Research Article
Open Access
CrossMark

Robotic training in the management of adhesive capsulitis: a randomized controlled trial protocol

Abstract

Background: Adhesive capsulitis (AC) is characterized by pain and limitation of active and passive range of motion. Its development leads to functional limitation and cortical reorganization. There is no consensus regarding the treatment of this condition as the pathophysiology is not yet clearly understood. Rehabilitation focuses on functional tasks during physical therapy sessions to improve patient autonomy. The purpose of this study is to evaluate the efficacy of robotic training compared to conventional rehabilitation in patients with AC.

Materials and methods: It's a single-blind, randomized, controlled trial conducted at the Department of Physical Medicine and Rehabilitation, Rabat University Hospital, Morocco. This prospective analytical study compares robotic training with the Armeo® Spring device combined with passive continuous mobilization to conventional physical therapy in patients with AC. Participants will be evaluated prior to randomization and followed up at 3 weeks, 6 weeks, 3 months, 6 months, and 12 months. The main outcome is the Shoulder Pain and Disability Index (SPADI). Secondary outcomes are: pain, active and passive range of motion, SF-36 index.

Volume 8 Issue 2 - 2023

Sara Skalli,[1] Samia Karkouri[1]
[1]PRM department, University Hospital of Rabat, Mohammed V University, Morocco

Correspondence: Sara Skalli, PRM department, University Hospital of Rabat, Mohammed V University, Faculty of medicine and Pharmacy of Rabat, Morocco, Tel +212 6 61 50 42 51, Email dr.skalli.sar@gmail.com

Received: August 06, 2023 | **Published:** August 23, 2023

Background

Adhesive capsulitis (AC) is a condition characterized by pain and three-dimensional limitation of active and passive range of motion (ROM) of the shoulder,[1] leading to underuse of the affected extremity and, in some cases, Kinesiophobia – fear of moving.[2] This limits the function of the affected limb, impairs activities of daily living, and limits social and professional participation. The result is a frozen shoulder and poor quality of life.[3] The prevalence of AC in the general population is 2% to 5%, especially in women aged 40 to 60 years.[4] The goals of treatment are to reduce pain and increase shoulder range of motion to improve shoulder function. Treatment protocols include pharmacological and non-pharmacological modalities.[5] Medications involve analgesics, anti-inflammatory drugs, intra-articular steroid injections, or hydro dilation (dilation of the shoulder joint by injecting saline or contrast media under general or local anesthesia).[6] Non-pharmacological approaches include functional rehabilitation. This is the core of treatment and can be continued long-term through home self-program:[7,8]

I. Passive, manual or instrumental mobilization of the glenohumeral joint while respecting the pain threshold and specific mobilization by a combination of pulling and rotation to release the joint capsule.

II. Analytical or functional active mobilization

III. Strengthening of the shoulder muscles with exercises related to activities of daily living and personal needs (work, leisure, etc.).

To propose an instrumental rehabilitation for AC patients based on the above measures, we conduct this randomized controlled trial to evaluate the effectiveness of robotic training compared with conventional rehabilitation for AC patients

Materials and methods

Study design

This is a single, blinded, randomized controlled study It is a prospective comparative analytical study to evaluate the utility of appliance rehabilitation using a combination of upper extremity exoskeleton and continuous passive mobilization in the treatment of AC Figure 1. Study design complies with the SPIRIT guidelines Appendix 1. All eligible patients are informed of the study and its progress. They are invited to participate by the investigator, a physician in the Department of Physical and Rehabilitation Medicine (PRM), Rabat University Hospital, Morocco. If agreeing to participate, the patient will provide and sign an informed consent form Appendix 2.

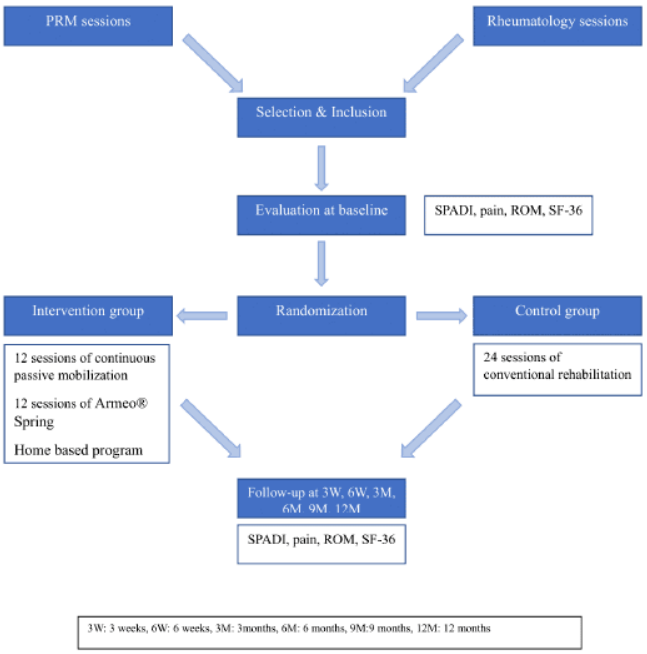

Figure 1 Study design.

Setting and location

Patients are recruited from the PRM and Rheumatology sessions at Rabat University Hospital. This study will be conducted at the PRM department at Rabat University Hospital.

Selection criteria

Included participants met the following criteria Table 1.

Intervention

Participants were divided into groups:

Intervention group: Receive:

I. 12 sessions of continuous passive mobilization on the Kinetec® Centura:

Sessions were scheduled according to this program:

During the first week, patients received 1 session per day for 5 days, performing only simple movements. Device setup was adjusted according to clinical examination at baseline and gradually increased according to pain threshold.

In the following weeks, the patient will have 3 sessions per week. Composite exercise is started.

Physiotherapist records ROM achieved at the end of each session.

II. 12 sessions of robotic therapy at Armeo® Spring, Hocoma Switzerland.

The Armeo® Spring is an ergonomic, adjustable upper limb exoskeleton that combines robotic assistance and virtual reality. It has seven axes, allowing for virtual play in a vast three-dimensional (3D) workspace. It features both arm weights and forearm braces. The gravity compensation system can be adjusted in 9 settings for arms and forearms. This robotic rehabilitation device is connected to software and provides voluntary virtual exercises with visual and auditory feedback. The patient receives 3 sessions per week of 40 minutes each. Each session includes 4 games combining 2D and 3D movements. Functional work is first performed in assisted active mode with maximum lightening, then the workspace is gradually increased and the support system is reduced. A standardized training program have been stablished (Table 2, Appendix 3).

III. Patients will be given a self-program booklet provided in a French or Arabic dialect with instructions forhome training. It Contains 22 exercises. Each exercise is described with text and pictures (start and end positions) to make the movements easier to understand. Patients record their progress (Appendix 4).

Table 1 Selection criteria

Inclusion criteria	Exclusion criteria
• Patients >18 years of age • Shoulder pain and/or movement limitation • Idiopathic AC or associated with confirmed systemic disease (e.g., diabetes or dyslipidemia)	• Cognitive impairment • History of surgery • Fracture or dislocation of the shoulder • History of shoulder tendinopathy • History of inflammatory or degenerative disease • Infection • Neurological disease (Parkinson's disease, stroke, multiple sclerosis, neurological • Manipulation under anesthesia, hydro dilation or hyaluronic acid infiltration within the last 6 months.

Table 2 Armeo training program

Week	Session(40min)	Program
	1	High Flyer, Rain Mug, Brick Breaker, Supermarket
1	2	High Flyer, Brick Breaker, Balloons, Roll the Ball
	3	High Flyer, Pirates, Balloons, Cleaning
	1	Roll the Ball, Balloons, Save the Monster, Farmer
2	2	Roll the Ball, Balloons, Pirates, Cleaning
	3	Roll the Ball, Fishing, Cleaning, Supermarket
	1	Balloons, Roll the Ball, Diving, Cleaning
3	2	Balloons, Fishing, Diving, Farmer
	3	Balloons, Fishing, Diving, Supermarket
	1	Farmer, Fishing, Cleaning, Supermarket
4	2	Farmer, Fishing, Diving, Supermarket
	3	Farmer, Fishing, Diving, Supermarket

Control group

Undergo conventional rehabilitation 24 times. Prescriptions include pain-relieving physiotherapy, passive mobilization, active functional work, and self-programmed learning with a physiotherapist.

Participant safety, failure and withdrawal

Adjuvant treatments allowed during the study were analgesics, anti-inflammatory drugs, corticosteroid infiltration, or topical treatments. Participants may contact the principal investigator with questions or adverse events at any time. In case of pain or injury, they refer to the PRM department where they will be examined by an investigator. The study is considered failed if there is no improvement or worsening after 6 weeks of rehabilitation. The patient will be discontinued from the study and offered another alternative therapy. All participants may withdraw from the study at any time without giving a reason.

Outcomes

Primary outcome:

The primary outcome is the Shoulder Pain and Disability Index (SPADI). This is a self-written questionnaire. It consists of two subscales. The first assesses the importance of pain felt on five items. Pain scores range from 0 to 50. The second evaluates the difficulty of

activities of daily living based on eight questions. Impairment scores range from 0 to 80. Final scores range from 0 to 130, with higher scores indicating greater pain and disability.

We used the validated Tunisian version (9) Appendix 5.

Secondary outcomes:

I. Assess pain using a visual analogue scale (VAS). This is a 100 mm ruler that allows patients to rank their pain on a continuum from no pain to extreme pain. The patient places the indicator on a level that represents their current pain.

II. Active and passive range of motion is clinically assessed using a goniometer while standing. We measured abduction, extension and external rotation.

III. Quality of Life is assessed using the SF-36 Index Appendix 6. This is a self-administered scale that includes eight-point scores for physical activity, life and relationships, physical distress, perceived health, vitality, mental state limits, physical state limits, and mental health. Scores for each domain range from 0 to 100, with higher scores defined as better health Figure 2.

3WFW: 3 weeks follow-up, 6WFW: 6 weeks follow-up, 3MFW: 3 months follow-up, 6MFW: 6 months follow-up, 9MFW: 9 months follow-up, 12MFW: 12 months follow-up
VAS: visual analogic scale

Figure 2 Timeline.

Sample size

The target sample size was calculated in collaboration with a team from the Institute of Biostatistics and Clinical Epidemiology, Faculty of Medicine and Pharmacy, Mohammed V University, Rabat, Morocco. The hypothesis is an 18-point improvement in SPADI in the intervention group compared with the control group, with an alpha risk of 0.05, a beta power of 0.8, and a dropout rate of 10%, 16 patients per group must be included.

Randomization

Patients are randomly assigned to one of two groups. The Computer-generated list was handed over by the Institute of Statistics, Faculty of Medicine and Pharmacy, Rabat. A randomization list is given to a member of the team who does not know the participant; The randomization is based on the number assigned to each subject.

Data management

All data will be recorded in a notebook by the principal investigator. Each participant will have their own paper exercise book, which will be kept safe by the lead researcher. Data are transcribed progressively and updated regularly in Excel spreadsheets in digital form to keep a copy of the non-nominated data and to prepare static analysis.

Statistical analysis

Statistical analysis is performed using JAMOVI software. Descriptive statistics are used to examine demographic information such as gender, age, laterality, affected shoulders and concomitant diseases (diabetes). Qualitative variables are expressed as numbers and percentages, quantitative variables are expressed as means and standard deviations for normal distributions, and medians and quartiles for worst cases. Students' T-tests are performed to compare two independent groups based on the alternative hypothesis of superiority of robotic rehabilitation compared to standard care in patients with AC. A repeated measures ANOVA is used to examine changes in scores over time at follow-up in both the intervention and control groups.

Discussion

AC is defined by pain and a gradual decrease in active and passive ROM associated with contraction of the inflammatory capsule.[10] Therefore, patients fear aggressive movements and mobilizations by physical therapists, especially if they are suddenly stretched. As a result, they cause inhibition of mechanical motion.[11] Therefore, it makes sense to rely on continuous passive movement. A motorized device gently moves the shoulder joint in three planes during the session. On the one hand, it helps reduce kinesiophobia and gives patients confidence in respecting pain thresholds. On the other hand, it allows progressive tension and thus stretching of the capsule, allowing the improvement of ROM.

Patient-experienced shoulder pain limits use of the affected limb through cortical reorganization and body schema disruption.[12] Somatosensory memory is also affected and overly focused on pain.[13] This can be exacerbated by comorbidities such as sleep disorders, depressive disorders, and anxiety disorders.[14] Armeo® Spring exercises can relieve shoulder pain in patients. By focusing on games with audiovisual feedback, the patient's attention is no longer on their shoulders, but on an enjoyable rehabilitation session.[15] Patients are therefore more active and more actively involved in rehabilitation programs. This ergonomic upper limb exoskeleton, with its gravity-assisted system, can help in mechanical movement, reducing patient discomfort.[16] This allows patients to progress painlessly and gradually through exercise to increase ROM.

Armeo® Spring, Hocoma, is a medically certified robotic rehabilitation device originally used in the field of neurorehabilitation. It is based on the principle of motor learning. The above cortical reorganizations involve motor learning in addition to body schema

modifications. Training is based on repetitive, task-oriented exercises in a virtual environment that help improve limb function.[17] Robotic training is a new modality that offers the potential for more effective functional training and repetition.[18] To our knowledge, a rehabilitation protocol for AC with exoskeleton that combines passive and active mobilization has not yet been developed. The purpose of this randomized controlled trial was to compare robot training with standard care in patients with AC.

Limitations

I. Relatively small sample size and designed for functional endpoints (SPADI) only.

II. The protocol proposes an exoskeleton available in our rehabilitation department, not necessarily in other centers. This may affect the reproducibility of clinical studies. Especially because instrument rehabilitation is expensive.

III. For organizational reasons, the clinical trial is single-blind. For better science, investigators assessing patients at baseline and follow-up should not know their randomization groups.

Trial status

Patient enrollment began in March 2021, and at the time of submission of this study protocol, the study is ongoing and is recruiting patients. To date, 26 patients have participated in the study. Final results will be published regardless of whether the results are positive, negative or inconclusive.

Declarations

Ethical approval and consent to participation

The clinical study was approved by the Biomedical Research Ethics Committee of the Rabat Faculty of Medicine and Pharmacy Appendix 7. This approval is based on the Declaration of Helsinki and the guidelines of the International Council on Medical Ethics for Biomedical Research Involving Humans. In the event of significant protocol changes or adverse events, the Principal Investigator will notify the Ethics Committee. Informed consent to participate is obtained from patients prior to enrollment in the study. Only the principal investigator holds personal information about registered participants.

Consent to publication

Informed consent was taken from participants to share their image in submission.

Data availability statement

An Excel spreadsheet containing demographic information and follow-up of patients enrolled to date is available. Corresponding author may be contacted for access or information.

Conflicts of interest

Team Members declare no conflict of interest.

Funding

This study received no funding from any investment agency.

Acknowledgments

Lftah Youssef and Sohaib Reda Physiotherapists at PRM Department, Rabat University Hospital, help in preparing the booklet. He consents to publication Appendix 8.

Dr. Belahcen Amina, at the Institute of Biostatistics and Clinical Epidemiology, Faculty of Medicine and Pharmacy, Mohammed V University, Rabat, Morocco.

Author Dr. Mohamed Guermazi approved the use of the validated Tunisian version of SPADI.

Author's contribution

Both authors were involved in the methodological development of the study protocol. The authors declare that they have written and reviewed the manuscript. They also consent to publication.

References

1. Zuckerman JD, Rokito A. Frozen shoulder: a consensus definition. *J Shoulder Elbow Surg*. 2011;20(2):322–325.
2. De Baets L, Matheve T, Traxler J, et al. Pain-related beliefs are associated with arm function in persons with frozen shoulder. *Shoulder Elb*. 2020;12(6):432–440.
3. Fernandes MR. Correlation between functional disability and quality of life in patients with adhesive capsulitis. *Acta Ortop Bras*. 2015;23(2):81–84.
4. Neviaser AS, Neviaser RJ. Adhesive capsulitis of the shoulder. *J Am Acad Orthop Surg*. 2011;19(9):536–542.
5. Ramirez J. Adhesive Capsulitis: Diagnosis and Management. *Am Fam Physician*. 2019;99(5):297–300.
6. Redler LH, Dennis ER. Treatment of Adhesive Capsulitis of the Shoulder. *J Am Acad Orthop Surg*. 2019;27(12):e544–e554.
7. Page MJ, Green S, Kramer S, et al. Manual therapy and exercise for adhesive capsulitis (frozen shoulder). *Cochrane Database Syst Rev [Internet]*. 2014;26(8):CD011275.
8. Costantino C, Nuresi C, Ammendolia A, et al. Rehabilitative treatments in adhesive capsulitis: a systematic review. *J Sports Med Phys Fitness*. 2022;62(11):1505–1511.
9. Guermazi M, Ghorbel S, Yahia A, et al. Traduction et validation en arabe de l'indice SPADI. *Ann Phys Rehabil Med*. 2011;54:e241.
10. Itoi E, Arce G, Bain GI, et al. Shoulder Stiffness: Current Concepts and Concerns. *Arthrosc J Arthrosc Relat Surg Off Publ Arthrosc Assoc N Am Int Arthrosc Assoc*. 2016;32(7):1402–1414.
11. Legrain V, Bultitude JH, De Paepe AL, et al. Pain, body, and space: what do patients with complex regional pain syndrome really neglect? *Pain*. 2012;153(5):948–951.
12. Reinersmann A, Landwehrt J, Krumova EK, et al. Impaired spatial body representation in complex regional pain syndrome type 1 (CRPS I). *Pain*. 2012;153(11):2174–2181.
13. Moseley GL, Zalucki N, Birklein F, et al. Thinking about movement hurts: the effect of motor imagery on pain and swelling in people with chronic arm pain. *Arthritis Rheum*. 2008;59(5):623–631.
14. Brindisino F, Silvestri E, Gallo C, et al. Depression and Anxiety Are Associated With Worse Subjective and Functional Baseline Scores in Patients With Frozen Shoulder Contracture Syndrome: A Systematic Review. *Arthrosc Sports Med Rehabil*. 2022;4(3):e1219–e1234.
15. Lewis GN, Rosie JA. Virtual reality games for movement rehabilitation in neurological conditions: how do we meet the needs and expectations of the users? *Disabil Rehabil*. 2012;34(22):1880–1886.
16. Perry BE, Evans EK, Stokic DS. Weight compensation characteristics of Armeo®Spring exoskeleton : implications for clinical practice and research. *J Neuroengineering Rehabil*. 2017;14(1):14.

17. Grimm F, Naros G, Gharabaghi A. Closed-Loop Task Difficulty Adaptation during Virtual Reality Reach-to-Grasp Training Assisted with an Exoskeleton for Stroke Rehabilitation. *Front Neurosci*. 2016;10:518.

18. Bertani R, Melegari C, De Cola MC, et al. Effects of robot-assisted upper limb rehabilitation in stroke patients: a systematic review with meta-analysis. *Neurol Sci Off J Ital Neurol Soc Ital Soc Clin Neurophysiol*. 2017;38(9):1561–1569.

Citation: Skalli S, Karkouri S. Robotic training in the management of adhesive capsulitis: a randomized controlled trial protocol. *Int Phys Med Rehab J*. 2023;8(2):167–171. DOI: 10.15406/ipmrj.2023.08.00354