

Official Title: Effects of Knowledge of Results as an Augmented Feedback Intervention on Clinical Outcomes, Physical Performance and Psychosocial Parameters in Rotator Cuff-Related Shoulder Pain: A Randomized Controlled Trial

NCT Number: NCT ID not yet assigned.

Ethical Approval: Hacettepe University Institutional Review Board approved the protocol for this study (FTREK26/28, 30/04/2026).

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Background: Research indicates that augmented feedback is effective in improving motor skills and performance in both healthy individuals and those with neurological conditions. However, while the effect of Knowledge of Results (KR)—a specific augmented feedback strategy—on supporting motor learning has been established, its role in enhancing rehabilitation efficacy remains unclear. Indeed, to date, there are no studies in the literature investigating the effects of augmented feedback strategies in individuals with rotator cuff-related shoulder pain (RCRSP). Accordingly, the aim of this study is to investigate the effects of a KR intervention on clinical outcomes, physical performance, and psychosocial parameters in individuals with RCRSP.

Study Design: Two-arm, prospective, parallel-group, randomized controlled trial.

Participants: Physically active individuals aged 18 to 35 diagnosed with RCRSP will be included in the study.

Inclusion Criteria:

- Aged between 18 and 35 years;
- Presence of unilateral shoulder pain lasting for at least 3 months;
- Confirmed diagnosis of at least one of the following conditions by a physician, based on clinical evaluation and magnetic resonance imaging (MRI) or ultrasonography (USG) findings: subacromial impingement syndrome, subacromial bursitis, rotator cuff tendinopathy, or partial rotator cuff tear (< 1 cm);
- Presence of a positive painful arc during flexion or abduction, at least one positive impingement test (Neer or Hawkins-Kennedy), and provocation of symptoms during resisted humeral external rotation, abduction, or scapular plane elevation at 90° of elevation [19];
- A physical activity score of 5 or higher according to the Tegner Activity Level Scale.

Exclusion Criteria:

- Presence of bilateral shoulder pain;
- Presence of a full-thickness or massive rotator cuff tear;
- History of shoulder trauma, fracture, or instability;
- Restriction in passive range of motion;
- Receipt of any injection to the shoulder joint within the previous 6 weeks;
- History of previous shoulder surgery or dislocation;
- Pregnancy;
- Presence of cervical radiculopathy symptoms or peripheral nerve entrapment syndromes;
- A score of 14 or higher on the Beck Depression Inventory-II [20];
- Diagnosis of hypertension, cardiovascular disease, peripheral vascular disease, history of deep vein thrombosis, neurological disorders, systemic inflammation, diabetes, cancer, or rheumatological diseases;
- Presence of obesity or metabolic syndrome;
- Participation in any rehabilitation program for a shoulder problem within the past year;
- Unwillingness to participate in the study (or failure to provide informed consent).

Study Protocol: Participants meeting the inclusion criteria will be randomly assigned to the intervention and control groups (n = 28; standard rehabilitation program) using a computer-based randomization program (www.sealedenvelope.com). Both groups will follow the same routine exercise-based treatment protocol for 8 weeks, consisting of one physiotherapist-supervised session per week and a home exercise program on the remaining days. While the control group will receive only the standard rehabilitation program, the intervention group will receive a "knowledge of results" intervention—where assessment results are regularly shared

throughout the treatment process—in addition to the standard program. In the control group, these data will only be shared with the participants at the end of the 8-week period.

Sample Size: The sample size calculation was performed using G*Power software. The calculation was based on a clinically meaningful difference of 13.2 points between the groups at the 2-month follow-up, with an estimated standard deviation of 17 points for the SPADI score. Setting the significance level at 0.05 and the statistical power at 80%, and accounting for a potential 20% dropout rate, it was determined that 28 participants would be required in each group.

Data Analysis: Statistical analyses will be performed using SPSS software (SPSS Inc., Chicago, IL, USA). The normality of the data distribution will be assessed using appropriate statistical tests (Shapiro-Wilk or Kolmogorov-Smirnov test). Measures of central tendency and dispersion will be expressed as the mean \pm standard deviation. To determine group differences in continuous variables (e.g., pain scores, external rotation isometric strength), between-group comparisons will be analyzed using a 2 \times 3 repeated-measures analysis of variance (ANOVA) with group (intervention or control) and time (e.g., baseline, week 8) as factors. Within-group comparisons will be conducted using a one-way repeated-measures ANOVA, and a Bonferroni correction will be applied to adjust the significance levels for multiple comparisons. Furthermore, patients' response to treatment and time to recovery, as measured by the GROC score, will be evaluated using survival analysis based on a minimal clinically important difference (MCID) of a 3-point change. The probability and time-to-event outcomes will be analyzed using the Kaplan-Meier method, and between-group comparisons will be performed using the Log-Rank test. The level of statistical significance will be set at $P < 0.05$.