Comparison of the Effectiveness of Proprioceptive Neuromuscular Facilitation Exercises and Shoulder Mobilization Patients with Subacromial Impingement Syndrome: A Randomised Clinical Trial

Study Protocol with Statistical Analysis Plan (SAP) and Informed Consent Form (ICF)

March 3, 2017

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Study Protocol

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Study Protocol

Study titled 'Comparison of the Effectiveness of Proprioceptive Neuromuscular Facilitation Exercises and Shoulder Mobilization Patients with Subacromial Impingement Syndrome: A Randomised Clinical Trial' was approved by Marmara University Faculty of Medicine Clinical Researches Ethics Committee meeting on 03.03.2017 with approval number: 09.2017.200.

The participants in the study were informed about the aim, duration and the programs to be applied throughout the study. Volunteer Information Form has been signed and approved in accordance with the standards deemed appropriate by the Clinical Researches Ethics Committee of Marmara University Faculty of Medicine (This form can be seen on Informed Consent Form (ICF) section). The study was conducted in accordance with the Declaration of Helsinki.

Randomization of the Study Groups

Individuals with Subacromial Impingement Syndrome (SIS) who applied to Sevgi Medical Center for physiotherapy and rehabilitation were invited to participate to the study. Individuals who volunteered to participate and whom met the criteria for participation were randomized with 'Research Randomizer' program and divided into three groups. In all three groups participants received conventional physiotherapy program. The shoulder mobilization techniques was added to the program of the Group II (The Shoulder Mobilization Group). Proprioceptive Neuromuscular Facilitation (PNF) techniques was added to the program of the Group III (The PNF Group).

Inclusion Criteria

- Volunteered to participte,
- Aged between 25-65 years old,
- Having the diagnosis of Subacromial Impingement Syndrome (SIS),
- Having shoulder pain at least for four weeks

Exclusion Criteria

- Patients with a neuromuscular disease, pregnancy, history of cancer, unstable angina, a history of surgery at neck, shoulder, elbow or/and hand, communication problem, pulmonary and/or vascular problems, systemic anti-inflammatory joint disease, any condition which was contraindicated for electrical stimulation and/or exercise, cervical disc herniation or radiculopathy, previous physiotherapy on the same shoulder due to SIS, a history of corticosteroid injection in last three months, any orthopedic, rheumatologic, or congenital condition that effect the targeted shoulder

Applied Evaluations

1. **Shoulder Pain**

Pain was defined with Visual Analog Scale (VAS). A 10-cm long horizontal visual analog scale (VAS) with marks 0 point (no pain) and 10 point (unbearable pain) was used for evaluating the pain severity. The patients were asked to mark the representing point of their pain levels. The values were recorded in cm. The pain severity was asked in three occasions as: at resting (VASr), during activity (VASa) and during night (VASn).

2. **Function of the Shoulder**

The Disabilities of the Arm, Shoulder and Hand (DASH) Score was used to evaluate the upper extremity physical function. DASH includes two modules as disability / symptom section and work section. The scores are ranged between 0-100. Higher scores indicate lower functionality.

In addition to DASH, the Constant-Murley score was used to evaluate the functionality of the shoulder. Constant-Murley score is a 100-point scoring system and consisted of four sub-scores as pain (15 points), daily living activities (20 points), active range of motion (40 points), and muscle strength (25 points).

3. **Range of Motion**

The active range of motion was assessed by using a universal goniometer.

4. Muscle Strength

The muscle strength of shoulder flexion, shoulder abduction, shoulder adduction, shoulder external rotation, and shoulder internal rotation were determined by using Baseline Push-Pull (New York, USA) dynamometer. The dynamometer was placed in a 90 degrees angle on the location and the patient was asked to contract in maximum for two seconds and then maintain this position for five seconds. Two assessments were performed, and average values were recorded. Pain was avoided during the measurements.

Treatment Program

The participants in our study were all treated in Sevgi Medical Center five days a week for 4 weeks, a total of 20 sessions (Duration of one session is 60 minutes) and follow-up for 12 weeks, total follow- up time was 16 weeks.

The conventional physiotherapy consisted of electrotherapy and exercise approaches. The electrotherapy program consisted of infrared application (for 15 minutes, from 70 cm distance with Hanau 201, Germany device), conventional TENS was applied in an encircled region (for 20 minutes with Intelect 2778 Combo, Chattanooga Group device; with 4 electrodes, 100 Hz, 100 msec), and therapeutic Ultrasound was applied (for 3 minutes with Intelect 2778 Combo, Chattanooga Group device; 1 MHz, power: 1,5 W/cm^2).

A physiotherapist supervised entire exercise program performed following the electrotherapy program. Elastic resistive exercises were added at the week three. While, the first set of wand exercises and elastic resistive exercises was performed under supervision, two sets were given as the home exercise program.

The PNF group received PNF exercises with contract-relax technique, in the patterns of “flexion-abduction-external rotation”, “extension-adduction-internal rotation”, “flexion-adduction-external rotation” and “extension-abduction-internal rotation” along with the verbal and manual facilitation of the physiotherapist.

In the mobilization group, while the shoulder joint was placed in the traction, anterior, posterior, and inferior glidings and circumduction were applied to the humerus for 2-3 minutes. All mobilization applications were performed in painless ROM limits. The degree of traction and glidings were increased as the relaxing obtained in the tissues.

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Statistical Analysis Plan (SAP)

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Statistical Analysis Plan (SAP)

The statistical program Statistical Package for Social Sciences (SPSS) Version 16.0 (SPSS Inc., Chicago, IL, USA) was used in the data analysis of the study. The p value of $p<0.05$ was considered to be statistically significant in the data analysis. Shaphiro-Wilks test was used to investigate the appropriateness of the variables to normal distribution. Kruskal-Wallis and Mann-Whitney U tests were used to compare the groups.

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Informed Consent Form (ICF)

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Informed Consent Form (ICF)

Description of the Physiotherapist

This study, if you accept your child to be participated, is a scientific research and it is titled as 'Comparison of the Effectiveness of Proprioceptive Neuromuscular Facilitation Exercises and Shoulder Mobilization Patients with Subacromial Impingement Syndrome: A Randomised Clinical Trial'. In this study, individuals with Subacromial Impingement Syndrome (SIS) will be evaluated in terms of arm functions, arm joints range of motion with universal goniometer, muscle strength with push-pull dynamometer, pain with visual analog scale (VAS), functional with The Disabilities of the Arm, Shoulder and Hand (DASH) score and Constant-Murley Score. The study, which is planned to last in 16 weeks, requires participants to attend the study regularly for 5 days a week for 4 weeks and each day for one session which is 60 minutes, and come back in the 16th week for final evaluations. There will be no disruption of the body during the process.

This research will be carried out by Physiotherapist Sultan IGREK (Tel: +90 537 210 06 54) and will be under the supervision of Assoc. Prof. Tuğba KURU ÇOLAK at Marmara University, Institute of Health Sciences, Department of Physiotherapy and Rehabilitation.

You are being invited to a research project. It is very important you to understand why and how this research will be done before making a decision. Please take some time and read the following informations carefully, discuss it with others if you wish. If you have an unclear section or need more detailed information, you can get information from us. You are invited to our research because we think your child matches the criterias to be included. We would like to note that participation is voluntary and that refusal to participate does not lead to any penalty or loss of any benefit. In the same way, you can withdraw from the research at any time.

After getting the demographic information of the participants, you will be measured by the above physiotherapist and with the mentioned tests. The evaluation tests will be repeated 4 times throughout the treatment. The data obtained from the assessments will be recorded in the computer and the changes during pre- and post-treatment will be analyzed.

The assessments applied to the participants in our research do not have any known harm. In the event of any unexpected damage in the evaluation process or during the rehabilitation process, the information will be given immediately to you. In case of any damage to the participants, the necessary applications shall be covered by the researchers without any recourse. For this, you will not be charged any fees, neither you nor your social security insurance.

While participation in the research does not help you immediately, it is hoped that our research results will have benefits for the organization, society or science in the future. You will not be charged any fees for the purposes of the research or for the social security institution to which you are affiliated.

Consent of the Participant

I have read the entire information form clearly and understood or because I do not know how to read/not able to or do not understand the language it was read or translated to me. I was given the opportunity to ask, evaluate and decide on my health status both during and after my application and when filling this form in. All kinds of treatment and diagnostic alternatives, including the possibility of not getting the treatment, their risks and dangers are explained.

Name and the Surname of the Participant and/or Legal Representative:

Date: **Signature:**

Name and Surname of the Withness:
Date: **Signature:**

Declaration of the Physiotherapist

I gave the patient the necessary information about the study and the procedures to be performed. I believe that the patient understood this information, asked me the questions that she/he wanted to ask, and accepted the process with her/his free will.

Researcher: Physiotherapist Sultan Igrek
Address: Sevgi Medical Center – Nene Hatun Street Nr. 9/A Arnavutkoy / Istanbul / Turkey
Mobile Phone: +90 537 210 06 54 **E-mail:** sultanigrek@gmail.com
Date: **Signature:**

Declaration of the Participant / Legal Representative

Ms. Sultan Igrek stated that a medical research will be carried out and the above information about this research was explained to me. I know I am invited to this research as a participant. If I participate in this research, I believe that the confidentiality of my information during research will be treated with great care and respect. I was given enough information that my personal information would be protected with care during the use of the research and the results will only used for educational and scientific purposes. During the research I can withdraw from the study at any time without any cause (But in that case I am aware of the difficult situation it would cause to the reaseachers if I do not give any notice). I don't take any financial responsibility for the research expenses. There will be no payment for me. Whether directly, indirectly arised any health problem that may occur during the research, I will not undergo any monetary burden. When we encounter any health problem during the research; at any hour, I know I can call physiotherapist Sultan Igrek from +90 537 210 06 54 (mobile).

I do not have to be participated in this research or may not participate. We have not experienced any compelling behavior to participate in the research. If we refuse to participate, I know that this will not bring any harm to our medical care and our relationship with my physiotherapist.

I have understood all the explanations made to me in detail. At the end of a certain period of thinking on my own, I decided that my child could take part in this research project as a participant. I accept this invitation voluntarily.

Voluntary Approval Form

I have read the text above which shows the information that should be given to the volunteer before investigating. These were written and was explained verbally. With these conditions, I agree to participate in this research without any pressure or compulsion on me and my child. A signed 2 copies of this form, which consists of 4 pages, a copy of the documents will be given to me.

Name and the Surname of the Participant and/or Legal Representative:

Date: **Signature:**

Name and Surname of the Withness (who have witnessed the process of receipt until the end**):**
Date: **Signature:**

The researcher who made the explanations,
Researcher: Physiotherapist Sultan Igrek
Address: Sevgi Medical Center – Nene Hatun Street Nr. 9/A Arnavutkoy / Istanbul / Turkey
Mobile Phone: +90 537 210 06 54 **E-mail:** sultanigrek@gmail.com
Date: **Signature:**