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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

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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 programmes 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 programme.

Methods and analysis A single-centre, randomised, 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 randomised into two groups, with both receiving paper-based exercises, and the experimental group will also be 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 the Shoulder Pain and Disability Index, measured at baseline, 3 weeks, 3 months (primary analysis) and 6 months. Secondary outcomes will be the patient's pain intensity during the last week (rest, during movement and at night); expectations of improvement; satisfaction with treatment; impression of improvement; perceived usability, usefulness and satisfaction of multimedia animations; and adherence to exercises. Generalised least squares regression models with an autoregressive-moving average lag one 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 programme of this study will be reported in detail following current recommendations to facilitate its reproducibility and clinical implementation.
⇒ The web-based animations require an 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% and 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] which 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 subacromial pain syndrome has been scrutinised 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 in the study design because a specific treatment might work in a subgroup of patients but not in others.

Currently, there is high-quality evidence suggesting that surgical procedures for patients with RCRSP are not superior to sham surgery.[9] For that reason, exercise is proposed as the first-line treatment for

patients suffering from RCRSP 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 by physical therapists.[17] However, despite exercise being an effective, accessible and low-cost intervention with few adverse effects,[18] there are still some barriers to its implementation within clinical practice.[19 20]

First, there is inappropriate content reporting about exercise programmes 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 programmes is poor when they last a long time in a home setting.[24] Some strategies have been implemented to improve adherence to therapeutic exercise programmes, such as the use of videos or multimedia animations,[25–27] which 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 randomised controlled trials with better content reporting of exercise programmes[21 22] that investigate the utility of the implementation of new technologies to improve patients' adherence,[25] and thus optimising treatment effectiveness.[18]

The main hypothesis of this randomised controlled trial is that the implementation of a home-based exercise programme 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 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 with them.

METHODS AND ANALYSIS

Design and setting

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

Randomisation and allocation

The randomisation 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

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

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

labours. 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 7 April 2023, and the estimated study completion date is expected to be on 1 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.
- The presence of RCRSP, diagnosed as unilateral shoulder pain, located in the anterior and/or lateral deltoid region, which is reproduced by active elevation and/or lying on the ipsilateral side, and with the following orthopaedic tests: Neer, Hawkins-Kennedy and/or empty can.
- Pain lasting for at least 3 months.
- Pain intensity at rest, during movement and sleeping of ≥3/10 points on a numeric pain rating scale (NPRS).
- To have a mobile phone, tablet or computer with an 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 Shoulder Pain and Disability Index (SPADI) at 3-month follow-up (primary outcome), from an analysis of covariance including baseline measure as a covariate. According to the results of previous publications, an equal 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% CI width of 16 was considered acceptable because the smallest value of the minimum clinically important difference reported in the literature for SPADI is eight 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 for 3 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 the 6-week and 12-week follow-ups.

Exercise programmes

All the subjects will receive printed exercises with pictures and explanatory text, but subjects in the 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 online supplemental material 2, and the didactic methodology implemented within the videos is presented in online supplemental material 3.

Clear documentation of the exercise programmes implemented within research is crucial for improving reproducibility between studies and for 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. To improve these aspects, a detailed description of the exercise programmes is presented in online supplemental material 4, and the description of each of the CERT domains is presented in online supplemental material 5.

Patient education

Patients will be provided with education about their shoulder disorders 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 (online supplemental material 6).

Analgesic co-adjuvants

Patients will be provided with hot/cold packs and/or analgesic drugs if needed at the beginning of the treatment, only when pain intensity makes it impossible to start with the exercise programmes. 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 programmes. 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 enrollment to the study which is presented in online supplemental 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 the patient's pain intensity during the last week at rest, during movement and at night; expectations of improvement; satisfaction with treatment; global impression of improvement; perceived usability, usefulness and satisfaction of the multimedia animations; and 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 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=0.40 to 0.80).

Pain intensity

Pain intensity during the last week at rest, during movement, and at night will be measured with an 11-point NPRS, which ranges from zero (no pain) to ten (worst pain imaginable). The NPRS has shown 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 one (very much worse) through four (no change) to seven (very much better).

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

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

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

Patient's adherence to the exercise programme

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 of 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, SD, median, first and third quartiles and range will be reported. For categorical variables, absolute frequencies and percentages will be reported.

The analysis of between-group differences in quantitative outcome measures will be conducted using a generalised 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, 12 and 24 weeks) will be modelled using a linear spline with one knot (since there is only one unique internal value within the 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 does not 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 analysed using a logistic regression model. Multiple imputations (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% CIs 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 in the outcome measures of the participants. The list of participants ID numbers with names and contact information will be kept on 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 3/2018, of December 5 (Spain).

Patient and public involvement

None.

ETHICS AND DISSEMINATION

The protocol of this randomised 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.

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