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STUDY PROTOCOL

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Effect of a multicomponent exercise program focused on multivariable fatigue improvement versus standard care for glenohumeral instability: MoveUS study protocol

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Abstract

Background Glenohumeral instability is a highly prevalent pathology; however, there are problems in defining it. Traditionally, structural problems such as labral injury or bone loss in the glenoid cavity and/or humeral side were considered the main causes; but recently, it has been seen that motor control plays a very relevant role. This means that currently, there is a disparity of action protocols, and the treatment of this pathology is a great challenge.

Aim The primary aim of this study is to evaluate the effectiveness of a supervised multicomponent therapeutic exercise program in reducing multivariable fatigue in patients with instability of the glenohumeral joint.

Methods A single-blind randomized controlled trial will be carried out, in which 108 adult patients who have suffered at least one episode of glenohumeral instability in the last year will be recruited by the Department of Traumatology and Rehabilitation of Axarquia Hospital (Málaga). Patients will be randomized to the intervention group, which will carry out a multicomponent therapeutic exercise program supervised by physiotherapists (MoveUS Program); or to the control group, which will receive the usual care. All subjects will be evaluated at baseline, mid-treatment, after the intervention, and three months later at the follow-up. In these evaluations, range of movement, maximum peak of isometric force, kinematic, physiological, and psychometric fatigue, return to activity, motor control, and number of recurrences will be assessed; as well as the quality of life measured through the Western Ontario Shoulder Instability Index, which will be the main outcome variable. A multivariate analysis will be performed through a statistical program to better determine the factors that could influence the results.

Discussion This study aims to determine if therapeutic exercise supervised by physiotherapists is capable of reducing multivariable fatigue, reducing the number of recurrences, and improving quality of life; to be able to implement it in the future in public and private clinics since materials are available and physiotherapist have enough

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skills in the field of therapeutic exercise, so it is expected to be a quality tool in the approach to glenohumeral instability.

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Keywords Instability, Shoulder, Exercise, Fatigue

Background

The glenohumeral joint presents a high incidence of dislocation (15.3–56.3 per 100,000 people per year), often accompanied by injury to the glenoid labrum. Still, dislocation episodes are frequently associated with damage to bone components of the humeral head and glenoid cavity too [1]. However, there are problems when it comes to giving a clear and agreed definition among experts since the term "recurrent glenohumeral instability" has been used in the scientific literature to encompass many terms such as dislocation, subluxation, apprehension, and instability [2].

Glenohumeral instability is a pathological condition in which patients suffer an excessive translation of the humeral head on the glenoid fossa [3], generating discomfort and loss of shoulder functionality, being these symptoms the only three common points found in most definitions [4].

Traditionally, biomechanics have attributed glenohumeral instability to structural defects, pointing to bone loss in the glenoid cavity and Hill-Sachs lesion as its main causes [5]. Nonetheless, it has been shown that abnormal muscle activation patterns of the periarticular muscles of the shoulder may be the cause of said instability without the need for structural damage [6].

Taking this last clarification into account, in 2020 an observational study [7] developed by various experts in the field of shoulder surgery established a standard in the classification of functional shoulder instability (FSI), dividing it into two large groups defined as positional FSI when the shoulder subluxation or dislocation occurs during arm movement and is reduced when returning to neutral position; and non-positional FSI, when this glenohumeral dislocation occurs with the shoulder in a neutral position. Nevertheless, only part of the scientific community agrees with this new classification to the detriment of other classifications.

Additionally, a subdivision is made based on the patient's ability to control the occurrence of the event, which is related to the symptoms it generates [7].

In a more detailed analysis of individuals suffering from functional shoulder instability, electromyography found increased activity in the muscles that stabilize the humeral head and decreased activity in those responsible for mobility. Likewise, a decrease in superointernal scapular rotation was found during arm elevation, generating a descent of the humeral head, which is increased if it is accompanied by ligament hyperlaxity [8].

The lack of glenohumeral stability can generate a wide variety of signs and symptoms such as pain, limited range of motion, loss of strength, kinesiophobia, and a continuous sensation of instability [9]. Added to all this is fatigue, whose early detection can play a very relevant role in the prevention of shoulder injuries, but its evaluation is a great challenge since the term fatigue encompasses several variables [10]: kinematic, refers to both the lack of stability to raise the upper limb and the loss of movement speed whose monitoring can be useful to estimate the number of repetitions before muscle failure [11]; physiological, referred to the inability to generate adenosine triphosphate to maintain a movement over time – the so-called neuromuscular fatigue- [12]; and psychometric, manifested at the behavioral level, with a decrease in precision in the work carried out; and on a psychological level, with a feeling of exhaustion, weakness, and demotivation [13]. In addition to the differentiation of these three variables, when addressing the problem of fatigue, it must be taken into account that there are significant differences related to age and sex [14].

Taking these findings as a reference, there are already several studies that suggest the need to analyze it in greater depth and establish agreed-upon management protocols [15].

Exercise plays a fundamental role in this pathology, both in the conservative approach and in rehabilitation after the surgical approach; since it has been proven that a therapeutic exercise program optimizes the function of dynamic stabilizers [16].

In the conservative approach, the protocol with a higher effect size is the Watson, which program presents six stages that progress over 12 weeks with the strengthening of the axioscapular muscles, the rotator cuff, and the deltoid, until the patient is included in their activities of daily living and sports [17]. This intervention has shown significant improvements compared to the Rockwood program in the Western Ontario Shoulder Instability Index, in the reduction of pain, flexor strength, and in scapular coordination [18].

Within this non-surgical approach, the SINEX program is the most widely used and is based on 12 weeks of neuromuscular exercises supervised by a physiotherapist with a progression through 7 levels. This intervention reported significant improvements compared to other

interventions such as the HOMEX program, especially in apprehension and in the ability to perform sports activities [19]. Also, in other studies, the authors concluded that exercise programs based on strengthening and proprioception, such as the Derby program [20] or the HEAVY program [21], can generate significant improvements in shoulder instability symptoms and patient compliance.

When the conservative approach is not successful, there is some trauma in the clinical history or there are concomitant injuries such as Hill-Sachs or Bankart, arthroscopic surgical techniques are used [22]. After surgery, early supervised mobilization of the involved joint is necessary to optimize the results of the intervention, minimize pain, maximize the range of motion, and return to sports activity [23–25].

The fact of betting on accelerated rehabilitation, in which the patient is subjected to strength and proprioception training with high demand, makes it necessary for the exercise program treatment is supervised by a qualified professional in the area [26].

The current challenge in this field is to design an individualized therapeutic exercise program that considers the differences in the initial factors between the different individuals, the union between the reduction of symptoms and the return to work and/or sports activity, individual potential, and the conjunction between the protection of tissues and the maximization of capacities; in order to optimize the results of the recovery [27].

For these reasons, betting on the conservative approach as a target, the main objective of this study is to evaluate the effectiveness of a supervised multicomponent therapeutic exercise program in reducing multivariable fatigue in patients with instability of the glenohumeral joint.

Methods

Study design and setting

This protocol describes a single-blind, parallel-group, randomized controlled trial (RCT) that will be conducted among people with glenohumeral instability, which is expected to start in 2023. This protocol has been reported according to the Standard Protocol Items: Recommendations for Interventional Trials Declaration [28]. The study will be published following the Consolidated Standards of Reporting Trials (CONSORT) guidelines [29, 30], comparing a supervised multicomponent therapeutic exercise program versus a control group with traditional intervention. The trial was registered in clinicaltrials.gov, with reference number NCT05443295 (https://clinicaltrials.gov/study/NCT05443295), and was approved by the Malaga Ethics Committee with reference number 1311-N-22.

A simple random assignment will be done by a blinded investigator through computer-generated random numbers using the Statistical Package for the Social Sciences (SPSS) for Windows (version 19.0, SPSS Inc., Chicago, IL, USA), and the evaluator will be masked to reduce interpretation bias. An external physiotherapist will be used to supervise the intervention.

The reference population will be patients who have been treated at Axarquia Hospital (Málaga) presenting symptoms compatible with those included in the glenohumeral instability standard [6]. Moreover, these patients will have radiographs or resonance imaging confirming the diagnosis. In radiographs, the criteria used to determine the diagnosis allude to an anteroposterior image in which the radiologist can see the humeral head out of the glenoid cavity. As for the resonance imaging, the criteria alludes to injuries that appear as a consequence of a shoulder dislocation such as loss of bone in the glenoid cavity or the humeral head, rupture of the glenohumeral ligaments, or lesions in the glenoid labrum. and they will be classified into traumatic and atraumatic groups by clinical assessment developed by an orthopedic physician. The criteria used for this classification alludes to the etiology of the dislocation: traumatic if it appeared as a consequence of a trauma; or atraumatic, if it appears without any history of trauma.

The patients included will meet the following inclusion criteria:

- At least one episode of glenohumeral instability in the last year.
- Ages between 18 and 64 years.
- Signed informed consent.
- Score equal to or less than 6 on the Instability Severity Index Score [31].

Likewise, patients who, even meeting the eligibility requirements, present any of the following exclusion criteria will be excluded:

- Population that may suppose ethical and/or cultural barriers.
- Subjects who do not master the Spanish language.
- Underlying diseases or concomitant treatments that modify the ability to perform physical exercise.
- Participants in other clinical trials.
- Patients with a score equal to or greater than 1800 on the Western Ontario Shoulder Instability Index [32].

The expected flowchart is shown in Fig. 1.

Intervention

All patients will undergo a 12-week treatment, regardless of the group they belong to.

The intervention group will carry out the MoveUS program (Figs. 2 and 3), whose main objective is to gain

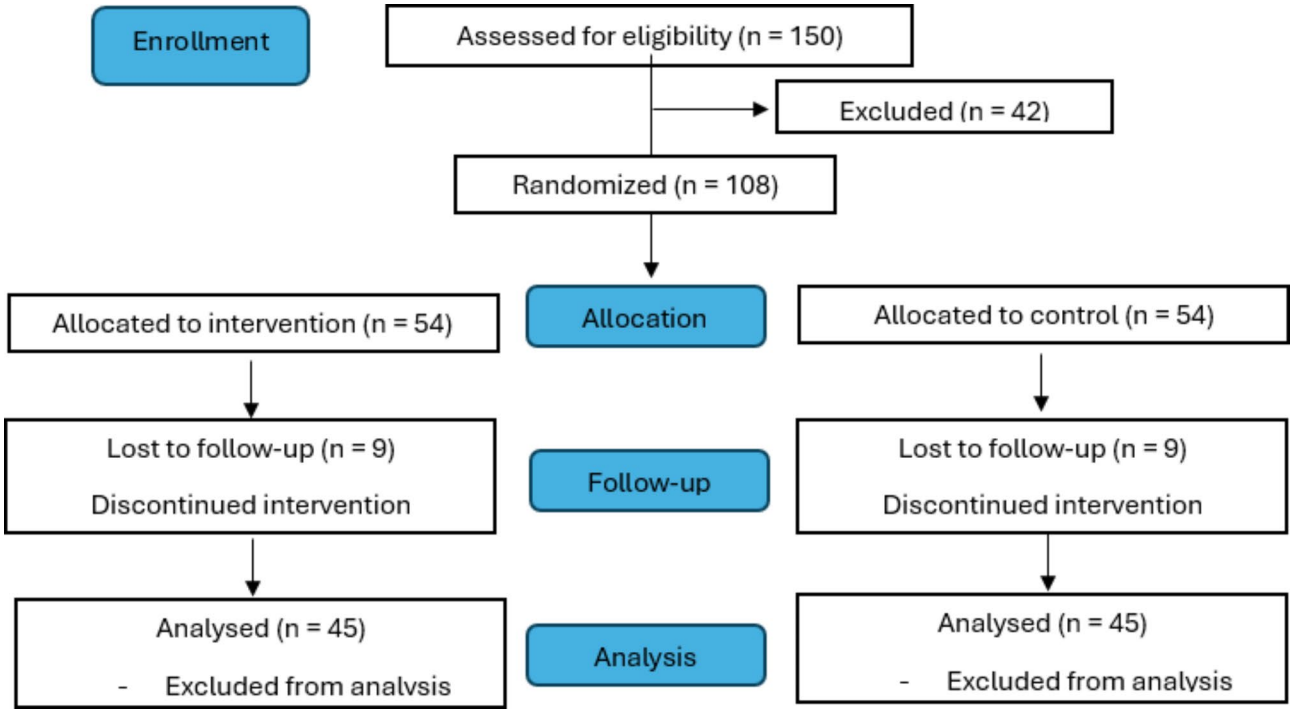

Fig. 1 Expected flowchart

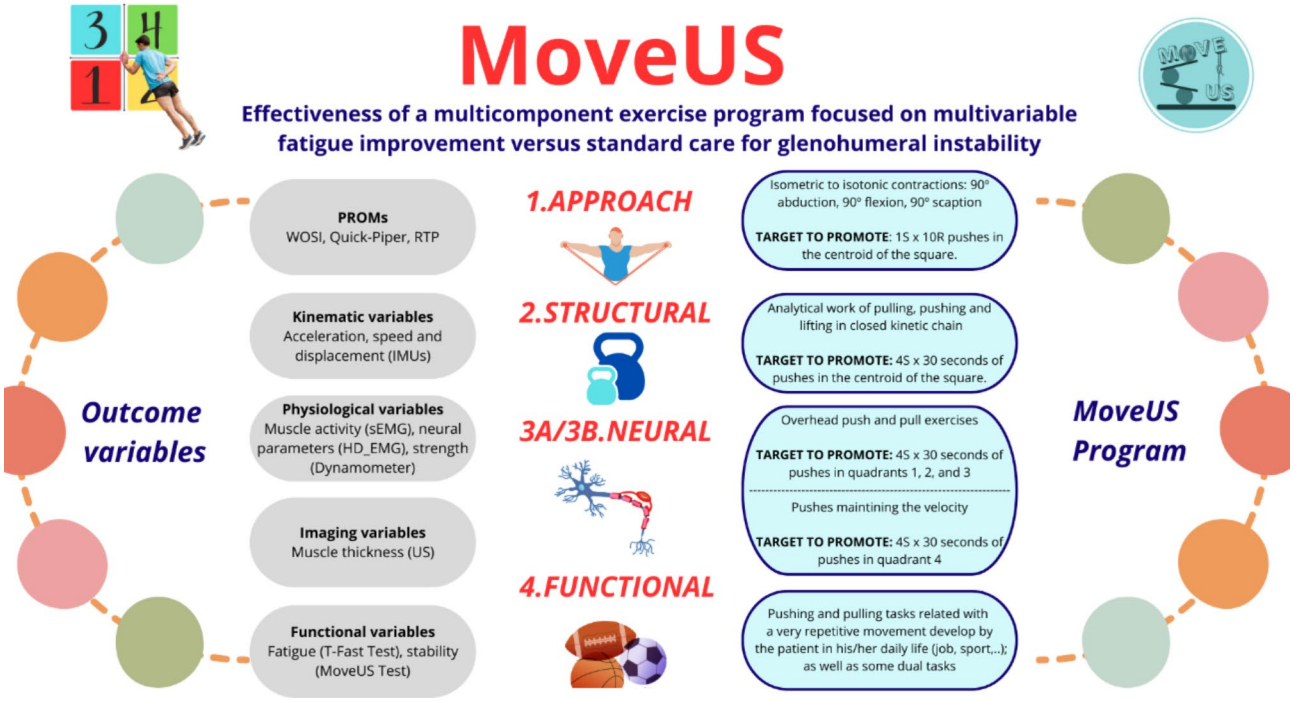

Fig. 2 MoveUS program

scapular-humeral motor control prior to strengthening the periarticular muscles. This program is structured in 4 different stages, which begin with the gain of motor control, continue in progression with strength exercises in the muscles involved in the affected joint, followed by a neural retraining stage, and end with the patient's return to functional and/or sports activity. The MoveUS program is based on carrying out three sessions per week of therapeutic exercise, of which 1 session will be face-to-face with continuous monitoring by the physiotherapist;

Fig. 3 (See legend on next page.)

(See figure on previous page.)

Fig. 3 Exercises developed in each stage of the MoveUS program
1. Isometric abduction at 90º abduction; 2. Isometric forward flexion at 90º; 3. Isometric scaption at 90º; 4. Isotonic abduction from 90º to 120º; 5. Isotonic forward flexion from 90º to 120º; 6. Isotonic scaption from 90º to 120º; 7a/7b. Unilateral wall push-ups at 90º flexion; 8a/8b. Rowing with resistance bands; 9a/9b. Semi-inclined push-ups; 10a/10b. Arnold press with dumbbells; 11a/11b. Pull to face with resistance bands; 12a/12b. Unilateral wall push-ups with the shoulder in adduction and internal rotation; 13. Diagonal pattern of flexion + abduction with resistance bands; 14. Diagonal pattern of extension + adduction with resistance bands; 15a/15b. Bench press; 16a/16b. Unilateral wall push-ups with the shoulder in abduction and external rotation; 17a/17b. Overhead throwing with a medicine ball; 18. Inverted plane push-ups; 19. Baseball batting; 20a/20b. Kick-boxing punches with a fitball

and 2 will be performed at the hospital without presential monitoring.

The control group will be subjected to the traditional guidelines [33] in the management of shoulder instability: immobilization for three weeks with a sling in internal rotation, cryotherapy, passive mobilization, and standard protocol of shoulder exercises based on previous studies [34]. These patients will be offered a first consultation in which the guidelines to follow will be explained, the traditional protocol will be given to them in printed format, and a monthly educational rehabilitation session based on explaining the etiology of shoulder instability and general recommendations for the recovery process and the management of pain [35].

Measurements

During the study, participants will complete various questionnaires and undergo different physical evaluation tests.

The required data will be collected through four measurements:

- Initial evaluation: it will be carried out after recruiting the study participants and before starting the intervention. This first evaluation will fulfill one of the specific objectives, since after it a description of the main biomechanical, physiological and psychological characteristics of patients will obtain. Moreover, it will serve as a baseline.
- Intermediate evaluation: it will be carried out when 6 weeks have passed since the beginning of the intervention, which will allow it to collect preliminary results in relation to the hypothesis contrast. Also, this evaluation will serve to facilitate the task of estimating the ideal duration for the program's design.
- Final evaluation: it will be done 12 weeks after the start of the intervention, that is, precisely at the end of the experimental period. It will be the point at which the real differences found can be established if they exist.
- Follow-up: it will be done at 24 weeks to evaluate the stability of the changes obtained.

These evaluation procedures will be carried out by the main researcher of the project (physiotherapist) together with the coordinator of the research group (physiotherapist and PhD) and will follow up a meticulous process of standardized and objective measurements. The measurement tools and the coding of the outcome variables are shown in Table 1.

Primary outcome

The primary outcome will be quality of life, assessed by the Western Ontario Shoulder Instability Index, which has shown high reliability ($r=0.969$ to 0.049; $p<0.001$) for the assessment of patients suffering from glenohumeral instability [32].

Secondary outcomes

The secondary outcome variables will be especially related to the ability to control symptoms.

The improvement of the range of movement, taking the difference between the passive and the active range, whose measurement will be carried out with a digital inclinometer, has shown reliability from good to excellent ($r=0.86$ to 0.97; $p<0.01$) in active shoulder movement [36]. Similarly, the improvement of motor control and scapulohumeral rhythm will be measured through bipolar surface electromyography in the upper trapezius, lateral deltoid, anterior deltoid, and biceps brachii, which has shown high reliability ($r=0.95$ to 0.87; $p<0.01$) in the muscular activity of the axioscapular musculature [37].

Fatigue understood as a multi-component term is subdivided into three variables. Kinematic fatigue [11], whose measurement will be carried out through inertial sensors (Shimmer) that have shown good reliability ($r=0.88$ to 0.74; $p<0.01$) in the loss of movement speed during the execution of the repetitions ordered [38]. Physiological fatigue [12], alluding to the ability to perform both short alactic and lactic anaerobic efforts, as well as long efforts involving aerobic glycolysis, which will be quantified by high-density surface electromyography in lateral deltoid, which has shown a high level of reliability ($r=0.998$ to 0.764; $p<0.01$) in recording muscle activity during repetitive exercises [39]. Psychometric fatigue [13], concerning the level of self-perceived tiredness or psychological exhaustion and behavioral variations, which will be measured with the Quick Piper Fatigue Scale-revised questionnaire, which has shown high reliability ($r=0.947$; $p<0.001$) in the quantification of the different dimensions of fatigue [40, 41].

The maximum peak of isometric force in lateral abduction will be evaluated through a dynamometer (K-Push,

Table 1 Description and operationalization of outcome variables

outcome variable	coding	measurement tool	psychometric properties
Primary outcome:			
-Quality of life	WOSI	Western Ontario Shoulder Instability Index	r = 0,969 a 0,049; p < 0,001
Secondary outcome:			
-Range of movement	ROM	Digital inclinometer	r = 0.86 to 0.97; p < 0.01
-Scapulohumeral rhythm	SHR	Bipolar surface electromyography	r = 0,95 a 0,87; p < 0,01
-Kinematic fatigue	K_F	Inertial sensors	r = 0,88 a 0,74; p < 0,01
-Physiological fatigue	PH_F	High density surface electromyography	r = 0,998 a 0,764; p < 0,01
-Psychometric fatigue	PS_F	Quick Piper Fatigue Scale	r = 0,947; p < 0,001
-Maximum isometric force	MIF	Electromechanical dynamometer	r = 0,93 a 0,84; p < 0,01
-Return to play	RTP	Questionnaire "return to play"	V de Aiken = 0,93 a 0,97; p < 0,01
-Number of recurrences	Nº REC	Individualized notebook	Non-applicable
-Glenohumeral stability	STAB	MoveUS Test	Non-applicable
-Muscular fatigue	M_F	Modified T-Fast Test	Non-applicable

K-Invent Physio, Montpellier, France), which has reached a high level of reliability (r=0.93 to 0.84; p<0.01) in the recording of the maximum isometric force of the rotator cuff muscles [42]. Likewise, the return to play will be assessed by the Questionnaire on the self-perception of the athlete for the return to standardized training after an injury, which has shown an adequate level of validity and utility (Aiken's V=0.97 to 0.93; p<0.01) in the evaluation of the psychological perception of the patient about his return to sports activity [43] Finally, the number of recurrences will be quantified through an individualized diary in which each patient will record the recurrences of their glenohumeral instability, including both dislocations and subluxations.

Moreover, two functional tests will be carried out: the "MoveUS" test to determine glenohumeral stability in four quadrants in space with the patient performing push-ups in the wall with one hand positioned in different locations with four variations of the range of motion of the shoulder; and the "modified T-Fast" test based on Shah et al. [44] to evaluate muscular fatigue depending on loading dose and time, with the patient performing lifting of a kettlebell from a chair to a table trying to perform as much as repetitions as possible as quickly as possible, during 30 s, and after that, during 120 s.

Transversely to these variables, it will consider gender, age, and the type of glenohumeral instability as possible confounding variables.

Statistical treatment

For the analysis of the results, a database will be created using the information collected from the physical tests, questionnaires, and participant's notebooks). Intention-to-treat analysis of all participants will be developed.

After the intervention phase, descriptive statistics will be performed with measures of central tendency and dispersion of morphophysiological and psychological variables, which will constitute the first part of the proposed study. This will be followed by inferential analysis by different values between the outcome variables in both groups. Moreover, multiple regression analysis will be carried out to establish the corresponding causal relationships, isolating the confounding variables.

The size of the intergroup effect will be calculated (Cohen's d), taking the following references: an effect size<0.2 reflects a despicable difference, between ≥0.2 and ≤0.5 a small difference, between ≥0.5 and ≤0.8 a moderate difference, and ≥0.8 a large difference. A value of p<0.05 will be considered statistically significant. Jamovi 2.2.2 will be used in the Windows version for data analysis.

Sample size

Version 3.1 G-Power was used to estimate the sample size. Taking a level of statistical significance of 5% and a statistical power of 80% to be able to detect the possible differences in the hypothesis contrast proposed; based on previous studies with which the population, intervention, and main outcome variable are shared, which have shown an effect size of 0.6 (95% CI 0.0–1.3) [18], and adding 20% to alleviate possible losses during follow-up, that is, we will recruit a minimum of 108 patients, 54 for each group.

Discussion

The study results will be quickly applied in clinical practice guidelines thanks to the internal and external validity of the study. If the intervention proposed were beneficial, it could be implemented in both the public and private systems, since it only requires dumbbells and resistance bands, being these material resources or infrastructure that are not available in any rehabilitation room or gym. Likewise, physiotherapists have sufficient skills and training to carry out the intervention without the need for the system to make an economic outlay to achieve the paradigm shift.

For this reason, it is considered that the study has a great transfer potential, so it is expected that the

proposed therapeutic exercise program and the clinical description carried out could be another quality tool in the therapeutic arsenal for addressing glenohumeral instability.

Moreover, regression analysis may open up new niche clinical studies on this question.

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s12891-024-08193-4.

Supplementary Material 1

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Author contributions
A.I.C.V. and L.R.P. have contributed to the conception of this study and made substantial contributions to protocol design. L.R.P. rote the main manuscript text and prepared fitures. A.I.C.V. was the main supervisor of the paper. All the authors have given final approval of the version to be published.

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Data availability
The full protocol is available at https://clinicaltrials.gov/study/NCT05443295.

Declarations

Ethical approval and consent to participate
The study has been approved by the Portal de Ética de la Investigación Biomédica de Andalucía and Malaga Ethics Committee (1311-N-22). The principles of the Declaration of Helsinki and the standard of Good Clinical Practice are respected. Likewise, participants are given an information sheet and informed consent in which all the potential risks and benefits are specified. Also, consent is requested to include the data obtained in scientific publications or other knowledge dissemination activities. The data provided by the patients will be kept by the main researcher of the project to ensure confidentiality.

Consent for publication
Not applicable.

Competing interests
The authors declare no competing interests.

Trial status
This study is open for participant recruitment at the time of submission.

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