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Original Article

Comparing the Effects of Tele-Physical therapy and Supervised Physical Therapy on Pain, Range of Motion, Function, and Satisfaction in Patients with Sub Acromial Pain Syndrome: A Protocol of Randomized Clinical Trial

Fatemeh Ehteshami[1,2], MSc; Nastaran Ghotbi[1], PhD; Khadije Otadi[1,3*], PhD

[1]Department of Physical Therapy, School of Rehabilitation Sciences, Tehran University of Medical Sciences, Tehran, Iran
[2]Student Research Committee, Tehran University of Medical Sciences, Tehran, Iran
[3]Rehabilitation Sciences Research Center, Tehran University of Medical Sciences, Tehran, Iran

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ABSTRACT

Background: Subacromial Pain Syndrome (SAPS) is one of the most common causes of shoulder pain, leading to long-lasting disability if left untreated or if there is no access to a rehabilitation center. Treating musculoskeletal shoulder pain is challenging; however, evidence suggests that a combination of Exercise Therapy (ET) and Manual Therapy (MT) can be an effective approach for addressing shoulder dysfunctions. To ensure timely treatment and prevent the pain from becoming chronic, tele-physical therapy appears to be an effective method for properly delivering ET and MT

Methods: A prospective, assessor-blind, randomized controlled clinical trial study protocol

will be designed to include 33 patients with SAPS. These patients will be divided into three groups (11 participants in each group): The Control group (supervised (ET)+(MT)), the Videoconferencing group (ET+self-release therapy), and the Video-based group (ET+self-release therapy). Self-release therapies include self-joint mobilization and self-myofascial release with a tennis ball. MT includes joint mobilization techniques and transverse friction massages. ET consists of stretching and strengthening exercises. Each patient in the three groups will receive 10 sessions of ET and MT over three weeks. Assessments will be conducted three times: at baseline, midterm, and post-treatment. The Visual Analogue Scale, function by the Shoulder Pain and Disability Index, and Range of Motion will measure pain. The Telehealth Satisfaction Scale and Physical Therapy Patient Satisfaction Questionnaire will also be assessed.

Results: Repeated measures ANOVA will be used for analysis of data after data gathering

Conclusion: This trial will focus on the assessment of tele-physical therapy based on ET and myofascial release, in comparison to a face-to-face approach with supervised ET and MT, on pain, function, Range of Motion, and patient satisfaction.

Introduction

Shoulder pain ranks the third most common reason for patients seeking medical and rehabilitative care [1]. Although it has a linear correlation with aging, a diminishing trend is seen after retirement due to a decrease in workload [2]. Chronic shoulder pain is prevalent among adults and juveniles 18-24 years old, with incidences of 23% and 43.5%, respectively, among older adolescent athletes. This can be attributed to mal-

*Corresponding author: Khadije Otadi, Department of Physiotherapy, School of Rehabilitation, Tehran University of Medical Science, Enghelab St, Pich-e Shemiran, Tehran, Iran. **Tel:**+98 21 77533939;
Email: k_otadi@sina.tums.ac.ir

posture, overuse, and long periods of sitting due to technological advances [3, 4]. This situation can burden society due to work absenteeism and the consumption of healthcare resources [5].

Subacromial Pain Syndrome (SAPS) stands out as the most common cause among all cases of shoulder pain [6]. Several structures are enclosed in a limited space, as much as 1 cm long, within the acromion and humeral head [7]. If coordinated movements of the rotator cuff (RC) muscles during shoulder elevation are not fulfilled, abnormal GH joint translation occurs, leading to damage to the surrounding structures [8]. Thus, poor recruitment of neuromuscular, humorous internal rotation and dysfunction in shoulder complex biomechanics lead to incorrect timing of the RC and cause this situation [9].

SAPS characteristics include non-traumatic shoulder problems usually localized on the acromion, which aggravate with lifting heavy objects. SAPS is an umbrella term for various pathologies, for instance, bursitis, calcification tendonitis, Supraspinatus and biceps tendinopathy, or partial tear or degeneration [10].

To treat SAPS, the first line of remedy is conservative management, including supervised non-operative rehabilitation that leads to pain reduction and functional gain [11]. According to a recent systematic review in 2022, exercise therapy had a large effect size for improving pain and function for patients with SAPS [12]. Therapeutic exercises must focus on RC strengthening and scapular stabilization to dynamically place the head of the humerus across the glenoid [13] and posterior capsular and RC stretch [14]. Based on the evidence, Manual Therapy (MT) in addition to Exercise Therapy (ET) is more beneficial than ET alone [15, 16]. For the sake of MT, transverse friction massage, joint mobilization, and myofascial release are helpful [17]. MT aims to alleviate inflammation, recover the shoulder's pain-free range of motion, and restore the proper function of soft tissue and joints [16].

Self-myofascial release (SMR) is a kind of myofascial release implemented by clients alone, usually with simple instruments like a tennis ball or foam roller [18]. These techniques can restore movements and decrease Delayed Onset Muscle Soreness (DOMS) [19]. SMR is cost-effective, easy to use at any time, and ultimately reduces the workload on the therapist's wrists and shoulders [19].

Héctor Gutiérrez-Espinoza et al., based on a systematic review, found that home-based exercise therapy did not differ from supervised exercise therapy [20]. During the COVID-19 crisis, people are inclined to use remote medical methods for their non-urgent healthcare needs [21]. The approach of tele-physical therapy concerns conveying rehabilitative therapies through telecommunication technologies [22]. This approach can provide people with a vast range of rehabilitative services, for instance, assessment, evaluation, coaching, intervention, counseling, and education [23]. It can facilitate in-person obstacles like saving time commuting to clinics, reducing the cost of PT, and decreasing the time on the waiting list [24].

Our research mainly aims to compare tele-exercise therapy in combination with self-release and supervised exercise therapy and manual therapy on pain, function, range of motion, and satisfaction in Subacromial Pain Syndrome patients.

Methods

Study Design

This randomized controlled trial will be a parallel-group study with two arms and will be assessor-blinded. The flow chart is illustrated in Figure 1. The research is registered at the Iranian Registry of Clinical Trials (IRCT20220622055252N1, on December 29, 2022) with approval ID: IR.TUMS.FNM.REC.1401.015, granted by the Ethics Committee of Tehran University of Medical Sciences. This protocol will adhere to the Standard Protocol Items Recommendations for Interventional Trials (SPIRIT) for reporting the study's findings (attachment 3). Enrollments will be conducted by posting study posters on social media until adequate participants are achieved. The study will be conducted at the clinics of the School of Rehabilitation, Tehran University of Medical Sciences (TUMS). In our institute, every investigation is closely monitored through a specialized study process, and the progress is carefully tracked.

Subjects

Participants with Subacromial Pain Syndrome will be recruited by placing advertisements in hospitals and clinics and posting posters on social media platforms covered by the Tehran University of Medical Science and physiotherapy clinics in Tehran city.

Inclusion Criteria

1) age 18-50, 2) onset of pain is more than three months, 3) patient with subacromial related shoulder pain (rotator cuff tendinitis or partial tear, bursitis), 4) positive Hawkins-Kennedy test, painful arc test, and infraspinatus resistance test, 5) internet accessibility, 6) literacy, 7) All patients should have at least one trigger point in Trapezius, Deltoid, Supraspinatus, Infraspinatus, Teres minor, Teres Major, or Latissimus Dorsi, not all muscles.

Exclusion Criteria

1) individuals with mental disorders like Alzheimer's disease or psychological problems such as depression, 2) individuals who don't have access to smartphones, the internet, or video conferences, 3) if acute response to therapies appears, 4) patients with calcific tendonitis, 5) patients with a full rotator cuff tear, 6) if any unbearable pain is provoked, 7) patients who have had shoulder surgery recently, 8) pains related to the cervical region.

Randomization, Allocation, and Blinding

The target population will consist of 33 participants (considering a 10% dropout) with SAPS. They will be randomized with a 1:1:1 allocation ratio. Randomization will be conducted by placing letters A, B, and C, written on small sheets, in a basket. Participants who draw the letter A (control group) will be assigned to the first interventional group, which will receive supervised ET and MT.

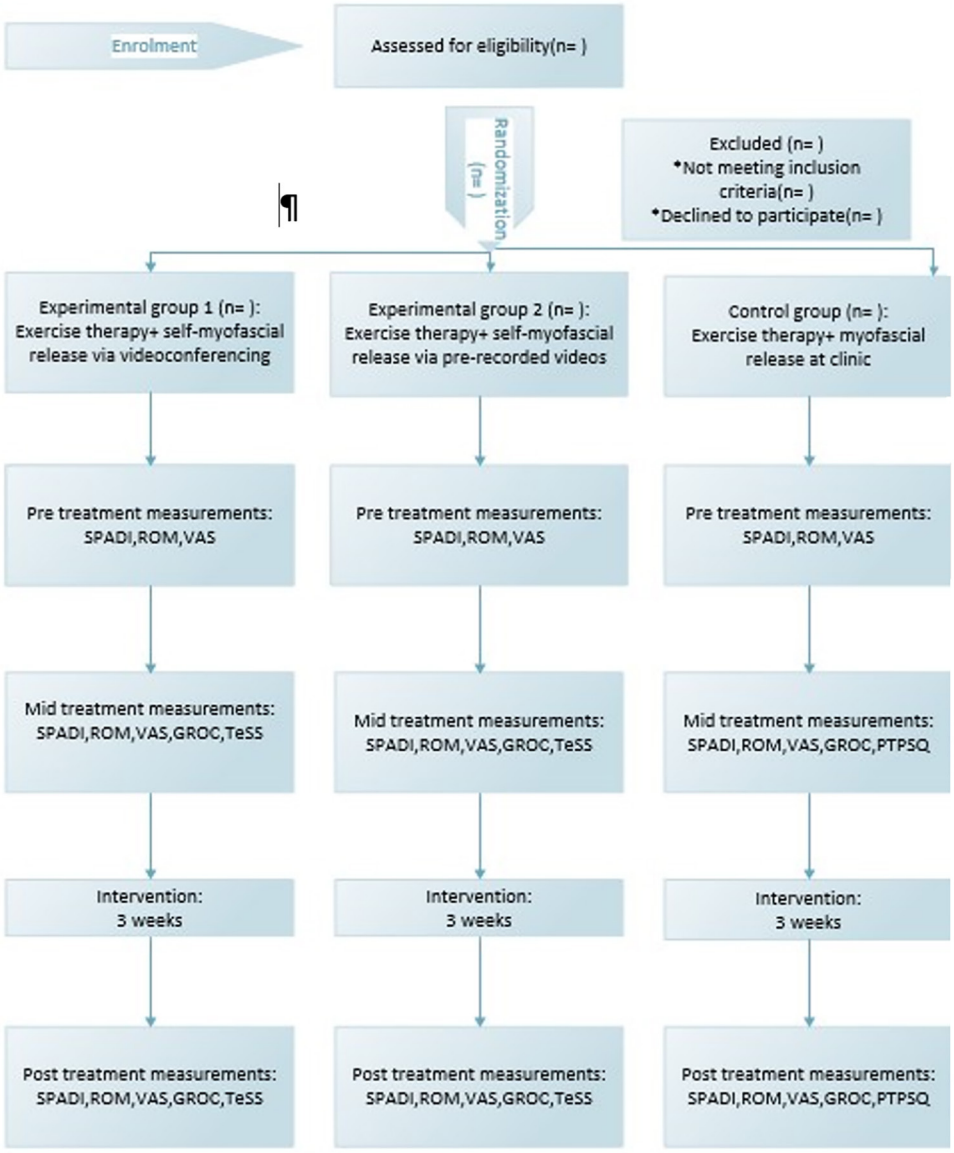

Figure 1: Flow chart of participants' enrollment process of study

Participants who draw the letter B will be assigned to the second group, receiving tele-physical therapy via video conferencing using accessible applications. Participants who draw the letter C will be assigned to the third interventional group, receiving a therapeutic plan via prepared videos. A trained physical therapist will handle the enrollment, grouping of participants and implementation of the treatment procedure, and she will present the consent form to volunteers. The primary investigator, a trained physical therapist, will perform outcome measurements while blinded to the group assignments.

Intervention

Each volunteer will participate in 10 sessions of ET and three sessions of MT over three weeks, divided into three groups. MT will consist of myofascial release and joint mobilization. A blinded assessor will conduct special tests to recruit patients with Subacromial Pain Syndrome before randomization. Depending on the health and wellness of their shoulder joint, volunteers will be given a combination of 3 or 4 stretching and strengthening exercises in a single session. Data will be collected at three separate time points: before the first interventional session, in the middle, and after the completion of the treatment sessions at the clinic. Each client in both tele-physical therapy groups will receive a tennis ball and a Thera band.

The first interventional group (control group) will attend the clinic and receive a hands-on approach from the therapist. All exercises will be conducted under the supervision of a trained physical therapist. A trained PT will perform the MT in the control group, consisting of shoulder joint mobilizations and transverse friction massages.

In the second interventional group, patients will receive ET and MT via video conferencing using mobile-based applications or other devices such as WhatsApp, Google Meet, Skype, or any other platform that allows them to communicate with the therapist visually and in real-time. This approach aims to ensure the correct execution of exercises and self-releases.

Participants in the third interventional group will receive prepared videos and exercise explanations. Individuals in the tele-physical therapy groups can also maintain contact with the therapist via social media chat.

Self-releases involve moving a tennis ball on tender spots between the body and a wall to stimulate a transverse friction massage for a few seconds. They also include self-joint mobilization techniques.

In this study, self-joint mobilization comprises self-caudal glide and self-posterior glide. Self-caudal glide occurs when the client sits on a chair or a bed, grasps the edge of it, and leans away from the fixed arm [25]. When a patient is positioned in a prone stance, propped up on both elbows, a self-posterior glide of the shoulder occurs as the body weight shifts downward between the arms [25].

Before applying self-release on the tissue, the anatomy of the related muscles will be explained to the patient. Moreover, they will be required to perform strengthening exercises ten times each in 3 sets and stretching exercises for 30 seconds in 3 sets. The meeting will continue until they fully understand the exercises and it is confirmed that they have performed them correctly.

To apply self-myofascial release techniques on muscles with a tennis ball, patients can use different motions, such as moving back and forth by leaning on a tennis ball that is placed against a wall or applying a static compressive force for 6-30 seconds, which is similar to the ischemic compression technique [19].

To begin with, massaging the Trapezius muscle with a tennis ball is especially effective when patients stand against a wall and apply strokes and movements with slight pressure along the edge of the shoulder [26]. To release the Deltoid muscle, the client must place a lacrosse ball between themselves and the wall, then repeatedly move back and forth with slight pressure [26].

It is recommended to use fingers to release tender spots of the Supraspinatus. For this purpose, clients should place their fingers between the spine of the scapula and the tip of the Trapezius and then perform circular or transverse motions for a few seconds [26].

To release the Infraspinatus, the patient would be better off standing against the wall at a 45-degree angle, then starting to move and apply massage on it [26]. To treat Teres Minor, patients stand across the wall at an angle with a lacrosse ball in between, then apply pressure and move for some time [26]. The Teres Major can be treated using the same self-release technique as the Teres Minor [26].

To release the Latissimus Dorsi, the patient has to sit against the wall with a tennis ball in between, under the inferior angle of the scapula. 8-12 strokes in that area are enough [26].

According to one study, the signs and symptoms of patients with SAPS improved after exerting a caudal glide on the shoulder joint [27]. To apply hands-on MT, the patient lies in a supine position close to the edge of the bed. Afterward, the therapist grasps the humerus near the joint, which is in neutral int/ext rotation, while the other hand supports the arm's weight. Then, a caudal (inferior) glide is applied [28].

All patients in the three groups will receive the same ET, as mentioned in Appendix 1. The exercises should be performed with minimal or negligible discomfort. If the patient experiences an escalation in pain by the end of the week, the advancement of the exercise regimen will be delayed, and the patient will repeat the exercises for that particular week. The program's advancement relies on the patient's feedback and symptoms. During the treatment, patients will be advised to abstain from using painkillers without consulting with the physician, as it will aid in a better assessment of the treatment's effectiveness.

Outcome Measures

The following tools will be used for the assessment of pain, function, Range of Motion, and patient satisfaction respectively: VAS (Visual Analogue Scale), Shoulder Pain and Disability Index (SPADI), goniometer, Telehealth Satisfaction Scale (TeSS), and Physical Therapy Patient Satisfaction Questionnaire (PTPSQ). All of these will be assessed at three stages: at baseline, in the middle of treatment, and at the end.

Pain Intensity

The Visual Analogue Scale will be used for pain intensity assessment. On this scale, pain ranges from zero, which describes 'No pain,' to 10, which defines the 'worst pain' possible [29].

Function

SPADI

This validated and reliable questionnaire evaluates pain and disability in patients with shoulder pain [30]. It is a numeric scale that consists of a pain domain covered in 5 questions with a total score of 50 and a disability domain covered in 8 questions with a total summation score of up to 80. The SPADI has 13 questions, yielding a maximum score of 130. Each item is scored on a Numeric Rating Scale (NRS) ranging from 0 to 10 points, with a lower score indicating improvement [31].

ROM

The normal Range of Motion (ROM) for shoulder flexion and abduction is 180 degrees, and 90 degrees for external rotation [32]. Both Passive Range of Motion (PROM) and Active Range of Motion (AROM) will be measured with a universal, double-armed, full-circle protractor made of transparent plastic, specifically the Saehan "360-D1" plastic goniometer, which is 15cm in size. This method of assessment has been validated and is reliable [33].

GROC

This outcome aims to score self-perceived improvement and is often used to determine the smallest amount of clinically significant change. The Global Rating of Change (GROC) is a single-item, recall-based questionnaire with a self-report scale of 15 or 11 points [34-36]. In this study, an 11-point scale will be applied, ranging from -5 to 5.

Satisfaction

TeSS

This is a 10-item questionnaire that has been used in previous telehealth studies in Saskatchewan. The aim of developing this survey was to improve specialist access through telehealth applications [37]. The Likert scale used

to rate the items consists of four points, with a score of 1 representing 'poor,' 2 representing 'fair,' 3 representing 'good,' and four representing 'excellent.' The total score varies between 10 and 40, with higher scores indicating greater satisfaction. We will use the validated and reliable Persian version of the questionnaire. The first and second interventional groups will be examined via TeSS.

Physical Therapy Patient's Satisfaction Questionnaire or PTPSQ

PTPSQ has 26 items in five dimensions (access, administrative, technical management, clinical, technical management, interpersonal management, and continuity of care) with validated and reliable measurement into two sections [38]. Six questions will gather information about the patient's demographic details in the first section, and 20 questions will assess the patient's satisfaction in the next section. The patient will choose from five options: strongly agree to strongly disagree. The average scores in each domain are used to determine the level of satisfaction (total score range from 20-100).to examine the quality of treatment in physical therapy clinics [39temsAsXml]. The control group will be assessed through this questionnaire because this questionnaire' is specific for the assessment of patients in the physiotherapy clinic. Higher scores in this questionnaire indicate more satisfaction and improvement.

Data Collection and Sources of Data

A total of 33 volunteers will be interviewed to collect demographic data, including age, gender, occupation, sport, height, weight, BMI, and the onset of pain. Patients will be randomly allocated into two experimental groups or one control group. Outcome measures will be recorded at baseline, midterm, and three weeks after the baseline by a physical therapy specialist blinded to group assignments. Patient recruitment began in December 2022, and data collection is ongoing. The demographic profile of the participants will be analyzed. The changes in outcome measures before and after treatment for each group and the differences between groups will be statistically analyzed and reported. We anticipate that our results will be released in Spring 2023.

Statistical Analysis

The sample size, consisting of 11 individuals in each group, was calculated based on the SPADI using G power, with an effect size of 0.56 and considering a 10% dropout rate. After data collection, we will input the data into IBM SPSS version 25 for analysis and use appropriate statistical charts and tables to present the data [22]. The Kolmogorov-Smirnov test will be used to assess the normal distribution of variables. Primary differences between groups will be checked using an independent sample t-test. A repeated measures ANOVA will be conducted to evaluate the effectiveness of interventions. All participants who withdraw will be excluded from the study. Subgroup analyses will be conducted to check for potentially significant differences between athletic patients and non-athletes and to investigate participants who frequently use their shoulders. A P value less than 0.05 will be considered statistically significant.

Discussion

Based on the information provided, no existing study directly compares the effectiveness of tele-physical therapy with clinic-based treatments, specifically focusing on exercise therapy and manual therapy for patients with subacromial pain syndrome. Given the limited evidence available on videoconferencing via smartphones and the accessibility of prepared videos about shoulder pain, we decided to design a method to demonstrate their potential as effective treatments. These could be viable alternatives in special situations, such as the Covid-19 pandemic [40-41]. Tele-physical therapy can also eliminate barriers for clients living in remote areas [42]. Exercise therapy is a safe method to reduce patient disabilities and can be more effective when combined with manual therapy.

Self-release application effectively alleviates muscle soreness, even after engaging in sports or heavy work. It is beneficial in preventing chronic musculoskeletal problems [43]. If timely intervention is not performed, the prognosis for shoulder improvement deteriorates over time.

The strengths of this study include its design as a randomized control study, and the intervention will be conducted by a therapist experienced in the field of virtual reality. Furthermore, manual therapies in tele-physical therapy groups are simulated to match clinical manual therapies and exercise therapies, ensuring consistency across all three intervention groups. If the results demonstrate the efficacy of tele-physical therapy, therapists can consider it a viable option during crises such as pandemics. This method could also benefit patients living in remote areas, especially with the advancement of technology.

However, the study has certain limitations. Double or triple blinding is not feasible due to the nature of the intervention. Patients with technological barriers, such as internet disconnections, technological corruption, or lack thereof, will not be included in this study. Any events that impact the internet connection quality can disrupt the treatment process. Additionally, patients older than 50 years are not included in this study.

This study aims to provide evidence about the effectiveness of ET plus MT delivered via a telehealth approach, compared to hands-on Physical Therapy at clinics, in terms of pain, function, Range of Motion, and patient satisfaction.

Conclusion

The study will address a relevant and important topic about effects of Tele-Physical therapy and Supervised Physical Therapy on Pain, Range of Motion, Function, and Satisfaction in Patients with Sub acromial Pain Syndrome

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Appendix 1: Exercise Therapy protocol

Week	Session	Exercises	Description
1	1	Capsular stretch	Side lying with shoulder and elbow flexion
			3 sets * 30 seconds hold
		Pendular exercise	Leaning in front of a chair
			1-2 minutes of freely circular motion
		Trapezius stretch	Sitting position
			3 sets * 30 seconds hold
	2	Pectoralis minor stretch	Corner stretch , standing
			3 sets * 30 seconds hold
		Pectoral muscles stretch	Supine lying with shoulder and elbow in 90-90 flexion
			3 sets of 10 repetition
		Levator scapulae stretch	Sitting position
			3 sets * 30 seconds hold
	3	Latissimus dorsi stretch	Sitting position
			3 sets * 30 seconds hold
		Shoulder external rotation	Standing position
			3 sets of 10 repetition
2	4	Scapular adduction/abduction	Standing against a wall, scapular protraction and retraction
			3 sets of 10 repetition
		Shoulder horizontal abductuion	Standing position, shoulder and elbow in 90-90 abd and flx
			3 sets of 10 repetition
	5	Scapular clock exercise	Standing in front of a wall with a ball in 90 shoulder flexion
			3 sets of 10 repetition (circular motion)
		Scapular clock exercise	Standing position beside a table with a ball in hand
			3 sets of 10 repetition (circular motion)
	6	PNF exercise – D_1 diagonal	Standing position
			3 sets of 10 repetition
		PNF exercise – D_2 diagonal	Standing position
			3 sets of 10 repetition
	7	T exercise	Prone on swiss ball (horizontal abduction)
			3 sets of 10 repetition
		Y exercise	Prone on swiss ball, shoulder in 135 degree flexion
			3 sets of 10 repetition
	8	Resisted external rotation	Standing position with a thera-band in one hand
			3 sets of 10 repetition (arm rest next to the chest)
		Resisted external rotation	Standing position with a thera-band in both hands
			3 sets of 10 repetition (arm rest next to the chest)
3	9	Resisted external rotation	Standing, shoulder in 90 abduction with thera-band
			3 sets of 10 repetition
		Serratus anterior punch	Standing against a bar, punching with a thera-band
			3 sets of 10 repetition
	10	PNF resistive exercise	Standing position
		D_1 diagonal	3 sets of 10 repetition
		PNF resistive exercise	Standing position
		D_2 diagonal	3 sets of 10 repetition