Official title: Efficacy of Balance Training in Patients With Rotator Cuff Disease: A Randomized Controlled Trial

NCT number: NCT03054129

Date: 02/13/2017

Study Protocol:

Descriptive information:

Brief title: Efficacy of Balance Training in Patients With Rotator Cuff Disease

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Brief Summary:

We evaluated the efficacy of adding balance training to a physical therapy program on postural control and health-related quality of life in patients with rotator cuff disease. Forty-two participants were randomly allocated to the control and intervention groups. Both groups received physical therapy (education, stretching, supervised strength training, home exercise program) 3 days/week for 6 weeks. The intervention group was instructed to perform balance exercises at home. The primary outcomes were the stability index, the Fourier transformation (F5, F6), the weight distribution index, and the fall index, as assessed by the posturography during eight conditions with different combinations of standing (solid surface, pillows, different head positions) and vision (eyes open/closed). The secondary outcomes included the Western Ontario Rotator Cuff Index to assess the health-related quality of life, the Shoulder Pain and Disability Index, and the Numeric Pain Rating Scale. The adherence to in-person and home-based therapy was high (>83%). The intervention group significantly improved the stability index, F5, and F6 parameters but each in only one conditions (p<0.05). No significant improvement was found in other conditions for the selected primary and secondary outcomes (p>0.05). We conclude that adding the balance training protocol to the physical therapy program does not improve postural control and health-related quality of life in patients with rotator cuff disease.

Primary Purpose: The primary aim of this study was to determine the effectiveness of adding balance training to an established physical therapy program compared with physical therapy alone on postural control in patients with rotator cuff disease. The secondary aim was

to assess the effects on health-related quality of life. It was hypothesized that adding balance training would be superior to physical therapy alone.

Study Design: This study was a randomized controlled clinical trial with two parallel groups. A random number table was used to perform block randomization with a 1:1 allocation, according to which the participants were assigned to the control or the intervention group. Both groups received the same physical therapy program for 3 days/week and were instructed to perform a daily home exercise program. The intervention group additionally received a daily non-supervised balance training program. The treatment period lasted six weeks.

Study Type: A randomized controlled clinical trial with two parallel groups.

Primary Disease or Condition Being Studied in the Trial, or the Focus of the Study: Unilateral rotator cuff disease

Intervention Name(s), for each intervention studied: Rehabilitation VS Rehabilitation and balance training

Intervention Description, for each intervention studied:

Rehabilitation: Each patient will attend rehabilitation program for three days per week for six weeks. Patients will receive supervised rehabilitation program which is including patient education, stretching and strengthening exercises. Patients will also implement home exercise program. Rehabilitation program: Rehabilitation program will be same in this group except balance exercises.

Rehabilitation and balance training: Each patient will attend rehabilitation program for three days per week for six weeks. Patients will receive balance training in addition to supervised rehabilitation program which is including patient education, stretching and strengthening exercises. Patients will also implement home exercise program. Balance training will be non-supervised program. Rehabilitation and balance training: Stretching will be applied as hold-relax technique in Proprioceptive Neuromuscular Facilitation for shoulder flexion,

abduction, internal and external rotations. Isotonic exercises will be done with elastic bands for strengthening. Home exercises will include postural, stretching and strengthening exercises. Balance exercises will receive as non-supervised program.

Intervention Type, for each intervention studied: All treatment procedures include conservative approach.

Study Start Date: July 2017

Primary Completion Date: August 2019

Study Completion Date: September 2019

Primary Outcome Measure Information: Postural parameters were assessed with a computerized static posturography (Tetrax Interactive Balance System, Beam Med. Ltd., Petah Tikva, Israel). The software analyses the pressure fluctuations of the soles of the feet while standing on the four-foot plates that emit electronic signals. The participant stood in an upright position with the arms hanging freely. The assessment was performed in eight standing and vision conditions (32 seconds each): solid surface, eyes open (NO); solid surface, eyes closed (NC); standing on pillows, eyes open (PO); standing on pillows, eyes closed (PC); head turned right 45°, eyes closed (HR); head turn left 45°, eyes closed (HL); head raised backward 30°, eyes closed (HB); head downward 30°, eyes closed (HF).

Secondary Outcome Measure Information: The 21-item Western Ontario Rotator Cuff Index is a disease-specific, self-reported quality of life questionnaire for patients with rotator cuff disease. Each item is scored on a 100-mm visual analog scale (total score range 0 to 2,100). The data were converted to a percentage score ranging from 0 (worst score possible) to 100 (best score possible).

The 13-item Shoulder Pain and Disability Index is a shoulder-specific self-reported outcome. Each item is rated on a 0–10 scale (total score 0 to 100). A higher score indicates worse pain and disability.

The level of pain intensity was measured by the 11-point Numeric Pain Rating Scale (0=no pain, 10=worst possible pain). The participants were scored the level of pain on movement, at rest, and at night.

Since cognitive factors may affect postural control, the cognitive function was assessed at baseline with the Mini-Mental State Examination (maximum score 30).

Recruitment information:

Eligibility Criteria: Inclusion criteria were age between 18 and 70 years; shoulder pain for at least four weeks; ability to understand written and oral information. Exclusion criteria were adhesive capsulitis; systemic disease (e.g., rheumatoid arthritis); pain in the spine or lower extremities; injury to the lower extremity affecting functionality; previous surgery in the shoulder region, spine, or lower extremities; neurological or cardiovascular diseases that affect balance; taking drugs that affect the central nervous system; already involved in balance training.

Sex/Gender: Male/Female

Age Limits: 18-70 years

Accepts Healthy Volunteers: None.

Overall Recruitment Status: Forty-two patients were enrolled. The study was finished with 39 patients (Control: 19, Intervention: 20)

Details of final publication:

Şahinoğlu E, Ünver B, Erkuş S, Yamak K. Efficacy of balance training on postural control in patients with rotator cuff disease: a randomized controlled study. Int J Rehabil Res. 2022. doi: 10.1097/MRR.0000000000000521.

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Administrative data:

Human Subjects Protection Review Board Status: The study was approved by the Noninvasive Research Ethics Board of Dokuz Eylül University School of Medicine.

Unique Protocol Identification Number: Protocol no. 2110–GOA, decision no. 2016/12–52.

Record Verification Date: 02/13/2017

Statistical Analysis Plan:

The Shapiro-Wilk test was used to determine whether the data follow a normal distribution. Since the distribution was non-normal, non-parametric tests were used. The comparisons of the demographic and clinical characteristics between the groups were performed by the Mann-Whitney U test. The before-after differences between the groups in primary outcome measures and the Western Ontario Rotator Cuff Index scores were compared using the Mann-Whitney U test. Within-group differences in the Western Ontario Rotator Cuff Index, Shoulder Pain and Disability Index, and Numeric Pain Rating Scale scores from before to after the treatment were analyzed by the Wilcoxon signed-rank test. A p-value of <0.05 was considered statistically significant. The effect sizes were calculated using the z-value and interpreted according to Cohen's guidelines.