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RESPONSE TO LETTER

Exercise Into Pain in Chronic Rotator Cuff-Related Shoulder Pain: A Randomized Controlled Trial with 6-Month Follow-Up [Response to Letter]

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Dear editor

We thank you for giving us the opportunity to respond to the letter to the Editor by Swarup Ghosh et al. We appreciate the comments raised by the authors on our study "Exercise into Pain in Chronic Rotator Cuff-Related Shoulder Pain: A Randomized Controlled Trial with 6-Month Follow-Up"¹ published *in Open Access Journal of Sports Medicine*. We value the concerns and suggestions provided in the letter, and we would like to address and clarify several points raised.

Title and Hypothesis

You suggested as title "Comparing Exercise with Pain versus Exercise without Pain on Disability, Pain, Fear of Pain, Fear-Avoidance Beliefs, Strength, and Range of Motion in Patients with Chronic Rotator Cuff-Related Shoulder Pain: A Randomized Clinical Trial with 6-Month Follow-Up". Although your suggested title is more specific to the outcomes and the comparison performed in the study, we think that our title is concise and to-the-point for the reader who is approaching to read the article and can deepen the reading in the abstract and then in the full-text article. Moreover, we also measured quality of life, adherence, patients' satisfaction and recovery, additional treatments, and adverse effects. We think that the title cannot include everything and therefore we kept it more general.

You mentioned that the term "Clinical Trial" would be more suitable than "Controlled Trial" because there is no true control group in our study. We think that it depends on the meaning of "true control" as there is no strict definition of it.² If you mean a "no treatment" group, then the aim of the study would have been to test painful exercises vs the natural course of RCRSP. If you mean a "placebo treatment", it was not ethically possible for us to give a placebo like deactivated ultrasound or fake taping. Moreover, we already know that exercise is per se effective in RCRSP, and the question is more about the dose and type of exercise, allowing or avoiding pain during exercise and other parameters.³ Nevertheless, it would be interesting to have a third parallel group to understand how painful/non-painful exercises compare to the natural course of RCRSP, and it is in fact the first limitation mentioned at the end of the discussion.

We are glad to give some clarifications on our initial hypothesis. We thought that exercising into pain would induce higher exercise hypoalgesia, improving fear-related beliefs and gaining confidence in the painful movement while restoring muscular strength.

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Intervention Protocol

You mentioned that there was a limited number of supervised sessions, especially in an initial phase, and details on exercises are lacking. We are happy to direct you to the supplementary information included in the supplementary material A, where you can find detailed information about the intervention. We also summarize the treatment below.

Patients had a prescription for 9 or 18 sessions as standard procedure of care in Belgium. There were 4 progressively loaded exercises conducted over a 12-week period, with 9 supervised sessions. At the end of the 12th week, two scenarios were possible: additional sessions were added if necessary in case the patients were prescribed only 9 sessions, or the patients stopped earlier with the supervised sessions, in case the prescription was for 18 sessions. The additional sessions after 12 weeks were registered in both scenarios at the end of the 6-month follow-up, and details can be found in the supplementary information 4.

All patients attended one supervised session per week and two additional unsupervised exercises per week. We agree that the initial phase should be more supervised, and in fact, the first 5 supervised sessions were typically planned within the first 5 weeks, while the remaining 4 were spread over the following 7 weeks. However, we had to remain consistent with the 9 sessions over 12-week period. During the unsupervised weeks, patients were instructed to exercise at home three times per week. The results on adherence to the exercises are described in the supplementary information 4. Details on the type of exercise and progression can be found in the supplementary table 1 and supplementary information 1.

Stretching Technique

We are glad to give more details about the manual therapy treatment applied on the posterior soft tissues of the shoulder during every physiotherapy session (10–15 minutes).

The patient was lying prone on the treatment table and the physiotherapist (PT) first evaluated the non-affected arm. The PT flexed the elbow of the patient at 90° and passively moved the humerus into a stretching position of 30° of extension and 60° of abduction with maximum internal rotation (trying to reach the highest point possible behind the back), stretching the upper and lower posteroinferior glenohumeral capsule and posterior shoulder tissues. Then, the PT assessed the affected arm to verify differences with the non-affected arm in terms of pain, range of motion and scapular compensating movements (scapular winging, scapular protraction, scapular external rotation).

The stretching consisted in passively holding the maximum internal rotation position for 1 minute, aiming to reach maximum stretching within the acceptable pain limits of the patient, as in Figure 1. One hand of the therapist was holding



Figure I Stretching of the posterior shoulder soft tissues.

the scapula to avoid compensating scapular movements. This procedure was repeated 10 times with an interval of 20/ 30 seconds, during which passive relaxing glenohumeral mobilisation (distraction) was given.

Participants Characteristics

We agree that age might play a significant role in RCRSP. However, the eligibility criteria were fairly strict to exclude pathologies such as capsular adhesions and rotator cuff tears. We report here some specific exclusion criteria used during the trial: clinical signs of full-thickness rotator cuff tears (positive external and internal rotation lag tests and drop arm test), evidence of frozen shoulder (reduction of 50% or above 30° of loss in passive external rotation),⁴ primary diagnosis of acromioclavicular pathology or shoulder instability, previous medical imaging confirming the presence of fracture or calcification larger than 5 mm. Moreover, if the patient was a young (or old) athlete playing overhead sport, he/she would have been excluded because the criteria was maximum 4h of training per week. The other exclusion criteria are described in the published study.¹ We also would like to point out that the age of the 2 groups was not very different, as described in the results: G1 was 47 ± 8.8 years old and G2 was 48 ± 11 years old (in Table 1 – baseline characteristics).

Baseline Data

We agree that baseline SPADI, fear of pain, fear-avoidance beliefs are important indicators of status of patients with chronic RCRSP. We did not use a cut-off for initial inclusion, as we were interested to include all levels of SPADI, fear of pain and fear-avoidance. These outcomes were in fact collected during the trial at all timepoints, and you can find the initial baseline values at T0 for both groups in the Supplementary Table 3. If you were addressing more the fact that we did not include every baseline measure in the relevant model (ie, SPADI baseline in the model of SPADI outcome), the reason is that we were mostly interested in the interaction of group-by-time and not on the effect of the baseline values on the final outcome. We chose the same covariates for all models for consistency (age, sex, durations of symptoms) and then a stepwise backwards approach was used as described in the data analysis.

We would like to add that we did not perform a subgroup analysis, also considering the small sample (41 patients) of our trial. However, it might be interesting to see in a larger sample if patients with high initial fear-avoidance would show different clinical outcomes compared to patients with low initial fear-avoidance.

Conclusion

We hope to have provided the necessary clarifications and exhaustive answers to Swarup Ghosh et al, and we trust that this letter will foster future discussion on the topic of rehabilitation in RCRSP.

Disclosure

The authors declared that they have no conflicts of interest in this communication.

References

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