BMJ Open

Web Application Based on Multimedia Animations to Support Therapeutic Exercise for Rotator Cuff Related Shoulder Pain: Protocol for a Randomized Clinical Trial

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2024-085381
Article Type:	Protocol
Date Submitted by the Author:	15-Feb-2024
Complete List of Authors:	Pérez-Porta, Irene; Hospital Universitario Fundación Alcorcón, Physical Therapy and Rehabilitation Unit; Universidad Rey Juan Carlos, International Doctoral School Flórez-García, Mariano; Hospital Universitario Fundacion Alcorcon, Physical Therapy and Rehabilitation Unit García-Pérez, Fernando; Hospital Universitario Fundacion Alcorcon, Physical Therapy and Rehabilitation Unit Fernández-Matías, Rubén; Hospital Universitario Fundacion Alcorcon, Research Unit; Universitat de Valencia, Doctoral School, Department of Physical Therapy Pérez-Manzanero, M Ángeles; Hospital Universitario Fundacion Alcorcon, Physical Therapy and Rehabilitation Unit Araujo-Narváez, Aurora; Hospital Universitario Fundacion Alcorcon, Physical Therapy and Rehabilitation Unit Urraca-Gesto, M Alicia ; Hospital Universitario Fundacion Alcorcon, Physical Therapy and Rehabilitation Unit; Universidad Rey Juan Carlos, Department of Physical Therapy, Occupational Therapy, and Rehabilitation and Physical Medicine Fernández-Lagarejos, César; Hospital Universitario Fundacion Alcorcon, Physical Therapy and Rehabilitation Unit Plaza-Manzano, Gustavo; Universidad Complutense de Madrid, Department of Radiology, Rehabilitation, and Physical Therapy; Hospital Clínico San Carlos, Fisioterapia Contemporánea (InPhysio) Research Group, Health Research Institute Pérez-Fernández, Elia; Hospital Universitario Fundacion Alcorcon, Research Unit Velasco-Arribas, María; Hospital Universitario Fundacion Alcorcon, Research Unit; Universidad Rey Juan Carlos, Department of Medical Specialties and Public Health
Keywords:	Shoulder < ORTHOPAEDIC & TRAUMA SURGERY, Randomized Controlled Trial, REHABILITATION MEDICINE, Physical Therapy Modalities

Web Application Based on Multimedia Animations to Support Therapeutic Exercise for Rotator Cuff Related Shoulder Pain: Protocol for a Randomized Clinical Trial

Irene Pérez-Porta, MD, PhD Student[1,2]; Mariano Tomás Flórez-García, MD, PhD[1]; Fernando García-Pérez, MD, MSc[1]; Rubén Fernández-Matías, PT, PhD Student[1,3,4]; M Ángeles Pérez-Manzanero, PT[1]; Aurora Araujo-Narváez, PT[1]; M Alicia Urraca-Gesto, PT, PhD[1,5]; César Fernández-Lagarejos, PT[1]; Gustavo Plaza-Manzano, PT, PhD[6,7]; Elia Pérez-Fernández, BS, MSc[3]; María Velasco-Arribas, MD, PhD[3,8]

[1] Physical Therapy and Rehabilitation Unit, Hospital Universitario Fundación Alcorcón, Madrid, Spain

[2] International Doctoral School, Universidad Rey Juan Carlos, Madrid, Spain

[3] Research Unit, Hospital Universitario Fundación Alcorcón, Madrid, Spain

[4] Doctoral School, Department of Physical Therapy, Universitat de València, Valencia, Spain.

[5] Department of Physical Therapy, Occupational Therapy, and Rehabilitation and Physical Medicine, Universidad Rey Juan Carlos, Madrid, Spain.

[6] Department of Radiology, Rehabilitation, and Physical Therapy, Universidad Complutense de Madrid, Madrid, Spain.

[7] Fisioterapia Contemporánea (InPhysio) Research Group, Health Research Institute, Hospital Clínico San Carlos, Madrid, Spain.

[8] Department of Medical Specialties and Public Health, Universidad Rey Juan Carlos, Madrid, Spain.

Correspondence:

Rubén Fernández-Matías, PT, PhD Student

Address: Physical Therapy and Rehabilitation Unit, Hospital Universitario Fundación Alcorcón, Street Budapest 1, 28922 Alcorcón, Madrid, Spain

Email: ruben.fernanmat@gmail.com

Funding: This study, with grant number PI19/01490, was funded by the Instituto de Salud Carlos III (ISCIII) from Spain, and cofounded by the European Union.

Conflict of interest: The authors declare no conflict of interest.

ClinicalTrials number: NCT05770908

Web Application Based on Multimedia Animations to Support Therapeutic Exercise for Rotator Cuff Related Shoulder Pain: Protocol for a Randomized Clinical Trial

ABSTRACT

Introduction Subacromial pain syndrome (SPS) is the most common cause of shoulder pain. Currently, exercise is proposed as the first-line treatment for patients suffering from SPS. However, it seems that adherence to therapeutic exercise programs is poor when they last a long time in home-setting. The aim of this study is to evaluate the effects of adding video animations to a traditional paper-based exercise program.

Methods and analysis A randomized open-labelled clinical trial will be conducted. Adults between 18-80 years diagnosed with SPS who accomplish eligibility criteria will be included. Patients (n = 132) will be randomized into two groups, both receiving paper-based exercises, and the experimental group been provided also with video animations. The participants will receive 7 face-to-face physical therapy sessions and will be asked to perform the exercises at home for 6 months. The primary outcome measure will be Shoulder Pain and Disability Index, measured at baseline, 3 weeks, 3 months (primary analysis), and 6 months. Secondary outcomes will include pain intensity, patients' satisfaction, patients' perceived improvement, and adherence to the exercises. An intention-to-treat analysis will be implemented.

Key words Subacromial pain; Rotator Cuff Tendinopathy; Protocol; Randomized Controlled Trial; Exercise

Ethics and dissemination This study has been approved by an ethics committee with reference number CI18/16.

Trial registration number NCT05770908

STRENGTHS AND LIMITATIONS

- This trial will be the first study to evaluate the benefits of adding videos to a classic paper-based exercise program in subjects with rotator cuff tendinopathy.
- The exercise program of this study will be reported in detail following current recommendations to facilitate its reproducibility and clinical implementation.
- The effects of adding the videos to the exercise program can depend on the specific exercises prescribed, so the results of this study may not generalize to other exercises.

1. INTRODUCTION

Shoulder pain is a common symptom that can be considered as the third cause of complaints in subjects with musculoskeletal disorders,[1] with nearly 65% of the whole population suffering from it in a lifetime.[2] Furthermore, its annual incidence has been estimated between 0.3% to 5.5%, and its point prevalence between 2.4% and 21%.[3]

Subacromial pain syndrome (SPS) is the most common cause of shoulder pain,[4] that may have a significant impact on daily life, cause sleep disorders and reduce quality of life,[5] as well as a decrease in productivity, with an increase in sick leave.[6]

The SPS has been scrutinized as a misleading and umbrella terminology,[7] with at least 27 unique terms covered within it (impingement, tendinopathy, rotator cuff disease…).[8] Diagnosis plays a crucial role within study design, because a specific treatment might work in subgroup of patients, but not in others.

Currently, there is high quality evidence suggesting that surgical procedures for patients with SPS are not superior to sham surgery.[9] For that reason, exercise is proposed as the first-line treatment for patients suffering from SPS in clinical practice guidelines,[9–11] because it can improve shoulder pain, mobility, and function.[12–15]

Overall, patients perceive exercise as a good choice for the management its shoulder pain,[16] and it is the most implemented treatment within physical therapists.[17] However, despite exercise being an effective, accessible, and low-cost intervention with few adverse effects,[18] there are still some barriers for its implementation within clinical practice.[19,20]

First, there is inappropriate content reporting about exercise programs within published clinical trials, both in the description of the exercises itself, the dosage, and the rules implemented for the progression and regression in exercise load,[21,22] thus leading to uncertainty about the better type of exercises, and the optimal dosage.[13,15,23] Second, exercise is an active patient-dependent intervention, meaning that it will only be effective if the patient performs it.[19] However, it seems that adherence to therapeutic exercise programs is poor when they last a long time in home-setting.[24] Some strategies has been implemented in aim to improve adherence to therapeutic exercise programs, such as the use of videos or multimedia animations,[25–27] that may improve self-efficacy, and adherence.[25–29] Nevertheless, the evidence of its superiority over traditional paper-based exercises is not clear.[25]

For all these reasons, there is a need for more randomized controlled trials with better content reporting of the exercise programs,[21,22] that investigate the utility of the implementation of new technologies in aim to improve patients' adherence,[25] and thus optimizing treatment effectiveness.[18]

The main hypothesis of this randomized controlled trial is that the implementation of a home-based exercise program using multimedia animations is better regarding improvements in shoulder disability than a traditional paper-based one. As secondary objectives, the hypothesis is that multimedia animations will also improve more patients' expectations, satisfaction, and adherence. Finally, the study also aims to evaluate the usability of the implemented multimedia animations, and the patients' perceived utility of them.

2. METHODS AND ANALYSIS

2.1. Design and setting

This is a study protocol of an open-labelled parallel-randomized clinical trial reported as per recommendations of the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) 2013 (Supplementary File 1).[30] The research will take place in Hospital Universitario Fundación Alcorcón (Madrid, Spain). In **TABLE 1** it is presented the study schedule.

Table 1. Study schedule.

	Study Period					
	Enrollment	**Allocation**		**Post-allocation**		**Closeout**
Time point	**T_{-1}**	**T_0**	**3-week**	**6-week**	**12-week**	**24-week**
Enrollment	X					
Eligibility screen	X					
Informed consent	X					
Allocation		X				
Interventions:						
Paper only exercises		◆—	—◆	◆	◆	
Paper plus video exercises		◆—	—◆	◆	◆	
Assessments:						
Demographic data	X					
Pain intensity	X			X	X	X
SPADI	X			X	X	X
Expectations	X	X	X	X		
Satisfaction				X		X
PGI-I				X	X	X
Adherence			X	X	X	X

Abbreviations: SPADI, Shoulder Pain and Disability Index; PGI-I, Patient Global Impression of Improvement

2.2. Randomization and allocation

The randomization procedure was conducted with a 1:1 allocation ratio using the software Epidat v4.2 (Xunta de Galicia, Spain), by a statistician not involved in other study labors. Allocation concealment will be achieved using sequentially numbered opaque envelopes.

2.3. Blinding

Investigators who will recruit subjects will be blinded to group allocation. Evaluators, therapists, and patients will not be blinded to group allocation.

2.4. Recruitment, inclusion and exclusion criteria

Subjects' recruitment will be conducted by three rehabilitative physicians who will be unaware of treatment allocation. The recruitment process will be carried out in Hospital Universitario Fundación Alcorcon. All patients attending consult with shoulder pain from non-traumatic origin will be evaluated for their inclusion in the study. The recruitment started on April 7th, 2023, and the estimated study completion date is expected to be on 1st December, 2024.

The inclusion and exclusion criteria were based on a previously published systematic review.[31] To be included the subjects must meet the following inclusion criteria:

- Age between 18 and 80 years old.
- Presence of rotator cuff related shoulder pain, diagnosed as unilateral shoulder pain, located in the anterior and/or lateral deltoid region, which is reproduced by active elevation and/or lying on ipsilateral side, and with the following orthopaedic tests: Neer, Hawkins-Kennedy and/or empty can).

- Pain lasting from at least 3-months.
- Pain intensity at rest, during movement, and sleeping ≥ 3/10 points on a numeric pain rating scale.
- To have a mobile phone, tablet, or computer with internet connection.
- To understand written and spoken Spanish language.

Furthermore, the subjects will not have to present with the following exclusion criteria:

- History of major trauma or surgery on the shoulder, elbow, or cervical spine.
- Signs of other shoulder pathologies such as instability, frozen shoulder, calcific tendonitis, severe arthrosis, or neuralgic amyotrophy.
- Presence of full-thickness rotator cuff tears on ultrasound imaging.
- Signs and/or symptoms of neck-related shoulder pain and/or radiculopathy or radicular pain.
- Systemic diseases such as cancer, rheumatic disorders, sclerosis multiple, neurological disorders, etc.
- Severe psychiatric disorders.

2.5. Sample size

The sample size calculation was conducted using the '*MBESS'* package[32] of the software R v4.1.0 and was based on the precision of the adjusted between-group mean difference at 3-month follow-up, from an analysis of covariance (ANCOVA) including baseline measure as a covariate. According to the results of previous publications, an equal standard deviation (SD) of 25 points was considered for both groups.[33] It was assumed a 1:1 allocation ratio, and a

correlation of 0.50 between repeated measures.[34] A 95% confidence interval (CI) width of 16 was considered acceptable because the smallest value of the minimum clinically important difference reported in literature for SPADI is 8 points.[35] The estimated sample size was 112 subjects. Assuming a 10% drop-out rate, the final sample size was composed of 132 subjects (66 per group).

2.6. Interventions

The interventions will be carried out by two physical therapists in Hospital Universitario Fundación Alcorcon. Both groups will receive five face-to-face sessions (half an hour each) every other day along three-weeks. After that, all patients will receive two additional face-to-face sessions to review the exercises, and to update the dosage of exercise load, at 6-week and 12-week follow-ups.

2.6.1. Exercise programs

All the subjects will receive printed exercises with pictures and an explanatory text, but subjects in experimental group will also be provided access to a webpage with self-explanatory videos of the prescribed exercises. The description of the web application is presented in Supplementary Material 2, and the didactic methodology implemented within the videos is presented in Supplementary Material 3.

Clear documentation of the exercise programs implemented within research is crucial for improving reproducibility between studies, and for the clinicians to be able to implement the results of research into their clinical practice. For this reason, the Consensus on Exercise Reporting Template (CERT) was proposed in 2016.[36] This template is composed of different domains that every study including exercise interventions should report. In aim to improve these aspects,

a detailed description of the exercise programs is presented in Supplementary Material 4, and the description of each of the CERT domains is presented in Supplementary Material 5.

2.6.2. Patient's education

Patients will be provided with education about their shoulder disorder throughout all treatment sessions. They will be given explanations about their shoulder pain, the importance of therapeutic exercise in its management, and some recommendations for daily living activities. Furthermore, they will be provided with a document with some information about rotator cuff tendinopathy and the importance of exercise at the beginning of the treatment (Supplementary Material 6).

2.6.3. Analgesic co-adjuvants

Patients will be provided with hot/cold packs, and/or well as analgesic drugs if needed at the beginning of the treatment, only when pain intensity makes it impossible to start with the exercise programs. The use of any co-adjuvant therapy will be registered and reported in the final publication of the clinical trial.

2.7. Measurements

All the measurements will be conducted in Hospital Universitario Fundación Alcorcón. The rehabilitative physicians in charge of enrolling patients will collect demographic data, and baseline and 24-week follow-up outcome measures. The outcome measures at 3-week, 6-week, and 12-week follow-ups will be collected by the physiotherapists who will guide the therapeutic exercise programs. The full measurement schedule is presented in **TABLE 1.** Adverse events will be registered in the patients' clinical history.

All patients will receive and sign an informed consent before any enrolling the study. The following demographic data will be collected: age, height, weight, body mass index, sex, dominant side, painful side, and time with shoulder pain. The outcome measures that will be collected are shoulder pain-related disability; pain intensity at rest, during movement, and at night; patient's global impression of improvement, expectations, and satisfaction.

2.7.1. Shoulder pain-related disability

The primary outcome measure will be shoulder pain-related disability measured with the Shoulder Pain and Disability Index (SPADI). This questionnaire is composed of 13 items, each rating from zero to ten, with the overall questionnaire ranging from 0% (minimum degree of disability) to 100% (maximum degree of disability). The transcultural adaptation of the SPADI from English to Spanish language was conducted in 2015,[37] showing good internal consistency (α = 0.86 and 0.916), good reliability (ICC = 0.91), and good construct validity (r = 040 to 0.80).

2.7.2. Pain intensity

Pain intensity at rest, during movement, and at night will be measured with an 11-point numeric pain rating scale (NPRS), which ranges from zero (no pain) to ten (worst pain imaginable). The NPRS has showed good levels of reliability (r = 0.95), and good levels of construct validity (r = 0.86 to 0.95).[38]

2.7.3. Patient's expectations and satisfaction

Patient's expectations and satisfaction with received treatment will be measured using an 11-point numeric rating scale, ranging from zero ("no expectation of

improvement" / "not at all satisfied with the treatment received") to ten ("full recovery expectation" / "fully satisfied with the treatment received").

2.7.4. Patient's impression of improvement

Patient's impression of improvement will be measured with the Patient Global Impression of Improvement (PGI-I) scale. The PGI-I is a seven-point ordinal scale ranging from 1 (very much better), through 4 (no change), to 7 (very much better).

2.8. Data analysis

Data distribution of quantitative variables will be evaluated with visual inspection of histograms, and Q-Q plots, as well as kurtosis and skewness measures. For the descriptive analysis of quantitative variables, the mean, standard deviation, median, 1st and 3rd quartiles, and range will be reported. For categorical variables, absolute frequencies and percentages will be reported.

The analysis of between-group differences on quantitative outcome measures will be conducted using a generalized least squares model fitted by restricted maximum likelihood, using the R package *'rms'* (Frank E Harrell Jr, 2022). Measurement at baseline will be included as a covariate to obtain adjusted between-group mean differences. Time (6-week, 12-week, and 24-week) will be modeled using a linear spline with one knot (since there is only one unique internal value within time variable), and assuming an autoregressive-moving average lag 1 (AR1) correlation structure. *Post hoc* pairwise comparisons will be controlled for familywise error rate using Bonferroni's correction. The variograms, and residual plots (by group will be reported for each model. If any quantitative variable doesn't accomplish the needed assumptions, robust analogous methods will be used instead.[39]

For patient's impression of improvement, a rank-based between-by-within analysis will be conducted, following the approach of Brunner, Domhof, and Langer (2002). Post hoc pairwise comparisons will be conducted controlling familywise error rate using Rom's method of the Benjamini-Hochberg method.[39]

Reasons for missing data will be reported, as well as a missing data map. Furthermore, the relationship between missingness and any measured variable at baseline will be analyzed using a logistic regression model. Multiple imputation (5 to 20 imputations) or sensitivity analyses using worst-best case and best-worst case scenarios will be implemented if missing data is present, based on the percentage and nature of missing data. Finally, an intention-to-treat approach will be used.

All the analyses will be conducted using R software v4.1.0 (R Core Team (2021). R: A language and environment for statistical computing. R Foundation for Statistical Computing, Vienna, Austria. URL https://www.R-project.org/). An α level of 0.05 with 95% confidence intervals (CI) will be assumed for all analyses. All analyses will be conducted blinded to group allocation, and a blinded interpretation of the results will be published in the final article as supplementary material.

3. DATA MANAGEMENT

All data collected during the study schedule will be kept under lock and key in the office of the principal investigating physician. Personal data will not be included within the outcome measures of the participants. The list of participants ID

number with name and contact information will be kept in an Excel document in the computer of the three physicians who will be recruiting subjects within the hospital security system. This file will not be moved to any other computer at any time. All data will be managed according to the Law on the Protection of Personal Data (LOPD) 3/2018, of December 5 (Spain).

4. ETHICS AND DISSEMINATION

The protocol of this randomized controlled trial has been reviewed and approved by the ethics committee of Hospital Universitario Fundación Alcorcón (Madrid, Spain), with reference number CI18/16, and it was registered in ClinicalTrials.gov (NCT05770908). The study will be conducted according to the Declaration of Helsinki. All participants will sign an informed consent before participating in the study. The results of this study will be published in a peer-reviewed scientific journal. Patients or the public were not involved in the design, or conduct, or reporting, or dissemination plans of our research.

AUTHORS' CONTRIBUTIONS

Design of the study: IPP, MTFG, FGP, MAPM, AAN, AUG, EPF, CFL, GPM, and MVA. Statistical analysis plan: EPF, and RFM. Writing the protocol manuscript: IPP, MTFG, FGP, and RFM. All authors have read and approved the final manuscript.

FUNDING STATEMENT

This study, with grant number PI19/01490, was funded by the Instituto de Salud Carlos III (ISCIII) from Spain, and cofounded by the European Union.

COMPETING INTEREST STATEMENT

The authors declare no conflict of interest.

ACKNOWLEDGEMENTS

The authors would like to thank all the people who supported them while conducting this research, specially their colleagues at Hospital Universitario Fundación Alcorcón.

5. REFERENCES

1 Haas R, Gorelik A, Busija L, *et al.* Prevalence and characteristics of musculoskeletal complaints in primary care: an analysis from the population level and analysis reporting (POLAR) database. *BMC Prim care* 2023;**24**. doi:10.1186/S12875-023-01976-Z

2 Luime JJ, Koes BW, Hendriksen IJM, *et al.* Prevalence and incidence of shoulder pain in the general population; a systematic review. *Scand J Rheumatol* 2004;**33**:73–81. doi:10.1080/03009740310004667

3 Littlewood C, May S, Walters S. Epidemiology of Rotator Cuff Tendinopathy: A Systematic Review. *Shoulder Elb* 2013;**5**:256–65. doi:10.1111/sae.12028

4 Linsell L, Dawson J, Zondervan K, *et al.* Prevalence and incidence of adults consulting for shoulder conditions in UK primary care; patterns of diagnosis and referral. *Rheumatology* 2006;**45**:215–21. doi:10.1093/rheumatology/kei139

5 Hwang Y, Oh J. The relationship between shoulder pain and shoulder disability in women: The mediating role of sleep quality and psychological disorders. *Medicine (Baltimore)* 2022;**101**:E31118. doi:10.1097/MD.0000000000031118

6 Clausen M, Nielsen M, Merrild M, *et al.* High incidence of lost workdays in patients with subacromial impingement syndrome. *Dan Med J* 2021;**68**:A07200496.

7 Horowitz EH, Aibinder WR. Shoulder Impingement Syndrome. *Phys Med*

Rehabil Clin N Am 2023;**34**:311–34. doi:10.1016/J.PMR.2022.12.001

8 Witten A, Mikkelsen K, Wagenblast Mayntzhusen T, *et al.* Terminology and diagnostic criteria used in studies investigating patients with subacromial pain syndrome from 1972 to 2019: a scoping review. *Br J Sports Med* 2023;**57**:864–71. doi:10.1136/BJSPORTS-2022-106340

9 Vandvik PO, Lähdeoja T, Ardern C, *et al.* Subacromial decompression surgery for adults with shoulder pain: a clinical practice guideline. *BMJ* 2019;**364**:l294–l294. doi:10.1136/bmj.l294

10 Lowry V, Lavigne P, Zidarov D, *et al.* A Systematic Review of Clinical Practice Guidelines on the Diagnosis and Management of Various Shoulder Disorders. *Arch Phys Med Rehabil* 2023;**105**:411–26. doi:10.1016/J.APMR.2023.09.022

11 Lafrance S, Charron M, Roy JS, *et al.* Diagnosing, Managing, and Supporting Return to Work of Adults With Rotator Cuff Disorders: A Clinical Practice Guideline. *J Orthop Sports Phys Ther* 2022;**52**:647–64. doi:10.2519/JOSPT.2022.11306

12 Naunton J, Street G, Littlewood C, *et al.* Effectiveness of progressive and resisted and non-progressive or non-resisted exercise in rotator cuff related shoulder pain: a systematic review and meta-analysis of randomized controlled trials. *Clin Rehabil* 2020;**34**:1198–216. doi:10.1177/0269215520934147

13 Dominguez-Romero JG, Jiménez-Rejano JJ, Ridao-Fernández C, *et al.* Exercise-Based Muscle Development Programmes and Their Effectiveness in the Functional Recovery of Rotator Cuff Tendinopathy: A

Systematic Review. *Diagnostics (Basel, Switzerland)* 2021;**11**. doi:10.3390/DIAGNOSTICS11030529

14 McConnell R, Klopper M, Rhon DI, *et al.* The influence of exercise therapy dosing on pain and functional outcomes in patients with subacromial pain syndrome: A systematic review. *Shoulder Elb* Published Online First: 13 September 2022. doi:10.1177/17585732221124303

15 Medeiros de-Queiroz JH, De-Medeiros MB, De-Lima RN, *et al.* Exercise for rotator cuff tendinopathy. *Rev Bras Med Trab* 2023;**20**:498–504. doi:10.47626/1679-4435-2022-698

16 Shim J, Pavlova A V., Moss RA, *et al.* Patient ratings in exercise therapy for the management of tendinopathy: a systematic review with meta-analysis. *Physiotherapy* 2023;**120**:78–94. doi:10.1016/J.PHYSIO.2023.05.002

17 Powell JK, Schram B, Lewis J, *et al.* Physiotherapists nearly always prescribe exercise for rotator cuff-related shoulder pain; but why? A cross-sectional international survey of physiotherapists. *Musculoskeletal Care* 2023;**21**:253–63. doi:10.1002/MSC.1699

18 Powell JK, Schram B, Lewis J, *et al.* 'You have (rotator cuff related) shoulder pain, and to treat it, I recommend exercise.' A scoping review of the possible mechanisms underpinning exercise therapy. *Musculoskelet Sci Pract* 2022;**62**. doi:10.1016/J.MSKSP.2022.102646

19 Dickson C, de Zoete RMJ, Berryman C, *et al.* Patient-related barriers and enablers to the implementation of high-value physiotherapy for chronic pain: a systematic review. *Pain Med* 2023;**25**:104–15.

doi:10.1093/PM/PNAD134

20 O'Shea A, Drennan J, Littlewood C, *et al.* Barriers and facilitators related to self-management of shoulderpain: a systematic review and qualitative synthesis. *Clin Rehabil* 2022;**36**:1539. doi:10.1177/02692155221108553

21 Major DH, Røe Y, Grotle M, *et al.* Content reporting of exercise interventions in rotator cuff disease trials: results from application of the Consensus on Exercise Reporting Template (CERT). *BMJ Open Sport Exerc Med* 2019;**5**:e000656. doi:10.1136/BMJSEM-2019-000656

22 Kucksdorf JJ, Bartley J, Rhon DI, *et al.* Reproducibility of Exercise Interventions in Randomized Controlled Trials for the Treatment of Rotator Cuff-Related Shoulder Pain: A Systematic Review. *Arch Phys Med Rehabil* 2023;:S0003-9993(23)00531-2. doi:10.1016/J.APMR.2023.09.007

23 Pieters L, Lewis J, Kuppens K, *et al.* An Update of Systematic Reviews Examining the Effectiveness of Conservative Physical Therapy Interventions for Subacromial Shoulder Pain. *J Orthop Sport Phys Ther* 2020;**50**:131–41. doi:10.2519/jospt.2020.8498

24 Burns D, Boyer P, Razmjou H, *et al.* Adherence Patterns and Dose Response of Physiotherapy for Rotator Cuff Pathology: Longitudinal Cohort Study. *JMIR Rehabil Assist Technol* 2021;**8**. doi:10.2196/21374

25 Emmerson KB, Harding KE, Taylor NF. Providing exercise instructions using multimedia may improve adherence but not patient outcomes: a systematic review and meta-analysis. *Clin Rehabil* 2019;**33**:607–18. doi:10.1177/0269215518819706

26 Kingston G, Gray MA, Williams G. A critical review of the evidence on the use of videotapes or DVD to promote patient compliance with home programmes. *Disabil Rehabil Assist Technol* 2010;**5**:153–63. doi:10.3109/17483101003671709

27 Davergne T, Meidinger P, Dechartres A, *et al.* The Effectiveness of Digital Apps Providing Personalized Exercise Videos: Systematic Review With Meta-Analysis. *J Med Internet Res* 2023;**25**. doi:10.2196/45207

28 Park KH, Song MR. Development of a Web Exercise Video for Patients With Shoulder Problems. *Comput Inform Nurs* 2017;**35**:255–61. doi:10.1097/CIN.0000000000000303

29 Rizzato A, Pizzichemi M, Gobbi E, *et al.* Effectiveness and therapeutic compliance of digital therapy in shoulder rehabilitation: a randomized controlled trial. *J Neuroeng Rehabil* 2023;**20**. doi:10.1186/S12984-023-01188-7

30 Chan AW, Tetzlaff JM, Altman DG, *et al.* SPIRIT 2013 statement: defining standard protocol items for clinical trials. *Ann Intern Med* 2013;**158**:200–7. doi:10.7326/0003-4819-158-3-201302050-00583

31 Watts AR, Williams B, Kim SW, *et al.* Shoulder impingement syndrome: a systematic review of clinical trial participant selection criteria. *Shoulder Elb* 2017;**9**:31–41. doi:10.1177/1758573216663201

32 Lai K, Kelley K. Accuracy in parameter estimation for ANCOVA and ANOVA contrasts: sample size planning via narrow confidence intervals. *Br J Math Stat Psychol* 2012;**65**:350–70. doi:10.1111/J.2044-8317.2011.02029.X

33 Hopewell S, Keene DJ, Marian IR, *et al.* Progressive exercise compared with best practice advice, with or without corticosteroid injection, for the treatment of patients with rotator cuff disorders (GRASP): a multicentre, pragmatic, 2 × 2 factorial, randomised controlled trial. *Lancet* 2021;**398**:416–28. doi:10.1016/S0140-6736(21)00846-1

34 Walters SJ, Jacques RM, Henriques-Cadby IBDA, *et al.* Sample size estimation for randomised controlled trials with repeated assessment of patient-reported outcomes: what correlation between baseline and follow-up outcomes should we assume? *Trials* 2019;**20**:566. doi:10.1186/S13063-019-3671-2

35 Dabija DI, Jain NB. Minimal Clinically Important Difference of Shoulder Outcome Measures and Diagnoses: A Systematic Review. *Am J Phys Med Rehabil* 2019;**98**:671–6. doi:10.1097/PHM.0000000000001169

36 Slade SC, Dionne CE, Underwood M, *et al.* Consensus on Exercise Reporting Template (CERT): Explanation and Elaboration Statement. *Br J Sports Med* 2016;**50**:1428–37. doi:10.1136/bjsports-2016-096651

37 Membrilla-Mesa MD, Cuesta-Vargas AI, Pozuelo-Calvo R, *et al.* Shoulder pain and disability index: Cross cultural validation and evaluation of psychometric properties of the Spanish version. *Health Qual Life Outcomes* 2015;**13**:200. doi:10.1186/s12955-015-0397-z

38 Hawker GA, Mian S, Kendzerska T, *et al.* Measures of adult pain: Visual Analog Scale for Pain (VAS Pain), Numeric Rating Scale for Pain (NRS Pain), McGill Pain Questionnaire (MPQ), Short-Form McGill Pain Questionnaire (SF-MPQ), Chronic Pain Grade Scale (CPGS), Short

Form-36 Bodily Pain Scale (SF. *Arthritis Care Res (Hoboken)* 2011;**63**:S240-52. doi:10.1002/acr.20543

39 Wilcox RR. *Introduction to robust estimation and hypothesis testing*. 3. ed. Amsterdam [u.a.]: : Elsevier, AP 2012.

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item	Description	Page
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	13
	2b	All items from the World Health Organization Trial Registration Data Set	13
Protocol version	3	Date and version identifier	NA
Funding	4	Sources and types of financial, material, and other support	14
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	1
	5b	Name and contact information for the trial sponsor	1
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	NA
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	14

Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	4-5
	6b	Explanation for choice of comparators	4-5
Objectives	7	Specific objectives or hypotheses	5
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	6
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	6
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	7-8
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	9-10
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	10
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	10
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	10

Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size
Methods: Assignment of interventions (for controlled trials)		
Allocation:		
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how

10-12			
6			
8			
7			
6-7			
7			
6			
7			

	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	NA
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	10-12
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	NA
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	13-14
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	12-13
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	12-13
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	12-13
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	NA

	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	NA
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	10
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	NA
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	14
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	NA
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	7
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	NA
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	13-14
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	14
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	NA

Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	NA
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	NA
	31b	Authorship eligibility guidelines and any intended use of professional writers	NA
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	NA
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	13
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	NA

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

SUPPLEMENTARY MATERIAL 2

Description of the web application

The exercise application is a web-based video library hosted on a server connected to the Internet. There are two versions of the web application. The first version (hosted in http://rhbhombro.com/profesional) is aimed at health professionals, and it allows for personalization of the specific exercises to include in each program for a particular patient. The second version (hosted in http://rhbhombro.com/) is a reduced version that contains predefined exercise programs for the treatment of rotator cuff tendinopathy, supraspinatus tears, massive rotator cuff tears, and frozen shoulder. For this randomized controlled trial, six predefined programs for rotator cuff tendinopathy, contained in the second reduced version of the web application, will be used. All the videos and the information contained in the application are on Spanish language.

Software development

The web application has been developed with PHP 7.2.2 programming language (http://php.net/releases/7_2_2.php) and a MVC (Model - View - Controller) infrastructure Laravel Framework 5.6.3 (http://laravel.com). Furthermore, it integrates the API of the professional streaming platform Vimeo (http://vimeo.com) that allows the distribution of videos to professionals and patients for different devices. The application is hosted on a VPS with Debian 8 (Jessie) (64 bits) with Apache 2.4.10 and MySql 14.14 database engine.

Selection of the exercises and design of the videos

First, a search was conducted in Medline/Pubmed, Cochrane, PEDRO, and AMED databases regarding published randomized controlled trials evaluating exercise programs for the management of each one of the four abovementioned disorders. The trials with the lowest risk of bias, and the greatest content reporting of the exercise programs were selected.

Second, a multidisciplinary consensus meeting was conducted to reach consensus, based on the published literature, on the specific exercises to include for the treatment of each pathology, as well as the prescription parameters. For this purpose, the following points were considered: 1) proven effectiveness and detailed description in low risk-of-bias randomized controlled trials; 2) recommendations for exercise prescription parameters of The American College of Sports Medicine; and 3) adaptation of the abovementioned

literature to the patients' profile seen at the hospital in which the web application was meant to be implemented.

Finally, the group of healthcare professionals collaborated with a team of graphic designers to create the animated videos of the selected exercises.

Web application features

Prescribe an exercise program, choosing from a series of previously designed exercises, depending on the pathology and clinical characteristics of the patient.

The healthcare professional can select the specific exercise to prescribe to a given patient using the first abovementioned version of the web application, or the select one of the predefined programs within the second version of the application, that can also be tailored to patients' clinical characteristics (Figure 1).

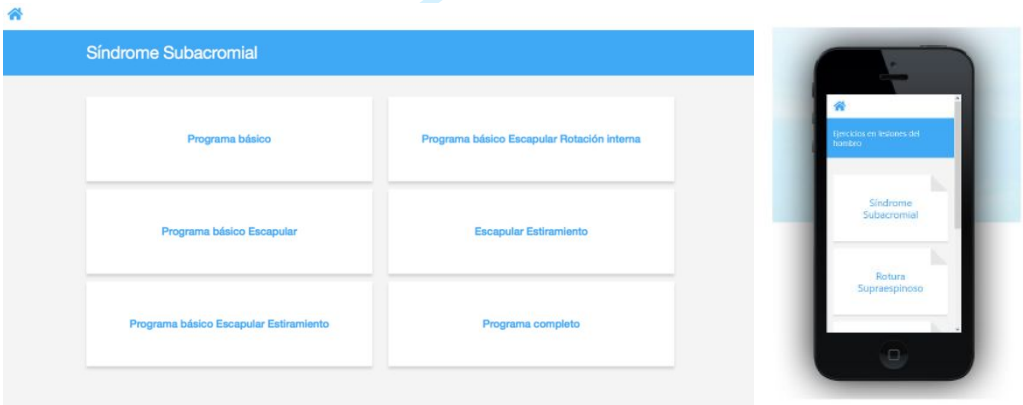


Figure 1. Screenshot of the web application. Left = laptop/tablet; right = smartphone.

For this randomized controlled trial, six predefined programs within the rotator cuff tendinopathy section of the second version of the web application will be used, namely: basic program, basic program plus scapular exercises, basic program plus scapular exercises and stretching, basic program plus scapular exercises and internal rotation, scapular exercise and stretching program, and full exercise program. Detailed description of the exercises are programs is presented in Supplementary Material 4.

View the videos included in the exercise program from different electronic devices (computer, tablet, or smartphone) without the need to install any specific software.

Each of the animated videos is composed of an animated person who performs the intended exercise, allowing the watcher to see the performance from different angles and planes. Furthermore, the video displays an audio-recorded explanation of the exercise performance, along with subtitles (Figure 2).

Figure 2. Example of an animated video from a smartphone device.

It allows the program chosen by the professional to be sent to the patient by means of a link generated.

The specific exercise program prescribed can be facilitated to the patient by means of a link generated, so the patient has only access to the prescribed exercises by the healthcare provider.

SUPPLEMENTARY MATERIAL 3

Didactic methodology of the exercise application

The 3D multimedia animations have been designed in an attempt to reduce the cognitive load (the amount of information that working memory cand hold at one time).[1] To this end, the technical aspects, the content and the form of instruction have been taken into account:[2]

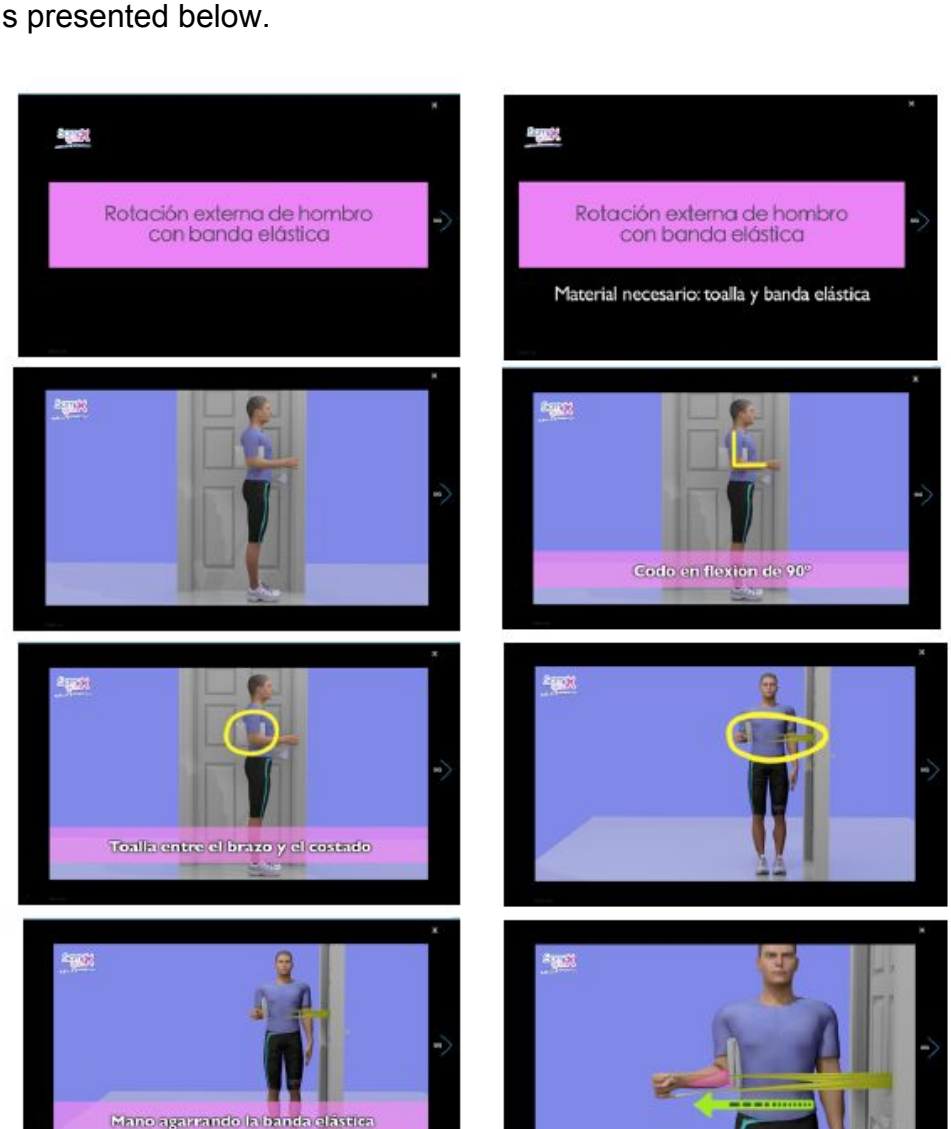
- **Technical aspects:** Visual quality, audio quality, coordination of audio and video, and use of graphic elements (arrows, position signs, time markers...) to highlight important information.
- **Content:** The instructional objective is explicit and clear. There is an explicit call to continued action teaching the way to progress.
- **Instructions:** The instructional techniques focus on patient engagement. The content is presented in an organized way. Short sequences of information are used to allow learners to engage. All extraneous information that doesn't contribute to the learning goal or help build relationships is eliminated.

The videos are 3D animations that allow to visualize an exercise from different perspectives, and are accompanied by audio, text, and animated graphic elements such as arrows, position signs, and time markers that facilitate the understanding and correct completion of the exercise. In addition, each exercise indicates the material necessary to perform it, the starting position, the correct way to do it, and the different parameters to consider (intensity, frequency and duration) and how to progress. Several aspects have been taken into account in the teaching methodology:

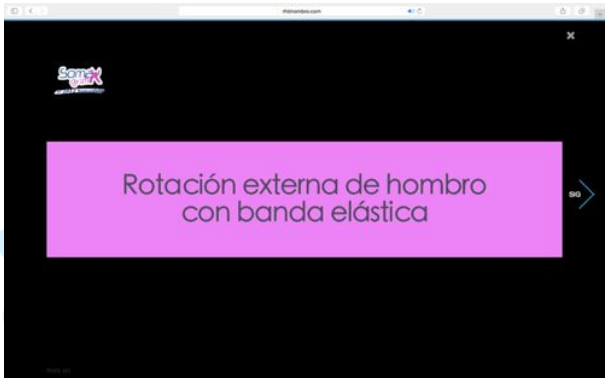
1. **Nomenclature of the exercise:** A short name is used to quickly identify the exercise to be performed.
2. **Necessary material:** Description, in the audio and in the text, of the material required to perform each exercise.
3. **Starting position:** Description and visualization from various perspectives of the initial position, which is considered adequate to begin the exercise. Position marks are used to facilitate this.
4. **Execution of the exercise:** Description of the correct way to perform the exercise. Arrows are introduced to mark the direction in which the movement should be performed, signs indicating the final position to be reached and a marker of the time to maintain this position.

Example of didactic methodology with one of the included exercises

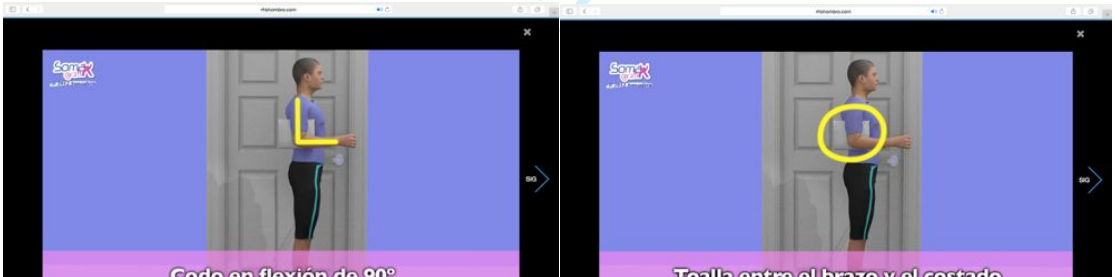
The whole video sequence of the shoulder external rotation exercise with elastic band is presented below.



The video begins by naming the exercise to be performed: external rotation of the shoulder with an elastic band. This allows the exercise to be easily identified, both by the professional who is going to teach it and by the patient who is going to do it.



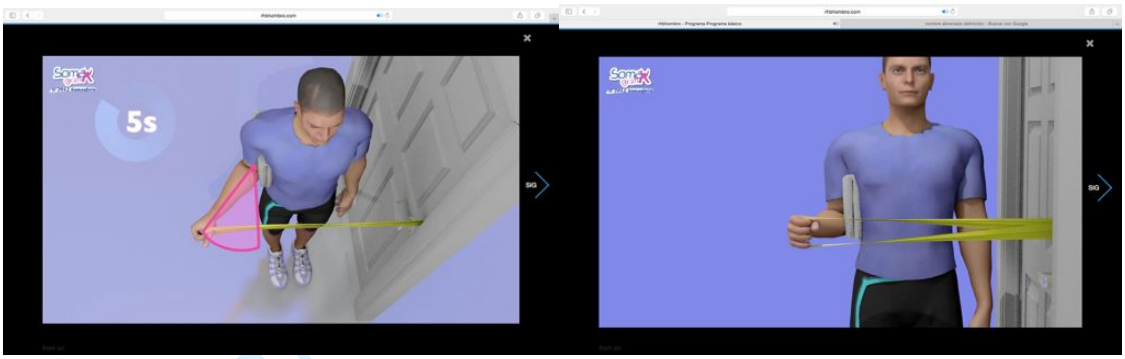
Next, the starting position is described, standing next to a door, with the elbow of the arm with which the exercise is to be performed in a 90° flexed position and placement of the folded towel between the elbow and the side. Several position and text marks are introduced to focus the patient's attention on those aspects that are a frequent source of error.



After this, a change of perspective is made so that the patient can visualize the starting position from another angle and the position of the elastic band with respect to the door (caught with the door or hooked to the door handle) and the hand holding the elastic band, which should be in slight tension, is specified.

The video goes on to specify the execution of the exercise, pulling the elastic band, making it taut to form an arc of about 45º and emphasizing not to move the rest of the body or allow the towel to fall to the floor. It is common to make the mistake of helping with the rest of the body to make the movement or separating the elbow from the body, so with these explanations we intend to reduce the possibility of such errors. An arrow marker is introduced for the direction of the movement and another for the magnitude of the arc of the movement to be performed.

Finally, the time to hold that final position is specified, 5 seconds and slowly return to the starting position.



REFERENCES

1 Castro-Alonso JC, de Koning BB, Fiorella L, *et al.* Five Strategies for Optimizing Instructional Materials: Instructor- and Learner-Managed Cognitive Load. *Educ Psychol Rev* 2021;**33**:1379–407. doi:10.1007/S10648-021-09606-9

2 Beemer LR, Tackett W, Schwartz A, *et al.* Use of a Novel Theory-Based Pragmatic Tool to Evaluate the Quality of Instructor-Led Exercise Videos to Promote Youth Physical Activity at Home: Preliminary Findings. *Int J Environ Res Public Health* 2023;**20**. doi:10.3390/IJERPH20166561

SUPPLEMENTARY MATERIAL 4

Description of the exercise programs

CRITERIA FOR THE ELABORATION OF THE EXERCISE PROGRAMS

Exercise is the fist-line treatment for patients with rotator cuff tendinopathy,[1] but there is no consensus on which program is the most appropriate.[2] The selection of the exercise programs was based on current research, and clinical knowledge of the research team.

The majority of the investigated programs include strengthening and stretching exercises of the rotator cuff and scapular muscles.[3] Some authors have suggested that scapular-focused exercises can add benefits to a rotator cuff strengthening exercises program at short term (i.e., 6-weeks), but not mid-term (i.e., 3-months) follow-up.[4] Furthermore, there seems to be no difference between concentric and eccentric exercises for the management of rotator cuff tendinopathy.[5]

There seems to be no differences between supervised and home-based exercise settings.[6]

Despite there is conflicting evidence regarding the value of high-load exercises compared to low-load ones,[7] it seems that load progression is a key factor within exercise programs.[6,8]

Pain intensity within exercise performance seems to be the best indicator when modulating load progression and regression.[9] Even though moderate or severe pain intensity during the performance of the exercise is not recommended, it seems that a slight-pain reproduction is not detrimental for its possible benefit.[6]

There is no consensus regarding optimal dosage for exercise programs. Some authors have proposed that three sets may be preferable to two or one set.[6]

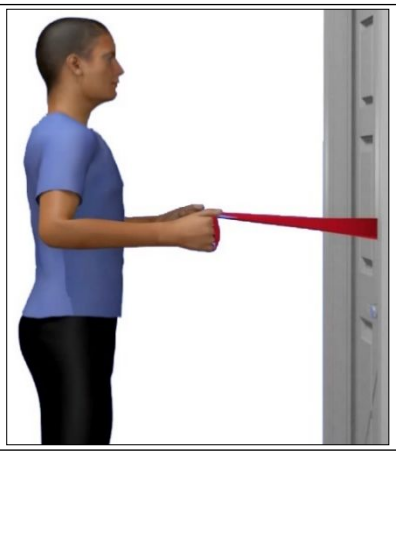
Finally, it is recommended that the exercise programs be maintained a minimum of three months.[6]

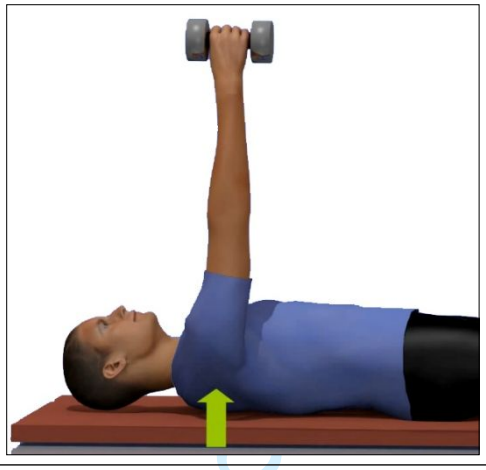
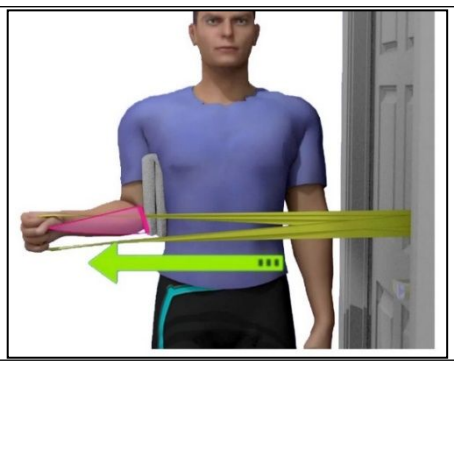
DETAILED DESCRIPTION OF THE EXERCISE PROGRAMS

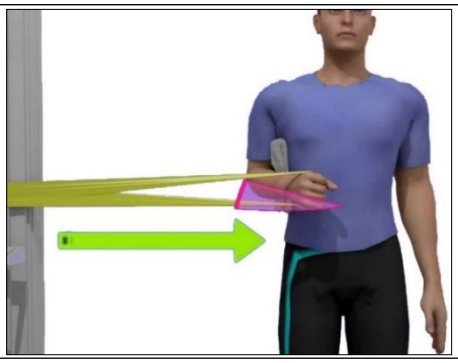
Six exercise programs were created based on the information provided above. The programs 1 (basic), 2 (basic plus scapular and internal rotation), and 3 (basic plus scapular) are aimed at patients no mobility limitation (strengthening exercises only). On the other hand, the programs 4 (scapular and stretching), 5 (basic plus scapular and stretching), and 6 (complete) are aimed at patients with limited mobility. The exercises included within each program are presented in the following table:

Exercises	Program					
	1	2	3	4	5	6
Horizontal row		X	X	X	X	X
Supine scapular protraction		X	X	X	X	X
Scaption	X	X	X		X	X
External rotation	X	X	X		X	X
Internal rotation		X				X
Posterior capsule stretching				X	X	X

The included exercises are as follows:

HORIZONTAL ROW	
	Arms with elbows bent at 90º. Pull the band with your hands making it tense, bringing the elbows and hands backwards, bringing the shoulder blades together. Hold for 5 seconds and return to starting position.

SUPINE SCAPULAR PROTRACTION	
	Shoulder elevated at 90º, and elbow extended holding a weight with the hand. Raise the weight while keeping the arm vertical. Hold the position for 5 seconds and return to the starting position.
SCAPTION	
	Slowly separate the arm upwards pulling the band without getting the arm horizontal. Hold for 5 seconds and return to the starting position.
EXTERNAL ROTATION	
	With a towel between the body and the arm and the elbow flexed 90º. Pull the band outwards about 45º. Hold for 5 seconds and return to the starting position.

INTERNAL ROTATION	
	With a towel between the body and the arm and the elbow flexed 90º. Pull the band inward about 45º. Hold for 5 seconds and return to the starting position.
POSTERIOR CAPSULE STRETCHING	
	Perform a 90º flexion of the shoulder and place the hand of the affected side over the healthy shoulder. With the other hand push the elbow backwards.

The detailed description of each exercise that was provided to the patient is as follows:

HORIZONTAL ROW

- You need an elastic band to perform this exercise.
- The starting position is standing/sitting in front of a closed door, with an elastic band hooked to the door handle.
- The arms should be about 45° away from the trunk and the elbows are kept bent at 90°.
- The band and forearms should be parallel to the floor.
- The spine must be kept straight during the performance of the exercise.
- To perform the exercise, pull the elastic band with your hands making it taut, bringing the elbows and hands backwards, bringing the shoulder blades together.
- Hold this position for 5 seconds and slowly return to the starting position.

SUPINE SCAPULAR PROTRACTION

- You need a dumbbell to perform this exercise.
- The starting position is lying on the floor face up. If you are more comfortable, you can place a cushion under your head.
- The arm with which the exercise is going to be performed remains perpendicular to the floor, with the elbow stretched out, while holding a dumbbell in your hand.
- The spine shouldn't be twisted during the performance of the exercise.
- To perform the exercise, take your shoulder off the floor by bringing your arm upwards, holding the weight towards the ceiling.
- Hold this position for 5 seconds and slowly return to the starting position.

SCAPTION

- You need an elastic band to perform this exercise.
- The starting position is standing facing forward with legs slightly apart, arms straight and relaxed along the body.
- One end of the band should be stepped on with the foot, and the other grasped with the hand of the symptomatic arm.
- The band should be slightly taut.
- The spine must be kept straight during the performance of the exercise.
- To perform the exercise the entire arm should be slowly pulled upward by pulling the band up to 30-40 degrees of elevation in the scapular plane.
- During the performance of the exercise, the elbow should be kept straight, the body shouldn't be rotated, and the shoulder shouldn't be shrugged.
- Hold this position for 5 seconds and slowly return to the starting position.

EXTERNAL ROTATION

- You need an elastic band and a towel to perform this exercise.
- The elastic band is attached to a door handle, and you must stand next to it.

- The elbow should be in 90º flexion forming a right angle, holding the towel between the elbow and the body.
- To perform the exercise, pull the elastic band outwards by about 45º of external rotation, making it taut without dropping the towel.
- The rest of the body should not move during the performance of the exercise.
- Hold this position for 5 seconds and slowly return to the starting position.

INTERNAL ROTATION

- You need an elastic band and a towel to perform this exercise.
- The elastic band is attached to a door handle, and you must stand next to it.
- The elbow should be in 90º flexion forming a right angle, holding the towel between the elbow and the body.
- To perform the exercise, pull the elastic band inward by about 45º of internal rotation, making it taut without dropping the towel.
- The rest of the body should not move during the performance of the exercise.
- Hold this position for 5 seconds and slowly return to the starting position.

POSTERIOR CAPSULE STRETCHING

- The starting position is standing.
- The palm of the hand of the side to be stretched is placed on top of the other shoulder, and the hand of the side that is to assist the stretch is placed resting on the opposite elbow.
- To perform the exercise, direct the elbow toward the opposite shoulder while your hand slides lightly down the back of the shoulder. Try to increase the movement by pushing slowly with the other hand on the elbow, without rotating the trunk.
- Hold this position for 20 seconds and slowly return to the starting position.

REFERENCES

1. Hanratty CE, McVeigh JG, Kerr DP, et al. The Effectiveness of Physiotherapy Exercises in Subacromial Impingement Syndrome: A Systematic Review and Meta-Analysis. *Semin Arthritis Rheum* 2012; 42: 297–316.

2. Dominguez-Romero JG, Jiménez-Rejano JJ, Ridao-Fernández C, et al. Exercise-Based Muscle Development Programmes and Their Effectiveness in the Functional Recovery of Rotator Cuff Tendinopathy: A Systematic Review. *Diagnostics (Basel, Switzerland)*; 11. Epub ahead of print 1 March 2021. DOI: 10.3390/DIAGNOSTICS11030529.

3. Gutiérrez-Espinoza H, Araya-Quintanilla F, Cereceda-Muriel C, et al. Effect of supervised physiotherapy versus home exercise program in patients with subacromial impingement syndrome: A systematic review and meta-analysis. *Physical Therapy in Sport* 2020; 41: 34–42.

4. Bury J, West M, Chamorro-Moriana G, et al. Effectiveness of scapula-focused approaches in patients with rotator cuff related shoulder pain: A systematic review and meta-analysis. *Man Ther* 2016; 25: 35–42.

5. Camargo PR, Alburquerque-Sendin F, Salvini TF. Eccentric training as a new approach for rotator cuff tendinopathy: Review and perspectives. *WORLD J Orthop* 2014; 5: 634–644.

6. Littlewood C, Malliaras P, Chance-Larsen K. Therapeutic Exercise for rotator cuff tendinopathy: A systematic review of contextual factors and prescription parameters. *Int J Rehabil Res* 2015; 38: 95–106.

7. Malliaras P, Johnston R, Street G, et al. The Efficacy of Higher Versus Lower Dose Exercise in Rotator Cuff Tendinopathy: A Systematic Review of Randomized Controlled Trials. *Arch Phys Med Rehabil* 2020; 101: 1822–1834.

8. Naunton J, Street G, Littlewood C, et al. Effectiveness of progressive and resisted and non-progressive or non-resisted exercise in rotator cuff related shoulder pain: a systematic review and meta-analysis of randomized controlled trials. *https://doi.org/101177/0269215520934147*

2020; 34: 1198–1216.

9. Ortega-Castillo M, Cuesta-Vargas A, Luque-Teba A, et al. The role of progressive, therapeutic exercise in the management of upper limb tendinopathies: A systematic review and meta-analysis. *Musculoskelet Sci Pract*; 62. Epub ahead of print 1 December 2022. DOI: 10.1016/J.MSKSP.2022.102645.

SUPPLEMENTARY MATERIAL 5

Consensus on Exercise Reporting Template (CERT)

Item 1: Detailed description of the type of exercise equipment

The needed equipment to perform the exercises are:

- Elastic bands (Thera-Band®) with a length of 155cm and a width of 14.5cm. There are six type of bands which, in order from least to most resistant, are as follows: yellow, red, green, blue, black, and silver.[1]
- Dumbbells with varying weights from 1kg to 4kg.
- Small size towel.

1. Uchida MC, Nishida MM, Sampaio RAC, et al. Thera-band® elastic band tension: reference values for physicalactivity. *J Phys Ther Sci* 2016; 28: 1266.

Item 2: Detailed descriptions of the qualifications, teaching/supervising expertise and/or training undertaken by the exercise instructor

The exercise instructors will be two physical therapists working at the Hospital Universitario Fundación Alcorcón. They have 4 to 30 years of experience treating patients with musculoskeletal shoulder disorders using therapeutic exercise. All the therapists were provided with a teaching session for the instruction on the exercise program, in aim to standardize the explanations given to the patients, as well as criteria for load progression and regression.

Item 3: Describe whether the exercises are performed individually or in a group

All sessions that patients will receive at the hospital will be performed individually with a 30-minute duration. The patients will attend 5 sessions every other day, and two revision sessions, one at 1-month, and another one at 3 month-follow-up.

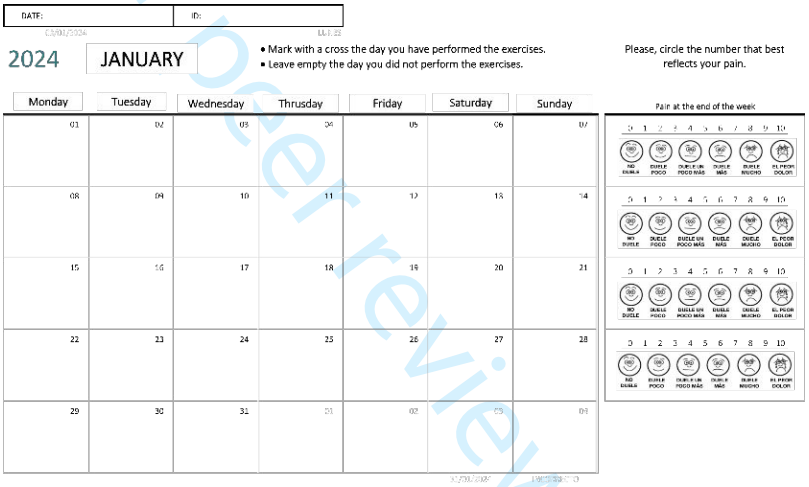
Item 4: Describe whether exercises are supervised or unsupervised and how they are delivered.

The abovementioned seven exercise sessions will be supervised at the hospital with a physical therapist. However, the patient will be asked to perform the trained exercise at home all days until three-month follow-up. After that, the patient will be encouraged to keep up with the exercise at least 3-days per week until last follow-up with the medical doctor at 6-month follow-up.

During the supervised sessions, the physical therapist will observe the exercise performance, and correct any compensations made by the patient, ensuring an adequate pattern of movement. Furthermore, the dosage will be modified according to patients' characteristics at each session.

Item 5: Detailed description of how adherence to exercise is measured and reported.

Adherence to the exercise program will be measured using a self-reported calendar, in which the patient should mark the days he/she will perform the exercises. Furthermore, patient's will be asked to rate their pain intensity within last week on Sundays.



Item 6: Detailed description of the motivation strategies.

In order to motivate the patient to perform the exercises, information will be provided throughout the treatment sessions about his or her pathology and the importance of exercise in his or her recovery. In addition, the physiotherapists will give positive feedback in the face-to-face sessions, with motivational messages, placing greater emphasis on the points well performed by the patients within each exercise and their progress in tolerance to the load.

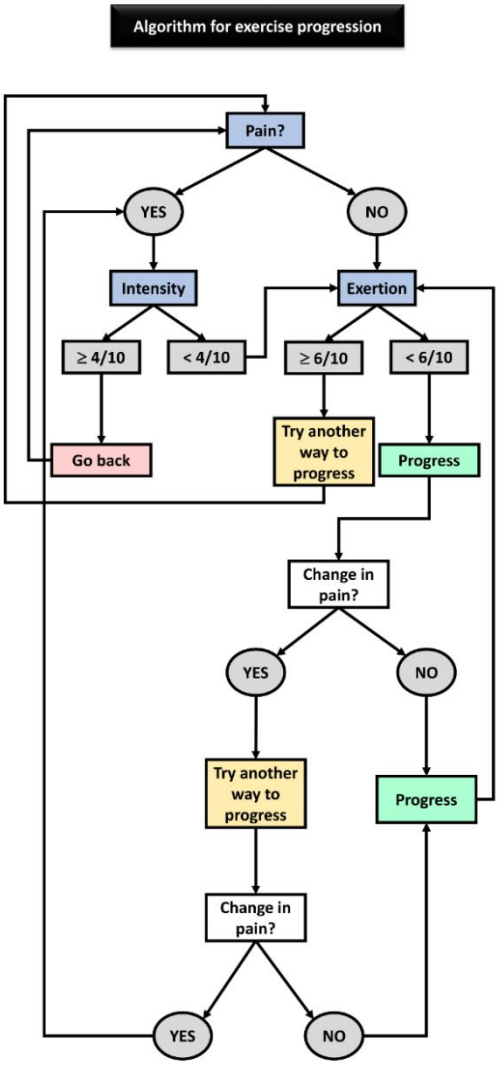
Item 7(a): Detailed description of the rule(s) for determining exercise progression.

Two criteria were used for progression/regression of exercise load: pain intensity and perceived sensation of exertion.

The intensity of pain should be mild during the exercises (i.e., ≤ 4/10 in a verbal numeric pain rating scale). Furthermore, although there may be a small increase in pain with exercise, it should return to baseline within 2 to 3 hours after exercise.

In addition, the patient should feel a sensation of moderate effort when performing the exercises, with a perceived exertion value equal or greater than 6 in a 0-10 verbal rating scale.

The first criterion to consider is pain intensity, followed by perceived sensation of exertion. If the patient does not have moderate pain within the exercise, and has low perceived exertion, the load will be increased. If, after that, the pain increases, he/she would be asked to return to the initial load. The algorithm of guidance provided to the physiotherapists for the loading profession is presented as follows.



Item 7(b): Detailed description of how the exercise program is progressed (eg, number of repetitions, resistance, load, speed, etc.)

The exercises will start with three sets (unless patient is unable to perform three sets), trying a minimum of 5 repetitions per set. At the beginning of the program, the progression will be made by increasing repetitions up to a maximum of 10 (first three months). Later in the program, the progression will be made by decreasing sets to 1 or 2, with 8 to 10 repetitions, and increasing load (i.e., elastic band resistance or dumbbell weight). Furthermore, at the beginning the exercises will be performed daily, and later in the program the exercises will be performed every other day.

The only exception is the posterior capsule stretching exercise, that will be performed with 3 sets of 20 seconds the entire program, that will be progressed by increasing the tension of the stretching.

Item 8: Detailed description of each exercise to enable replication (eg, photographs, illustrations, video, Smartphone app, website, protocol paper, etc).

The detailed description of each exercise is presented in Supplementary Material 4.

Item 9: Detailed description of any home programme component (eg, other exercises, stretching, functional tasks, etc).

The same exercises trained at the hospital will be performed at home by the patient.

Item 10: Describe whether there are any non-exercise components (eg, training or information materials, education, cognitive– behavioural therapy, massage, etc).

All patients will be provided with an information document with clarifications regarding their shoulder pathology (Supplementary Material 6), and explanations on the importance of therapeutic exercise. Furthermore, all patients from both groups will be provided with a document containing photos and explanation of

the exercise to be performed. Finally, patients will be provided with analgesic drugs if needed.

Item 11: Describe the type and number of adverse events that occur during exercise.

All adverse events will be registered in the patient's medical record during the entire course of the study.

Item 12: Describe the setting in which the exercises are performed.

The face-to-face sessions will be provided at the hospital setting, and the trained exercises will be performed at home by the patients for the entire duration of the study.

Item 13: Detailed description of the exercise intervention including, but not limited to, number of exercise repetitions/sets/sessions, session duration, programme duration, etc.

Exercises will be performed between 1-3 sets and 5-10 repetitions, according to the progression stated in item 7-b. All face-to-face sessions at the hospital will last 30 minutes, with a total of 7 sessions.

Item 14(a): Describe whether the exercises are generic (one size fits all) or tailored.

Exercises will be tailored according to the specifications provided in Supplementary Material 4.

Item 14(b): Detailed description of how exercises are tailored to the individual.

Exercises will be tailored according to the specifications provided in Supplementary Material 4.

Item 15: Describe the decision rule for determining the starting level at which people start an exercise programme (eg, beginner, intermediate, advanced, etc).

At the beginning of the program, patients without range of motion issues will be provided one of the first three exercises programs, while patients with range of

motion difficulties will be provided with one of the last three programs (Supplementary Material 4). Furthermore, subjects with moderate-severe pain intensity will start with the scapular-only programs, while those with mild pain intensity will start with the scapular plus internal rotation program (Supplementary Material 4).

Item 16(a): Describe how adherence or fidelity to the exercise intervention is assessed/measured.

The description of how adherence will be measures is presented in item 5.

Item 16(b): Describe the extent to which the intervention was delivered as planned.

Any deviations from intended intervention will be registered. All data will be analyzed at the end of the study using an intention-to-treat approach.

SUPPLEMENTARY MATERIAL 6

Information given to patients about the importance of exercise in the management of rotator cuff tendinopathy

EXERCISE FOR THE TREATMENT OF ROTATOR CUFF TENDINOPATHY

Exercise programs are the most effective treatment for shoulder tendinopathy in the medium and long term. Exercise therapy has the advantages that it has almost no adverse effects, and that the improvement achieved is usually maintained over time (although it may take a few weeks to appear).

Why is exercise important for treating rotator cuff tendinopathy?

The most common shoulder problem is rotator cuff tendinopathy. Pain appears at the level of the tendons of the muscles that surround the humeral head and form the rotator cuff. The rotator cuff is formed by four muscles surrounding the humeral head: supraspinatus, subscapularis, infraspinatus, and teres minor. It is a pain that appears especially when raising the arm, when bringing the hand towards the back or when lying on the bed on the side supporting the shoulder.

The reasons for the appearance of rotator cuff pain are not well understood, but it is known that the most important contributor is the load imposed to the shoulder. For example, increasing shoulder work in a high amount in a short period of time, or be for a prolonged period of time of low load, and then resume normal shoulder work. However, other factors such as sleep quality, or stress, can also influence on it. The result is a shoulder with tissues that become unaccustomed to the imposed load, producing the sensation of pain, even though the load is not harmful to the shoulder.

For that reason, the treatment of choice for this musculoskeletal disorder is therapeutic exercise, aimed at strengthening the shoulder musculature with exercise programs increases the stability of the glenohumeral joint. If the exercises are performed for several weeks the pain will begin to improve in most patients (although it is common to feel some discomfort initially when doing the exercises). Strength and endurance will also improve, and the ability to perform activities with the arm without pain will increase.

How is exercise performed?

The exercise programs to be used are simple and will be adapted to the characteristics of each individual. You will be instructed by a physical therapist, very familiar with this type of shoulder injury, who will select the most

appropriate combination of exercises for your specific situation. Once you have learned the exercises you will be provided with the necessary equipment, and you will have to continue doing them at home for at least 3 months. The physical therapist and the medical doctor of the rehabilitation unit will review you periodically. You will be indicated the necessary modifications to progress in the exercises in aim to achieve the maximum improvement.

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item	Description	Page
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	13
	2b	All items from the World Health Organization Trial Registration Data Set	13
Protocol version	3	Date and version identifier	NA
Funding	4	Sources and types of financial, material, and other support	14
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	1
	5b	Name and contact information for the trial sponsor	1
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	NA
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	14

Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	4-5
	6b	Explanation for choice of comparators	4-5
Objectives	7	Specific objectives or hypotheses	5
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	6
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	6
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	7-8
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	9-10
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	10
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	10
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	10

Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size
Methods: Assignment of interventions (for controlled trials)		
Allocation:		
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how

Outcomes	10-12
Participant timeline	6
Sample size	8
Recruitment	7
Allocation:	
Sequence generation	6-7
Allocation concealment mechanism	7
Implementation	6
Blinding (masking)	7

	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	NA
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	10-12
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	NA
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	13-14
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	12-13
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	12-13
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	12-13
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	NA

	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	NA
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	10
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	NA
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	14
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	NA
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	7
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	NA
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	13-14
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	14
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	NA

Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	NA
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	NA
	31b	Authorship eligibility guidelines and any intended use of professional writers	NA
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	NA
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	13
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	NA

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

BMJ Open

Effects of a web application based on multimedia animations to support therapeutic exercise for rotator cuff-related shoulder pain: protocol for an open-label randomized controlled trial

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2024-085381.R1
Article Type:	Protocol
Date Submitted by the Author:	30-Apr-2024
Complete List of Authors:	Pérez-Porta, Irene; Hospital Universitario Fundación Alcorcón, Physical Therapy and Rehabilitation Unit; Universidad Rey Juan Carlos, International Doctoral School Flórez-García, Mariano; Hospital Universitario Fundacion Alcorcon, Physical Therapy and Rehabilitation Unit García-Pérez, Fernando; Hospital Universitario Fundacion Alcorcon, Physical Therapy and Rehabilitation Unit Fernández-Matías, Rubén; Hospital Universitario Fundacion Alcorcon, Research Unit; Universitat de Valencia, Doctoral School, Department of Physical Therapy Pérez-Manzanero, M Ángeles; Hospital Universitario Fundacion Alcorcon, Physical Therapy and Rehabilitation Unit Araujo-Narváez, Aurora; Hospital Universitario Fundacion Alcorcon, Physical Therapy and Rehabilitation Unit Urraca-Gesto, M Alicia ; Hospital Universitario Fundacion Alcorcon, Physical Therapy and Rehabilitation Unit; Universidad Rey Juan Carlos, Department of Physical Therapy, Occupational Therapy, and Rehabilitation and Physical Medicine Fernández-Lagarejos, César; Hospital Universitario Fundacion Alcorcon, Physical Therapy and Rehabilitation Unit Plaza-Manzano, Gustavo; Universidad Complutense de Madrid, Department of Radiology, Rehabilitation, and Physical Therapy; Hospital Clínico San Carlos, Fisioterapia Contemporánea (InPhysio) Research Group, Health Research Institute Pérez-Fernández, Elia; Hospital Universitario Fundacion Alcorcon, Research Unit Velasco-Arribas, María; Hospital Universitario Fundacion Alcorcon, Research Unit; Universidad Rey Juan Carlos, Department of Medical Specialties and Public Health
Primary Subject Heading:	Rehabilitation medicine
Secondary Subject Heading:	Evidence based practice
Keywords:	Shoulder < ORTHOPAEDIC & TRAUMA SURGERY, Randomized Controlled Trial, REHABILITATION MEDICINE, Physical Therapy Modalities

Effects of a web application based on multimedia animations to support therapeutic exercise for rotator cuff-related shoulder pain: protocol for an open-label randomized controlled trial

Irene Pérez-Porta, MD, PhD Student[1,2]; Mariano Tomás Flórez-García, MD, PhD[1]; Fernando García-Pérez, MD, MSc[1]; Rubén Fernández-Matías, PT, PhD Student[1,3,4]; M Ángeles Pérez-Manzanero, PT[1]; Aurora Araujo-Narváez, PT[1]; M Alicia Urraca-Gesto, PT, PhD[1,5]; César Fernández-Lagarejos, PT[1]; Gustavo Plaza-Manzano, PT, PhD[6,7]; Elia Pérez-Fernández, BS, MSc[3]; María Velasco-Arribas, MD, PhD[3,8]

[1] Physical Therapy and Rehabilitation Unit, Hospital Universitario Fundación Alcorcón, Madrid, Spain

[2] International Doctoral School, Universidad Rey Juan Carlos, Madrid, Spain

[3] Research Unit, Hospital Universitario Fundación Alcorcón, Madrid, Spain

[4] Doctoral School, Department of Physical Therapy, Universitat de València, Valencia, Spain.

[5] Department of Physical Therapy, Occupational Therapy, and Rehabilitation and Physical Medicine, Universidad Rey Juan Carlos, Madrid, Spain.

[6] Department of Radiology, Rehabilitation, and Physical Therapy, Universidad Complutense de Madrid, Madrid, Spain.

[7] Fisioterapia Contemporánea (InPhysio) Research Group, Health Research Institute, Hospital Clínico San Carlos, Madrid, Spain.

[8] Department of Medical Specialties and Public Health, Universidad Rey Juan Carlos, Madrid, Spain.

Correspondence:

Rubén Fernández-Matías, PT, PhD Student

Address: Physical Therapy and Rehabilitation Unit, Hospital Universitario Fundación Alcorcón, Street Budapest 1, 28922 Alcorcón, Madrid, Spain

Email: ruben.fernanmat@gmail.com

Funding: This study, with grant number PI19/01490, was funded by the Instituto de Salud Carlos III (ISCIII) from Spain, and cofounded by the European Union.

Conflict of interest: The authors declare no conflict of interest.

ClinicalTrials number: NCT05770908

Web Application Based on Multimedia Animations to Support Therapeutic Exercise for Rotator Cuff-Related Shoulder Pain: Protocol for a Randomized Clinical Trial

ABSTRACT

Introduction Rotator cuff-related shoulder pain (RCRSP) is the most common cause of shoulder pain. Currently, exercise is proposed as the first-line treatment for patients suffering from RCRSP. However, it seems that adherence to therapeutic exercise programs is poor when they last a long time in home-setting. The aim of this study is to evaluate the effects of adding video animations to a traditional paper-based exercise program.

Methods and analysis A single-center randomized open-labelled clinical trial will be conducted in a hospital in Spain. Adults between 18-80 years diagnosed with RCRSP who accomplish eligibility criteria will be included. Patients (n = 132) will be randomized into two groups, both receiving paper-based exercises, and the experimental group been provided also with video animations. The participants will receive 7 face-to-face physical therapy sessions and will be asked to perform the exercises at home for 6 months. The primary outcome measure will be Shoulder Pain and Disability Index, measured at baseline, 3 weeks, 3 months (primary analysis), and 6 months. Secondary outcomes will include pain intensity, patients' satisfaction, patients' perceived improvement, patients' perceived usability and usefulness of multimedia animations, and adherence to the exercises. Generalized least squares regression models with an autoregressive-moving average lag 1 correlation structure will be implemented, with an intention-to-treat analysis.

Ethics and dissemination This study has been approved by the ethics committee of Hospital Universitario Fundación Alcorcón (Madrid, Spain), with reference number CI18/16. All participants will sign an informed consent. The results will be published in a peer-reviewed scientific journal.

Trial registration number NCT05770908

Key words Subacromial pain; Rotator Cuff Tendinopathy; Protocol; Randomized Controlled Trial; Exercise

STRENGTHS AND LIMITATIONS

- This study will include a large sample size to estimate treatment effectiveness with adequate precision.
- The exercise program of this study will be reported in detail following current recommendations to facilitate its reproducibility and clinical implementation.
- The effects of adding the videos to the exercise program can depend on the specific exercises prescribed, so the results of this study may not generalize to other exercises.

1. INTRODUCTION

Shoulder pain is a common symptom that can be considered as the third cause of complaints in subjects with musculoskeletal disorders,[1] with nearly 65% of the whole population suffering from it in a lifetime.[2] Furthermore, its annual incidence has been estimated between 0.3% to 5.5%, and its point prevalence between 2.4% and 21%.[3]

Rotator-cuff related shoulder pain (RCRSP) is the most common cause of shoulder pain,[4] that may have a significant impact on daily life, cause sleep disorders and reduce quality of life,[5] as well as a decrease in productivity, with an increase in sick leave.[6]

The SPS has been scrutinized as a misleading and umbrella terminology,[7] with at least 27 unique terms covered within it (impingement, tendinopathy, rotator cuff disease…).[8] Diagnosis plays a crucial role within study design, because a specific treatment might work in subgroup of patients, but not in others.

Currently, there is high quality evidence suggesting that surgical procedures for patients with SPS are not superior to sham surgery.[9] For that reason, exercise is proposed as the first-line treatment for patients suffering from SPS in clinical practice guidelines,[9–11] because it can improve shoulder pain, mobility, and function.[12–15]

Overall, patients perceive exercise as a good choice for the management its shoulder pain,[16] and it is the most implemented treatment within physical therapists.[17] However, despite exercise being an effective, accessible, and low-cost intervention with few adverse effects,[18] there are still some barriers for its implementation within clinical practice.[19,20]

First, there is inappropriate content reporting about exercise programs within published clinical trials, both in the description of the exercises itself, the dosage, and the rules implemented for the progression and regression in exercise load,[21,22] thus leading to uncertainty about the better type of exercises, and the optimal dosage.[13,15,23] Second, exercise is an active patient-dependent intervention, meaning that it will only be effective if the patient performs it.[19] However, it seems that adherence to therapeutic exercise programs is poor when they last a long time in home-setting.[24] Some strategies has been implemented in aim to improve adherence to therapeutic exercise programs, such as the use of videos or multimedia animations,[25–27] that may improve self-efficacy, and adherence.[25–29] Nevertheless, the evidence of its superiority over traditional paper-based exercises is not clear in patients with RCRSP.[25]

For all these reasons, there is a need for more randomized controlled trials with better content reporting of the exercise programs,[21,22] that investigate the utility of the implementation of new technologies in aim to improve patients' adherence,[25] and thus optimizing treatment effectiveness.[18]

The main hypothesis of this randomized controlled trial is that the implementation of a home-based exercise program using multimedia animations is better regarding improvements in shoulder disability than a traditional paper-based one. As secondary objectives, the hypothesis is that multimedia animations will also improve more patients' expectations, satisfaction, and adherence. Finally, the study also aims to evaluate the usability of the implemented multimedia animations, and the patients' perceived utility of them.

2. METHODS AND ANALYSIS

2.1. Design and setting

This is a study protocol of a single-center open-labelled parallel-randomized clinical trial reported as per recommendations of the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) 2013 (Supplementary Material 1).[30] The research will take place in Hospital Universitario Fundación Alcorcón (Madrid, Spain). In **TABLE 1** it is presented the study schedule.

Table 1. Study schedule.

	Study Period					
	Enrollment	**Allocation**		**Post-allocation**		**Closeout**
Time point	**T_{-1}**	**T_0**	**3-week**	**6-week**	**12-week**	**24-week**
Enrollment	X					
Eligibility screen	X					
Informed consent	X					
Allocation		X				
Interventions:						
Paper only exercises		◆—	—◆	◆	◆	
Paper plus video exercises		◆—	—◆	◆	◆	
Assessments:						
Demographic data	X					
Pain intensity	X			X	X	X
SPADI	X			X	X	X
Expectations	X	X	X	X		
Satisfaction				X		X
PGI-I				X	X	X
SUS					X	
Animations' usefulness					X	
Adherence			X	X	X	X

Abbreviations: SPADI, Shoulder Pain and Disability Index; PGI-I, Patient Global Impression of Improvement; SUS, System Usability Scale.

2.2. Randomization and allocation

The randomization procedure was conducted with a 1:1 allocation ratio using the software Epidat v4.2 (Xunta de Galicia, Spain), by a statistician not involved in other study labors. Allocation concealment will be achieved using sequentially numbered opaque envelopes.

2.3. Blinding

Investigators who will recruit subjects will be blinded to group allocation. Evaluators, therapists, and patients will not be blinded to group allocation.

2.4. Recruitment, inclusion and exclusion criteria

Subjects' recruitment will be conducted by three rehabilitative physicians who will be unaware of treatment allocation. The recruitment process will be carried out in Hospital Universitario Fundación Alcorcon. All patients attending consult with shoulder pain from non-traumatic origin will be evaluated for their inclusion in the study. The recruitment started on April 7th, 2023, and the estimated study completion date is expected to be on 1st December, 2024.

The inclusion and exclusion criteria were based on a previously published systematic review.[31] To be included the subjects must meet the following inclusion criteria:

- Age between 18 and 80 years old.
- Presence of rotator cuff related shoulder pain, diagnosed as unilateral shoulder pain, located in the anterior and/or lateral deltoid region, which is reproduced by active elevation and/or lying on ipsilateral side, and with the following orthopaedic tests: Neer, Hawkins-Kennedy and/or empty can).

- Pain lasting from at least 3-months.
- Pain intensity at rest, during movement, and sleeping ≥ 3/10 points on a numeric pain rating scale.
- To have a mobile phone, tablet, or computer with internet connection.
- To understand written and spoken Spanish language.

Furthermore, the subjects will not have to present with the following exclusion criteria:

- History of major trauma or surgery on the shoulder, elbow, or cervical spine.
- Signs of other shoulder pathologies such as instability, frozen shoulder, calcific tendonitis, severe arthrosis, or neuralgic amyotrophy.
- Presence of full-thickness rotator cuff tears on ultrasound imaging.
- Signs and/or symptoms of neck-related shoulder pain and/or radiculopathy or radicular pain.
- Systemic diseases such as cancer, rheumatic disorders, sclerosis multiple, neurological disorders, etc.
- Severe psychiatric disorders.

2.5. Sample size

The sample size calculation was conducted using the '*MBESS'* package[32] of the software R v4.1.0 and was based on the precision of the adjusted between-group mean difference in SPADI at 3-month follow-up, from an analysis of covariance (ANCOVA) including baseline measure as a covariate. According to the results of previous publications, an equal standard deviation (SD) of 25 points was considered for both groups.[33] It was assumed a 1:1 allocation ratio, and a

correlation of 0.50 between repeated measures.[34] A 95% confidence interval (CI) width of 16 was considered acceptable because the smallest value of the minimum clinically important difference reported in literature for SPADI is 8 points.[35] The estimated sample size was 112 subjects. Assuming a 15% drop-out rate, the final sample size was composed of 132 subjects (66 per group).

2.6. Interventions

The interventions will be carried out by two physical therapists in Hospital Universitario Fundación Alcorcon. Both groups will receive five face-to-face sessions (half an hour each) every other day along three-weeks. After that, all patients will receive two additional face-to-face sessions to review the exercises, and to update the dosage of exercise load, at 6-week and 12-week follow-ups.

2.6.1. Exercise programs

All the subjects will receive printed exercises with pictures and an explanatory text, but subjects in experimental group will also be provided access to a webpage with self-explanatory videos of the prescribed exercises. The description of the web application is presented in Supplementary Material 2, and the didactic methodology implemented within the videos is presented in Supplementary Material 3.

Clear documentation of the exercise programs implemented within research is crucial for improving reproducibility between studies, and for the clinicians to be able to implement the results of research into their clinical practice. For this reason, the Consensus on Exercise Reporting Template (CERT) was proposed in 2016.[36] This template is composed of different domains that every study including exercise interventions should report. In aim to improve these aspects,

a detailed description of the exercise programs is presented in Supplementary Material 4, and the description of each of the CERT domains is presented in Supplementary Material 5.

2.6.2. Patient's education

Patients will be provided with education about their shoulder disorder throughout all treatment sessions. They will be given explanations about their shoulder pain, the importance of therapeutic exercise in its management, and some recommendations for daily living activities. Furthermore, they will be provided with a document with some information about rotator cuff tendinopathy and the importance of exercise at the beginning of the treatment (Supplementary Material 6).

2.6.3. Analgesic co-adjuvants

Patients will be provided with hot/cold packs, and/or well as analgesic drugs if needed at the beginning of the treatment, only when pain intensity makes it impossible to start with the exercise programs. The use of any co-adjuvant therapy will be registered and reported in the final publication of the clinical trial.

2.7. Measurements

All the measurements will be conducted in Hospital Universitario Fundación Alcorcón. The rehabilitative physicians in charge of enrolling patients will collect demographic data, and baseline and 24-week follow-up outcome measures. The outcome measures at 3-week, 6-week, and 12-week follow-ups will be collected by the physiotherapists who will guide the therapeutic exercise programs. The full measurement schedule is presented in **TABLE 1.** Adverse events will be registered in the patients' clinical history.

All patients will receive and sign an informed consent before any enrolling the study (Supplementary Material 7). The following demographic data will be collected: age, height, weight, body mass index, sex, dominant side, painful side, and time with shoulder pain. The main outcome measure will be shoulder pain-related disability. On the other hand, the secondary outcome measures will be: pain intensity at rest, during movement, and at night; patient's global impression of improvement, expectations, satisfaction, and perceived usability and usefulness of the multimedia animations. In the original protocol, we aimed to measure patient's ability to adequately perform the prescribed exercises as a secondary outcome, but later it was decided not to measure this variable because of the lack of valid and reliable tools to do so in the hospital setting.

2.7.1. Shoulder pain-related disability

The primary outcome measure will be shoulder pain-related disability measured with the Shoulder Pain and Disability Index (SPADI). This questionnaire is composed of 13 items, each rating from zero to ten, with the overall questionnaire ranging from 0% (minimum degree of disability) to 100% (maximum degree of disability). The transcultural adaptation of the SPADI from English to Spanish language was conducted in 2015,[37] showing good internal consistency (α = 0.86 and 0.916), good reliability (ICC = 0.91), and good construct validity (r = 040 to 0.80).

2.7.2. Pain intensity

Pain intensity at rest, during movement, and at night will be measured with an 11-point numeric pain rating scale (NPRS), which ranges from zero (no pain) to ten

(worst pain imaginable). The NPRS has showed good levels of reliability (r = 0.95), and good levels of construct validity (r = 0.86 to 0.95).[38]

2.7.3. Patient's expectations and satisfaction

Patient's expectations and satisfaction with received treatment will be measured using an 11-point numeric rating scale, ranging from zero ("no expectation of improvement" / "not at all satisfied with the treatment received") to ten ("full recovery expectation" / "fully satisfied with the treatment received").

2.7.4. Patient's impression of improvement

Patient's impression of improvement will be measured with the Patient Global Impression of Improvement (PGI-I) scale. The PGI-I is a seven-point ordinal scale ranging from 1 (very much better), through 4 (no change), to 7 (very much better).

2.7.5. Patient's adherence to the exercise program

Patient's home adherence to the prescribed exercises will be measured with self-registered calendars, as the percentage of days performing the exercises at home over the maximum days available between the first physical therapy session and the last follow-up.

2.7.6. Patient's perceived usability and usefulness of multimedia animations.

Patient's perceptions on the usability of the multimedia animations will be measured at 12-week follow-up, with the System Usability Scale (SUS),[39] which is composed of 10 items that are rated in a 5-point Likert-type scale from 1 (strongly disagree) to 5 (strongly agree), with an overall rating ranging from 0% of perceived usability to 100% of perceived usability.

Finally, patient's perceived usefulness of multimedia animations will be measured at 12-week follow-up, with a 5-point Likert-type scale, which ranges from 1 (strongly disagree) to 5 (strongly agree).

2.8. Data analysis

Data distribution of quantitative variables will be evaluated with visual inspection of histograms, and Q-Q plots, as well as kurtosis and skewness measures. For the descriptive analysis of quantitative variables, the mean, standard deviation, median, 1st and 3rd quartiles, and range will be reported. For categorical variables, absolute frequencies and percentages will be reported.

The analysis of between-group differences on quantitative outcome measures will be conducted using a generalized least squares model fitted by restricted maximum likelihood, using the R package *'rms'* (Frank E Harrell Jr, 2022). Measurement at baseline will be included as a covariate to obtain adjusted between-group mean differences. Time (6-week, 12-week, and 24-week) will be modeled using a linear spline with one knot (since there is only one unique internal value within time variable), and assuming an autoregressive-moving average lag 1 (AR1) correlation structure. *Post hoc* pairwise comparisons will be controlled for familywise error rate using Bonferroni's correction. The variograms, and residual plots (by group will be reported for each model. If any quantitative variable doesn't accomplish the needed assumptions, robust analogous methods will be used instead.[40]

For ordinal variables, a rank-based between-by-within analysis will be conducted, following the approach of Brunner, Domhof, and Langer (2002). Post hoc pairwise

comparisons will be conducted controlling familywise error rate using Rom's method of the Benjamini-Hochberg method.[40]

Reasons for missing data will be reported, as well as a missing data map. Furthermore, the relationship between missingness and any measured variable at baseline will be analyzed using a logistic regression model. Multiple imputation (5 to 20 imputations) will be performed if data seems to be missing at random or completely at random. On the other hand, if there seems to be a relationship between baseline variables and missingness, multiple imputation along with sensitivity analyses using worst-best case and best-worst case scenarios will be implemented. Finally, an intention-to-treat approach will be used.

All the analyses will be conducted using R software v4.1.0 (R Core Team (2021). R: A language and environment for statistical computing. R Foundation for Statistical Computing, Vienna, Austria. URL https://www.R-project.org/). An α level of 0.05 with 95% confidence intervals (CI) will be assumed for all analyses. All analyses will be conducted blinded to group allocation, and a blinded interpretation of the results will be published in the final article as supplementary material.

2.9. Data management

All data collected during the study schedule will be kept under lock and key in the office of the principal investigating physician. Personal data will not be included within the outcome measures of the participants. The list of participants ID number with name and contact information will be kept in an Excel document in the computer of the three physicians who will be recruiting subjects within the hospital security system. This file will not be moved to any other computer at any

time. All data will be managed according to the Law on the Protection of Personal Data (LOPD) 3/2018, of December 5 (Spain).

2.10. Patient and public involvement

None.

3. ETHICS AND DISSEMINATION

The protocol of this randomized controlled trial has been reviewed and approved by the ethics committee of Hospital Universitario Fundación Alcorcón (Madrid, Spain), with reference number CI18/16, and it was registered in ClinicalTrials.gov (NCT05770908). The study will be conducted according to the Declaration of Helsinki. All participants will sign an informed consent before participating in the study. The results of this study will be published in a peer-reviewed scientific journal.

AUTHORS' CONTRIBUTIONS

Design of the study: IPP, MTFG, FGP, MAPM, AAN, AUG, EPF, CFL, GPM, and MVA. Statistical analysis plan: EPF, and RFM. Writing the protocol manuscript: IPP, MTFG, FGP, and RFM. All authors have read and approved the final manuscript.

FUNDING STATEMENT

This study, with grant number PI19/01490, was funded by the Instituto de Salud Carlos III (ISCIII) from Spain, and cofounded by the European Union.

COMPETING INTEREST STATEMENT

The authors declare no conflict of interest.

ACKNOWLEDGEMENTS

The authors would like to thank all the people who supported them while conducting this research, specially their colleagues at Hospital Universitario Fundación Alcorcón.

4. REFERENCES

1 Haas R, Gorelik A, Busija L, *et al.* Prevalence and characteristics of musculoskeletal complaints in primary care: an analysis from the population level and analysis reporting (POLAR) database. *BMC Prim care* 2023;**24**. doi:10.1186/S12875-023-01976-Z

2 Luime JJ, Koes BW, Hendriksen IJM, *et al.* Prevalence and incidence of shoulder pain in the general population; a systematic review. *Scand J Rheumatol* 2004;**33**:73–81. doi:10.1080/03009740310004667

3 Littlewood C, May S, Walters S. Epidemiology of Rotator Cuff Tendinopathy: A Systematic Review. *Shoulder Elb* 2013;**5**:256–65. doi:10.1111/sae.12028

4 Linsell L, Dawson J, Zondervan K, *et al.* Prevalence and incidence of adults consulting for shoulder conditions in UK primary care; patterns of diagnosis and referral. *Rheumatology* 2006;**45**:215–21. doi:10.1093/rheumatology/kei139

5 Hwang Y, Oh J. The relationship between shoulder pain and shoulder disability in women: The mediating role of sleep quality and psychological disorders. *Medicine (Baltimore)* 2022;**101**:E31118. doi:10.1097/MD.0000000000031118

6 Clausen M, Nielsen M, Merrild M, *et al.* High incidence of lost workdays in patients with subacromial impingement syndrome. *Dan Med J* 2021;**68**:A07200496.

7 Horowitz EH, Aibinder WR. Shoulder Impingement Syndrome. *Phys Med*

Rehabil Clin N Am 2023;**34**:311–34. doi:10.1016/J.PMR.2022.12.001

8 Witten A, Mikkelsen K, Wagenblast Mayntzhusen T, *et al.* Terminology and diagnostic criteria used in studies investigating patients with subacromial pain syndrome from 1972 to 2019: a scoping review. *Br J Sports Med* 2023;**57**:864–71. doi:10.1136/BJSPORTS-2022-106340

9 Vandvik PO, Lähdeoja T, Ardern C, *et al.* Subacromial decompression surgery for adults with shoulder pain: a clinical practice guideline. *BMJ* 2019;**364**:l294–l294. doi:10.1136/bmj.l294

10 Lowry V, Lavigne P, Zidarov D, *et al.* A Systematic Review of Clinical Practice Guidelines on the Diagnosis and Management of Various Shoulder Disorders. *Arch Phys Med Rehabil* 2023;**105**:411–26. doi:10.1016/J.APMR.2023.09.022

11 Lafrance S, Charron M, Roy JS, *et al.* Diagnosing, Managing, and Supporting Return to Work of Adults With Rotator Cuff Disorders: A Clinical Practice Guideline. *J Orthop Sports Phys Ther* 2022;**52**:647–64. doi:10.2519/JOSPT.2022.11306

12 Naunton J, Street G, Littlewood C, *et al.* Effectiveness of progressive and resisted and non-progressive or non-resisted exercise in rotator cuff related shoulder pain: a systematic review and meta-analysis of randomized controlled trials. *Clin Rehabil* 2020;**34**:1198–216. doi:10.1177/0269215520934147

13 Dominguez-Romero JG, Jiménez-Rejano JJ, Ridao-Fernández C, *et al.* Exercise-Based Muscle Development Programmes and Their Effectiveness in the Functional Recovery of Rotator Cuff Tendinopathy: A

Systematic Review. *Diagnostics (Basel, Switzerland)* 2021;**11**. doi:10.3390/DIAGNOSTICS11030529

14 McConnell R, Klopper M, Rhon DI, *et al.* The influence of exercise therapy dosing on pain and functional outcomes in patients with subacromial pain syndrome: A systematic review. *Shoulder Elb* Published Online First: 13 September 2022. doi:10.1177/17585732221124303

15 Medeiros de-Queiroz JH, De-Medeiros MB, De-Lima RN, *et al.* Exercise for rotator cuff tendinopathy. *Rev Bras Med Trab* 2023;**20**:498–504. doi:10.47626/1679-4435-2022-698

16 Shim J, Pavlova A V., Moss RA, *et al.* Patient ratings in exercise therapy for the management of tendinopathy: a systematic review with meta-analysis. *Physiotherapy* 2023;**120**:78–94. doi:10.1016/J.PHYSIO.2023.05.002

17 Powell JK, Schram B, Lewis J, *et al.* Physiotherapists nearly always prescribe exercise for rotator cuff-related shoulder pain; but why? A cross-sectional international survey of physiotherapists. *Musculoskeletal Care* 2023;**21**:253–63. doi:10.1002/MSC.1699

18 Powell JK, Schram B, Lewis J, *et al.* 'You have (rotator cuff related) shoulder pain, and to treat it, I recommend exercise.' A scoping review of the possible mechanisms underpinning exercise therapy. *Musculoskelet Sci Pract* 2022;**62**. doi:10.1016/J.MSKSP.2022.102646

19 Dickson C, de Zoete RMJ, Berryman C, *et al.* Patient-related barriers and enablers to the implementation of high-value physiotherapy for chronic pain: a systematic review. *Pain Med* 2023;**25**:104–15.

doi:10.1093/PM/PNAD134

20 O'Shea A, Drennan J, Littlewood C, *et al.* Barriers and facilitators related to self-management of shoulderpain: a systematic review and qualitative synthesis. *Clin Rehabil* 2022;**36**:1539. doi:10.1177/02692155221108553

21 Major DH, Røe Y, Grotle M, *et al.* Content reporting of exercise interventions in rotator cuff disease trials: results from application of the Consensus on Exercise Reporting Template (CERT). *BMJ Open Sport Exerc Med* 2019;**5**:e000656. doi:10.1136/BMJSEM-2019-000656

22 Kucksdorf JJ, Bartley J, Rhon DI, *et al.* Reproducibility of Exercise Interventions in Randomized Controlled Trials for the Treatment of Rotator Cuff-Related Shoulder Pain: A Systematic Review. *Arch Phys Med Rehabil* 2023;:S0003-9993(23)00531-2. doi:10.1016/J.APMR.2023.09.007

23 Pieters L, Lewis J, Kuppens K, *et al.* An Update of Systematic Reviews Examining the Effectiveness of Conservative Physical Therapy Interventions for Subacromial Shoulder Pain. *J Orthop Sport Phys Ther* 2020;**50**:131–41. doi:10.2519/jospt.2020.8498

24 Burns D, Boyer P, Razmjou H, *et al.* Adherence Patterns and Dose Response of Physiotherapy for Rotator Cuff Pathology: Longitudinal Cohort Study. *JMIR Rehabil Assist Technol* 2021;**8**. doi:10.2196/21374

25 Emmerson KB, Harding KE, Taylor NF. Providing exercise instructions using multimedia may improve adherence but not patient outcomes: a systematic review and meta-analysis. *Clin Rehabil* 2019;**33**:607–18. doi:10.1177/0269215518819706

26 Kingston G, Gray MA, Williams G. A critical review of the evidence on the use of videotapes or DVD to promote patient compliance with home programmes. *Disabil Rehabil Assist Technol* 2010;**5**:153–63. doi:10.3109/17483101003671709

27 Davergne T, Meidinger P, Dechartres A, *et al.* The Effectiveness of Digital Apps Providing Personalized Exercise Videos: Systematic Review With Meta-Analysis. *J Med Internet Res* 2023;**25**. doi:10.2196/45207

28 Park KH, Song MR. Development of a Web Exercise Video for Patients With Shoulder Problems. *Comput Inform Nurs* 2017;**35**:255–61. doi:10.1097/CIN.0000000000000303

29 Rizzato A, Pizzichemi M, Gobbi E, *et al.* Effectiveness and therapeutic compliance of digital therapy in shoulder rehabilitation: a randomized controlled trial. *J Neuroeng Rehabil* 2023;**20**. doi:10.1186/S12984-023-01188-7

30 Chan AW, Tetzlaff JM, Altman DG, *et al.* SPIRIT 2013 statement: defining standard protocol items for clinical trials. *Ann Intern Med* 2013;**158**:200–7. doi:10.7326/0003-4819-158-3-201302050-00583

31 Watts AR, Williams B, Kim SW, *et al.* Shoulder impingement syndrome: a systematic review of clinical trial participant selection criteria. *Shoulder Elb* 2017;**9**:31–41. doi:10.1177/1758573216663201

32 Lai K, Kelley K. Accuracy in parameter estimation for ANCOVA and ANOVA contrasts: sample size planning via narrow confidence intervals. *Br J Math Stat Psychol* 2012;**65**:350–70. doi:10.1111/J.2044-8317.2011.02029.X

33 Hopewell S, Keene DJ, Marian IR, *et al.* Progressive exercise compared with best practice advice, with or without corticosteroid injection, for the treatment of patients with rotator cuff disorders (GRASP): a multicentre, pragmatic, 2 × 2 factorial, randomised controlled trial. *Lancet* 2021;**398**:416–28. doi:10.1016/S0140-6736(21)00846-1

34 Walters SJ, Jacques RM, Henriques-Cadby IBDA, *et al.* Sample size estimation for randomised controlled trials with repeated assessment of patient-reported outcomes: what correlation between baseline and follow-up outcomes should we assume? *Trials* 2019;**20**:566. doi:10.1186/S13063-019-3671-2

35 Dabija DI, Jain NB. Minimal Clinically Important Difference of Shoulder Outcome Measures and Diagnoses: A Systematic Review. *Am J Phys Med Rehabil* 2019;**98**:671–6. doi:10.1097/PHM.0000000000001169

36 Slade SC, Dionne CE, Underwood M, *et al.* Consensus on Exercise Reporting Template (CERT): Explanation and Elaboration Statement. *Br J Sports Med* 2016;**50**:1428–37. doi:10.1136/bjsports-2016-096651

37 Membrilla-Mesa MD, Cuesta-Vargas AI, Pozuelo-Calvo R, *et al.* Shoulder pain and disability index: Cross cultural validation and evaluation of psychometric properties of the Spanish version. *Health Qual Life Outcomes* 2015;**13**:200. doi:10.1186/s12955-015-0397-z

38 Hawker GA, Mian S, Kendzerska T, *et al.* Measures of adult pain: Visual Analog Scale for Pain (VAS Pain), Numeric Rating Scale for Pain (NRS Pain), McGill Pain Questionnaire (MPQ), Short-Form McGill Pain Questionnaire (SF-MPQ), Chronic Pain Grade Scale (CPGS), Short

Form-36 Bodily Pain Scale (SF. *Arthritis Care Res (Hoboken)* 2011;**63**:S240-52. doi:10.1002/acr.20543

39 Del Rocio Sevilla-Gonzalez M, Loaeza LM, Lazaro-Carrera LS, *et al.* Spanish Version of the System Usability Scale for the Assessment of Electronic Tools: Development and Validation. *JMIR Hum factors* 2020;**7**:e21161. doi:10.2196/21161

40 Wilcox RR. *Introduction to robust estimation and hypothesis testing*. 3. ed. Amsterdam [u.a.]: : Elsevier, AP 2012.

SUPPLEMENTARY MATERIAL 1

SPIRIT

STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item	Description	Manuscript section
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	Title page
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	Ethics and dissemination
	2b	All items from the World Health Organization Trial Registration Data Set	Ethics and dissemination
Protocol version	3	Date and version identifier	NA
Funding	4	Sources and types of financial, material, and other support	Funding statement
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	Title page
	5b	Name and contact information for the trial sponsor	Title page
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	NA

	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	Author's contributions
Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	Introduction
	6b	Explanation for choice of comparators	Introduction
Objectives	7	Specific objectives or hypotheses	Introduction
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	Introduction
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	Design and setting
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	Recruitment, inclusion, and exclusion criteria
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	Interventions

	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	Analgesic co-adjuvants
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	Patient's education, patient's adherence to the exercise program, and supplementary material
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	Analgesic co-adjuvants
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	Measurements
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	Table 1
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	Sample size
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	Recruitment, inclusion, and exclusion criteria

Methods: Assignment of interventions (for controlled trials)

Allocation:

Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	Randomization, and allocation
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	Randomization, and allocation
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	Randomization, and allocation
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	Blinding
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	NA
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	Measurements
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	NA

Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	Data management
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	Data analysis
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	Data analysis
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	Data analysis
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	NA
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	NA
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	Analgesic co-adjuvants
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	NA
Ethics and dissemination			

Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	Ethics and dissemination
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	NA
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	Measurements
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	NA
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	Data management
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	Funding statement, and competing interest statement
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	NA
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	NA
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	NA
	31b	Authorship eligibility guidelines and any intended use of professional writers	NA

	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	NA
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	Supplementary Material
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	NA

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation and Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

SUPPLEMENTARY MATERIAL 2

Description of the web application

The exercise application is a web-based video library hosted on a server connected to the Internet. There are two versions of the web application. The first version (hosted in http://rhbhombro.com/profesional) is aimed at health professionals, and it allows for personalization of the specific exercises to include in each program for a particular patient. The second version (hosted in http://rhbhombro.com/) is a reduced version that contains predefined exercise programs for the treatment of rotator cuff tendinopathy, supraspinatus tears, massive rotator cuff tears, and frozen shoulder. For this randomized controlled trial, six predefined programs for rotator cuff tendinopathy, contained in the second reduced version of the web application, will be used. All the videos and the information contained in the application are on Spanish language.

Software development

The web application has been developed with PHP 7.2.2 programming language (http://php.net/releases/7_2_2.php) and a MVC (Model - View - Controller) infrastructure Laravel Framework 5.6.3 (http://laravel.com). Furthermore, it integrates the API of the professional streaming platform Vimeo (http://vimeo.com) that allows the distribution of videos to professionals and patients for different devices. The application is hosted on a VPS with Debian 8 (Jessie) (64 bits) with Apache 2.4.10 and MySql 14.14 database engine.

Selection of the exercises and design of the videos

First, a search was conducted in Medline/Pubmed, Cochrane, PEDRO, and AMED databases regarding published randomized controlled trials evaluating exercise programs for the management of each one of the four abovementioned disorders. The trials with the lowest risk of bias, and the greatest content reporting of the exercise programs were selected.

Second, a multidisciplinary consensus meeting was conducted to reach consensus, based on the published literature, on the specific exercises to include for the treatment of each pathology, as well as the prescription parameters. For this purpose, the following points were considered: 1) proven effectiveness and detailed description in low risk-of-bias randomized controlled trials; 2) recommendations for exercise prescription parameters of The American College of Sports Medicine; and 3) adaptation of the abovementioned

literature to the patients' profile seen at the hospital in which the web application was meant to be implemented.

Finally, the group of healthcare professionals collaborated with a team of graphic designers to create the animated videos of the selected exercises.

Web application features

Prescribe an exercise program, choosing from a series of previously designed exercises, depending on the pathology and clinical characteristics of the patient.

The healthcare professional can select the specific exercise to prescribe to a given patient using the first abovementioned version of the web application, or the select one of the predefined programs within the second version of the application, that can also be tailored to patients' clinical characteristics (Figure 1).

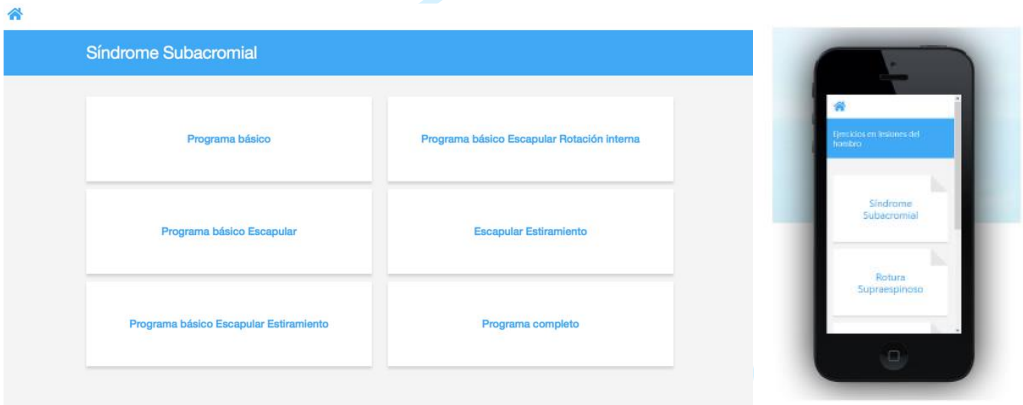


Figure 1. Screenshot of the web application. Left = laptop/tablet; right = smartphone.

For this randomized controlled trial, six predefined programs within the rotator cuff tendinopathy section of the second version of the web application will be used, namely: basic program, basic program plus scapular exercises, basic program plus scapular exercises and stretching, basic program plus scapular exercises and internal rotation, scapular exercise and stretching program, and full exercise program. Detailed description of the exercises are programs is presented in Supplementary Material 4.

View the videos included in the exercise program from different electronic devices (computer, tablet, or smartphone) without the need to install any specific software.

Each of the animated videos is composed of an animated person who performs the intended exercise, allowing the watcher to see the performance from different angles and planes. Furthermore, the video displays an audio-recorded explanation of the exercise performance, along with subtitles (Figure 2).

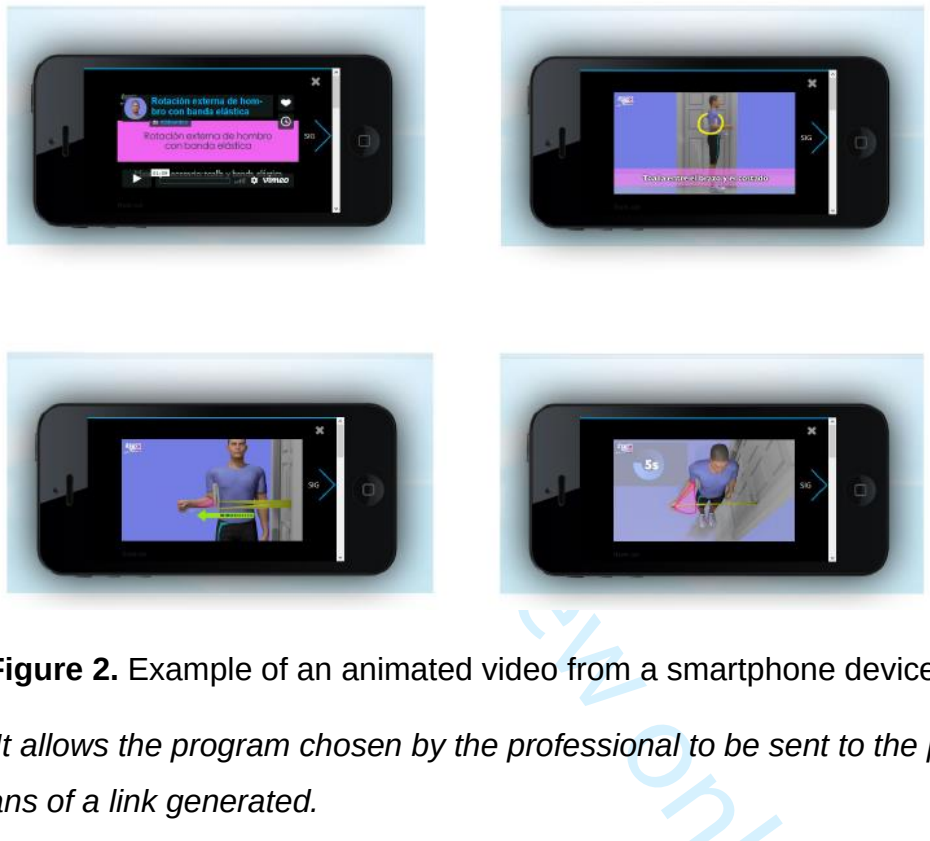


Figure 2. Example of an animated video from a smartphone device.

It allows the program chosen by the professional to be sent to the patient by means of a link generated.

The specific exercise program prescribed can be facilitated to the patient by means of a link generated, so the patient has only access to the prescribed exercises by the healthcare provider.

SUPPLEMENTARY MATERIAL 3

Didactic methodology of the exercise application

The 3D multimedia animations have been designed in an attempt to reduce the cognitive load (the amount of information that working memory cand hold at one time).[1] To this end, the technical aspects, the content and the form of instruction have been taken into account:[2]

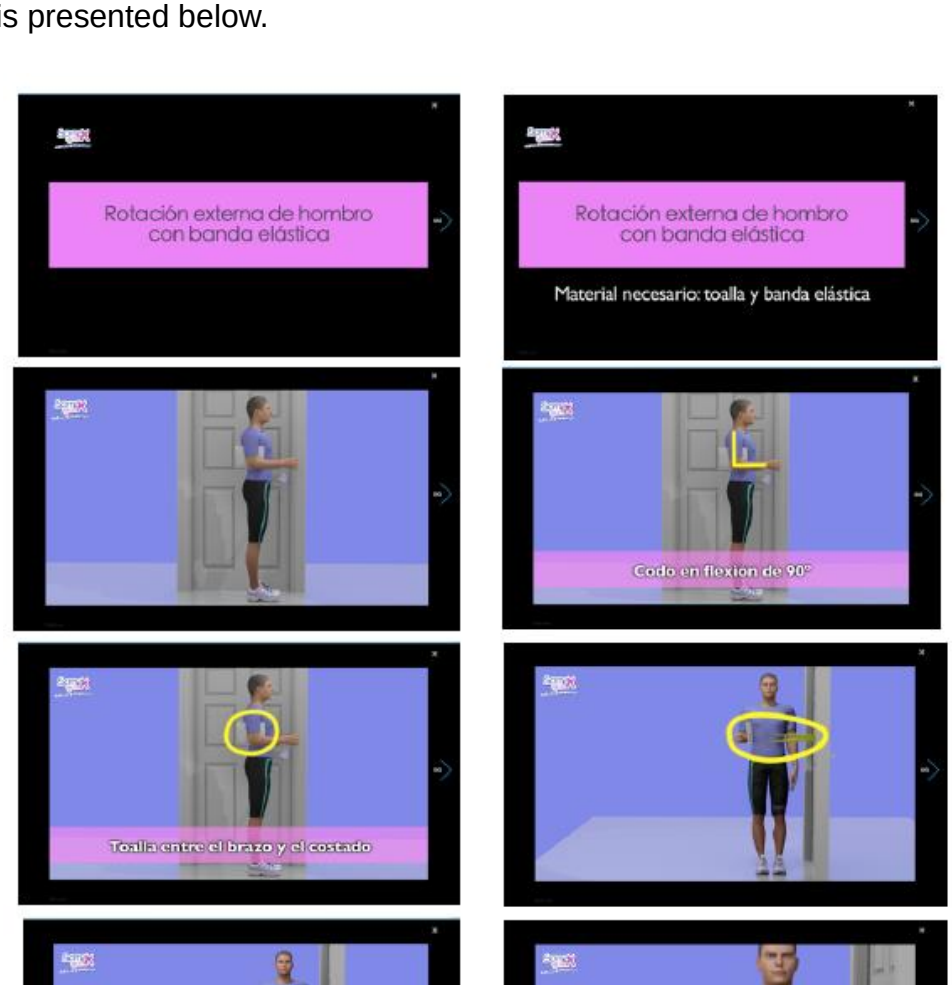
- **Technical aspects:** Visual quality, audio quality, coordination of audio and video, and use of graphic elements (arrows, position signs, time markers...) to highlight important information.
- **Content:** The instructional objective is explicit and clear. There is an explicit call to continued action teaching the way to progress.
- **Instructions:** The instructional techniques focus on patient engagement. The content is presented in an organized way. Short sequences of information are used to allow learners to engage. All extraneous information that doesn't contribute to the learning goal or help build relationships is eliminated.

The videos are 3D animations that allow to visualize an exercise from different perspectives, and are accompanied by audio, text, and animated graphic elements such as arrows, position signs, and time markers that facilitate the understanding and correct completion of the exercise. In addition, each exercise indicates the material necessary to perform it, the starting position, the correct way to do it, and the different parameters to consider (intensity, frequency and duration) and how to progress. Several aspects have been taken into account in the teaching methodology:

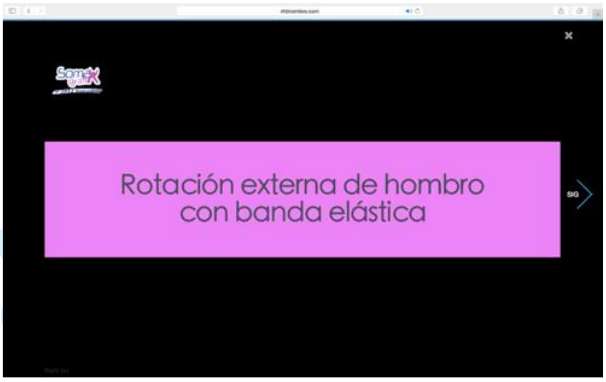
1. **Nomenclature of the exercise:** A short name is used to quickly identify the exercise to be performed.
2. **Necessary material:** Description, in the audio and in the text, of the material required to perform each exercise.
3. **Starting position:** Description and visualization from various perspectives of the initial position, which is considered adequate to begin the exercise. Position marks are used to facilitate this.
4. **Execution of the exercise:** Description of the correct way to perform the exercise. Arrows are introduced to mark the direction in which the movement should be performed, signs indicating the final position to be reached and a marker of the time to maintain this position.

Example of didactic methodology with one of the included exercises

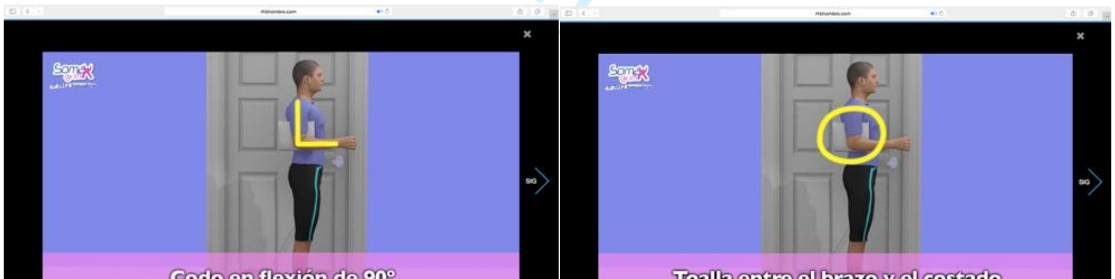
The whole video sequence of the shoulder external rotation exercise with elastic band is presented below.



The video begins by naming the exercise to be performed: external rotation of the shoulder with an elastic band. This allows the exercise to be easily identified, both by the professional who is going to teach it and by the patient who is going to do it.



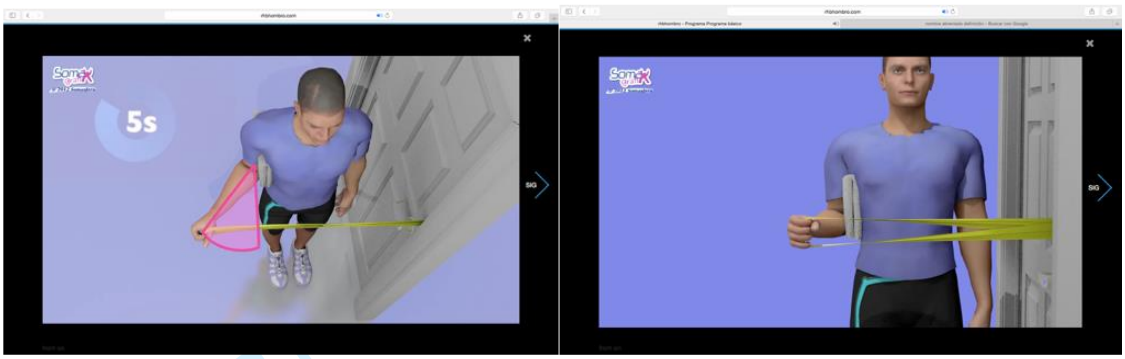
Next, the starting position is described, standing next to a door, with the elbow of the arm with which the exercise is to be performed in a 90° flexed position and placement of the folded towel between the elbow and the side. Several position and text marks are introduced to focus the patient's attention on those aspects that are a frequent source of error.



After this, a change of perspective is made so that the patient can visualize the starting position from another angle and the position of the elastic band with respect to the door (caught with the door or hooked to the door handle) and the hand holding the elastic band, which should be in slight tension, is specified.

The video goes on to specify the execution of the exercise, pulling the elastic band, making it taut to form an arc of about 45º and emphasizing not to move the rest of the body or allow the towel to fall to the floor. It is common to make the mistake of helping with the rest of the body to make the movement or separating the elbow from the body, so with these explanations we intend to reduce the possibility of such errors. An arrow marker is introduced for the direction of the movement and another for the magnitude of the arc of the movement to be performed.

Finally, the time to hold that final position is specified, 5 seconds and slowly return to the starting position.



REFERENCES

1 Castro-Alonso JC, de Koning BB, Fiorella L, *et al.* Five Strategies for Optimizing Instructional Materials: Instructor- and Learner-Managed Cognitive Load. *Educ Psychol Rev* 2021;**33**:1379–407. doi:10.1007/S10648-021-09606-9

2 Beemer LR, Tackett W, Schwartz A, *et al.* Use of a Novel Theory-Based Pragmatic Tool to Evaluate the Quality of Instructor-Led Exercise Videos to Promote Youth Physical Activity at Home: Preliminary Findings. *Int J Environ Res Public Health* 2023;**20**. doi:10.3390/IJERPH20166561

SUPPLEMENTARY MATERIAL 4

Description of the exercise programs

CRITERIA FOR THE ELABORATION OF THE EXERCISE PROGRAMS

Exercise is the fist-line treatment for patients with rotator cuff tendinopathy,[1] but there is no consensus on which program is the most appropriate.[2] The selection of the exercise programs was based on current research, and clinical knowledge of the research team.

The majority of the investigated programs include strengthening and stretching exercises of the rotator cuff and scapular muscles.[3] Some authors have suggested that scapular-focused exercises can add benefits to a rotator cuff strengthening exercises program at short term (i.e., 6-weeks), but not mid-term (i.e., 3-months) follow-up.[4] Furthermore, there seems to be no difference between concentric and eccentric exercises for the management of rotator cuff tendinopathy.[5]

There seems to be no differences between supervised and home-based exercise settings.[6]

Despite there is conflicting evidence regarding the value of high-load exercises compared to low-load ones,[7] it seems that load progression is a key factor within exercise programs.[6,8]

Pain intensity within exercise performance seems to be the best indicator when modulating load progression and regression.[9] Even though moderate or severe pain intensity during the performance of the exercise is not recommended, it seems that a slight-pain reproduction is not detrimental for its possible benefit.[6]

There is no consensus regarding optimal dosage for exercise programs. Some authors have proposed that three sets may be preferable to two or one set.[6]

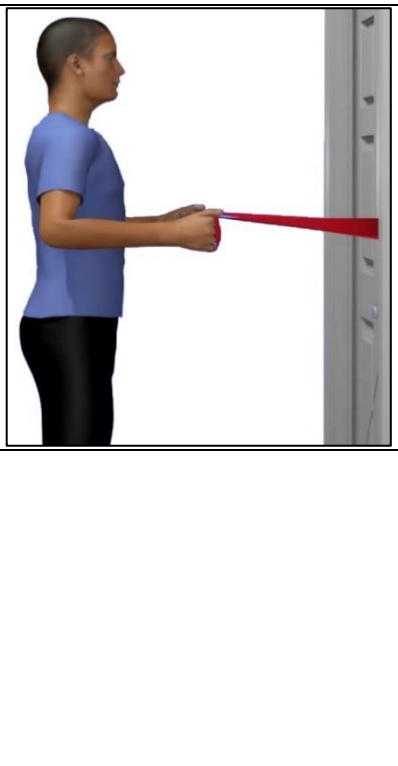
Finally, it is recommended that the exercise programs be maintained a minimum of three months.[6]

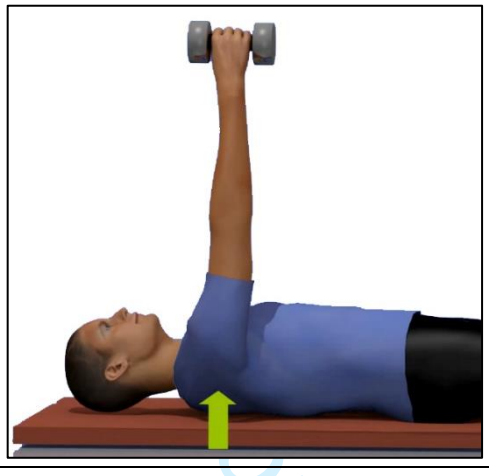
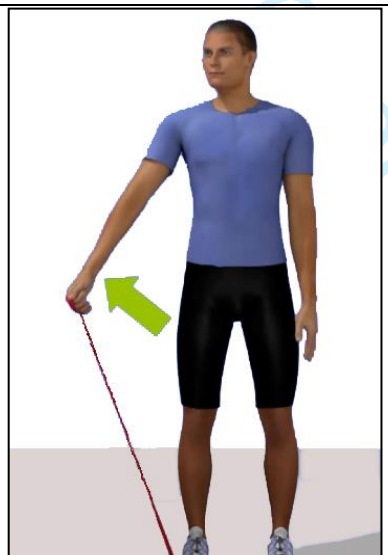
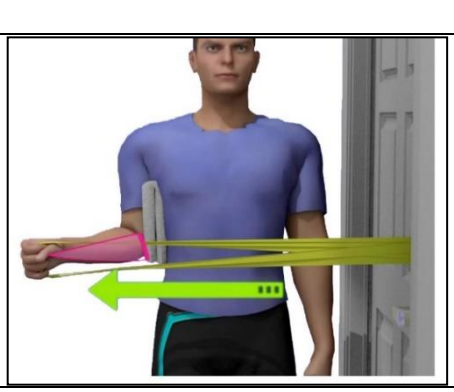
DETAILED DESCRIPTION OF THE EXERCISE PROGRAMS

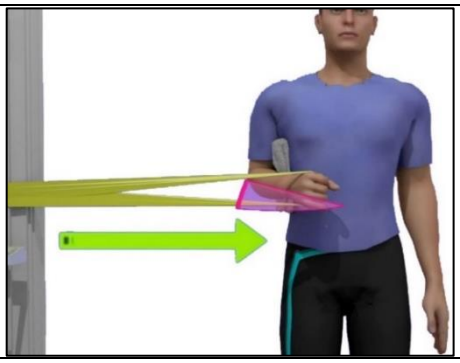
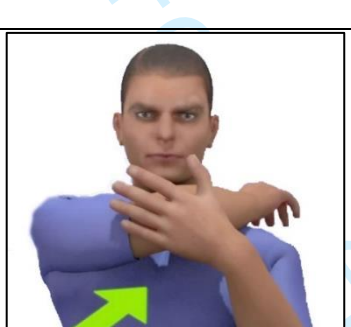
Six exercise programs were created based on the information provided above. The programs 1 (basic), 2 (basic plus scapular and internal rotation), and 3 (basic plus scapular) are aimed at patients no mobility limitation (strengthening exercises only). On the other hand, the programs 4 (scapular and stretching), 5 (basic plus scapular and stretching), and 6 (complete) are aimed at patients with limited mobility. The exercises included within each program are presented in the following table:

Exercises	Program					
	1	2	3	4	5	6
Horizontal row		X	X	X	X	X
Supine scapular protraction		X	X	X	X	X
Scaption	X	X	X		X	X
External rotation	X	X	X		X	X
Internal rotation		X				X
Posterior capsule stretching				X	X	X

The included exercises are as follows:

HORIZONTAL ROW	
	Arms with elbows bent at 90º. Pull the band with your hands making it tense, bringing the elbows and hands backwards, bringing the shoulder blades together. Hold for 5 seconds and return to starting position.

SUPINE SCAPULAR PROTRACTION	
	Shoulder elevated at 90º, and elbow extended holding a weight with the hand. Raise the weight while keeping the arm vertical. Hold the position for 5 seconds and return to the starting position.
SCAPTION	
	Slowly separate the arm upwards pulling the band without getting the arm horizontal. Hold for 5 seconds and return to the starting position.
EXTERNAL ROTATION	
	With a towel between the body and the arm and the elbow flexed 90º. Pull the band outwards about 45º. Hold for 5 seconds and return to the starting position.

INTERNAL ROTATION	
	With a towel between the body and the arm and the elbow flexed 90º. Pull the band inward about 45º. Hold for 5 seconds and return to the starting position.
POSTERIOR CAPSULE STRETCHING	
	Perform a 90º flexion of the shoulder and place the hand of the affected side over the healthy shoulder. With the other hand push the elbow backwards.

The detailed description of each exercise that was provided to the patient is as follows:

HORIZONTAL ROW

- You need an elastic band to perform this exercise.
- The starting position is standing/sitting in front of a closed door, with an elastic band hooked to the door handle.
- The arms should be about 45° away from the trunk and the elbows are kept bent at 90°.
- The band and forearms should be parallel to the floor.
- The spine must be kept straight during the performance of the exercise.
- To perform the exercise, pull the elastic band with your hands making it taut, bringing the elbows and hands backwards, bringing the shoulder blades together.
- Hold this position for 5 seconds and slowly return to the starting position.

SUPINE SCAPULAR PROTRACTION

- You need a dumbbell to perform this exercise.
- The starting position is lying on the floor face up. If you are more comfortable, you can place a cushion under your head.
- The arm with which the exercise is going to be performed remains perpendicular to the floor, with the elbow stretched out, while holding a dumbbell in your hand.
- The spine shouldn't be twisted during the performance of the exercise.
- To perform the exercise, take your shoulder off the floor by bringing your arm upwards, holding the weight towards the ceiling.
- Hold this position for 5 seconds and slowly return to the starting position.

SCAPTION

- You need an elastic band to perform this exercise.
- The starting position is standing facing forward with legs slightly apart, arms straight and relaxed along the body.
- One end of the band should be stepped on with the foot, and the other grasped with the hand of the symptomatic arm.
- The band should be slightly taut.
- The spine must be kept straight during the performance of the exercise.
- To perform the exercise the entire arm should be slowly pulled upward by pulling the band up to 30-40 degrees of elevation in the scapular plane.
- During the performance of the exercise, the elbow should be kept straight, the body shouldn't be rotated, and the shoulder shouldn't be shrugged.
- Hold this position for 5 seconds and slowly return to the starting position.

EXTERNAL ROTATION

- You need an elastic band and a towel to perform this exercise.
- The elastic band is attached to a door handle, and you must stand next to it.

- The elbow should be in 90º flexion forming a right angle, holding the towel between the elbow and the body.
- To perform the exercise, pull the elastic band outwards by about 45º of external rotation, making it taut without dropping the towel.
- The rest of the body should not move during the performance of the exercise.
- Hold this position for 5 seconds and slowly return to the starting position.

INTERNAL ROTATION

- You need an elastic band and a towel to perform this exercise.
- The elastic band is attached to a door handle, and you must stand next to it.
- The elbow should be in 90º flexion forming a right angle, holding the towel between the elbow and the body.
- To perform the exercise, pull the elastic band inward by about 45º of internal rotation, making it taut without dropping the towel.
- The rest of the body should not move during the performance of the exercise.
- Hold this position for 5 seconds and slowly return to the starting position.

POSTERIOR CAPSULE STRETCHING

- The starting position is standing.
- The palm of the hand of the side to be stretched is placed on top of the other shoulder, and the hand of the side that is to assist the stretch is placed resting on the opposite elbow.
- To perform the exercise, direct the elbow toward the opposite shoulder while your hand slides lightly down the back of the shoulder. Try to increase the movement by pushing slowly with the other hand on the elbow, without rotating the trunk.
- Hold this position for 20 seconds and slowly return to the starting position.

REFERENCES

1. Hanratty CE, McVeigh JG, Kerr DP, et al. The Effectiveness of Physiotherapy Exercises in Subacromial Impingement Syndrome: A Systematic Review and Meta-Analysis. *Semin Arthritis Rheum* 2012; 42: 297–316.

2. Dominguez-Romero JG, Jiménez-Rejano JJ, Ridao-Fernández C, et al. Exercise-Based Muscle Development Programmes and Their Effectiveness in the Functional Recovery of Rotator Cuff Tendinopathy: A Systematic Review. *Diagnostics (Basel, Switzerland)*; 11. Epub ahead of print 1 March 2021. DOI: 10.3390/DIAGNOSTICS11030529.

3. Gutiérrez-Espinoza H, Araya-Quintanilla F, Cereceda-Muriel C, et al. Effect of supervised physiotherapy versus home exercise program in patients with subacromial impingement syndrome: A systematic review and meta-analysis. *Physical Therapy in Sport* 2020; 41: 34–42.

4. Bury J, West M, Chamorro-Moriana G, et al. Effectiveness of scapula-focused approaches in patients with rotator cuff related shoulder pain: A systematic review and meta-analysis. *Man Ther* 2016; 25: 35–42.

5. Camargo PR, Alburquerque-Sendin F, Salvini TF. Eccentric training as a new approach for rotator cuff tendinopathy: Review and perspectives. *WORLD J Orthop* 2014; 5: 634–644.

6. Littlewood C, Malliaras P, Chance-Larsen K. Therapeutic Exercise for rotator cuff tendinopathy: A systematic review of contextual factors and prescription parameters. *Int J Rehabil Res* 2015; 38: 95–106.

7. Malliaras P, Johnston R, Street G, et al. The Efficacy of Higher Versus Lower Dose Exercise in Rotator Cuff Tendinopathy: A Systematic Review of Randomized Controlled Trials. *Arch Phys Med Rehabil* 2020; 101: 1822–1834.

8. Naunton J, Street G, Littlewood C, et al. Effectiveness of progressive and resisted and non-progressive or non-resisted exercise in rotator cuff related shoulder pain: a systematic review and meta-analysis of randomized controlled trials. *https://doi.org/101177/0269215520934147*

2020; 34: 1198–1216.

9. Ortega-Castillo M, Cuesta-Vargas A, Luque-Teba A, et al. The role of progressive, therapeutic exercise in the management of upper limb tendinopathies: A systematic review and meta-analysis. *Musculoskelet Sci Pract*; 62. Epub ahead of print 1 December 2022. DOI: 10.1016/J.MSKSP.2022.102645.

SUPPLEMENTARY MATERIAL 5

Consensus on Exercise Reporting Template (CERT)

Item 1: Detailed description of the type of exercise equipment

The needed equipment to perform the exercises are:

- Elastic bands (Thera-Band®) with a length of 155cm and a width of 14.5cm. There are six type of bands which, in order from least to most resistant, are as follows: yellow, red, green, blue, black, and silver.[1]
- Dumbbells with varying weights from 1kg to 4kg.
- Small size towel.

1. Uchida MC, Nishida MM, Sampaio RAC, et al. Thera-band® elastic band tension: reference values for physicalactivity. *J Phys Ther Sci* 2016; 28: 1266.

Item 2: Detailed descriptions of the qualifications, teaching/supervising expertise and/or training undertaken by the exercise instructor

The exercise instructors will be two physical therapists working at the Hospital Universitario Fundación Alcorcón. They have 4 to 30 years of experience treating patients with musculoskeletal shoulder disorders using therapeutic exercise. All the therapists were provided with a teaching session for the instruction on the exercise program, in aim to standardize the explanations given to the patients, as well as criteria for load progression and regression.

Item 3: Describe whether the exercises are performed individually or in a group

All sessions that patients will receive at the hospital will be performed individually with a 30-minute duration. The patients will attend 5 sessions every other day, and two revision sessions, one at 1-month, and another one at 3 month-follow-up.

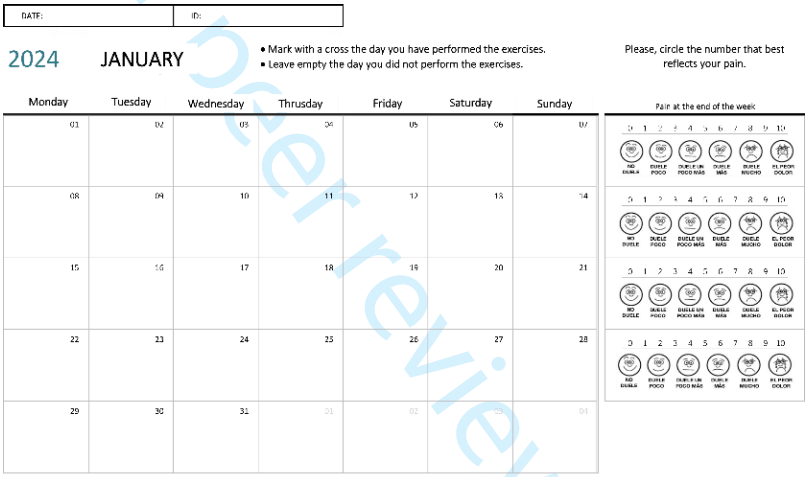
Item 4: Describe whether exercises are supervised or unsupervised and how they are delivered.

The abovementioned seven exercise sessions will be supervised at the hospital with a physical therapist. However, the patient will be asked to perform the trained exercise at home all days until three-month follow-up. After that, the patient will be encouraged to keep up with the exercise at least 3-days per week until last follow-up with the medical doctor at 6-month follow-up.

During the supervised sessions, the physical therapist will observe the exercise performance, and correct any compensations made by the patient, ensuring an adequate pattern of movement. Furthermore, the dosage will be modified according to patients' characteristics at each session.

Item 5: Detailed description of how adherence to exercise is measured and reported.

Adherence to the exercise program will be measured using a self-reported calendar, in which the patient should mark the days he/she will perform the exercises. Furthermore, patient's will be asked to rate their pain intensity within last week on Sundays.



Item 6: Detailed description of the motivation strategies.

In order to motivate the patient to perform the exercises, information will be provided throughout the treatment sessions about his or her pathology and the importance of exercise in his or her recovery. In addition, the physiotherapists will give positive feedback in the face-to-face sessions, with motivational messages, placing greater emphasis on the points well performed by the patients within each exercise and their progress in tolerance to the load.

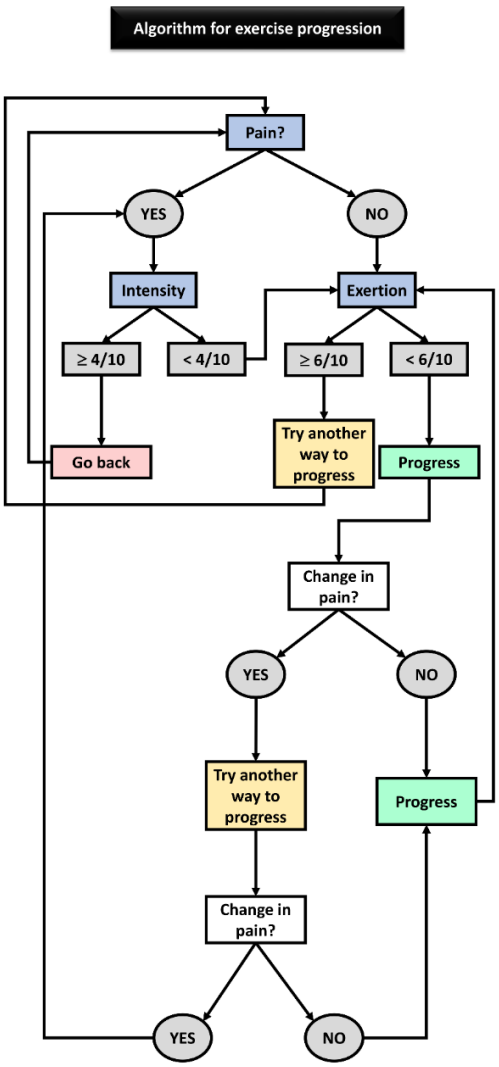
Item 7(a): Detailed description of the rule(s) for determining exercise progression.

Two criteria were used for progression/regression of exercise load: pain intensity and perceived sensation of exertion.

The intensity of pain should be mild during the exercises (i.e., ≤ 4/10 in a verbal numeric pain rating scale). Furthermore, although there may be a small increase in pain with exercise, it should return to baseline within 2 to 3 hours after exercise.

In addition, the patient should feel a sensation of moderate effort when performing the exercises, with a perceived exertion value equal or greater than 6 in a 0-10 verbal rating scale.

The first criterion to consider is pain intensity, followed by perceived sensation of exertion. If the patient does not have moderate pain within the exercise, and has low perceived exertion, the load will be increased. If, after that, the pain increases, he/she would be asked to return to the initial load. The algorithm of guidance provided to the physiotherapists for the loading profession is presented as follows.



Item 7(b): Detailed description of how the exercise program is progressed (eg, number of repetitions, resistance, load, speed, etc.)

The exercises will start with three sets (unless patient is unable to perform three sets), trying a minimum of 5 repetitions per set. At the beginning of the program, the progression will be made by increasing repetitions up to a maximum of 10 (first three months). Later in the program, the progression will be made by decreasing sets to 1 or 2, with 8 to 10 repetitions, and increasing load (i.e., elastic band resistance or dumbbell weight). Furthermore, at the beginning the exercises will be performed daily, and later in the program the exercises will be performed every other day.

The only exception is the posterior capsule stretching exercise, that will be performed with 3 sets of 20 seconds the entire program, that will be progressed by increasing the tension of the stretching.

Item 8: Detailed description of each exercise to enable replication (eg, photographs, illustrations, video, Smartphone app, website, protocol paper, etc).

The detailed description of each exercise is presented in Supplementary Material 4.

Item 9: Detailed description of any home programme component (eg, other exercises, stretching, functional tasks, etc).

The same exercises trained at the hospital will be performed at home by the patient.

Item 10: Describe whether there are any non-exercise components (eg, training or information materials, education, cognitive– behavioural therapy, massage, etc).

All patients will be provided with an information document with clarifications regarding their shoulder pathology (Supplementary Material 6), and explanations on the importance of therapeutic exercise. Furthermore, all patients from both groups will be provided with a document containing photos and explanation of

the exercise to be performed. Finally, patients will be provided with analgesic drugs if needed.

Item 11: Describe the type and number of adverse events that occur during exercise.

All adverse events will be registered in the patient's medical record during the entire course of the study.

Item 12: Describe the setting in which the exercises are performed.

The face-to-face sessions will be provided at the hospital setting, and the trained exercises will be performed at home by the patients for the entire duration of the study.

Item 13: Detailed description of the exercise intervention including, but not limited to, number of exercise repetitions/sets/sessions, session duration, programme duration, etc.

Exercises will be performed between 1-3 sets and 5-10 repetitions, according to the progression stated in item 7-b. All face-to-face sessions at the hospital will last 30 minutes, with a total of 7 sessions.

Item 14(a): Describe whether the exercises are generic (one size fits all) or tailored.

Exercises will be tailored according to the specifications provided in Supplementary Material 4.

Item 14(b): Detailed description of how exercises are tailored to the individual.

Exercises will be tailored according to the specifications provided in Supplementary Material 4.

Item 15: Describe the decision rule for determining the starting level at which people start an exercise programme (eg, beginner, intermediate, advanced, etc).

At the beginning of the program, patients without range of motion issues will be provided one of the first three exercises programs, while patients with range of

motion difficulties will be provided with one of the last three programs (Supplementary Material 4). Furthermore, subjects with moderate-severe pain intensity will start with the scapular-only programs, while those with mild pain intensity will start with the scapular plus internal rotation program (Supplementary Material 4).

Item 16(a): Describe how adherence or fidelity to the exercise intervention is assessed/measured.

The description of how adherence will be measures is presented in item 5.

Item 16(b): Describe the extent to which the intervention was delivered as planned.

Any deviations from intended intervention will be registered. All data will be analyzed at the end of the study using an intention-to-treat approach.

SUPPLEMENTARY MATERIAL 6

Information given to patients about the importance of exercise in the management of rotator cuff tendinopathy

EXERCISE FOR THE TREATMENT OF ROTATOR CUFF TENDINOPATHY

Exercise programs are the most effective treatment for shoulder tendinopathy in the medium and long term. Exercise therapy has the advantages that it has almost no adverse effects, and that the improvement achieved is usually maintained over time (although it may take a few weeks to appear).

Why is exercise important for treating rotator cuff tendinopathy?

The most common shoulder problem is rotator cuff tendinopathy. Pain appears at the level of the tendons of the muscles that surround the humeral head and form the rotator cuff. The rotator cuff is formed by four muscles surrounding the humeral head: supraspinatus, subscapularis, infraspinatus, and teres minor. It is a pain that appears especially when raising the arm, when bringing the hand towards the back or when lying on the bed on the side supporting the shoulder.

The reasons for the appearance of rotator cuff pain are not well understood, but it is known that the most important contributor is the load imposed to the shoulder. For example, increasing shoulder work in a high amount in a short period of time, or be for a prolonged period of time of low load, and then resume normal shoulder work. However, other factors such as sleep quality, or stress, can also influence on it. The result is a shoulder with tissues that become unaccustomed to the imposed load, producing the sensation of pain, even though the load is not harmful to the shoulder.

For that reason, the treatment of choice for this musculoskeletal disorder is therapeutic exercise, aimed at strengthening the shoulder musculature with exercise programs increases the stability of the glenohumeral joint. If the exercises are performed for several weeks the pain will begin to improve in most patients (although it is common to feel some discomfort initially when doing the exercises). Strength and endurance will also improve, and the ability to perform activities with the arm without pain will increase.

How is exercise performed?

The exercise programs to be used are simple and will be adapted to the characteristics of each individual. You will be instructed by a physical therapist, very familiar with this type of shoulder injury, who will select the most

appropriate combination of exercises for your specific situation. Once you have learned the exercises you will be provided with the necessary equipment, and you will have to continue doing them at home for at least 3 months. The physical therapist and the medical doctor of the rehabilitation unit will review you periodically. You will be indicated the necessary modifications to progress in the exercises in aim to achieve the maximum improvement.

SUPPLEMENTARY MATERIAL 7. Informed consent form for participants.

Study title: Effects of a web application based on multimedia animations to support therapeutic exercise for rotator cuff-related shoulder pain: an open-label randomized controlled trial

You are being asked to participate in a study related to physiotherapy treatment of shoulder pain. Please read carefully all the information below so you are able to decide whether to participate or not.

Therapeutic exercise is the treatment that has shown the best effects in the medium and long term for shoulder pain. For therapeutic exercise to have the best effects, exercise must become part of your daily routine and be performed over a certain period of time. It is very important that the exercises are performed correctly and that you feel confident and motivated to do them at home.

There will be two groups in this study. The only difference between them is the way the exercises are taught, with one group receiving access to a webpage with multimedia animations of the exercises. Both groups will have individualized treatment with a physiotherapist who will teach you the exercises that you will have to do at home. They will be strengthening and stretching exercises that have been shown to improve shoulder pain.

Assignment to one group or another will be random. The exercise protocol will be performed at home, once you have completed the training with a physical therapist, with regular supervision throughout the duration of the treatment.

In a first visit, a researcher will collect your personal data on your affiliation and your pain, disability and limitation of your daily activities, by means of questionnaires that you will have to fill in if you agree to participate in the study. If you have not yet undergone a shoulder ultrasound imaging, this test may be requested during the study. You will undergo physiotherapy treatment to learn the exercise program during 5 sessions on alternate days, and several evaluations will be made about your shoulder pain, and about the performance and progress of the treatment. These evaluations will be made at 6, 12 and 24 weeks. In this follow-up, the level of satisfaction with the treatment and the perception of overall improvement will also be assessed.

To begin the home treatment, you will be provided with the necessary material to carry out the exercise program. This material will include elastic bands and a compliance diary to be filled daily with the exercises performed and any difficulties encountered.

It is possible that you may experience, because of the exercise, some muscle or joint pain due to fatigue or overload or delayed muscle soreness. For the duration of the study, you will be under the supervision of your physiotherapist and, if this

happens, he/she will be able to explain the reasons and how to improve the symptoms.

The processing, communication, and transfer of personal data of all participating subjects will comply with the provisions of the Organic Law 3/2018 of December 5 on the protection of personal data. In accordance with the provisions of the aforementioned legislation, you may exercise the rights of deletion, opposition, portability, limitation, access and rectification, for which you should contact your professional researcher of the study. The data collected for the study will be identified by a code and only your study investigator/collaborators will be able to relate this data to you and your medical history. Therefore, your identity will not be disclosed to any person except in case of medical emergency or legal requirement. In accordance with current legislation, this data will be stored in a research file in the custody of the Hospital Universitario Fundación Alcorcón.

Participation in the study is completely voluntary. You may withdraw if you wish at any time, without having to give explanations and without any repercussions on your care and treatment.

In case of doubt or if you wish to obtain more information about the study and the treatment protocols used, you can contact us by e-mail or telephone:

Irene Pérez Porta, MD, Principal Investigator.

CONSENT FORM

Study title: Effects of a web application based on multimedia animations to support therapeutic exercise for rotator cuff-related shoulder pain: an open-label randomized controlled trial

I, Mr. / Mrs. _____

Once I have read the information sheet provided to me, I have understood what the study consists of and I have been able to ask all the desired information about it, thus resolving all my doubts in an adequate manner with a clear and understandable answer. Therefore, I agree to participate in this study on a voluntary basis, knowing that I can withdraw from the study at any time I wish without having to give any explanations.

I freely give my agreement to participate in the study and my consent to the use of my data in this study. I will receive a copy of this document so that I can consult my consent whenever I wish.

I am also aware that the confidentiality of my data is guaranteed, thus respecting my anonymity and privacy.

Participant's signature:	Investigator's Signature:
Full name:	Full name:
Date:	Date:

CONSENT FORM REVOCATION

Study title: Effects of a web application based on multimedia animations to support therapeutic exercise for rotator cuff-related shoulder pain: an open-label randomized controlled trial

I, Mr. / Mrs. _____

Would like to revoke my consent to use any of my information within the abovementioned study.

Participant's signature: Investigator's Signature:

Full name: Full name:

Date: Date:

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item	Description	~~Page~~Manuscript section
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	~~1~~Title page
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	~~13~~Ethics and dissemination
	2b	All items from the World Health Organization Trial Registration Data Set	Ethics and dissemination~~13~~
Protocol version	3	Date and version identifier	NA
Funding	4	Sources and types of financial, material, and other support	~~14~~Funding statement
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	Title page~~1~~
	5b	Name and contact information for the trial sponsor	Title page~~1~~
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	NA

	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	Author's contributions~~14~~
Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining key benefits and harms for each intervention	~~4-5~~Introduction
	6b	Explanation for choice of comparators	Introduction~~4-5~~
Objectives	7	Specific objectives or hypotheses	Introduction~~5~~
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	Introduction~~6~~
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	~~6~~Design and setting
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	~~7-8~~Recruitment, inclusion, and exclusion criteria
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	~~9-10~~Interventions

		11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	~~10~~Analgesic co-adjuvants
		11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	~~10~~Patient's education, patient's adherence to the exercise program, and supplementary material
		11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	Analgesic co-adjuvants~~10~~
	Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	~~10-12~~Measurements
	Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	Table ~~1~~6
	Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	Sample size~~8~~
	Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	Recruitment, inclusion, and exclusion criteria~~7~~

Methods: Assignment of interventions (for controlled trials)

Allocation:

Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	~~6-7~~Randomization, and allocation
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	Randomization, and allocation~~7~~
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	Randomization, and allocation~~6~~
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	Blinding~~7~~
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	NA
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	~~10-12~~Measurements
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	NA

Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	Data management~~13-14~~
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	~~12-13~~Data analysis
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	Data analysis~~12-13~~
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	Data analysis~~12-13~~
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	NA
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	NA
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	~~10~~Analgesic co-adjuvants
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	NA
Ethics and dissemination			

Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	~~14~~Ethics and dissemination
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, RECs/IRBs, trial participants, trial registries, journals, regulators)	NA
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	~~7~~Measurements
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	NA
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	~~13-14~~Data management
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	Funding statement, and competing interest statement~~14~~
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	NA
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	NA
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	NA
	31b	Authorship eligibility guidelines and any intended use of professional writers	NA

	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	NA
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	~~13~~Supplementary Material
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	NA

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

BMJ Open

Effects of a web application based on multimedia animations to support therapeutic exercise for rotator cuff-related shoulder pain: protocol for an open-label randomized controlled trial

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2024-085381.R2
Article Type:	Protocol
Date Submitted by the Author:	01-Jul-2024
Complete List of Authors:	Pérez-Porta, Irene; Hospital Universitario Fundación Alcorcón, Physical Therapy and Rehabilitation Unit; Universidad Rey Juan Carlos, International Doctoral School Flórez-García, Mariano; Hospital Universitario Fundacion Alcorcon, Physical Therapy and Rehabilitation Unit García-Pérez, Fernando; Hospital Universitario Fundacion Alcorcon, Physical Therapy and Rehabilitation Unit Fernández-Matías, Rubén; Hospital Universitario Fundacion Alcorcon, Research Unit; Universitat de Valencia, Doctoral School, Department of Physical Therapy Pérez-Manzanero, M Ángeles; Hospital Universitario Fundacion Alcorcon, Physical Therapy and Rehabilitation Unit Araujo-Narváez, Aurora; Hospital Universitario Fundacion Alcorcon, Physical Therapy and Rehabilitation Unit Urraca-Gesto, M Alicia ; Hospital Universitario Fundacion Alcorcon, Physical Therapy and Rehabilitation Unit; Universidad Rey Juan Carlos, Department of Physical Therapy, Occupational Therapy, and Rehabilitation and Physical Medicine Fernández-Lagarejos, César; Hospital Universitario Fundacion Alcorcon, Physical Therapy and Rehabilitation Unit Plaza-Manzano, Gustavo; Universidad Complutense de Madrid, Department of Radiology, Rehabilitation, and Physical Therapy; Hospital Clínico San Carlos, Fisioterapia Contemporánea (InPhysio) Research Group, Health Research Institute Pérez-Fernández, Elia; Hospital Universitario Fundacion Alcorcon, Research Unit Velasco-Arribas, María; Hospital Universitario Fundacion Alcorcon, Research Unit; Universidad Rey Juan Carlos, Department of Medical Specialties and Public Health
Primary Subject Heading:	Rehabilitation medicine
Secondary Subject Heading:	Evidence based practice
Keywords:	Shoulder < ORTHOPAEDIC & TRAUMA SURGERY, Randomized Controlled Trial, REHABILITATION MEDICINE, Physical Therapy Modalities

Effects of a web application based on multimedia animations to support therapeutic exercise for rotator cuff-related shoulder pain: protocol for an open-label randomized controlled trial

Irene Pérez-Porta, MD, PhD Student[1,2]; Mariano Tomás Flórez-García, MD, PhD[1]; Fernando García-Pérez, MD, MSc[1]; Rubén Fernández-Matías, PT, PhD Student[1,3,4]; M Ángeles Pérez-Manzanero, PT[1]; Aurora Araujo-Narváez, PT[1]; M Alicia Urraca-Gesto, PT, PhD[1,5]; César Fernández-Lagarejos, PT[1]; Gustavo Plaza-Manzano, PT, PhD[6,7]; Elia Pérez-Fernández, BS, MSc[3]; María Velasco-Arribas, MD, PhD[3,8]

[1] Physical Therapy and Rehabilitation Unit, Hospital Universitario Fundación Alcorcón, Madrid, Spain

[2] International Doctoral School, Universidad Rey Juan Carlos, Madrid, Spain

[3] Research Unit, Hospital Universitario Fundación Alcorcón, Madrid, Spain

[4] Doctoral School, Department of Physical Therapy, Universitat de València, Valencia, Spain.

[5] Department of Physical Therapy, Occupational Therapy, and Rehabilitation and Physical Medicine, Universidad Rey Juan Carlos, Madrid, Spain.

[6] Department of Radiology, Rehabilitation, and Physical Therapy, Universidad Complutense de Madrid, Madrid, Spain.

[7] Fisioterapia Contemporánea (InPhysio) Research Group, Health Research Institute, Hospital Clínico San Carlos, Madrid, Spain.

[8] Department of Medical Specialties and Public Health, Universidad Rey Juan Carlos, Madrid, Spain.

Correspondence to:

Rubén Fernández-Matías

Physical Therapy and Rehabilitation Unit, Hospital Universitario Fundación Alcorcón, Street Budapest 1, 28922 Alcorcón, Madrid, Spain

Email: ruben.fernanmat@gmail.com

Keywords Subacromial pain; Rotator Cuff Tendinopathy; Protocol; Randomized Controlled Trial; Exercise

ABSTRACT

Introduction: Rotator cuff-related shoulder pain (RCRSP) is the most common cause of shoulder pain. Currently, exercise is proposed as the first-line treatment for patients suffering from RCRSP. However, adherence to therapeutic exercise programs can be poor in the long term in a home setting. The aim of this study is to evaluate the effects of adding video animations to a traditional paper-based exercise program.

Methods and analysis: A single-center, randomized, open-labelled clinical trial will be conducted in a hospital in Spain. Adults aged between 18 and 80 years diagnosed with RCRSP who meet the eligibility criteria will be included. Patients (n=132) will be randomized into two groups, with both receiving paper-based exercises, and the experimental group also provided with video animations. The participants will receive seven face-to-face physical therapy sessions and will be asked to perform the exercises at home for 6 months. The primary outcome measure will be Shoulder Pain and Disability Index, measured at baseline, 3 weeks, 3 months (primary analysis), and 6 months. Secondary outcomes will be pain intensity during last week (rest, during movement, and at night), patients' expectations of improvement, patients' satisfaction with treatment, patients' impression of improvement, patients' perceived usability, usefulness, and

satisfaction of multimedia animations, and adherence to the exercises. Generalized least squares regression models with an autoregressive-moving average lag 1 correlation structure will be implemented, with an intention-to-treat analysis.

Ethics and dissemination: This study has been approved by the ethics committee of Hospital Universitario Fundación Alcorcón (Madrid, Spain), reference number CI18/16. All participants will sign an informed consent. The results will be published in a peer-reviewed scientific journal.

Trial registration: ClinicalTrials.gov, NCT05770908.

STRENGTHS AND LIMITATIONS OF THIS STUDY

- This study will include a large sample size to estimate treatment effectiveness with adequate precision.
- The exercise program of this study will be reported in detail following current recommendations to facilitate its reproducibility and clinical implementation.
- The web-based animations require internet connection so patients can watch the exercise videos.

INTRODUCTION

Shoulder pain is a common symptom that can be considered as the third cause of complaints in subjects with musculoskeletal disorders,[1] with nearly 65% of the whole population suffering from it in a lifetime.[2] Furthermore, its annual incidence has been estimated at between 0.3% to 5.5%, and its point prevalence between 2.4% and 21%.[3]

Rotator-cuff related shoulder pain (RCRSP) is the most common cause of shoulder pain,[4] that may have a significant impact on daily life, cause sleep disorders and reduce quality of life,[5] as well as a decrease in productivity, with an increase in sick leave.[6]

The SPS has been scrutinized as a misleading and umbrella terminology,[7] with at least 27 unique terms covered within it (impingement, tendinopathy, rotator cuff disease…).[8] Diagnosis plays a crucial role within study design, because a specific treatment might work in subgroup of patients, but not in others.

Currently, there is high quality evidence suggesting that surgical procedures for patients with SPS are not superior to sham surgery.[9] For that reason, exercise is proposed as the first-line treatment for patients suffering from SPS in clinical practice guidelines,[9–11] because it can improve shoulder pain, mobility, and function.[12–15]

Overall, patients perceive exercise as a good choice for managing their shoulder pain,[16] and it is the most implemented treatment within physical therapists.[17] However, despite exercise being an effective, accessible, and low-cost intervention with few adverse effects,[18] there are still some barriers for its implementation within clinical practice.[19,20]

First, there is inappropriate content reporting about exercise programs within published clinical trials, both in the description of the exercises itself, the dosage, and the rules implemented for the progression and regression in exercise load,[21,22] thus leading to uncertainty about the better type of exercises, and the optimal dosage.[13,15,23] Second, exercise is an active, patient-dependent intervention, which means it will only be effective if the patient performs it.[19] However, it seems that adherence to therapeutic exercise programs is poor when they last a long time in home-setting.[24] Some strategies have been implemented in aim to improve adherence to therapeutic exercise programs, such as the use of videos or multimedia animations,[25–27] that may improve self-efficacy and adherence.[25–29] Nevertheless, the evidence of its superiority over traditional paper-based exercises is not clear in patients with RCRSP.[25]

For all these reasons, there is a need for more randomized controlled trials with better content reporting of the exercise programs,[21,22] that investigate the utility of the implementation of new technologies in aim to improve patients' adherence,[25] and thus optimizing treatment effectiveness.[18]

The main hypothesis of this randomized controlled trial is that the implementation of a home-based exercise program using multimedia animations is better regarding improvements in shoulder disability than a traditional paper-based one. As secondary objectives, the hypothesis is that multimedia animations will also improve more patients' paint intensity, expectations, satisfaction, and adherence. Finally, the study also aims to evaluate the usability of the implemented multimedia animations, and the patients' perceived utility and satisfaction of them.

METHODS AND ANALYSIS

Design and setting

This is a study protocol of a single-center open-labelled parallel-randomized clinical trial reported as per recommendations of the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) 2013 (Supplementary Material 1).[30] The research will take place in Hospital Universitario Fundación Alcorcón (Madrid, Spain). The study schedule is presented in Table 1.

Table 1. Study schedule

	Study Period					
	Enrollment	**Allocation**		**Post-allocation**		**Closeout**
Time point	**T_{-1}**	**T_0**	**3-week**	**6-week**	**12-week**	**24-week**
Enrollment	X					
Eligibility screen	X					
Informed consent	X					
Allocation		X				
Interventions:						
Paper only exercises		◆—	—◆	◆	◆	
Paper plus video exercises		◆—	—◆	◆	◆	
Assessments:						
Demographic data	X					
Pain intensity	X			X	X	X
SPADI	X			X	X	X
Expectations	X	X	X	X		
Satisfaction				X		X
PGI-I				X	X	X
SUS					X	
Animations' usefulness and satisfaction					X	
Adherence			X	X	X	X

Abbreviations: SPADI, Shoulder Pain and Disability Index; PGI-I, Patient Global Impression of Improvement; SUS, System Usability Scale.

Randomization and allocation

The randomization procedure was conducted with a 1:1 allocation ratio using the software Epidat v4.2 (Xunta de Galicia, Spain), by a statistician not involved in other study labors. Allocation concealment will be achieved using sequentially numbered opaque envelopes.

Blinding

Investigators who will recruit subjects will be blinded to group allocation. Evaluators, therapists, and patients will not be blinded to group allocation.

Recruitment and inclusion and exclusion criteria

Subjects' recruitment will be conducted by three rehabilitative physicians who will be unaware of treatment allocation. The recruitment process will be carried out in Hospital Universitario Fundación Alcorcon. All patients attending consult with shoulder pain from non-traumatic origin will be evaluated for their inclusion in the study. The recruitment started on April 7th, 2023, and the estimated study completion date is expected to be on 1st December, 2024.

The inclusion and exclusion criteria were based on a previously published systematic review.[31] To be included the subjects must meet the following inclusion criteria:

- Age between 18 and 80 years old.
- Presence of rotator cuff related shoulder pain, diagnosed as unilateral shoulder pain, located in the anterior and/or lateral deltoid region, which is reproduced by active elevation and/or lying on ipsilateral side, and with the following orthopaedic tests: Neer, Hawkins-Kennedy and/or empty can).

- Pain lasting from at least 3-months.
- Pain intensity at rest, during movement, and sleeping ≥ 3/10 points on a numeric pain rating scale.
- To have a mobile phone, tablet, or computer with internet connection.
- To understand written and spoken Spanish language.

Furthermore, the subjects will not have to present with the following exclusion criteria:

- History of major trauma or surgery on the shoulder, elbow, or cervical spine.
- Signs of other shoulder pathologies such as instability, frozen shoulder, calcific tendonitis, severe arthrosis, or neuralgic amyotrophy.
- Presence of full-thickness rotator cuff tears on ultrasound imaging.
- Signs and/or symptoms of neck-related shoulder pain and/or radiculopathy or radicular pain.
- Systemic diseases such as cancer, rheumatic disorders, sclerosis multiple, neurological disorders, etc.
- Severe psychiatric disorders.

Sample size

The sample size calculation was conducted using the '*MBESS'* package[32] of the software R v4.1.0 and was based on the precision of the adjusted between-group mean difference in SPADI at 3-month follow-up (primary outcome), from an analysis of covariance (ANCOVA) including baseline measure as a covariate. According to the results of previous publications, an equal standard deviation (SD) of 25 points was considered for both groups.[33] It was assumed a 1:1

allocation ratio, and a correlation of 0.50 between repeated measures.[34] A 95% confidence interval (CI) width of 16 was considered acceptable because the smallest value of the minimum clinically important difference reported in literature for SPADI is 8 points.[35] The estimated sample size was 112 subjects. Assuming a 15% drop-out rate, the final sample size was composed of 132 subjects (66 per group).

Interventions

The interventions will be carried out by two physical therapists in Hospital Universitario Fundación Alcorcon. Both groups will receive five face-to-face sessions (half an hour each) every other day along three-weeks. After that, all patients will receive two additional face-to-face sessions to review the exercises, and to update the dosage of exercise load, at 6-week and 12-week follow-ups.

Exercise programs

All the subjects will receive printed exercises with pictures and an explanatory text, but subjects in experimental group will also be provided access to a webpage with self-explanatory videos of the prescribed exercises. The description of the web application is presented in Supplementary Material 2, and the didactic methodology implemented within the videos is presented in Supplementary Material 3.

Clear documentation of the exercise programs implemented within research is crucial for improving reproducibility between studies, and for the clinicians to be able to implement the results of research into their clinical practice. For this reason, the Consensus on Exercise Reporting Template (CERT) was proposed in 2016.[36] This template is composed of different domains that every study

including exercise interventions should report. In aim to improve these aspects, a detailed description of the exercise programs is presented in Supplementary Material 4, and the description of each of the CERT domains is presented in Supplementary Material 5.

Patient education

Patients will be provided with education about their shoulder disorder throughout all treatment sessions. They will be given explanations about their shoulder pain, the importance of therapeutic exercise in its management, and some recommendations for daily living activities. Furthermore, they will be provided with a document with some information about rotator cuff tendinopathy and the importance of exercise at the beginning of the treatment (Supplementary Material 6).

Analgesic co-adjuvants

Patients will be provided with hot/cold packs, and/or well as analgesic drugs if needed at the beginning of the treatment, only when pain intensity makes it impossible to start with the exercise programs. The use of any co-adjuvant therapy will be registered and reported in the final publication of the clinical trial.

Measurements

All the measurements will be conducted in Hospital Universitario Fundación Alcorcón. The rehabilitative physicians in charge of enrolling patients will collect demographic data, and baseline and 24-week follow-up outcome measures. The outcome measures at 3-week, 6-week, and 12-week follow-ups will be collected by the physiotherapists who will guide the therapeutic exercise programs. The full

measurement schedule is presented in Table 1**.** Adverse events will be registered in the patients' clinical history.

All patients will receive and sign an informed consent before any enrolling the study (Supplementary Material 7). The following demographic data will be collected: age, height, weight, body mass index, sex, dominant side, painful side, and time with shoulder pain. The primary outcome measure will be shoulder pain-related disability. The secondary outcome measures will be pain intensity during last week at rest, during movement, and at night, patients' expectations of improvement, patients' satisfaction with treatment, patient's global impression of improvement, patients' perceived usability, usefulness, and satisfaction of the multimedia animations, and patient's adherence to the exercises. Originally, we aimed to measure patients' ability to adequately perform the prescribed exercises as a secondary outcome, but later it was decided not to measure this variable because of the lack of valid and reliable tools to do so in the hospital setting.

Shoulder pain-related disability

The primary outcome measure will be shoulder pain-related disability measured with the Shoulder Pain and Disability Index (SPADI). This questionnaire is composed of 13 items, each rating from zero to ten, with the overall questionnaire ranging from 0% (minimum degree of disability) to 100% (maximum degree of disability). The transcultural adaptation of the SPADI from English to Spanish language was conducted in 2015,[37] showing good internal consistency (α = 0.86 and 0.916), good reliability (ICC = 0.91), and good construct validity (r = 040 to 0.80).

Pain intensity

Pain intensity during last week at rest, during movement, and at night will be measured with an 11-point numeric pain rating scale (NPRS), which ranges from zero (no pain) to ten (worst pain imaginable). The NPRS has showed good levels of reliability (r = 0.95), and good levels of construct validity (r = 0.86 to 0.95).[38]

Patient's expectations and satisfaction

Patient's expectations of improvement and satisfaction with received treatment will be measured using an 11-point numeric rating scale, ranging from zero ("no expectation of improvement" / "not at all satisfied with the treatment received") to ten ("full recovery expectation" / "fully satisfied with the treatment received").

Patient's impression of improvement

Patient's impression of improvement will be measured with the Patient Global Impression of Improvement (PGI-I) scale. The PGI-I is a seven-point ordinal scale ranging from 1 (very much better), through 4 (no change), to 7 (very much better).

Patient's perceived usability, usefulness, and satisfaction of multimedia animations

Patient's perceptions on the usability of the multimedia animations will be measured at 12-week follow-up, with the System Usability Scale (SUS),[39] which is composed of 10 items that are rated in a 5-point Likert-type scale from 1 (strongly disagree) to 5 (strongly agree), with an overall rating ranging from 0% of perceived usability to 100% of perceived usability.

Patient's perceived usefulness, and satisfaction of multimedia animations will be measured at 12-week follow-up, with a 5-point Likert-type scale, which ranges from 1 (strongly disagree) to 5 (strongly agree).

Patient's adherence to the exercise program

Patient's home adherence to the prescribed exercises will be measured with self-registered calendars, as the percentage of days performing the exercises at home over the maximum days available between the first physical therapy session and the last follow-up.

Data analysis

Data distribution of quantitative variables will be evaluated with visual inspection of histograms, and Q-Q plots, as well as kurtosis and skewness measures. For the descriptive analysis of quantitative variables, the mean, standard deviation, median, 1st and 3rd quartiles, and range will be reported. For categorical variables, absolute frequencies and percentages will be reported.

The analysis of between-group differences on quantitative outcome measures will be conducted using a generalized least squares model fitted by restricted maximum likelihood, using the R package *'rms'* (Frank E Harrell Jr, 2022). Measurement at baseline will be included as a covariate to obtain adjusted between-group mean differences. Time (6-week, 12-week, and 24-week) will be modeled using a linear spline with one knot (since there is only one unique internal value within time variable), and assuming an autoregressive-moving average lag 1 (AR1) correlation structure. *Post hoc* pairwise comparisons will be controlled for familywise error rate using Bonferroni's correction. The variograms, and residual plots (by group will be reported for each model. If any quantitative

variable doesn't accomplish the needed assumptions, robust analogous methods will be used instead.[40]

For ordinal variables, a rank-based between-by-within analysis will be conducted, following the approach of Brunner, Domhof, and Langer (2002). Post hoc pairwise comparisons will be conducted controlling familywise error rate using Rom's method of the Benjamini-Hochberg method.[40]

Reasons for missing data will be reported, as well as a missing data map. Furthermore, the relationship between missingness and any measured variable at baseline will be analyzed using a logistic regression model. Multiple imputation (5 to 20 imputations) will be performed if data seems to be missing at random or completely at random. On the other hand, if there seems to be a relationship between baseline variables and missingness, multiple imputation along with sensitivity analyses using worst-best case and best-worst case scenarios will be implemented. Finally, an intention-to-treat approach will be used.

All the analyses will be conducted using R software v4.1.0 (R Core Team (2021). R: A language and environment for statistical computing. R Foundation for Statistical Computing, Vienna, Austria. URL https://www.R-project.org/). An α level of 0.05 with 95% confidence intervals (CI) will be assumed for all analyses. All analyses will be conducted blinded to group allocation, and a blinded interpretation of the results will be published in the final article as supplementary material.

Data management

All data collected during the study schedule will be kept under lock and key in the office of the principal investigating physician. Personal data will not be included

within the outcome measures of the participants. The list of participants ID number with name and contact information will be kept in an Excel document in the computer of the three physicians who will be recruiting subjects within the hospital security system. This file will not be moved to any other computer at any time. All data will be managed according to the Law on the Protection of Personal Data (LOPD) 3/2018, of December 5 (Spain).

Patient and public involvement

None.

ETHICS AND DISSEMINATION

The protocol of this randomized controlled trial has been reviewed and approved by the ethics committee of Hospital Universitario Fundación Alcorcón (Madrid, Spain), with reference number CI18/16. The study is registered at ClinicalTrials.gov (NCT05770908). The study will be conducted according to the Declaration of Helsinki. All participants will sign an informed consent before participating in the study. The results of this study will be published in a peer-reviewed scientific journal.

CONTRIBUTORS

Design of the study: IPP, MTFG, FGP, MAPM, AAN, AUG, EPF, CFL, GPM, and MVA. Statistical analysis plan: EPF, and RFM. Writing the protocol manuscript: IPP, MTFG, FGP, and RFM. All authors have read and approved the final manuscript. Guarantor: IPP.

FUNDING

This study (grant number PI19/01490) was funded by the Instituto de Salud Carlos III (ISCIII), Spain, and co-funded by the European Union.

COMPETING INTERESTS

The authors declare no competing interests.

ACKNOWLEDGEMENTS

The authors would like to thank all the people who supported them while conducting this research, specially their colleagues at Hospital Universitario Fundación Alcorcón.

REFERENCES

1 Haas R, Gorelik A, Busija L, *et al.* Prevalence and characteristics of musculoskeletal complaints in primary care: an analysis from the population level and analysis reporting (POLAR) database. *BMC Prim care* 2023;**24**. doi:10.1186/S12875-023-01976-Z

2 Luime JJ, Koes BW, Hendriksen IJM, *et al.* Prevalence and incidence of shoulder pain in the general population; a systematic review. *Scand J Rheumatol* 2004;**33**:73–81. doi:10.1080/03009740310004667

3 Littlewood C, May S, Walters S. Epidemiology of Rotator Cuff Tendinopathy: A Systematic Review. *Shoulder Elb* 2013;**5**:256–65. doi:10.1111/sae.12028

4 Linsell L, Dawson J, Zondervan K, *et al.* Prevalence and incidence of adults consulting for shoulder conditions in UK primary care; patterns of diagnosis and referral. *Rheumatology* 2006;**45**:215–21. doi:10.1093/rheumatology/kei139

5 Hwang Y, Oh J. The relationship between shoulder pain and shoulder disability in women: The mediating role of sleep quality and psychological disorders. *Medicine (Baltimore)* 2022;**101**:E31118. doi:10.1097/MD.0000000000031118

6 Clausen M, Nielsen M, Merrild M, *et al.* High incidence of lost workdays in patients with subacromial impingement syndrome. *Dan Med J* 2021;**68**:A07200496.

7 Horowitz EH, Aibinder WR. Shoulder Impingement Syndrome. *Phys Med*

Rehabil Clin N Am 2023;**34**:311–34. doi:10.1016/J.PMR.2022.12.001

8 Witten A, Mikkelsen K, Wagenblast Mayntzhusen T, *et al.* Terminology and diagnostic criteria used in studies investigating patients with subacromial pain syndrome from 1972 to 2019: a scoping review. *Br J Sports Med* 2023;**57**:864–71. doi:10.1136/BJSPORTS-2022-106340

9 Vandvik PO, Lähdeoja T, Ardern C, *et al.* Subacromial decompression surgery for adults with shoulder pain: a clinical practice guideline. *BMJ* 2019;**364**:l294–l294. doi:10.1136/bmj.l294

10 Lowry V, Lavigne P, Zidarov D, *et al.* A Systematic Review of Clinical Practice Guidelines on the Diagnosis and Management of Various Shoulder Disorders. *Arch Phys Med Rehabil* 2023;**105**:411–26. doi:10.1016/J.APMR.2023.09.022

11 Lafrance S, Charron M, Roy JS, *et al.* Diagnosing, Managing, and Supporting Return to Work of Adults With Rotator Cuff Disorders: A Clinical Practice Guideline. *J Orthop Sports Phys Ther* 2022;**52**:647–64. doi:10.2519/JOSPT.2022.11306

12 Naunton J, Street G, Littlewood C, *et al.* Effectiveness of progressive and resisted and non-progressive or non-resisted exercise in rotator cuff related shoulder pain: a systematic review and meta-analysis of randomized controlled trials. *Clin Rehabil* 2020;**34**:1198–216. doi:10.1177/0269215520934147

13 Dominguez-Romero JG, Jiménez-Rejano JJ, Ridao-Fernández C, *et al.* Exercise-Based Muscle Development Programmes and Their Effectiveness in the Functional Recovery of Rotator Cuff Tendinopathy: A

Systematic Review. *Diagnostics (Basel, Switzerland)* 2021;**11**. doi:10.3390/DIAGNOSTICS11030529

14 McConnell R, Klopper M, Rhon DI, *et al.* The influence of exercise therapy dosing on pain and functional outcomes in patients with subacromial pain syndrome: A systematic review. *Shoulder Elb* Published Online First: 13 September 2022. doi:10.1177/17585732221124303

15 Medeiros de-Queiroz JH, De-Medeiros MB, De-Lima RN, *et al.* Exercise for rotator cuff tendinopathy. *Rev Bras Med Trab* 2023;**20**:498–504. doi:10.47626/1679-4435-2022-698

16 Shim J, Pavlova A V., Moss RA, *et al.* Patient ratings in exercise therapy for the management of tendinopathy: a systematic review with meta-analysis. *Physiotherapy* 2023;**120**:78–94. doi:10.1016/J.PHYSIO.2023.05.002

17 Powell JK, Schram B, Lewis J, *et al.* Physiotherapists nearly always prescribe exercise for rotator cuff-related shoulder pain; but why? A cross-sectional international survey of physiotherapists. *Musculoskeletal Care* 2023;**21**:253–63. doi:10.1002/MSC.1699

18 Powell JK, Schram B, Lewis J, *et al.* 'You have (rotator cuff related) shoulder pain, and to treat it, I recommend exercise.' A scoping review of the possible mechanisms underpinning exercise therapy. *Musculoskelet Sci Pract* 2022;**62**. doi:10.1016/J.MSKSP.2022.102646

19 Dickson C, de Zoete RMJ, Berryman C, *et al.* Patient-related barriers and enablers to the implementation of high-value physiotherapy for chronic pain: a systematic review. *Pain Med* 2023;**25**:104–15.

doi:10.1093/PM/PNAD134

20 O'Shea A, Drennan J, Littlewood C, *et al.* Barriers and facilitators related to self-management of shoulderpain: a systematic review and qualitative synthesis. *Clin Rehabil* 2022;**36**:1539. doi:10.1177/02692155221108553

21 Major DH, Røe Y, Grotle M, *et al.* Content reporting of exercise interventions in rotator cuff disease trials: results from application of the Consensus on Exercise Reporting Template (CERT). *BMJ Open Sport Exerc Med* 2019;**5**:e000656. doi:10.1136/BMJSEM-2019-000656

22 Kucksdorf JJ, Bartley J, Rhon DI, *et al.* Reproducibility of Exercise Interventions in Randomized Controlled Trials for the Treatment of Rotator Cuff-Related Shoulder Pain: A Systematic Review. *Arch Phys Med Rehabil* 2023;:S0003-9993(23)00531-2. doi:10.1016/J.APMR.2023.09.007

23 Pieters L, Lewis J, Kuppens K, *et al.* An Update of Systematic Reviews Examining the Effectiveness of Conservative Physical Therapy Interventions for Subacromial Shoulder Pain. *J Orthop Sport Phys Ther* 2020;**50**:131–41. doi:10.2519/jospt.2020.8498

24 Burns D, Boyer P, Razmjou H, *et al.* Adherence Patterns and Dose Response of Physiotherapy for Rotator Cuff Pathology: Longitudinal Cohort Study. *JMIR Rehabil Assist Technol* 2021;**8**. doi:10.2196/21374

25 Emmerson KB, Harding KE, Taylor NF. Providing exercise instructions using multimedia may improve adherence but not patient outcomes: a systematic review and meta-analysis. *Clin Rehabil* 2019;**33**:607–18. doi:10.1177/0269215518819706

26 Kingston G, Gray MA, Williams G. A critical review of the evidence on the use of videotapes or DVD to promote patient compliance with home programmes. *Disabil Rehabil Assist Technol* 2010;**5**:153–63. doi:10.3109/17483101003671709

27 Davergne T, Meidinger P, Dechartres A, *et al.* The Effectiveness of Digital Apps Providing Personalized Exercise Videos: Systematic Review With Meta-Analysis. *J Med Internet Res* 2023;**25**. doi:10.2196/45207

28 Park KH, Song MR. Development of a Web Exercise Video for Patients With Shoulder Problems. *Comput Inform Nurs* 2017;**35**:255–61. doi:10.1097/CIN.0000000000000303

29 Rizzato A, Pizzichemi M, Gobbi E, *et al.* Effectiveness and therapeutic compliance of digital therapy in shoulder rehabilitation: a randomized controlled trial. *J Neuroeng Rehabil* 2023;**20**. doi:10.1186/S12984-023-01188-7

30 Chan AW, Tetzlaff JM, Altman DG, *et al.* SPIRIT 2013 statement: defining standard protocol items for clinical trials. *Ann Intern Med* 2013;**158**:200–7. doi:10.7326/0003-4819-158-3-201302050-00583

31 Watts AR, Williams B, Kim SW, *et al.* Shoulder impingement syndrome: a systematic review of clinical trial participant selection criteria. *Shoulder Elb* 2017;**9**:31–41. doi:10.1177/1758573216663201

32 Lai K, Kelley K. Accuracy in parameter estimation for ANCOVA and ANOVA contrasts: sample size planning via narrow confidence intervals. *Br J Math Stat Psychol* 2012;**65**:350–70. doi:10.1111/J.2044-8317.2011.02029.X

33 Hopewell S, Keene DJ, Marian IR, *et al.* Progressive exercise compared with best practice advice, with or without corticosteroid injection, for the treatment of patients with rotator cuff disorders (GRASP): a multicentre, pragmatic, 2 × 2 factorial, randomised controlled trial. *Lancet* 2021;**398**:416–28. doi:10.1016/S0140-6736(21)00846-1

34 Walters SJ, Jacques RM, Henriques-Cadby IBDA, *et al.* Sample size estimation for randomised controlled trials with repeated assessment of patient-reported outcomes: what correlation between baseline and follow-up outcomes should we assume? *Trials* 2019;**20**:566. doi:10.1186/S13063-019-3671-2

35 Dabija DI, Jain NB. Minimal Clinically Important Difference of Shoulder Outcome Measures and Diagnoses: A Systematic Review. *Am J Phys Med Rehabil* 2019;**98**:671–6. doi:10.1097/PHM.0000000000001169

36 Slade SC, Dionne CE, Underwood M, *et al.* Consensus on Exercise Reporting Template (CERT): Explanation and Elaboration Statement. *Br J Sports Med* 2016;**50**:1428–37. doi:10.1136/bjsports-2016-096651

37 Membrilla-Mesa MD, Cuesta-Vargas AI, Pozuelo-Calvo R, *et al.* Shoulder pain and disability index: Cross cultural validation and evaluation of psychometric properties of the Spanish version. *Health Qual Life Outcomes* 2015;**13**:200. doi:10.1186/s12955-015-0397-z

38 Hawker GA, Mian S, Kendzerska T, *et al.* Measures of adult pain: Visual Analog Scale for Pain (VAS Pain), Numeric Rating Scale for Pain (NRS Pain), McGill Pain Questionnaire (MPQ), Short-Form McGill Pain Questionnaire (SF-MPQ), Chronic Pain Grade Scale (CPGS), Short

Form-36 Bodily Pain Scale (SF. *Arthritis Care Res (Hoboken)* 2011;**63**:S240-52. doi:10.1002/acr.20543

39 Del Rocio Sevilla-Gonzalez M, Loaeza LM, Lazaro-Carrera LS, *et al.* Spanish Version of the System Usability Scale for the Assessment of Electronic Tools: Development and Validation. *JMIR Hum factors* 2020;**7**:e21161. doi:10.2196/21161

40 Wilcox RR. *Introduction to robust estimation and hypothesis testing*. 3. ed. Amsterdam [u.a.]: : Elsevier, AP 2012.

SUPPLEMENTARY MATERIAL 1

SPIRIT

STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item	Description	Manuscript section
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	Title page
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	Ethics and dissemination
	2b	All items from the World Health Organization Trial Registration Data Set	Ethics and dissemination
Protocol version	3	Date and version identifier	NA
Funding	4	Sources and types of financial, material, and other support	Funding statement
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	Title page
	5b	Name and contact information for the trial sponsor	Title page
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	NA

	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	Author's contributions
Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	Introduction
	6b	Explanation for choice of comparators	Introduction
Objectives	7	Specific objectives or hypotheses	Introduction
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	Introduction
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	Design and setting
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	Recruitment, inclusion, and exclusion criteria
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	Interventions

	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	Analgesic co-adjuvants
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	Patient's education, patient's adherence to the exercise program, and supplementary material
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	Analgesic co-adjuvants
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	Measurements
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	Table 1
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	Sample size
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	Recruitment, inclusion, and exclusion criteria

Methods: Assignment of interventions (for controlled trials)

Allocation:

Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	Randomization, and allocation
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	Randomization, and allocation
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	Randomization, and allocation
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	Blinding
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	NA
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	Measurements
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	NA

Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	Data management
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	Data analysis
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	Data analysis
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	Data analysis
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	NA
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	NA
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	Analgesic co-adjuvants
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	NA
Ethics and dissemination			

Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	Ethics and dissemination
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, RECs/IRBs, trial participants, trial registries, journals, regulators)	NA
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	Measurements
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	NA
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	Data management
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	Funding statement, and competing interest statement
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	NA
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	NA
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	NA
	31b	Authorship eligibility guidelines and any intended use of professional writers	NA

	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	NA
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	Supplementary Material
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	NA

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation and Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

SUPPLEMENTARY MATERIAL 2

Description of the web application

The exercise application is a web-based video library hosted on a server connected to the Internet. There are two versions of the web application. The first version (hosted in http://rhbhombro.com/profesional) is aimed at health professionals, and it allows for personalization of the specific exercises to include in each program for a particular patient. The second version (hosted in http://rhbhombro.com/) is a reduced version that contains predefined exercise programs for the treatment of rotator cuff tendinopathy, supraspinatus tears, massive rotator cuff tears, and frozen shoulder. For this randomized controlled trial, six predefined programs for rotator cuff tendinopathy, contained in the second reduced version of the web application, will be used. All the videos and the information contained in the application are on Spanish language.

Software development

The web application has been developed with PHP 7.2.2 programming language (http://php.net/releases/7_2_2.php) and a MVC (Model - View - Controller) infrastructure Laravel Framework 5.6.3 (http://laravel.com). Furthermore, it integrates the API of the professional streaming platform Vimeo (http://vimeo.com) that allows the distribution of videos to professionals and patients for different devices. The application is hosted on a VPS with Debian 8 (Jessie) (64 bits) with Apache 2.4.10 and MySql 14.14 database engine.

Selection of the exercises and design of the videos

First, a search was conducted in Medline/Pubmed, Cochrane, PEDRO, and AMED databases regarding published randomized controlled trials evaluating exercise programs for the management of each one of the four abovementioned disorders. The trials with the lowest risk of bias, and the greatest content reporting of the exercise programs were selected.

Second, a multidisciplinary consensus meeting was conducted to reach consensus, based on the published literature, on the specific exercises to include for the treatment of each pathology, as well as the prescription parameters. For this purpose, the following points were considered: 1) proven effectiveness and detailed description in low risk-of-bias randomized controlled trials; 2) recommendations for exercise prescription parameters of The American College of Sports Medicine; and 3) adaptation of the abovementioned

literature to the patients' profile seen at the hospital in which the web application was meant to be implemented.

Finally, the group of healthcare professionals collaborated with a team of graphic designers to create the animated videos of the selected exercises.

Web application features

Prescribe an exercise program, choosing from a series of previously designed exercises, depending on the pathology and clinical characteristics of the patient.

The healthcare professional can select the specific exercise to prescribe to a given patient using the first abovementioned version of the web application, or the select one of the predefined programs within the second version of the application, that can also be tailored to patients' clinical characteristics (Figure 1).

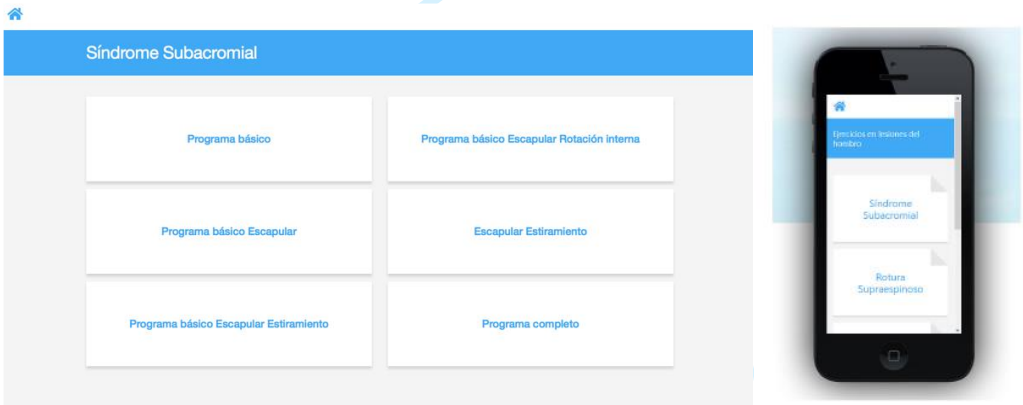


Figure 1. Screenshot of the web application. Left = laptop/tablet; right = smartphone.

For this randomized controlled trial, six predefined programs within the rotator cuff tendinopathy section of the second version of the web application will be used, namely: basic program, basic program plus scapular exercises, basic program plus scapular exercises and stretching, basic program plus scapular exercises and internal rotation, scapular exercise and stretching program, and full exercise program. Detailed description of the exercises are programs is presented in Supplementary Material 4.

View the videos included in the exercise program from different electronic devices (computer, tablet, or smartphone) without the need to install any specific software.

Each of the animated videos is composed of an animated person who performs the intended exercise, allowing the watcher to see the performance from different angles and planes. Furthermore, the video displays an audio-recorded explanation of the exercise performance, along with subtitles (Figure 2).

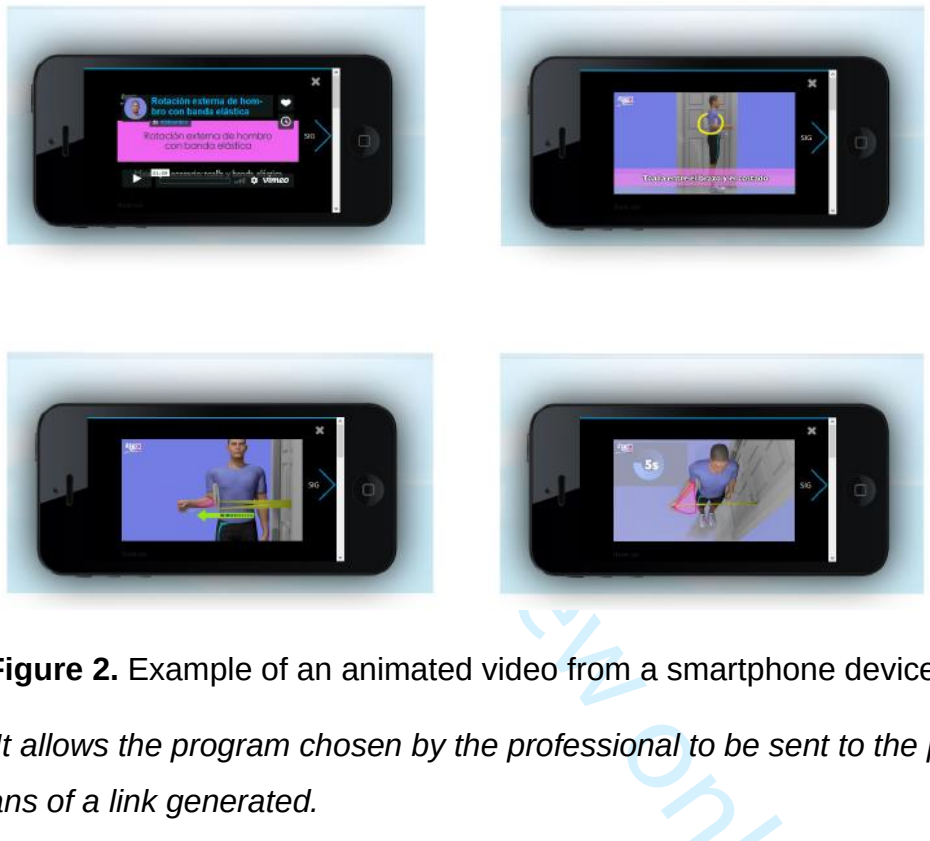


Figure 2. Example of an animated video from a smartphone device.

It allows the program chosen by the professional to be sent to the patient by means of a link generated.

The specific exercise program prescribed can be facilitated to the patient by means of a link generated, so the patient has only access to the prescribed exercises by the healthcare provider.

SUPPLEMENTARY MATERIAL 3

Didactic methodology of the exercise application

The 3D multimedia animations have been designed in an attempt to reduce the cognitive load (the amount of information that working memory cand hold at one time).[1] To this end, the technical aspects, the content and the form of instruction have been taken into account:[2]

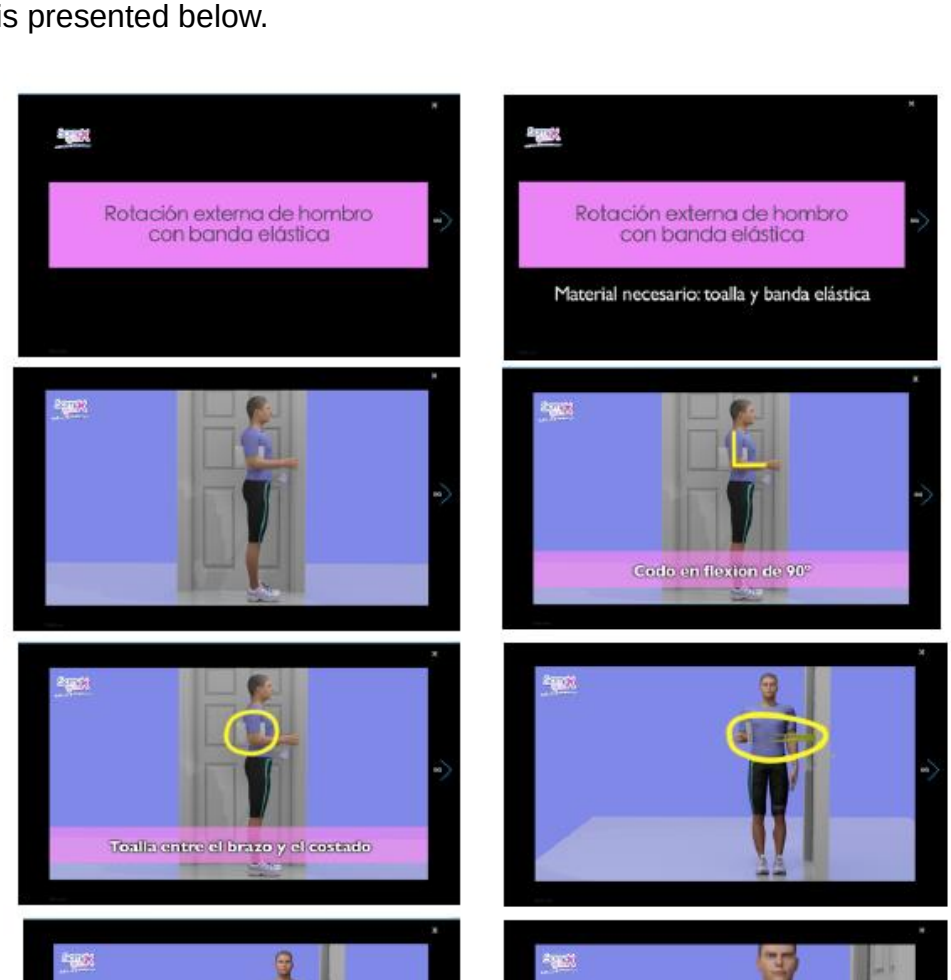
- **Technical aspects:** Visual quality, audio quality, coordination of audio and video, and use of graphic elements (arrows, position signs, time markers...) to highlight important information.
- **Content:** The instructional objective is explicit and clear. There is an explicit call to continued action teaching the way to progress.
- **Instructions:** The instructional techniques focus on patient engagement. The content is presented in an organized way. Short sequences of information are used to allow learners to engage. All extraneous information that doesn't contribute to the learning goal or help build relationships is eliminated.

The videos are 3D animations that allow to visualize an exercise from different perspectives, and are accompanied by audio, text, and animated graphic elements such as arrows, position signs, and time markers that facilitate the understanding and correct completion of the exercise. In addition, each exercise indicates the material necessary to perform it, the starting position, the correct way to do it, and the different parameters to consider (intensity, frequency and duration) and how to progress. Several aspects have been taken into account in the teaching methodology:

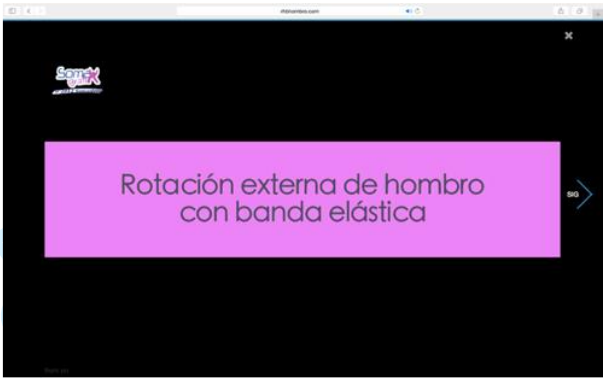
1. **Nomenclature of the exercise:** A short name is used to quickly identify the exercise to be performed.
2. **Necessary material:** Description, in the audio and in the text, of the material required to perform each exercise.
3. **Starting position:** Description and visualization from various perspectives of the initial position, which is considered adequate to begin the exercise. Position marks are used to facilitate this.
4. **Execution of the exercise:** Description of the correct way to perform the exercise. Arrows are introduced to mark the direction in which the movement should be performed, signs indicating the final position to be reached and a marker of the time to maintain this position.

Example of didactic methodology with one of the included exercises

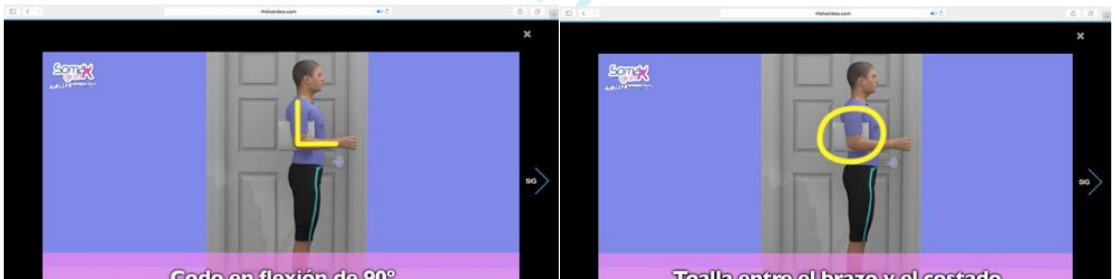
The whole video sequence of the shoulder external rotation exercise with elastic band is presented below.



The video begins by naming the exercise to be performed: external rotation of the shoulder with an elastic band. This allows the exercise to be easily identified, both by the professional who is going to teach it and by the patient who is going to do it.



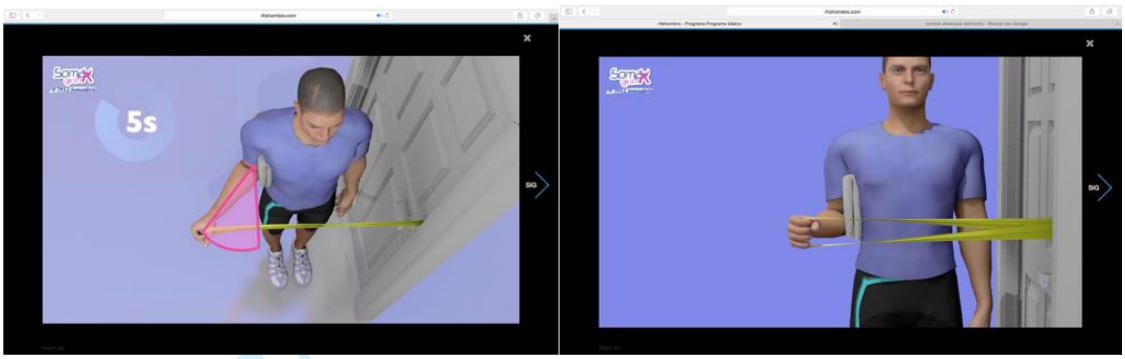
Next, the starting position is described, standing next to a door, with the elbow of the arm with which the exercise is to be performed in a 90° flexed position and placement of the folded towel between the elbow and the side. Several position and text marks are introduced to focus the patient's attention on those aspects that are a frequent source of error.



After this, a change of perspective is made so that the patient can visualize the starting position from another angle and the position of the elastic band with respect to the door (caught with the door or hooked to the door handle) and the hand holding the elastic band, which should be in slight tension, is specified.

The video goes on to specify the execution of the exercise, pulling the elastic band, making it taut to form an arc of about 45º and emphasizing not to move the rest of the body or allow the towel to fall to the floor. It is common to make the mistake of helping with the rest of the body to make the movement or separating the elbow from the body, so with these explanations we intend to reduce the possibility of such errors. An arrow marker is introduced for the direction of the movement and another for the magnitude of the arc of the movement to be performed.

Finally, the time to hold that final position is specified, 5 seconds and slowly return to the starting position.



REFERENCES

1 Castro-Alonso JC, de Koning BB, Fiorella L, *et al.* Five Strategies for Optimizing Instructional Materials: Instructor- and Learner-Managed Cognitive Load. *Educ Psychol Rev* 2021;**33**:1379–407. doi:10.1007/S10648-021-09606-9

2 Beemer LR, Tackett W, Schwartz A, *et al.* Use of a Novel Theory-Based Pragmatic Tool to Evaluate the Quality of Instructor-Led Exercise Videos to Promote Youth Physical Activity at Home: Preliminary Findings. *Int J Environ Res Public Health* 2023;**20**. doi:10.3390/IJERPH20166561

SUPPLEMENTARY MATERIAL 4

Description of the exercise programs

CRITERIA FOR THE ELABORATION OF THE EXERCISE PROGRAMS

Exercise is the fist-line treatment for patients with rotator cuff tendinopathy,[1] but there is no consensus on which program is the most appropriate.[2] The selection of the exercise programs was based on current research, and clinical knowledge of the research team.

The majority of the investigated programs include strengthening and stretching exercises of the rotator cuff and scapular muscles.[3] Some authors have suggested that scapular-focused exercises can add benefits to a rotator cuff strengthening exercises program at short term (i.e., 6-weeks), but not mid-term (i.e., 3-months) follow-up.[4] Furthermore, there seems to be no difference between concentric and eccentric exercises for the management of rotator cuff tendinopathy.[5]

There seems to be no differences between supervised and home-based exercise settings.[6]

Despite there is conflicting evidence regarding the value of high-load exercises compared to low-load ones,[7] it seems that load progression is a key factor within exercise programs.[6,8]

Pain intensity within exercise performance seems to be the best indicator when modulating load progression and regression.[9] Even though moderate or severe pain intensity during the performance of the exercise is not recommended, it seems that a slight-pain reproduction is not detrimental for its possible benefit.[6]

There is no consensus regarding optimal dosage for exercise programs. Some authors have proposed that three sets may be preferable to two or one set.[6]

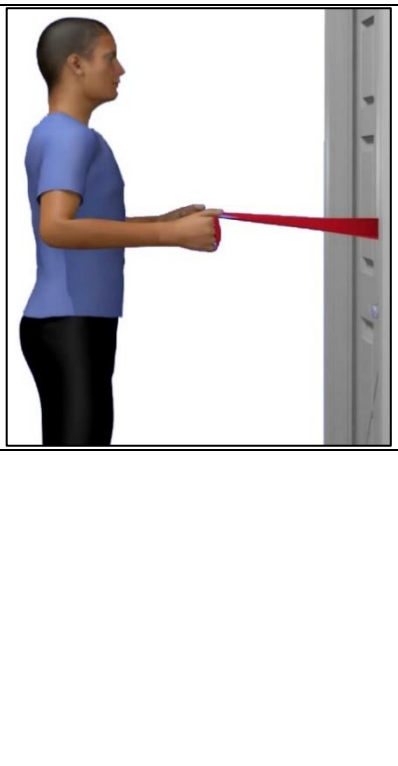
Finally, it is recommended that the exercise programs be maintained a minimum of three months.[6]

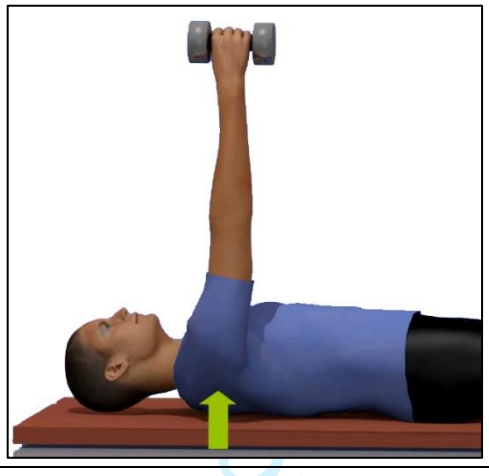
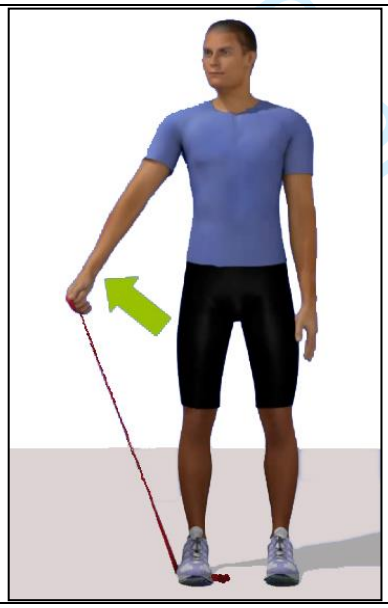
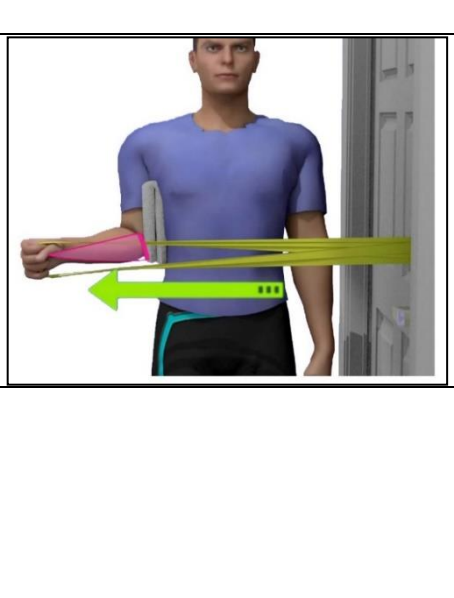
DETAILED DESCRIPTION OF THE EXERCISE PROGRAMS

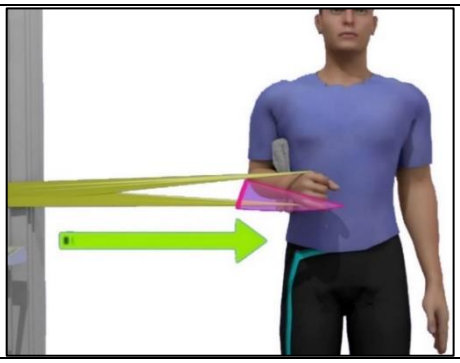
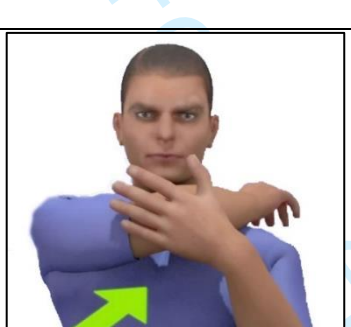
Six exercise programs were created based on the information provided above. The programs 1 (basic), 2 (basic plus scapular and internal rotation), and 3 (basic plus scapular) are aimed at patients no mobility limitation (strengthening exercises only). On the other hand, the programs 4 (scapular and stretching), 5 (basic plus scapular and stretching), and 6 (complete) are aimed at patients with limited mobility. The exercises included within each program are presented in the following table:

Exercises	Program					
	1	2	3	4	5	6
Horizontal row		X	X	X	X	X
Supine scapular protraction		X	X	X	X	X
Scaption	X	X	X		X	X
External rotation	X	X	X		X	X
Internal rotation		X				X
Posterior capsule stretching				X	X	X

The included exercises are as follows:

HORIZONTAL ROW	
	Arms with elbows bent at 90º. Pull the band with your hands making it tense, bringing the elbows and hands backwards, bringing the shoulder blades together. Hold for 5 seconds and return to starting position.

SUPINE SCAPULAR PROTRACTION	
	Shoulder elevated at 90º, and elbow extended holding a weight with the hand. Raise the weight while keeping the arm vertical. Hold the position for 5 seconds and return to the starting position.
SCAPTION	
	Slowly separate the arm upwards pulling the band without getting the arm horizontal. Hold for 5 seconds and return to the starting position.
EXTERNAL ROTATION	
	With a towel between the body and the arm and the elbow flexed 90º. Pull the band outwards about 45º. Hold for 5 seconds and return to the starting position.

INTERNAL ROTATION	
	With a towel between the body and the arm and the elbow flexed 90º. Pull the band inward about 45º. Hold for 5 seconds and return to the starting position.
POSTERIOR CAPSULE STRETCHING	
	Perform a 90º flexion of the shoulder and place the hand of the affected side over the healthy shoulder. With the other hand push the elbow backwards.

The detailed description of each exercise that was provided to the patient is as follows:

HORIZONTAL ROW

- You need an elastic band to perform this exercise.
- The starting position is standing/sitting in front of a closed door, with an elastic band hooked to the door handle.
- The arms should be about 45° away from the trunk and the elbows are kept bent at 90°.
- The band and forearms should be parallel to the floor.
- The spine must be kept straight during the performance of the exercise.
- To perform the exercise, pull the elastic band with your hands making it taut, bringing the elbows and hands backwards, bringing the shoulder blades together.
- Hold this position for 5 seconds and slowly return to the starting position.

SUPINE SCAPULAR PROTRACTION

- You need a dumbbell to perform this exercise.
- The starting position is lying on the floor face up. If you are more comfortable, you can place a cushion under your head.
- The arm with which the exercise is going to be performed remains perpendicular to the floor, with the elbow stretched out, while holding a dumbbell in your hand.
- The spine shouldn't be twisted during the performance of the exercise.
- To perform the exercise, take your shoulder off the floor by bringing your arm upwards, holding the weight towards the ceiling.
- Hold this position for 5 seconds and slowly return to the starting position.

SCAPTION

- You need an elastic band to perform this exercise.
- The starting position is standing facing forward with legs slightly apart, arms straight and relaxed along the body.
- One end of the band should be stepped on with the foot, and the other grasped with the hand of the symptomatic arm.
- The band should be slightly taut.
- The spine must be kept straight during the performance of the exercise.
- To perform the exercise the entire arm should be slowly pulled upward by pulling the band up to 30-40 degrees of elevation in the scapular plane.
- During the performance of the exercise, the elbow should be kept straight, the body shouldn't be rotated, and the shoulder shouldn't be shrugged.
- Hold this position for 5 seconds and slowly return to the starting position.

EXTERNAL ROTATION

- You need an elastic band and a towel to perform this exercise.
- The elastic band is attached to a door handle, and you must stand next to it.

- The elbow should be in 90º flexion forming a right angle, holding the towel between the elbow and the body.
- To perform the exercise, pull the elastic band outwards by about 45º of external rotation, making it taut without dropping the towel.
- The rest of the body should not move during the performance of the exercise.
- Hold this position for 5 seconds and slowly return to the starting position.

INTERNAL ROTATION

- You need an elastic band and a towel to perform this exercise.
- The elastic band is attached to a door handle, and you must stand next to it.
- The elbow should be in 90º flexion forming a right angle, holding the towel between the elbow and the body.
- To perform the exercise, pull the elastic band inward by about 45º of internal rotation, making it taut without dropping the towel.
- The rest of the body should not move during the performance of the exercise.
- Hold this position for 5 seconds and slowly return to the starting position.

POSTERIOR CAPSULE STRETCHING

- The starting position is standing.
- The palm of the hand of the side to be stretched is placed on top of the other shoulder, and the hand of the side that is to assist the stretch is placed resting on the opposite elbow.
- To perform the exercise, direct the elbow toward the opposite shoulder while your hand slides lightly down the back of the shoulder. Try to increase the movement by pushing slowly with the other hand on the elbow, without rotating the trunk.
- Hold this position for 20 seconds and slowly return to the starting position.

REFERENCES

1. Hanratty CE, McVeigh JG, Kerr DP, et al. The Effectiveness of Physiotherapy Exercises in Subacromial Impingement Syndrome: A Systematic Review and Meta-Analysis. *Semin Arthritis Rheum* 2012; 42: 297–316.

2. Dominguez-Romero JG, Jiménez-Rejano JJ, Ridao-Fernández C, et al. Exercise-Based Muscle Development Programmes and Their Effectiveness in the Functional Recovery of Rotator Cuff Tendinopathy: A Systematic Review. *Diagnostics (Basel, Switzerland)*; 11. Epub ahead of print 1 March 2021. DOI: 10.3390/DIAGNOSTICS11030529.

3. Gutiérrez-Espinoza H, Araya-Quintanilla F, Cereceda-Muriel C, et al. Effect of supervised physiotherapy versus home exercise program in patients with subacromial impingement syndrome: A systematic review and meta-analysis. *Physical Therapy in Sport* 2020; 41: 34–42.

4. Bury J, West M, Chamorro-Moriana G, et al. Effectiveness of scapula-focused approaches in patients with rotator cuff related shoulder pain: A systematic review and meta-analysis. *Man Ther* 2016; 25: 35–42.

5. Camargo PR, Alburquerque-Sendin F, Salvini TF. Eccentric training as a new approach for rotator cuff tendinopathy: Review and perspectives. *WORLD J Orthop* 2014; 5: 634–644.

6. Littlewood C, Malliaras P, Chance-Larsen K. Therapeutic Exercise for rotator cuff tendinopathy: A systematic review of contextual factors and prescription parameters. *Int J Rehabil Res* 2015; 38: 95–106.

7. Malliaras P, Johnston R, Street G, et al. The Efficacy of Higher Versus Lower Dose Exercise in Rotator Cuff Tendinopathy: A Systematic Review of Randomized Controlled Trials. *Arch Phys Med Rehabil* 2020; 101: 1822–1834.

8. Naunton J, Street G, Littlewood C, et al. Effectiveness of progressive and resisted and non-progressive or non-resisted exercise in rotator cuff related shoulder pain: a systematic review and meta-analysis of randomized controlled trials. *https://doi.org/101177/0269215520934147*

2020; 34: 1198–1216.

9. Ortega-Castillo M, Cuesta-Vargas A, Luque-Teba A, et al. The role of progressive, therapeutic exercise in the management of upper limb tendinopathies: A systematic review and meta-analysis. *Musculoskelet Sci Pract*; 62. Epub ahead of print 1 December 2022. DOI: 10.1016/J.MSKSP.2022.102645.

SUPPLEMENTARY MATERIAL 5

Consensus on Exercise Reporting Template (CERT)

Item 1: Detailed description of the type of exercise equipment

The needed equipment to perform the exercises are:

- Elastic bands (Thera-Band®) with a length of 155cm and a width of 14.5cm. There are six type of bands which, in order from least to most resistant, are as follows: yellow, red, green, blue, black, and silver.[1]
- Dumbbells with varying weights from 1kg to 4kg.
- Small size towel.

1. Uchida MC, Nishida MM, Sampaio RAC, et al. Thera-band® elastic band tension: reference values for physicalactivity. *J Phys Ther Sci* 2016; 28: 1266.

Item 2: Detailed descriptions of the qualifications, teaching/supervising expertise and/or training undertaken by the exercise instructor

The exercise instructors will be two physical therapists working at the Hospital Universitario Fundación Alcorcón. They have 4 to 30 years of experience treating patients with musculoskeletal shoulder disorders using therapeutic exercise. All the therapists were provided with a teaching session for the instruction on the exercise program, in aim to standardize the explanations given to the patients, as well as criteria for load progression and regression.

Item 3: Describe whether the exercises are performed individually or in a group

All sessions that patients will receive at the hospital will be performed individually with a 30-minute duration. The patients will attend 5 sessions every other day, and two revision sessions, one at 1-month, and another one at 3 month-follow-up.

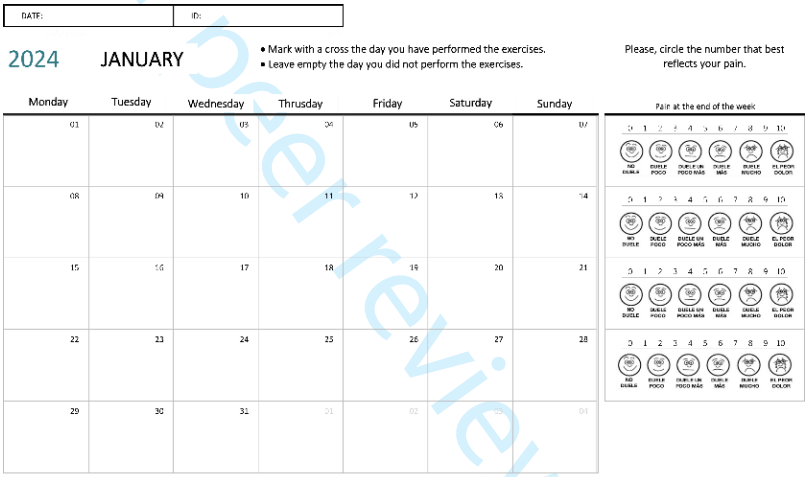
Item 4: Describe whether exercises are supervised or unsupervised and how they are delivered.

The abovementioned seven exercise sessions will be supervised at the hospital with a physical therapist. However, the patient will be asked to perform the trained exercise at home all days until three-month follow-up. After that, the patient will be encouraged to keep up with the exercise at least 3-days per week until last follow-up with the medical doctor at 6-month follow-up.

During the supervised sessions, the physical therapist will observe the exercise performance, and correct any compensations made by the patient, ensuring an adequate pattern of movement. Furthermore, the dosage will be modified according to patients' characteristics at each session.

Item 5: Detailed description of how adherence to exercise is measured and reported.

Adherence to the exercise program will be measured using a self-reported calendar, in which the patient should mark the days he/she will perform the exercises. Furthermore, patient's will be asked to rate their pain intensity within last week on Sundays.



Item 6: Detailed description of the motivation strategies.

In order to motivate the patient to perform the exercises, information will be provided throughout the treatment sessions about his or her pathology and the importance of exercise in his or her recovery. In addition, the physiotherapists will give positive feedback in the face-to-face sessions, with motivational messages, placing greater emphasis on the points well performed by the patients within each exercise and their progress in tolerance to the load.

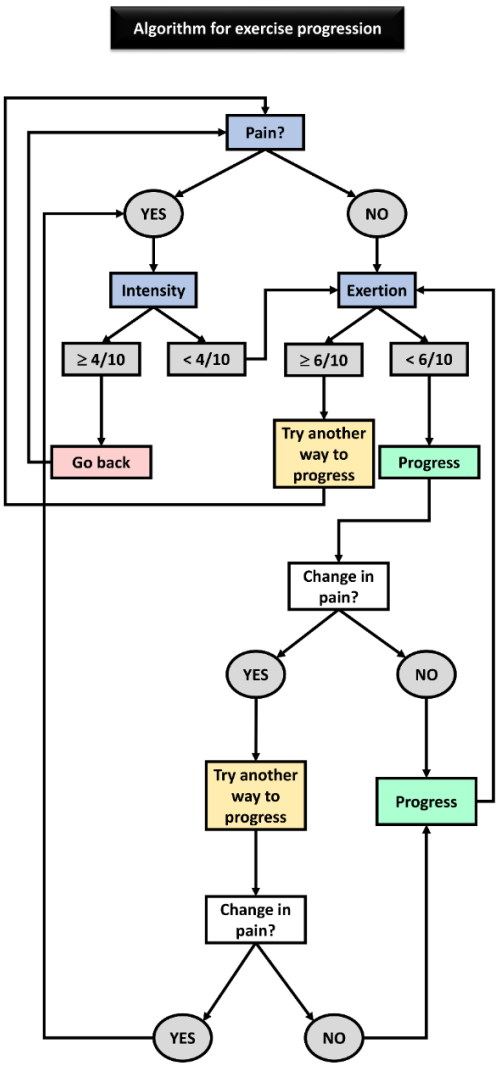
Item 7(a): Detailed description of the rule(s) for determining exercise progression.

Two criteria were used for progression/regression of exercise load: pain intensity and perceived sensation of exertion.

The intensity of pain should be mild during the exercises (i.e., ≤ 4/10 in a verbal numeric pain rating scale). Furthermore, although there may be a small increase in pain with exercise, it should return to baseline within 2 to 3 hours after exercise.

In addition, the patient should feel a sensation of moderate effort when performing the exercises, with a perceived exertion value equal or greater than 6 in a 0-10 verbal rating scale.

The first criterion to consider is pain intensity, followed by perceived sensation of exertion. If the patient does not have moderate pain within the exercise, and has low perceived exertion, the load will be increased. If, after that, the pain increases, he/she would be asked to return to the initial load. The algorithm of guidance provided to the physiotherapists for the loading profession is presented as follows.



Item 7(b): Detailed description of how the exercise program is progressed (eg, number of repetitions, resistance, load, speed, etc.)

The exercises will start with three sets (unless patient is unable to perform three sets), trying a minimum of 5 repetitions per set. At the beginning of the program, the progression will be made by increasing repetitions up to a maximum of 10 (first three months). Later in the program, the progression will be made by decreasing sets to 1 or 2, with 8 to 10 repetitions, and increasing load (i.e., elastic band resistance or dumbbell weight). Furthermore, at the beginning the exercises will be performed daily, and later in the program the exercises will be performed every other day.

The only exception is the posterior capsule stretching exercise, that will be performed with 3 sets of 20 seconds the entire program, that will be progressed by increasing the tension of the stretching.

Item 8: Detailed description of each exercise to enable replication (eg, photographs, illustrations, video, Smartphone app, website, protocol paper, etc).

The detailed description of each exercise is presented in Supplementary Material 4.

Item 9: Detailed description of any home programme component (eg, other exercises, stretching, functional tasks, etc).

The same exercises trained at the hospital will be performed at home by the patient.

Item 10: Describe whether there are any non-exercise components (eg, training or information materials, education, cognitive– behavioural therapy, massage, etc).

All patients will be provided with an information document with clarifications regarding their shoulder pathology (Supplementary Material 6), and explanations on the importance of therapeutic exercise. Furthermore, all patients from both groups will be provided with a document containing photos and explanation of

the exercise to be performed. Finally, patients will be provided with analgesic drugs if needed.

Item 11: Describe the type and number of adverse events that occur during exercise.

All adverse events will be registered in the patient's medical record during the entire course of the study.

Item 12: Describe the setting in which the exercises are performed.

The face-to-face sessions will be provided at the hospital setting, and the trained exercises will be performed at home by the patients for the entire duration of the study.

Item 13: Detailed description of the exercise intervention including, but not limited to, number of exercise repetitions/sets/sessions, session duration, programme duration, etc.

Exercises will be performed between 1-3 sets and 5-10 repetitions, according to the progression stated in item 7-b. All face-to-face sessions at the hospital will last 30 minutes, with a total of 7 sessions.

Item 14(a): Describe whether the exercises are generic (one size fits all) or tailored.

Exercises will be tailored according to the specifications provided in Supplementary Material 4.

Item 14(b): Detailed description of how exercises are tailored to the individual.

Exercises will be tailored according to the specifications provided in Supplementary Material 4.

Item 15: Describe the decision rule for determining the starting level at which people start an exercise programme (eg, beginner, intermediate, advanced, etc).

At the beginning of the program, patients without range of motion issues will be provided one of the first three exercises programs, while patients with range of

motion difficulties will be provided with one of the last three programs (Supplementary Material 4). Furthermore, subjects with moderate-severe pain intensity will start with the scapular-only programs, while those with mild pain intensity will start with the scapular plus internal rotation program (Supplementary Material 4).

Item 16(a): Describe how adherence or fidelity to the exercise intervention is assessed/measured.

The description of how adherence will be measures is presented in item 5.

Item 16(b): Describe the extent to which the intervention was delivered as planned.

Any deviations from intended intervention will be registered. All data will be analyzed at the end of the study using an intention-to-treat approach.

SUPPLEMENTARY MATERIAL 6

Information given to patients about the importance of exercise in the management of rotator cuff tendinopathy

EXERCISE FOR THE TREATMENT OF ROTATOR CUFF TENDINOPATHY

Exercise programs are the most effective treatment for shoulder tendinopathy in the medium and long term. Exercise therapy has the advantages that it has almost no adverse effects, and that the improvement achieved is usually maintained over time (although it may take a few weeks to appear).

Why is exercise important for treating rotator cuff tendinopathy?

The most common shoulder problem is rotator cuff tendinopathy. Pain appears at the level of the tendons of the muscles that surround the humeral head and form the rotator cuff. The rotator cuff is formed by four muscles surrounding the humeral head: supraspinatus, subscapularis, infraspinatus, and teres minor. It is a pain that appears especially when raising the arm, when bringing the hand towards the back or when lying on the bed on the side supporting the shoulder.

The reasons for the appearance of rotator cuff pain are not well understood, but it is known that the most important contributor is the load imposed to the shoulder. For example, increasing shoulder work in a high amount in a short period of time, or be for a prolonged period of time of low load, and then resume normal shoulder work. However, other factors such as sleep quality, or stress, can also influence on it. The result is a shoulder with tissues that become unaccustomed to the imposed load, producing the sensation of pain, even though the load is not harmful to the shoulder.

For that reason, the treatment of choice for this musculoskeletal disorder is therapeutic exercise, aimed at strengthening the shoulder musculature with exercise programs increases the stability of the glenohumeral joint. If the exercises are performed for several weeks the pain will begin to improve in most patients (although it is common to feel some discomfort initially when doing the exercises). Strength and endurance will also improve, and the ability to perform activities with the arm without pain will increase.

How is exercise performed?

The exercise programs to be used are simple and will be adapted to the characteristics of each individual. You will be instructed by a physical therapist, very familiar with this type of shoulder injury, who will select the most

appropriate combination of exercises for your specific situation. Once you have learned the exercises you will be provided with the necessary equipment, and you will have to continue doing them at home for at least 3 months. The physical therapist and the medical doctor of the rehabilitation unit will review you periodically. You will be indicated the necessary modifications to progress in the exercises in aim to achieve the maximum improvement.

SUPPLEMENTARY MATERIAL 7. Informed consent form for participants.

Study title: Effects of a web application based on multimedia animations to support therapeutic exercise for rotator cuff-related shoulder pain: an open-label randomized controlled trial

You are being asked to participate in a study related to physiotherapy treatment of shoulder pain. Please read carefully all the information below so you are able to decide whether to participate or not.

Therapeutic exercise is the treatment that has shown the best effects in the medium and long term for shoulder pain. For therapeutic exercise to have the best effects, exercise must become part of your daily routine and be performed over a certain period of time. It is very important that the exercises are performed correctly and that you feel confident and motivated to do them at home.

There will be two groups in this study. The only difference between them is the way the exercises are taught, with one group receiving access to a webpage with multimedia animations of the exercises. Both groups will have individualized treatment with a physiotherapist who will teach you the exercises that you will have to do at home. They will be strengthening and stretching exercises that have been shown to improve shoulder pain.

Assignment to one group or another will be random. The exercise protocol will be performed at home, once you have completed the training with a physical therapist, with regular supervision throughout the duration of the treatment.

In a first visit, a researcher will collect your personal data on your affiliation and your pain, disability and limitation of your daily activities, by means of questionnaires that you will have to fill in if you agree to participate in the study. If you have not yet undergone a shoulder ultrasound imaging, this test may be requested during the study. You will undergo physiotherapy treatment to learn the exercise program during 5 sessions on alternate days, and several evaluations will be made about your shoulder pain, and about the performance and progress of the treatment. These evaluations will be made at 6, 12 and 24 weeks. In this follow-up, the level of satisfaction with the treatment and the perception of overall improvement will also be assessed.

To begin the home treatment, you will be provided with the necessary material to carry out the exercise program. This material will include elastic bands and a compliance diary to be filled daily with the exercises performed and any difficulties encountered.

It is possible that you may experience, because of the exercise, some muscle or joint pain due to fatigue or overload or delayed muscle soreness. For the duration of the study, you will be under the supervision of your physiotherapist and, if this

happens, he/she will be able to explain the reasons and how to improve the symptoms.

The processing, communication, and transfer of personal data of all participating subjects will comply with the provisions of the Organic Law 3/2018 of December 5 on the protection of personal data. In accordance with the provisions of the aforementioned legislation, you may exercise the rights of deletion, opposition, portability, limitation, access and rectification, for which you should contact your professional researcher of the study. The data collected for the study will be identified by a code and only your study investigator/collaborators will be able to relate this data to you and your medical history. Therefore, your identity will not be disclosed to any person except in case of medical emergency or legal requirement. In accordance with current legislation, this data will be stored in a research file in the custody of the Hospital Universitario Fundación Alcorcón.

Participation in the study is completely voluntary. You may withdraw if you wish at any time, without having to give explanations and without any repercussions on your care and treatment.

In case of doubt or if you wish to obtain more information about the study and the treatment protocols used, you can contact us by e-mail or telephone:

Irene Pérez Porta, MD, Principal Investigator.

CONSENT FORM

Study title: Effects of a web application based on multimedia animations to support therapeutic exercise for rotator cuff-related shoulder pain: an open-label randomized controlled trial

I, Mr. / Mrs. _____

Once I have read the information sheet provided to me, I have understood what the study consists of and I have been able to ask all the desired information about it, thus resolving all my doubts in an adequate manner with a clear and understandable answer. Therefore, I agree to participate in this study on a voluntary basis, knowing that I can withdraw from the study at any time I wish without having to give any explanations.

I freely give my agreement to participate in the study and my consent to the use of my data in this study. I will receive a copy of this document so that I can consult my consent whenever I wish.

I am also aware that the confidentiality of my data is guaranteed, thus respecting my anonymity and privacy.

Participant's signature:	Investigator's Signature:
Full name:	Full name:
Date:	Date:

CONSENT FORM REVOCATION

Study title: Effects of a web application based on multimedia animations to support therapeutic exercise for rotator cuff-related shoulder pain: an open-label randomized controlled trial

I, Mr. / Mrs. _____

Would like to revoke my consent to use any of my information within the abovementioned study.

Participant's signature: Investigator's Signature:

Full name: Full name:

Date: Date:

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item	Description	~~Page~~Manuscript section
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	~~1~~Title page
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	~~13~~Ethics and dissemination
	2b	All items from the World Health Organization Trial Registration Data Set	Ethics and dissemination~~13~~
Protocol version	3	Date and version identifier	NA
Funding	4	Sources and types of financial, material, and other support	~~14~~Funding statement
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	Title page~~1~~
	5b	Name and contact information for the trial sponsor	Title page~~1~~
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	NA

	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	Author's contributions~~14~~
Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	~~4-5~~Introduction
	6b	Explanation for choice of comparators	Introduction~~4-5~~
Objectives	7	Specific objectives or hypotheses	Introduction~~5~~
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	Introduction~~6~~
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	~~6~~Design and setting
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	~~7-8~~Recruitment, inclusion, and exclusion criteria
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	~~9-10~~Interventions

		11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	~~10~~Analgesic co-adjuvants
		11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	~~10~~Patient's education, patient's adherence to the exercise program, and supplementary material
		11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	Analgesic co-adjuvants~~10~~
	Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	~~10-12~~Measurements
	Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	Table 1~~6~~
	Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	Sample size~~8~~
	Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	Recruitment, inclusion, and exclusion criteria~~7~~

Methods: Assignment of interventions (for controlled trials)

Allocation:

Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	~~6-7~~Randomization, and allocation
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	Randomization, and allocation~~7~~
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	Randomization, and allocation~~6~~
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	Blinding~~7~~
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	NA
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	~~10-12~~Measurements
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	NA

Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	Data management~~13-14~~
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	~~12-13~~Data analysis
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	Data analysis~~12-13~~
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	Data analysis~~12-13~~
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	NA
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	NA
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	~~10~~Analgesic co-adjuvants
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	NA
Ethics and dissemination			

Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	~~14~~Ethics and dissemination
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, RECs/IRBs, trial participants, trial registries, journals, regulators)	NA
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	~~7~~Measurements
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	NA
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	~~13-14~~Data management
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	Funding statement, and competing interest statement~~14~~
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	NA
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	NA
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	NA
	31b	Authorship eligibility guidelines and any intended use of professional writers	NA

	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	NA
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	~~13~~Supplementary Material
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	NA

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation and Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

Correction for 'Effects of a web application based on multimedia animations to support therapeutic exercise for rotator cuffrelated shoulder pain: protocol for an open-label randomised controlled trial'

Pérez-Porta I, FlórezGarcía MT, García-Pérez F, *et al*. Effects of a web application based on multimedia animations to support therapeutic exercise for rotator cuff-related shoulder pain: protocol for an open-label randomised controlled trial. *BMJ Open* 2024;14:e085381. doi:10.1136/bmjopen-20240 85 381

This article has been corrected since it was published online. The funding information has been updated. 'This trial has received funding from the Instituto de Salud Carlos III and the European Union (PI19/01490). The funder has no influence on the study's design, execution, analysis, or publication of results.'

BMJ Open 2025;**15**:e085381corr1. doi:10.1136/bmjopen-2024-085381corr1