Hallym University Dongtan Sacred Heart Hospital

Research Protocol

2021-11-29

1. Research Title

The correlation between neck posture and scapular posture & the effect stabilization exercises for the scapula

2. Principal Investigator

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3. Background and Purpose of the research

Recently, many office workers and young people have postural abnormalities, including forward head posture (FHP) and rounded shoulder posture (RSP). Most of these patients often complain of pain in the entire scapular area, including the trapezius muscle. Few studies examined the effectiveness of intervention exercises often used by clinicians to correct posture in these patients through training protocols.

To compare and analyze the changes in scapular position between normal people and patients with FHP and RSP and to evaluate the effect of exercise therapy for 3 months in these patients, including clinical results and changes in scapular position and cervical angle through objective data.

4. Research Contents

Comparative analysis of the clinical outcomes and 3D-CT results of changes in scapular position between normal people and patients with FHP and RSP and to evaluate the effect of exercise therapy for 3 months in these patients.

Clinical outcomes were compared based on PVAS, FVAS, and ASES, Shoulder pain and disability index (SPADI) scores. The degree of the changes in scapular position was assessed via 3D-CT examination. All statistical comparisons were analyzed using one-way analysis of variance (ANOVA).

5. Eligibility Criteria

Inclusion Criteria:

- Age between 20 and 40 years
- those with a C-shaped lordotic curve of the neck without scapular pain
- patients with Forward head posture and scapular pain
- Willing to participate and provide informed consent

Exclusion Criteria:

- Previous surgery on the affected shoulder or neck
- Disc space narrowing in the C-spine, or evidence of arthritis on plain x-rays of the neck and shoulders
- Frozen shoulders or suspected rotator cuff tears on ultrasound

6. Expected research period: 12 months

7. Research Methods

For patients with FHP and RSP who experience pain throughout the entire scapular region, including the trapezius muscle, we explain this study in outpatients. The research begins only for those who consent to participate. This study was conducted as a prospective non-randomized trial. Participants are divided into three groups, (Group A: Normal group, Group B: Self-exercise group, Group C: Professional exercise rehabilitation therapy group). The patients will visit the hospital twice a week for one-hour sessions with a physical therapist to perform scapular balancing exercises (stretching and strengthening). This exercise program will be conducted over 10 weeks for a total of 20 sessions. This researh compares the clinical outcomes and 3D-CT findings among these three groups. Results are compared by measuring VAS score, ASES and SPADI score during outpatient follow-up visits at 3 months after starting the exercise program. A 3D-CT scan is performed before starting the exercise program and again at the 3-month mark, with the results compared.

A power analysis was performed with clinical outcomes of pain visual analog scale (PVAS) score, function visual analog score (FVAS), and American Shoulder and Elbow Surgeons (ASES) score. With these parameters, the study required 21 patients per group to achieve a power of 0.80 and a significance level of 5%. The expected dropout rate was 15% *(Correlation between American shoulder and elbow surgeons and single assessment numerical evaluation score after rotator cuff or SLAP repair. Arthroscopy 2015;31:1688-92.)*

8. Safety considerations for subjects (e.g., trial discontinuation, management of serious adverse events)

1) Patient can discontinue the study if they experience severe pain during the exercise program.

9. Measures to Ensure Research Ethics (Compliance with the Declaration of Helsinki must be explicitly stated, and any additional requirements necessary to ensure the ethics of the research should be described)

Only patients who have signed the consent form will be included. Patient information security will be maintained with the utmost confidentiality, and all relevant laws and regulations (such as the Declaration of Helsinki) will be followed.

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Patient Consent Form

1. I have received an explanation from the medical staff regarding the content of this research, and having understood its purpose, I have decided to participate in the research. I confirm that I may withdraw from this research at any time if I choose to do so, and that I will not suffer any disadvantage as a result. I declare that my decision to participate in this research is made of my own free will.

2. Furthermore, I hereby consent to the use of my examination results and other medical records for purely research purposes.

3. I understand that if I have any questions about the details of the clinical trial, I can ask the responsible person at any time and receive a sufficient answer.

4. I understand that I will receive a copy of this consent form.

_____	_____	_____
Recipient's Name	Signature	Date (month/day/year)
_____	_____	_____
Principal Investigator Name	Signature	Date (month/day/year)
_____	_____	_____
Guardian or legal representative Name	Signature	Date (month/day/year)

5. Researcher Contact Information
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