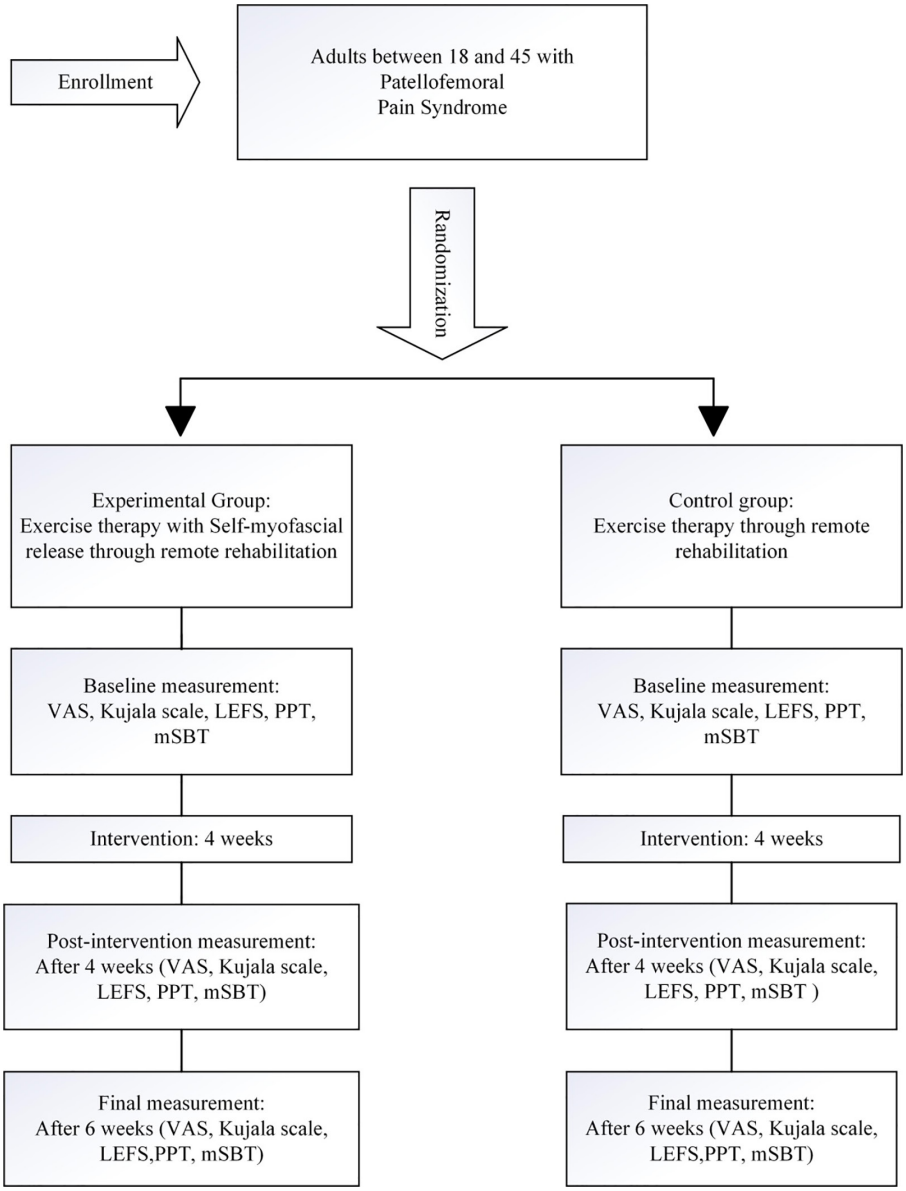

Figure 1: Study design

85/100 on Kujala patellofemoral pain scale, and 6) the presence of MTrPs in the gluteus medius muscle of the affected side, quadratus lumborum muscle of the opposite side, and at least one part of the quadriceps. Participants who have a history of injury to the back, hip, ankle, and/or other anatomical structures of the knee within six months prior to the study; a history of trauma to the lower limb in the six months prior to the study; knee surgery, lower limb surgery, meniscus and/or other knee ligament injury; patellar tendinopathy, patella dislocation, and/or knee intra-articular injection within the previous three months; systemic or local infections; referral pain from the lumbar region; inability to write or speak; systemic diseases such as rheumatoid arthritis and other joint inflammatory diseases; neurological diseases such as multiple sclerosis; cancer or a history of chemotherapy; and those receiving physiotherapy treatment for this condition from six months prior to the study will be excluded. The measurements will be taken at the Orthopedic Clinic, School of Rehabilitation, Shiraz University of Medical Science (SUMS), Shiraz, Iran. Each investigation in our institute has a special study process monitor, and the process will be supervised.

Sample Size

We calculated the sample size relying on the previous article [28]. A total sample size of 60 (30 individuals in each group) was computed based on the modified Star Excursion Balance Test variable of mentioned paper with a 95% confidence interval, 80% power and 20% dropout.

Group Assignment

The target population will be randomized (1:1 allocation), and the block randomization method will be applied through the Sealedenvelope.com site to assign patients to 15 blocks of four. Enrolling and assessing individuals based on eligibility criteria, obtaining informed consent from participants, and assigning them to groups and the treatment procedure will be performed by a trained physiotherapist. All measurements will be performed by another experienced physiotherapist who will be blinded to the group assignment.

Intervention

1) Experimental Group

On assessment day, all volunteers will receive a

pamphlet containing information about exercises along with related pictures and training about habit changes such as avoiding prolonged sitting.

Patients who are part of the intervention group (exercise therapy with quadriceps, gluteus medius, and quadratus lumborum muscles self-myofascial release) will receive weekly videos through WhatsApp, Telegram, or other social platforms. These videos will include hip and knee exercise programs for the relevant week and SMFR exercises for the mentioned muscles. Subsequently, the physiotherapist will make a video call with the participant to assess whether the exercises are being done correctly. These people are asked to do hip and knee exercises three times a week and SMFR exercises two of three days. They are supposed to employ a cold pack on the affected knee for 20 minutes before commencing the exercises [31]. The physiotherapist will follow patients during the week through phone call, text messages, or messages on social media to remind them to carry out the therapeutic exercises and improve their adherence to the program. The therapeutic program will last for four weeks. The therapeutic exercise program is shown in Table 1.

For SMFR exercises with a tennis ball, first the patients will be taught the anatomy of different parts of the quadriceps, gluteus medius, and quadratus lumborum muscles. Then, they will be taught how to perform the SMFR exercises. To release the rectus femoris muscle, patients will lie in a prone position with a tennis ball placed under the thigh in the trigger point area. Then, they will apply pressure with their body weight on the ball and move it slightly while their knees are flexed [32]. To release tension in the vastus lateralis muscle, the patients will be positioned on their affected side, and a tennis ball will be placed under the thigh in the trigger point area. With the help of hand movements, they will move their body weight on the ball and apply pressure [32]. To release the vastus medialis muscle, patients will hold a tennis ball with the opposite hand and apply pressure on the painful MTrP in a sitting position [32]. The gluteus medius muscle is located between the outer surface of the ilium and the greater trochanter [33]. To perform SMFR exercises on this muscle, individuals place the ball at the midpoint between these two areas while lying on their side. The upper limb on the same side should be used for support on the floor, while the contralateral hip is abducted and the knee is flexed [34]. To release the quadratus lumborum muscle, the ball should be located at the center of this muscle in the supine position, and the patients' body weight applies pressure [22].

For SMFR, patients should spend two minutes for each muscle. In the first minute, individuals should breathe, relax, and use their body weight (except for the vastus medialis) to provide pressure on the trigger point region. For the second minute, pressure is applied with some rotation of the ball. As the body adapts and muscles begin to relax, the intensity can be increased by applying more weight to the ball [22].

2) Control Group (Exercise Therapy)

The participants in this group will receive a therapeutic exercise program similar to the experimental group through telerehabilitation. They will also be recommended to use a cold pack for 20 minutes before starting their treatment program. SMFR exercises, however, will not be included in this group.

The exercises should be done almost painlessly. If the

Table 1: Exercise therapy protocol

Week	Exercises	Description
1	Hamstring stretch	Supine straight-leg raising (hip flexion with knee extension)
		3 sets* 30 seconds hold (for all weeks)
	Gastrocnemius stretch	Standing position
		3 sets*30 seconds hold (for all weeks)
	Quadriceps stretch	Standing position
		3 sets*30 seconds hold (for all weeks)
	Tensor Fascia Latae stretch	Long sitting position
		3 sets*30 seconds hold (for all weeks)
2	Quadriceps exercise	Supine, isometric terminal knee extension
		3 sets*10 repetitions, 5 seconds hold
	Side-lying abduction	3 sets, 10 repetitions in each set
	Side-lying clamshells	3 sets, 10 repetitions in each set
	Bridge exercise	3 sets, 10 repetitions in each set
3	Quadriceps exercise	supine straight-leg raises
		3 sets, 10 repetitions in each set
	Side-lying abduction	3 sets, 15 repetitions in each set
	Side-lying clamshells	3 sets, 15 repetitions in each set
	Bridge exercise	3 sets, 15 repetitions in each set
	Lateral bridge	3 sets*8 repetitions, 5 seconds hold
4	Quadriceps exercise	Supine straight-leg raises
		3 sets, 15 repetitions in each set
	Side-lying abduction	3 sets, 20 repetitions in each set
	Side-lying clamshells	3 sets, 20 repetitions in each set
	Bridge exercise	3 sets, 20 repetitions in each set
	Lateral bridge	3 sets*10 repetitions, 5 seconds hold
	Step	Exercise on a step with 18-20 cm height
		3 sets, 10 repetitions in each set

patients report an increase in pain at the end of each week, the progress of the exercises will be postponed, and they will repeat the same exercises in the next week. The progress of the program is based on the patient's feedback and symptoms. If anyone suffers from our program, that person will receive private treatment that includes various physiotherapy interventions such as manual therapy, Kinesio taping, and exercise therapy until the symptoms will improve (Table 1).

Outcome Measures

Outcome measures will include pain, pressure pain threshold (PPT), function, and balance measured by the Visual Analogue Scale (VAS), algometer, KUJALA patellofemoral pain scale, Lower Extremity Functional Scale (LEFS), and Modified Star Excursion Balance Test (mSBT), respectively. These outcome measures will be evaluated at baseline, the end of treatment, and two weeks after the end of treatment. VAS, a horizontal line of 100 mm or 10 cm which ranges from no pain to the worst pain , has been demonstrated to be valid and reliable for pain measurement [35]. The PPT of trigger points will be measured (force in kg/cm2) after identifying the trigger points in each muscle. To accomplish this, the algometer (FDIX25 Digital Force Gauge, Greenwich, CT, USA) will be put perpendicularly on the desired area of the skin, and pressure will be applied at a rate of 1 kg/cm2 [36]. The patient will be expected to report any pain sensation as soon as it is felt. This process will be repeated twice at 30-second intervals. The average of the two trials will be counted as the PPT [37]. The KUJALA patellofemoral pain scale is a 13-item self-reported questionnaire. The validity and reliability of the Persian version of the KUJALA patellofemoral pain scale have been confirmed in a previous study [38]. LEFS is a well-known scale consisting of 20 questions that is used to assess lower limb function. The validity and reliability of the Persian version of LEFS have been authenticated in a previous study [39]. Because performing eight directions in the Star Excursion Balance Test is time-consuming, mSBT, in which three directions (anterior, posteromedial, and posterolateral) are assessed, is usually used to measure balance [40]. The schedule of enrollment, interventions, and assessments is shown in Figure 2.

Data Collection and Sources

Once the participants have been informed and randomly allocated to their respective groups, data collection will commence for statistical analysis. We will encourage participants to complete our trial until follow-up through regular communication. This trial has defined start and end points, and all participants are expected to complete all specified steps. Patient recruitment began in September 2022, and data collection is currently underway. We anticipate that our results will be published as an article in a relevant journal in the summer of 2023. All personal information will be securely maintained, and the mean total results will be published. All investigators involved in this study have access to the trial dataset.

After ensuring the correctness of the data collection, we will enter the data into the software and employ appropriate statistical charts and tables to delineate the data**.** SPSS version 21 will be used for data analysis. First, the normality of data will be checked by the Kolmogorov-Smirnov test. If the data is normal, analysis of variance (2 groups x 3 times) will be used to compare

	STUDY PERIOD				
	Enrollment	Allocation	Post allocation		Close out
Time point	-T1	T0	T.1 (after 4 weeks)	T.2 (after 6 weeks)	
Enrollment					
Eligibility screen	×				
Informed consent	×				
Allocation		×			
Intervention					
Experimental group		▬	▬	▬	
Control group		▬	▬	▬	
Assessment					
VAS		×	×	×	
Kujala scale		×	×	×	
LEFS		×	×	×	
PPT		×	×	×	
mSBT		×	×	×	
Data collection		▬	▬	▬	
Statistical analysis					×

Figure 2: Schedule of enrollment, interventions and assessments

within- and between-group differences. If the group x time interaction is significant, repeated measures tests will be conducted in each group to evaluate the effects of time, and independent t-tests will be used to identify significant differences between groups. However, if the data does not follow a normal distribution, non-parametric tests such as Friedman test will be used for within-group and Mann-Whitney for between-groups analysis. All outcome measures will be examined from the aspects of means, SDs, and 95% CIs. A p-value of less than 0.05 will be set as the statistically significant level, and β will be considered 0.8. When we have the data of a participant at baseline and after treatment, if said participant does not cooperate in the follow-up, we will count intention-to-treat; otherwise, the data of this non-adherent person will be omitted.

Discussion

The presence of MTrPs in gluteus medius and quadratus lumborum muscles is a contributing factor to lower limb biomechanical malalignment and delayed muscle activation related to PFPS [13-15]. The quadriceps muscle MTrPs also lead to peripatellar and anterior knee pain. Consequently, diminishing these points in three muscles plays a crucial role in PFPS treatment. The use of SMFR techniques through telerehabilitation, which allows patients to manage their musculoskeletal disorders without the need for repeated visits to a clinic simply by training with a physiotherapist, would be helpful for both physiotherapists managing PFPS and their patients.

We have hypothesized that SMFR of quadriceps, gluteus medius, and quadratus lumborum muscles accompanied by exercise therapy will have greater effects on pain, PPT, function, and balance than exercise therapy alone through telerehabilitation in individuals with PFPS.

Our study has several limitations. Some volunteers may be excluded from telerehabilitation because of a lack of Internet access or an appropriate technology device to connect to the Internet. Additionally, some participants may not cooperate adequately during the intervention. Furthermore, neither the participants nor the physiotherapist carrying out the intervention will be blinded. Any adverse effects following this therapeutic plan will be reported. Patient enrollment and recruitment are ongoing.

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Conflict of Interest: None declared.

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