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Mobilização com Movimento na Dor do Ombro Relacionada com o Manguito Rotador

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Mobilização com Movimento na Dor do Ombro Relacionada com o Manguito Rotador

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Dedicatória

Dedico esta tese ao meu recém falecido pai que infelizmente não poderá compartilhar comigo deste importante momento da minha vida acadêmica. Mas ficam os ensinamentos, as lembranças e os belos momentos de convívio que tivemos.

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Epígrafe

“A ship is always safe at shore but that is not what it’s built for”

Albert Einstein.

RESUMO

A presente tese é constituída de dois estudos. **Artigo 1:** O primeiro estudo teve como finalidade publicar o protocolo do estudo principal desta tese. Através de um ensaio clínico randomizado e placebo controlado, 70 pacientes com dor crônica no ombro relacionada com o manguito rotador serão alocados em dois grupos distintos: mobilização com movimento (MWM) aplicada de forma pragmática + exercícios (MWM+E) e falsa MWM + exercício (SMWM+E). O período de tratamento será de cinco semanas com duas sessões semanais. Os desfechos primários são incapacidade (*shoulder pain and disability index) e* dor (*numeric pain rating scale*) que serão medidos no início, término do período de tratamento e *follow-up* de um mês. Os desfechos secundários são amplitude de movimento (ADM) ativa livre de dor, medida por um avaliador cegado, no início e término do tratamento; auto-eficácia medida no início, término do tratamento e *follow-up*; e, percepção da melhora geral, medida no término do tratamento e *follow-up*. **Artigo 2:** O segundo estudo desta tese apresenta os resultados obtidos da implementação do protocolo supracitado. A pesquisa envolveu 59 participantes (84% do total calculado) de ambos os sexos, com média de idade de 49 anos e duração mediana de dor de 9,5 meses. O grupo MWM+E apresentou resultados clínicos e estatísticos superiores em relação à incapacidade e ADM ativa a curto prazo e dor a curto prazo e *follow-up* de um mês. Não foram encontradas outras diferenças significativas para os outros desfechos. Consequentemente, os achados desta investigação sugerem que o uso de mobilizações com movimento de forma pragmática em conjunto com exercícios pode acelerar o processo de recuperação funcional (incapacidade, dor e ADM) em pacientes com dor no ombro relacionada com o manguito rotador.

Palavras-chave: Manipulações musculoesqueléticas; Mobilização com movimento; Dor no ombro; Incapacidade no ombro; Exercícios; Placebo.

ABSTRACT

This thesis is composed of two studies. **Article 1**: the first article aimed to publish the protocol for the main study of this thesis. A randomised, placebo-controlled, clinical trial will enroll 70 patients with chronic rotator cuff related pain, and will randomly allocate them to one of two groups: pragmatic application of mobilisation with movement + exercise (MWM+E) or sham mobilisation with movement + exercise (SMWM+E). The treatment period will last five weeks with two weekly sessions. The primary outcomes are: disability (shoulder pain and disability index) and pain (numeric pain rating scale), both will be measured at baseline, end of treatment and one-month follow-up. Secondary outcomes are active pain free ROM, measured at baseline and end of treatment by a blind assessor; self-efficacy measured at baseline, end of treatment and follow-up; and, global rating of improvement, measured at the end of treatment and follow-up. **Article 2:** The second article of this thesis presents the results obtained from the implementation of the aforementioned protocol. The research enrolled 59 female and male participants (84% of the total sample calculated), with a mean age of 49 years and a median duration of pain of 9.5 months. The MWM+E group obtained clinically and statistically superior results in relation to disability and ROM at the end of treatment and pain at the end of treatment and one-month follow-up. There were no significant differences for other outcomes. Thus, the findings from this investigation suggest that the pragmatic use of mobilisation with movement in conjunction with exercises might accelerate functional restoration (disability, pain and ROM) in patients with rotator cuff related pain.

Key words: Musculoskeletal manipulation; Mobilisation with movement; Shoulder pain; Shoulder disability; Exercises; Placebo.

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LISTA DE ABREVIATURAS E SIGLAS

ABD	Abduction
ANCOVA	Analysis of covariance
ANOVA	Analysis of variance
ADM	Amplitude de movimento
AROM	Active pain-free range of motion
BMI	Body mass index
CONSORT	Consolidated standards of reporting trials
CG	Exercise and sham mobilization with movement
EG	Exercise and mobilization with movement
EOT	End of the treatment
ER	External rotation
FACCAT	Faculdades Integradas de Taquara
FLX	Flexion
FU	Follow-up
GEE	Generalized estimating equation
GROC	Global rating scale of change
HBB	Hand behind back
M	Months
MCID	Minimal clinically important difference
MWM	Mobilisation with movement
MWM+E	Mobilisation with movement plus exercise
NPRS	Numeric pain rating scale
PPT	Pain pressure threshold
RB	Rafael Baeske
RD	Rafael Rodrigues Dall Olmo
RCRP	Rotator cuff related pain
ROM	Range of motion
SD	Standard deviation
SE	Self-efficacy
SMWM+E	Sham mobilization with movement plus exercise
SPADI	Shoulder pain and disability index

SPIRIT	Standard protocol items for randomized interventional trials
SPSS	Statistical package for social sciences software
T0	Baseline
T1	End of treatment
T2	Follow-up
Yrs	Years
95%CI	95% confidence interval

SUMÁRIO

1 CONTEXTUALIZAÇÃO

A mobilização com movimento (MWM) é um procedimento de terapia manual que envolve o uso de uma força manual passiva, aplicada a um determinado segmento de uma articulação sintomática, enquanto o indivíduo realiza um movimento disfuncional.[1] Desta forma, a MWM possui como principal objetivo terapêutico a melhora da amplitude de movimento (ADM) ativa livre de dor. Restrição dolorosa de movimento ativo dificultando atividades de vida diária e laborais é uma das principais queixas de pacientes com sintomas musculoesqueléticos que se apresentam para tratamento fisioterapêutico. Consequentemente, a MWM parece ser uma modalidade de tratamento plausível para pacientes com disfunções musculoesqueléticas dolorosas. Tal premissa é suportada por recentes revisões sistemáticas que têm sugerido resultados promissores com o uso de MWM para diversas regiões, como joelho,[2] cotovelo,[3] coluna cervical,[4] ombro,[5] entre outras.[6]

Inúmeras publicações têm proporcionado a profissionais da área da saúde descrições informativas e ilustrativas das diversas alternativas de aplicações das MWM.[1,7,8] Adicionalmente, instituições de ensino superior e cursos de formações extracurriculares proporcionam um momento importante para aquisição e desenvolvimento das habilidades práticas necessárias quando se considera o uso destes procedimentos de tratamento. No entanto, um aspecto chama atenção ao se examinar a fidelidade clínica[9] da vasta maioria das investigações científicas envolvendo pacientes e o uso das mobilizações com movimento.[2–4,6,10] Estas publicações utilizam apenas uma determinada alternativa de MWM nos pacientes recrutados e, muito corriqueiramente, em apenas uma direção de movimento. Uma característica importante da MWM é justamente a sua capacidade de se adequar e ajustar as necessidades específicas do paciente sendo atendido.[1,7] Exemplificando: dois pacientes com

dor no ombro e com a mesma limitação de movimento da articulação glenoumeral podem necessitar de duas alternativas distintas de MWM. Tal fato não é suficientemente investigado nos diferentes estudos das revisões sistemáticas supracitadas. Ademais, é comum que um paciente necessite aplicações de MWM diferentes em atendimentos subsequentes. Este pragmatismo clínico parece ser um fator fundamental para *experts* que usam os procedimentos de MWM.[11] Embora especulativo, um argumento poderia ser feito que os resultados dos ensaios clínicos da maioria dos estudos envolvendo MWM poderiam ser diferentes, caso o uso das MWM fosse utilizado de maneira pragmática, ou seja, buscando aquele procedimento que resulta em melhor resposta para o paciente.

Os artigos 1 e 2 desta tese procuram auxiliar a melhor compreender o uso das MWM de forma pragmática em conjunto com exercícios em pacientes com dor relacionadas com o manguito rotador. Desta forma, a importância da identificação da MWM mais adequada para cada paciente é explorada de forma empírica. Dor no ombro é considerada uma das principais causas de queixas musculoesqueléticas, acometendo cerca de 20% da população.[12] Adicionalmente, além desta alta prevalência, a história natural de pessoas com problema no ombro também merece atenção. Estudos têm indicado que pessoas com disfunções no ombro podem permanecer sintomáticas por pelo menos 12 meses.[13,14] Tal fato sugere que o ombro é uma região recalcitrante aos tratamentos propostos comumente e/ou que a resolução natural da maior parte das apresentações clínicas acometendo esta região é lenta, pelo menos quando se controla a evolução por 12 meses. Um interessante estudo ilustra bem o papel da fisioterapia e seus efeitos frente a história natural em pacientes com dor relacionada com o manguito rotador.[15] Este estudo indica que a fisioterapia foi minimamente superior a história natural, quando se considera a função e dor, apenas no primeiro *follow-up* de três meses. Adicionalmente, o estudo sugere que existe um platô terapêutico produzido pela fisioterapia. Sessões adicionais a esse platô não acarreta em melhores resultados clínicos. Desta forma, pode-se alegar que a quantidade de sessões talvez não seja o fator principal, mas sim, o que é realizado durante estas sessões.

Uma recente meta-análise indica que o uso da MWM está associado a melhora da dor, mobilidade e função em uma série de disfunções

musculoesqueléticas acometendo o ombro.[5] No entanto, alguns aspectos metodológicos devem ser levados em consideração quando os resultados deste estudo são interpretados. Primeiro, as diferentes pesquisas utilizaram apenas uma única técnica de MWM na população recrutada. Segundo, a vasta maioria dos estudos não utilizou MWM em conjunto com exercícios. Terceiro, o efeito placebo da MWM em conjunto com exercícios não foi devidamente explorado. Quarto, a maioria dos estudos explorou apenas os efeitos imediatos, sem o devido acompanhamento. Consequentemente, importantes lacunas científicas ainda precisam ser devidamente exploradas em pacientes com disfunções musculoesqueléticas do ombro.

Tendo em vista a potencial relevância das MWM em pacientes com dor no ombro, torna-se importante verificar sua importância dentro de um contexto terapêutico corriqueiro em pacientes com dor no ombro relacionada com o manguito rotador. Das diversas alternativas de tratamento conservador disponíveis para estes pacientes, o uso de exercícios parece ser o mais rotineiramente empregado e mais efetivo.[16,17,18] Desta forma, a investigação de um programa de tratamento que contempla exercícios e MWM merece escrutínio científico.

Levando em consideração a importância da fisioterapia na reabilitação funcional em pacientes com dor no ombro relacionada com o manguito rotador,[17] a investigação do uso pragmático da MWM em conjunto com exercícios e comparada com um procedimento placebo, torna-se necessária para melhor se compreender o seu papel em pacientes com dor relacionada com o manguito rotador.

REFERÊNCIAS

1. Hing W, Hall T, Mulligan BR. *The Mulligan Concept of Manual Therapy: Textbook of Techniques*; 2020.
2. Weleslassie GG, Temesgen MH, Alamer A, Tsegay GS, Hailemariam TT, Melese H. Effectiveness of Mobilization with Movement on the Management of Knee Osteoarthritis: A Systematic Review of Randomized Controlled Trials. *Pain Res Manag*. 2021;2021:8815682.
3. Lucado AM, Dale RB, Vincent J, Day JM. Do joint mobilizations assist in the recovery of lateral elbow tendinopathy? A systematic review and meta-analysis. *J Hand Ther*. 2019;32(2):262-276.e1.
4. Hidalgo B, Hall T, Bossert J, Dugeny A, Cagnie B, Pitance L. The efficacy of manual therapy and exercise for treating non-specific neck pain: A systematic review. *J Back Musculoskelet Rehabil*. 2017;30(6):1149-1169.
5. Satpute K, Reid S, Mitchell T, Mackay G, Hall T. Efficacy of mobilization with movement (MWM) for shoulder conditions: a systematic review and meta-analysis. *J Man Manip Ther*. 2022;30(1):13-32.
6. Stathopoulos N, Dimitriadis Z, Koumantakis GA. Effectiveness of Mulligan's Mobilization With Movement Techniques on Range of Motion in Peripheral Joint Pathologies: A Systematic Review With Meta-analysis Between 2008 and 2018. *J Manipulative Physiol Ther*. 2019;42(6):439-449.
7. Mulligan BR. *Manual Therapy: NAGS, SNAGS, MWMS, Etc*. 7th ed. Plane View Services Ltd; 2018.
8. Bessler, J., Counsell, S-A., Crowell, R., Miller, J., Stolz, C. *Therapiekonzepte in Der Physiotherapie Mulligan*. Georg Thieme Verlag KG; 2009.
9. Sanetti LMH, Cook BG, Cook, L. Treatment fidelity: What Is is and Why It Matters. *Learning Disabilities Research & Practice*. 2021;36(1):5-11.
10. Pourahmadi MR, Mohsenifar H, Dariush M, Aftabi A, Amiri A. Effectiveness of mobilization with movement (Mulligan concept techniques) on low back pain: a systematic review. *Clin Rehabil*. 2018;32(10):1289-1298.
11. Baeske R, Silva MF, Hall T. The clinical decision making process in the use of mobilisation with movement - A Delphi survey. *Musculoskelet Sci Pract*. 2020;49:102212.

12. Picavet HSJ, Schouten JS a. G. Musculoskeletal pain in the Netherlands: prevalences, consequences and risk groups, the DMC(3)-study. *Pain*. 2003;102(1-2):167-178.
13. Karel YHJM, Verhagen AP, Thoomes-de Graaf M, et al. Development of a Prognostic Model for Patients With Shoulder Complaints in Physical Therapist Practice. *Phys Ther*. 2017;97(1):72-80.
14. Cadogan A, Laslett M, Hing WA, McNair PJ, Coates MH. A prospective study of shoulder pain in primary care: prevalence of imaged pathology and response to guided diagnostic blocks. *BMC Musculoskelet Disord*. 2011;12:119.
15. Dickinson RN, Ayers GD, Archer KR, et al. Physical therapy versus natural history in outcomes of rotator cuff tears: the Rotator Cuff Outcomes Workgroup (ROW) cohort study. *J Shoulder Elbow Surg*. 2019;28(5):833-838.
16. Smythe A, Rathi S, Pavlova N, et al. Self-reported management among people with rotator cuff related shoulder pain: An observational study. *Musculoskelet Sci Pract*. 2021;51:102305.
17. 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(10):647-664.
18. Doiron-Cadrin P, Lafrance S, Saulnier M, et al. Shoulder Rotator Cuff Disorders: A Systematic Review of Clinical Practice Guidelines and Semantic Analyses of Recommendations. *Arch Phys Med Rehabil*. 2020;101(7):1233-1242.

2 OBJETIVOS

Artigo 1

Apresentar o protocolo do estudo a ser utilizado no estudo principal desta tese de doutorado.

Artigo 2

Investigar se o uso de mobilização com movimento + exercícios é superior a uma falsa mobilização com movimento + exercícios em pacientes com dor no ombro relacionada com o manguito rotador.

3 ARTIGO 1

THE INCLUSION OF MOBILISATION WITH MOVEMENT TO A STANDARD EXERCISE PROGRAMME FOR PATIENTS WITH ROTATOR CUFF RELATED PAIN: A RANDOMIZED, PLACEBO-CONTROLLED PROTOCOL TRIAL

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Abstract

Background: Rotator cuff related pain (RCRP) is one of the most common sources of musculoskeletal shoulder pain affecting the general population. Conservative treatment, in the form of exercise, is considered the first line approach, nonetheless, improvements seem to be modest. One therapeutic modality that might be an adjunct to the treatment of this condition is mobilisation with movement (MWM). MWM is a pain-free manual procedure that targets restricted and painful movements, commonly seen in patients with RCRP. The purpose of clinical trial is to determine whether MWM with exercise has benefits over sham MWM with exercise in RCRP.

Methods: A randomised, sham-controlled trial of 70 adults complaining of RCRP will compare the effects of MWM combined with exercise over sham MWM with exercise. Participants will be allocated to one of two groups: exercise and MWM (EG) or exercise and sham MWM (CG). Two weekly individual treatment sessions will be conducted over five weeks. All assessments will be performed by a blinded assessor. Primary outcome measures will be the shoulder pain and disability index (SPADI) and the numeric pain rating scale (NPRS), assessed at baseline, discharge and one-month follow-up. Secondary outcome measures will be active range of motion, self-efficacy and the global rating of change scale. The analyses will be conducted considering a statistically significant p-value ≤0.05. Normality will be assessed with the Kolmogorov-Smirnov test and homogeneity with the Levene's test. For the primary outcome measures (SPADI and NPRS) and self-efficacy, a 2 x 3 ANOVA with treatment group (EG versus CG) and time (baseline, end of the treatment and follow-up) factors will be performed. Separate 2 x 2 ANOVA will be used for range of motion (baseline and end of the treatment). Global rating scale of change analysis will be conducted using descriptive statistics. Intention-to-treat analysis will be adopted.

Discussion: As there is a paucity of longitudinal studies investigating the use of MWM in patients with RCRP, this study will help to better understand its role together with a structured exercise programme.

Trial registration: Clinical Trials Registry number NCT04175184. November, 2019.

Keywords: Musculoskeletal manipulations, Mobilisation with movement, Shoulder pain, Rotator cuff, Exercise

Background

Shoulder pain is one of the most common sources of musculoskeletal pain that affects up to 20% of the population [1]. Importantly, approximately 40% of people complaining of shoulder pain will still be symptomatic six months after onset [2]. Rotator cuff related pain (RCRP) or non-specific shoulder pain is a term that includes a diversity of shoulder conditions known as: subacromial impingement syndrome, rotator cuff tendinitis/tendinopathy, rotator cuff tear, and bursitis [3, 4]. The use of a broader term is useful as the diagnostic accuracy of special orthopaedic tests have been widely criticised and are unable to identify pathognomonic sources of symptoms in people presenting with shoulder pain [5–7]. Additionally, even though diagnostic imaging is capable of identifying pathology in patients with rotator cuff related pain, correlation of these findings with the clinical presentation is questionable [8–11].

Physiotherapy has an important role in the management of rotator cuff related pain, and exercise is the main therapeutic approach when considering pain and functional restriction [12–14]. However, the improvements seem to be modest [12, 15]. A recent update of systematic reviews has suggested that adding manual therapy to exercises might offer superior short-term decrease in pain [16]. However, this finding was based on few studies with low quality level.

Mobilisation with movement (MWM) is a musculoskeletal treatment approach that focuses on improving active pain-free range of motion [17]. One of the main cardinal signs in patients suffering from rotator cuff related pain is pain on active movement. MWM incorporates a passive glide force produced by the clinician, followed by an active movement executed by the patient. Different studies have suggested positive effects of MWM over a sham procedure in patients complaining of shoulder pain [18–20], while other studies reported no such effects [21, 22]. Several methodological aspects might have influenced this discrepancy in results, such as population studied, dosage and type of MWM utilized, as well as follow-up period and outcome measures. Of particular interest here is the fact that all studies that have investigated the use of MWM in

patients with shoulder pain, utilized only one form of MWM. This aspect does not explore all MWM possibilities for patients with shoulder pain [17]. Consequently, the use of MWM in patients with rotator cuff related pain deserves greater investigation. Therefore, the purpose of this study is to explore the effects of MWM applied pragmatically, reflecting usual clinical practice for this form of musculoskeletal disorder management.

Methods

Objectives

Due to the uncertainty in MWM effectiveness for shoulder pain, the current research aims to explore the inclusion of MWM to a 5-week exercise programme in patients with rotator cuff related pain on different functional outcome measures and pain. Additionally, a comparison will be made with a previously used sham MWM [18] to account for contextual effects of treatment procedures [23]. Furthermore, we will conduct different secondary analysis (to be published separately) exploring the effects of the interventions applied (MWM and sham MWM) on pain pressure threshold in order to verify whether the interventions used have different mechanisms of action. A further aim of this study to be published separately, is to evaluate expectation on treatment outcome, which will be investigated at baseline and during the third week of treatment.

Trial design

This randomized, placebo-controlled, parallel study design will be conducted in two different sites with data collection at baseline, after the treatment period and at one month follow-up. The study was designed following the standard protocol items for randomized interventional trials (SPIRIT) and the results will be reported in accordance with the consolidated standards of reporting trials (CONSORT) guidelines for randomized trials [24].

Study settings

The study will occur in two different locations, at the physiotherapy laboratory 1 at Faculdades Integradas de Taquara and a private practice (Clínica Albrecht). The Recruiment process and flow through study is depicted in Fig. 1.

Eligibility criteria

Inclusion and exclusion criteria can be found in Table 1. Criteria utilized are similar to studies investigating the use of manual therapy treatment procedures with or without exercise in patients with rotator cuff related pain [18, 19, 25–28].

Interventions

The treatment phase starts after the participant is deemed eligible and agreed to participate voluntarily and signed a structured consent form. After randomization, participants will be allocated to one of two groups described below. The treatment phase will last 5 weeks.

Experimental group (EG)

Exercise programme

The list of exercises to be conducted in all therapeutic sessions (Additional file 1) was constructed based on previous studies and following recommendations commonly reported in the literature [26, 29–31].Two to three sets of 10 to 15 repetitions will be performed using elastic therapeutic bands and dumbells. Three repetitions of 15 s of the stretching exercises will be performed after the strengthening exercises. Exercise progression load will be individually based and managed in a way that a value of a maximum pain score of 5/10 on a verbal rating scale (0 - no pain and 10 - maximal tolerable pain) should be observed during the execution of the exercises. If no such symptom

occurs, a score of 6 on a BORG scale (0 – rest and 10 – extremely strong) will be applied. Therefore, during the treatment sessions, the load utilized (dumbells or elastic bands) will be adjusted according to the perception of symptoms. On the first session, 2 sets of 10 repetitions respecting the aforementioned symptoms will be conducted. In this way, participants will become familiar with the exercise programme and this will also inform on immediate symptom reproduction after the session. On the second session, 3 sets of 10 repetitions will be performed. Then, every week after that, 3 sets of 15 repetitions will be conducted with the adjusted load (same load, more load or less load) based on the perception of symptoms. An interval of 45–60 s will be provided between sets and exercises. Participants will be informed about the importance of increasing the load, while still respecting symptoms. In addition, if symptoms provoked by the exercise programme are still present 24 h later, the exercise load will be diminished until this no longer occurs.

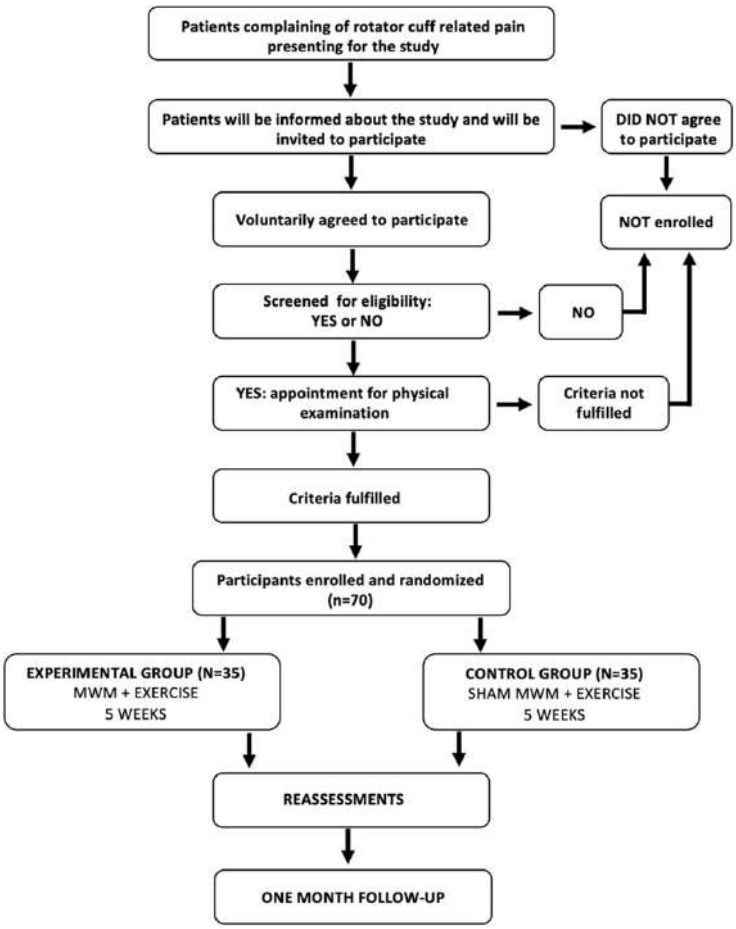

Fig. 1 Recruitment process and flow through study

Mobilisation with movement (MWM)

The participant and physiotherapist will decide on one active shoulder movement more functionally relevant to the individual. Following this, up to four attempts of MWM will be applied to different joints (cervical spine, thoracic region, scapulothoracic, as well as glenohumeral and acromioclavicular joints) and / or in different positions (standing, sitting or lying), in order to identify one particular MWM that improves significantly the shoulder movement previously selected [17]. The shoulder movement will be conducted to the onset of symptoms, should they occur. Then, one set of six to 10 repetitions will be applied repeating the same movement through pain-free range. This process of pragmatically applying MWM will be respected in every session, but from the second session onwards, two to three sets of 10 repetitions will be applied, with an interval of sixty seconds between sets. In case of failure to identify a MWM that improves the movement significantly, the patient will decide which one seems best and one set of six repetitions will be performed to the onset of discomfort.

Table 1 Inclusion and exclusion criteria

Inclusion criteria	Exclusion criteria
1. Age 18–65 years.	1. Shoulder pain following a traumatic event.
2. Unilateral shoulder pain of atraumatic origin.	2. History and clinical presentation compatible with complete rotator cuff and/or biceps brachii rupture
3. Scoring at least 3 out of 10 on a numeric pain rating scale.	3. Adhesive capsulitis.
4. Symptoms lasting more than 6 weeks.	4. History of dislocation.
5. Pain on active shoulder movement.	5. Glenohumeral osteoarthritis.
6. Pain provoked by at least three of the following tests: Hawkins-Kennedy, Neer, Painful arc, Empty/full can and Resisted external rotation.	6. Cancer 7. Systematic, local or auto-immune inflammatory conditions.
7. Patients referred by a shoulder specialist with diagnosis of rotator cuff injury (tendinitis/tendinosis), subacromial impingement syndrome, bursitis, subacromial pain, that fulfill the criteria above.	8. Previous shoulder or neck surgery or fracture. 9. Familiar pain provoked by neck movements. 10. Presence of radicular signs. 11. Use of corticosteroids over the past six months. 12. Diagnosis of fibromyalgia. 13. Clinical depression. 14. Participants under treatment for his/her shoulder conditions over the last 3 months.

Control group (CG)

Exercise programme

Exactly the same as the experimental group and conducted in the same way.

Sham mobilisation with movement (MWM)

The participant and physiotherapist will decide on one active shoulder movement that is more functionally relevant to the individual. Following this, a sham MWM [18] will be applied and the movement previously selected will be

repeated six to ten times in the first consultation. Briefly, the sham condition simulated the MWM procedure with a different hand positioning. The clinician, standing contralaterally to the treated shoulder, will place one hand over the superior aspect of the pectoralis major muscle and the other over the scapula, both hands will make skin contact only without any significant pressure. The participant will be informed that he or she should move to the onset of symptoms, if they occur. This process will be respected in every session, but from the second session onwards, two to three sets of 10 repetitions will be applied, with an interval of sixty seconds between sets. However, in case the sham MWM fails to improve the movement significantly, one set of six repetitions will be performed only.

Outcome measures

Primary outcome measures

Shoulder pain disability index (SPADI) SPADI is a self-reported questionnaire that contains 13 different items. There are two domains: pain (5 items) and functional activity (8 items). Each item ranges from 0 (no pain / no difficulty) to 10 (worst imaginable pain / so difficult that requires help). This questionnaire is a valid and well-established instrument that helps to discriminate those responding or not to a certain treatment [32]. A reduction of 8–13 points has been reported as being clinically significant [33]. The Brazilian validated version of SPADI will be used [34] at baseline, end of the treatment period, and the final follow-up.

Numeric pain rating scale (NPRS) A NRPS ranging from 0 (no pain) to 10 (worst imaginable pain) is used to measure pain intensity. Scores will be recorded for resting pain, night pain and pain during movement, all related to the previous 24h. Decreases in pain levels between 1.1 and 2.2 points or a reduction of 32–34% have been reported in the literature as being clinically significant [26, 35]. The scale will be applied at baseline, end of the treatment period and the final follow-up.

Secondary outcome measures

Active pain-free range of motion (AROM) AROM will be assessed for flexion, abduction [36], external rotation [37] and hand behind back [38]. All measurements will be conducted to the onset of pain and evaluated by an inclinometer (Baseline® Bubble Inclinometer, Enterprises Inc). Measurements will be taken at baseline and the end of the treatment period. Limitations in AROM might affect the ability to carry out activities of daily living in patients with RCRP [39] and, therefore, determining changes as a result of a treatment programme might be clinically relevant.

Pain pressure threshold (PPT) Measurements will be collected at three different sites: 5 cm distal to the lateral border of the acromion on both sides over the deltoid muscle, and 10 cm distal to the tibiofemoral joint line, over the tibialis anterior muscle on the unaffected side [40]. The importance of having a psychophysical measurement of general mechanical sensitivity is in helping to explore whether there are differences in pain, function, general pain pressure threshold and treatment outcomes in different groups. A calibrated digital algometer (Wagner instruments, model FPX 25) will be utilized for assessments. Three measurements with an interval of 30s will be taken. PPT will be assessed at baseline and end of the treatment period. This outcome measure will be analysed in a separate publication.

Global rating scale of change (GROC) GROC is a psychometric instrument that assesses the perception of improvement or deterioration from the patient's perspective [41]. The scale to be used in this study involves a 15-point Likert scale, ranging from − 7 (much worse) to + 7 (completely recovered). Using this scale, the participant will respond to the following question: "Regarding your shoulder problem, how do you assess your shoulder condition since your entry in the study". Despite evidence of instability in this scale [42], it is important to allow the participant to make an overall assessment of their condition as a result of the treatment delivered. The assessments will be taken at the end of treatment period and at the final follow-up. Previous research has adopted a value of + 5 as a cut-off point to consider that treatment was successful [26].

Expectations In health sciences, this construct assesses the beliefs that a patient has in relation to several aspects of implementation and results of therapeutic modalities [43]. Hence, expectations can be positive, negative or neutral. Factors such as a desire that something happens, previous experiences, reports from significant others, are a few of the aspects taken into account when making a prejudgment regarding a therapeutic encounter [44]. Recently, Chester and colleagues [45] investigated multiple putative factors associated with improved function and reduced pain at the end of physiotherapy treatment for people with shoulder pain. One of the strongest predictors found was the patient's expectation of recovery. Therefore, assessment of expectation in patients with shoulder pain seems important. In this study, the participant will be asked to answer the following question: "How much do you expect your shoulder problem to change as a result of physiotherapy treatment?" A seven-point Likert scale ranging from "completely recovered" to "worse than ever" will be used. Commonly, expectations are assessed prior to the start of a treatment programme. In this study, we will assess it at the beginning of the study and after 3 weeks of treatment. We understand that expectation is a dynamic construct that might vary throughout time and its assessment in two different time points may provide important inferences to be made afterwards. This outcome measure will be analysed and reported in a separate publication.

Self-efficacy (SE) SE relates to one's beliefs that he or she is capable of dealing and executing a certain course of action needed to manage actual and / or prospective events [46]. In health sciences, SE is related to pain and long-term incapacity [47], fear of movement [48], and in patients with shoulder pain, is an important factor associated with better therapeutic outcomes [45, 49]. The domains of pain and physical function of the validated Brazilian version of the chronic pain self-efficacy scale will be used in this research [50]. SE will be assessed at baseline, end of the treatment period and on follow-up.

Participant timeline

The enrollment process will begin from the end of February 2020. After entering the study, participants will have the following outcomes assessed at

baseline: SPADI, NPRS, AROM, PPT, expectations and SE; at the end of the treatment period: SPADI, NPRS, SE, AROM, PPT and GROC; and at one month follow-up: SPADI, NPRS, SE and GROC. Expectation is the only outcome measure to be collected during the third week of treatment. Figure 2 depicts enrolment, interventions and assessments timeframes throughout the study. Participants will attend ten individual sessions, twice a week (approximately 40 min each), in either of the available treatment sites, according to their geographic locations (see study settings). For the follow-up, participants will be contacted by a research member via email or mail to fill out the respective outcome measures. A telephone call will be made for participants that miss one treatment session without providing explanations.

Sample size

In order to calculate the number of subjects to be included in this study an alpha value of 0.05 and power of 80% was chosen together with a minimal clinically important difference of 10 points on the SPADI scale with standard deviation of 13.5 points [26]. An initial number of 28 participants in each group was required based on this calculation. With an estimated 20% loss to follow-up, we planned to recruit a total of 70 subjects (35 in each group).

Recruitment

Subjects will be recruited through a range of strategies. Initially, consecutive patients with shoulder pain seeking treatment at a private physiotherapy practice that agree to participate and fit the inclusion criteria, will be invited to enroll. Second, a research assistant will contact local orthopaedic specialists and inform about the study with an aim to request referrals. Third, study advertisements will be released on social media and a local printed newspaper. Lastly, a partnership established with the health secretary of São Leopoldo city will enable subject referral. Therefore, patients fitting the study criteria, referred to the local public physiotherapy service, will be invited to participate.

Allocation

Participants will be stratified by pain followed by sequence generation, using a computer-generated random number. In order to reduce predictability of random sequence, blocks of 4 and 6 random numbers will be used. Allocation sequence will be placed in sequentially numbered opaque, sealed envelopes. All allocation procedures will be conducted by a research assistant not involved in any other aspect of the study.

Blinding

Randomization and group allocation will be performed by a staff assistant not involved in any other aspect of the research. Outcome measures will be collected by a research assistant blind to group allocation, with a formal request not to discuss any aspect of the study with the participants. Data analysis will be conducted by a staff member blind to the nature of the interventions and not engaged in any other aspect of the study. Due to the characteristics of the study, the research assistant conducting the treatments cannot be blinded, nonetheless, this research assistant will not be involved in any of the above procedures. Blinding of participants will be analysed using a three-point scale, following specific orientations for this purpose [51].

	STUDY PERIOD			
	Enrolment	**Allocation**	**Post-allocation**	**Follow-up**
TIMEPOINT	***MAR 2020 to JAN 2022***	**MAR 2020 to JAN 2022**	***MAR 2020 to JAN 2022***	***1 month***
ENROLMENT:				
Eligibility screen	X	—	—	—
Informed consent	X	—	—	—
Allocation	—	X	—	—
INTERVENTIONS:				
Exercises + MWM	—		X	—
Exercises + sham MWM	—		X	—
ASSESSMENTS:				
SPADI[1] & NRPS[2]	—		Baseline & end of treatment	X
AROM[3] & PPT[4]	—		Baseline & end of treatment	—
SELF-EFFICACY	—		Baseline & end of treatment	X
EXPECTATIONS	—		Baseline and third week of treatment	—
BLINDING	—		After period of treatment	—
ADVERSE EVENTS	—		After every treatment session	—

Figure 2: Schedule of enrolment, interventions, and assessments. 1) Shoulder pain and disability index; 2) Numeric pain rating scale; 3) Active range of motion; 4) Pain pressure threshold.

Statistical analysis

Data will be analysed using the Statistical Package for Social Science software (SPSS v.20, Inc., Chicago, USA). The analyses will be conducted considering a statistically significant p-value ≤0.05. Data normality of the study

will be assessed with the Kolmogorov-Smirnov test and homogeneity with the Levene's test. The results will be reported as the mean with corresponding 95% confidence interval. Intention-to-treat analysis will be conducted so that all patients are analysed within their group allocation. Drop-outs and their reasons will be informed. All data input will be kept in two different files (double data entry) that will be updated every week by a research assistant.

A two-way analysis of variance will be conducted to assess between and within groups differences. For the primary outcome measures (SPADI and NPRS) a 2 x 3 ANOVA with treatment group (EG versus CG) and time (baseline, end of the treatment and follow-up) factors will be performed. Separate 2 Å~ 2 ANOVA will be used for ROM (baseline and end of the treatment period), and a 2 Å~ 3 ANOVA will be conducted for self-efficacy (baseline, end of the treatment period and follow-up). Additionally, appropriate post-hoc tests (Bonferroni) will be used if prior analysis indicates significant differences. GROC analysis will be conducted using descriptive statistics and participants will be classified according to treatment success. Those reporting + 5 or more will be classified as successful. Within groups differences will be calculated at the end of the treatment period and follow-up, and effect sizes will be calculated using Cohen effect size (0.2–0.5: small effect, 0.5–0.8: moderate effect, 0.8 or more: large effect size).

A second study will explore changes in expectation throughout treatment descriptively and whether those differences are associated with SPADI, NPRS and group allocated. Therefore, an ANCOVA will be conducted to analyze the influences of covariates (expectation and self-efficacy) on SPADI and NPRS. A separate 2 x 3 ANOVA will be used to examine PPT measurements in the three different body areas. Post-hoc tests (Bonferroni) will be used if prior analysis indicates significant differences.

Harms

Due to the nature of this study, we understand that it is important to control for adverse events that might occur as a result of the procedures applied. In order to monitor these, this study will use an adapted questionnaire

[52], where participants will respond to the following question: “Have you experienced any discomfort or unpleasant sensation as a result of this treatment?”. Participants will inform (discomfort, soreness, fatigue, etc), rate their sensation using the NPRS (0–10, 10 meaning highest value) and inform when it started (< 30 min after treatment, between 30 min - 4 h, etc) and if it has affected their home or work activities (nothing, little or much). This scale will be applied at each treatment session.

Research ethics approval, consent & confidentially

Ethical approval for this study was obtained from Universidade Federal de Ciências da Saúde de Porto Alegre Ethics Commitee (number 3.528.946) and the trial is registered at ClinicalTrials.gov with the identifier NCT04175184. Table 2 provides information regarding registration data set. Subjects will provide informed consent prior to participation in the trial. Participants personal data and their research data will be kept confidential and will not be disclosed to any other party not participating in the study.

Table 2 Trial registration data set

Category	Information
Primary registry and trial identifying number	ClinicalTrials.gov NCT 04175184
Date of registration in primary registry	November, 2019
Ethics Committee number	UFCSPA Ethics Committee CAEE: 3.528.946
Source(s) of monetary or material support	Self-funded
Contact for public queries	Rafael Baeske, rbaeske@yahoo.com
Contact for scientific queries	Rafael Baeske, rbaeske@yahoo.com
Public title	The use of MWM and exercises in shoulder pain.
Scientific title	The inclusion of Mobilisation with Movement to a standard exercise programme for patients with rotator cuff related pain a randomised, placebo-controlled protocol trial.
Countries of recruitment	Brazil
Health condition and problem studied	Shoulder pain related to rotator cuff
Intervention	Mobilisation with movement
Comparator	Sham mobilization with movement
Key inclusion and exclusion criteria	Age: 18-65 years; Inclusion criteria: $\geq$ 6 weeks shoulder pain of atraumatic origin; pain on movement. Exclusion criteria: specific shoulder conditions (fracture, dislocation, arthritis, adhesive capsulitis, cancer, previous surgery, radicular signs).
Study type	Interventional Allocation: randomised; sham-controlled clinical trial with parallel groups; double-blind.
Date of first enrolment	March, 2020
Target sample size	70
Recruitment status	Recruiting
Primary outcome(s)	Function and pain
Key secondary outcome(s)	Active range of motion, pain pressure threshold, global perceived effect, self-efficacy and expectations.

Discussion

The current evidence for the conservative management of RCRP suggests that exercise with or without manual therapy should be considered. However, despite being recognized as a manual therapy approach, MWM differs from many other manual therapy procedures as it involves active movement on the part of the patient combined with a passive manual therapy procedure. Usually, the active movement chosen is the specific impairment identified as the patient's main problem. This aspect is particularly important in patients with RCRP as painful and / or restricted movement is commonly encountered on physical examination and subjectively reported as a chief complaint.

Previous studies have found contradictory findings when comparing MWM to sham MWM [18, 19, 21]. The differences in the results observed might be due to methodological aspects (participants´ clinical profile, dosage, type and expertise of the MWM used, follow-up and outcome measures). However, none of the above studies have applied MWM pragmatically. This is considered a critical aspect of the use of MWM. Often in clinical practice, there is a need to change aspects related to the MWM procedure such as: force and direction of the glide, position of the patient, location where the MWM is applied and load used. Therefore, this clinical trial will assist in verifying whether these pragmatic aspects produce better results.

Another key point not sufficiently explored in previous studies is the incorporation of MWM together with exercise in the management of patients with RCRP, reflecting common clinical practice. Only one pilot study has investigated the use of MWM with exercise [22]. However, the age group (83.9 +/− 8.2 years) and clinical settings (nursing home) differs from the current study.

Taking into consideration the high prevalence of RCRP and limited spectrum of studies investigating MWM with exercises, there is a need to verify the impact of adding MWM to an exercise programme in this population. A study comparing different treatment options, that is sham controlled, will help inform healthcare professionals in the decision-making process related to the inclusion or not of MWM in patients with RCRP.

Supplementary Information

Supplementary information accompanies this paper at https://doi.org/10.1186/s12891-020-03765-6.

Abbreviations

ANCOVA: Analysis of covariance; ANOVA: Analysis of variance; AROM: Active range of motion; CONSORT: Consolidated standards of reporting trials; CG: Control group; EG: Experimental group; GROC: Global rating scale of change; MWM: Mobilisation with movement; NPRS: Numeric pain rating scale; PPT: Pain pressure threshold; RCRP: Rotator cuff related pain; SE: Self-efficacy; SPADI: Shoulder pain disability index; SPIRIT: Standard protocol items for randomised interventional trials; SPSS: Statistical package for social science

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Not Applicable.

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Availability of data and materials

Not yet applicable as the study has not started. However, future data will be available from the corresponding author on reasonable request.

Ethics approval and consent to participate

The study received ethics approval from Universidade Federal de Ciências da Saúde de Porto Alegre Ethics Research Committee (number: 3.528.946, August, 2019). Both study sites, Faculdades Integradas de Taquara and Clínica Albrecht, were approved by the aforementioned committee as the clinical locations for data collection. Study was prospectively registered at Clinical Trial Registry (NCT 04175184, November, 2019). Participants will be informed verbally and given the opportunity to request any further information prior to entering the study. Additionally, all participants will be requested to provide a written informed consent, prior to entering the study.

Consent for publication

Consent has been obtained from the individual in the images for the publication of their image.

References

1. Picavet HS, Schouten JS. Musculoskeletal pain in the Netherlands: prevalences, consequences and risk groups, the DMC(3)-study. Pain. 2003; 102(1–2):167–78.
2. Karel YHJM, Verhagen AP, Thoomes-de-Graaf M, Duijn E, van den Borne
MPJ, Beumer A, et al. Development of a prognostic model for patients with shoulder complaints in physical therapist practice. Phys Ther. 2017;91(1):72–80.
3. Ristori D, Miele S, Rossettini G, Monaldi E, Arceri D, Testa M. Towards an
integrated clinical framework for patient with shoulder pain. Arch Physiother. 2018;8:7.
4. Lewis JS. Rotator cuff tendinopathy. Br J Sports Med. 2009;43(4):236–41.
5. Hegedus EJ, Goode A, Campbell S, Morin A, Tamaddoni M, Moorman CT,
3rd, et al. Physical examination tests of the shoulder: a systematic review with meta-analysis of individual tests. Br J Sports Med. 2008;42(2):80–92; discussion.
6. Hegedus EJ, Cook C, Lewis J, Wright A, Park JY. Combining orthopedic

special tests to improve diagnosis of shoulder pathology. Phys Ther Sport. 2015;16(2):87–92.
7. Gismervik SO, Drogset JO, Granviken F, Ro M, Leivseth G. Physical examination tests of the shoulder: a systematic review and meta-analysis of diagnostic test performance. BMC Musculoskelet Disord. 2017;18(1):41.
8. Moosmayer S, Tariq R, Stiris MG, Smith HJ. MRI of symptomatic and asymptomatic full-thickness rotator cuff tears. A comparison of findings in 100 subjects. Acta Orthop. 2010;81(3):361–6.
9. Minagawa H, Yamamoto N, Abe H, Fukuda M, Seki N, Kikuchi K, et al. Prevalence of symptomatic and asymptomatic rotator cuff tears in the general population: from mass-screening in one village. J Orthop. 2013;10(1):8–12.
10. Schwartzberg R, Reuss BL, Burkhart BG, Butterfield M, Wu JY, McLean KW. High prevalence of superior Labral tears diagnosed by MRI in middle-aged patients with asymptomatic shoulders. Orthop J Sports Med. 2016;4(1): 2325967115623212.
11. Kvalvaag E, Anvar M, Karlberg AC, Brox JI, Engebretsen KB, Soberg HL, et al. Shoulder MRI features with clinical correlations in subacromial pain syndrome: a cross-sectional and prognostic study. BMC Musculoskelet Disord. 2017;18(1):469–78.
12. Abdulla SY, Southerst D, Côté P, Shearer HM, Sutton D, Randhawa K, et al. Is exercise effective for the management of subacromial impingement syndrome and other soft tissue injuries of the shoulder? A systematic review by the Ontario protocol for traffic injury management (OPTIMa) collaboration. Man Ther. 2015;20(5):646–56.
13. Page MJ, Green S, McBain B, Surace SJ, Deitch J, Lyttle N, et al. Manual therapy and exercise for rotator cuff disease. Cochrane Database Syst Rev. 2016;6.
14. Steuri R, Sattelmayer M, Elsig S, Kolly C, Tal A, Taeymans J, et al. Effectiveness of conservative interventions including exercise, manual therapy and medical management in adults with shoulder impingement: a systematic review and meta-analysis of RCTs. Br J Sports Med. 2017;51(18): 1340–7.
15. Dickinson RN, Ayers GD, Archer KR, Fan R, Page C, Higgins LD, et al. Physical therapy versus natural history in outcomes of rotator cuff tears: the rotator cuff outcomes workgroup (ROW) cohort study. J Shoulder Elb Surg. 2019; 28(5):833–8.
16. Pieters L, Lewis J, Kuppens K, Jochems J, Bruijstens T, Joossens L, et al. An update of systematic reviews examining the effectiveness of conservative physiotherapy interventions for subacromial shoulder pain. J Orthop Sports Phys Ther. 2019;15:1–33.
17. Mulligan BR. Manual therapy. NAGS, SNAGS, MWM, etc. Plane View services Ltd: Wellington; 2010.
18. Delgado-Gil JA, Prado-Robles E, Rodrigues-de-Souza DP, Cleland JA, Fernandez-de-las-Penas C, Alburquerque-Sendin F. Effects of mobilization with movement on pain and range of motion in patients with unilateral shoulder impingement syndrome: a randomized controlled trial. J Manip Physiol Ther. 2015;38(4):245–52.
19. Teys P, Bisset L, Vicenzino B. The initial effects of a Mulligan's mobilization with movement technique on range of movement and pressure pain threshold in pain-limited shoulders. Man Ther. 2008;13(1):37–42.

20. Satpute KH, Bhandari P, Hall T. Efficacy of hand behind Back mobilization with movement for acute shoulder pain and movement impairment: a randomized controlled trial. J Manip Physiol Ther. 2015;38(5):324–34.
21. Guimaraes JF, Salvini TF, Siqueira AL Jr, Ribeiro IL, Camargo PR, Alburquerque-Sendin F. Immediate effects of mobilization with movement vs sham technique on range of motion, strength, and function in patients with shoulder impingement syndrome: randomized clinical trial. J Manip Physiol Ther. 2016;39(9):605–15.
22. Romero CL, Lacomba MT, Montoro YC, Merino DP, Costa SP, Marchante MJV, et al. Mobilization with movement for shoulder dysfunction in older adults: a pilot trial. J Chiropract Med. 2015;14:249–58.
23. Benedetti F. The Patient's brain. The neuroscience behind the doctor patient
relationship. Oxford: Oxford University Press; 2011.
24. Boutron I, Moher D, Altman DG, Schulz KF, Ravaud P, Group C. Extending the CONSORT statement to randomized trials of nonpharmacologic treatment: explanation and elaboration. Ann Intern Med. 2008;148(4):295–309.
25. Bokshan SL, DePasse JM, Eltorai AE, Paxton ES, Green A, Daniels AH. An evidence-based approach to differentiating the cause of shoulder and cervical spine pain. Am J Med. 2016;129(9):913–8.
26. Mintken PE, McDevitt AW, Cleland JA, Boyles RE, Beardslee AR, Burns SA, et al. Cervicothoracic manual therapy plus exercise therapy versus exercise therapy alone in the Management of Individuals with Shoulder Pain: a Multicenter randomized controlled trial. J Orthop Sports Phys Ther. 2016; 46(8):617–28.
27. Watts AR, Williams B, Kim SW, Bramwell DC, Krishnan J. Shoulder impingement syndrome: a systematic review of clinical trial participant selection criteria. Shoulder Elbow. 2017;9(1):31–41.
28. Hermans J, Luime JJ, Meuffels DE, Reijman M, Simel DL, Bierma-Zeinstra SMA. Does this patient with shoulder pain have rotator cuff disease? The rational clinical examination systematic review. JAMA. 2013;310(8):837–47.
29. Lewis J, McCreesh K, Roy JS, Ginn K. Rotator cuff Tendinopathy: navigating the diagnosis-management conundrum. J Orthop Sports Phys Ther. 2015; 45(11):923–37.
30. 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(2):95–106.
31. Shire AR, Staehr TAB, Overby JB, Dahl MB, Jacobsen JS, Christiansen DH. Specific or general exercise strategy for subacromial impingement syndrome does it matter? A systematic review and meta-analysis. Musculoskelet Disord. 2017;18:158.
32. Huang H, Grant JA, Miller BS, Mirza FM, Gagnier JJ. A systematic review of the psychometric properties of patient-reported outcome instruments for use in patients with rotator cuff disease. Am J Sports Med. 2015;43(10): 2572–82.
33. Roy JS, MacDermid JC, Woodhouse LJ. Measuring shoulder function: a systematic review of four questionnaires. Arthritis Rheum. 2009;61(5):623–32.

34. Martins J, Napoles BV, Hoffman CB, Oliveira AS. Versão brasileira do Shoulder Pain and Disability Index: tradução, adaptação cultural e confiabilidade. Rev Bras Fisioter. 2010;14(6):527–36.
35. Olsen MF, Bjerre E, Hansen MD, Tendal B, Hilden J, Hróbjartsson A. Minimum clinically important differences in chronic pain vary considerably by baseline pain and methodological factors: systematic review of empirical studies. J Clin Epidemiol. 2018;101:87–106.
36. Kolber MJ, Vega F, Widmayer K, Cheng MS. The reliability and minimal detectable change of shoulder mobility measurements using a digital inclinometer. Physiother Theory Pract. 2011;27(2):176–84.
37. Cools AM, De Wilde L, Van Tongel A, Ceyssens C, Ryckewaert R, Cambier DC. Measuring shoulder external and internal rotation strength and range of motion: comprehensive intra-rater and inter-rater reliability study of several testing protocols. J Shoulder Elb Surg. 2014;23(10):1454–61.
38. Satpute K, Hall T, Kumar S, Deodhar A. A new method of measuring shoulder hand behind back movement: reliability, values in symptomatic and asymptomatic people, effect of hand dominance, and side-to-side variability. Physiother Theory Pract. 2016;32(7):520–7.
39. Page LM, DA O'C, Malek M, Hass R, Beaton D, Huang H, et al. Patients´ experience of shoulder disorders: a systematic review of qualitative studies for the OMERACT shoulder Core domain set. Rheumatology. 2019;58:1410–21.
40. Paul TM, Soo Hoo J, Chae J, Wilson RD. Central hypersensitivity in patients with subacromial impingement syndrome. Arch Phys Med Rehabil. 2012; 93(12):2206–9.
41. Kamper SJ, Maher CG, Mackay G. Global rating of change scales: a review of strengths and weaknesses and considerations for design. J Man Manip Ther. 2009;17(3):163–70.
42. Garrison C, Cook C. Clinimetrics corner: the global rating of change score (GRoC) poorly correlates with functional measures and is not temporally stable. J Man Manip Ther. 2012;20(4):178–81.
43. Bialosky JE, Bishop MD, Cleland JA. Individual expectation: an overlooked, but pertinent, factor in the treatment of individuals experiencing musculoskeletal pain. Phys Ther. 2010;90:1345–55.
44. Thompson AGH, Suñol R. Expectations as determinants of patient satisfaction: concepts, theory and evidence. Int J Qual Health Care. 1995; 7(2):127–41.
45. Chester R, Jerosch-Herold C, Lewis J, Shepstone L. Psychological factors are associated with the outcome of physiotherapy for people with shoulder pain: a multicentre longitudinal cohort study. Br J Sports Med. 2018;52(4): 269–75.
46. Bandura A. Self-efficacy in changing societies. Cambridge: Cambridge University Press; 1995.
47. Costal LCM, Maher C, Mcauley JH, Hancock MJ, Smeets RJEM. Self-efficacy is more important than fear of movement in mediating the relationship between pain and disability in chronic low back pain. Eur J Pain. 2011;15: 213-9.
48. Dehghani M, Sharpe L, Nicholas MK. Structural evaluation of the contemporary psychological models of chronic pain: does fear of pain work for all? Cogn Behav Ther. 2010;39(3):214–24.

49. Chester R, Khondoker M, Shepstone L, Lewis JS, Jerosch-Herold C. Self-efficacy and risk of persistent shoulder pain: results of a classification and regression tree (CART) analysis. Br J Sports Med. 2019;53(13):825–34.
50. Salvetti MG, Pimenta CAM. Validação da Chronic Pain Self-Efficacy Scale para a Língua Portuguesa. Rev Psiq Clín. 2005;32(4):202.
51. Bang H, Flaherty SP, Holahi J, Park J. Blinding assessment in clinical trials: a review of statistical methods and a proposal of blinding assessment protocol. Clin Res Regul Aff. 2010;27(2):42–51.
52. Hurwitz EL, Morgenstern H, Vassilaki M, Chiang LM. Adverse reactions to chiropractic treatment and their effects on satisfaction and clinical outcomes among patients enrolled in the UCLA neck pain study. J Manip Physiol Ther. 2004;27(1):16–25.

4 ARTIGO 2

MOBILISATION WITH MOVEMENT PLUS EXERCISE PROVIDE SHORT-TERM BENEFITS IN PEOPLE WITH ROTATOR CUFF RELATED PAIN: A RANDOMISED PLACEBO-CONTROLLED TRIAL

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ABSTRACT

Question(s): Does adding mobilisation with movement (MWM) to a standard exercise programme provide superior benefits in function and pain when compared to a sham MWM and exercise?

Design: a randomised, placebo-controlled, clinical trial with concealed allocation, blinding and intention-to-treat analysis.

Participants: fifty-nine participants (69% female, mean age 48 years), presenting with chronic atraumatic rotator cuff related pain.

Intervention: the experimental group received MWM plus exercises (MWM+E), the control group received a sham MWM plus exercise (SMWM+E). Treatments were delivered twice a week, for five weeks.

Outcome measures: primary outcomes were function and pain, assessed at baseline, end of the treatment (EOT) and one-month follow-up (FU). Secondary outcomes were self-efficacy, perception of improvement, and active pain free range of movement (AROM) all assessed at baseline, EOT, and/or FU.

Results: the MWM+E group demonstrated greater benefits at the EOT for function by 20 points (95%CI: 4-36); EOT and FU benefits for night pain by 2.5 points (95%CI: -4.2 to -0.23) and 1.78 points (95%CI: -3.5 to -.09), respectively; EOT and FU benefits for pain on movement by 2.34 (95%CI: -4 to -0.7) and 1.5 (95CI%: -2.9 to -0.5), respectively; improvement in AROM of flexion by 20^0 (95%CI: 5.8-33), abduction by 24^0 (95%CI: 3-30), external rotation by 9^0 (95%CI: 1-15) and hand behind back by 8^0 (95%CI: 2-18). No differences were found for other outcomes.

Conclusion: MWM+E might provide an accelerated improvement in function, pain and active range of motion when compared to SMWM+E.

Trial registration: Clinical Trials Registry number (NCT04175184).

INTRODUCTION

Shoulder pain is one of the main complaints of musculoskeletal pain that might affect up to 20% of the general population.[1] Rotator cuff related pain (RCRP) is a broad term that encompasses a variety of shoulder conditions such as: subacromial impingement syndrome, rotator cuff tendinopathy, bursitis, and is the most common source of shoulder pain, corresponding to 85% of all painful shoulder conditions.[2] Despite the increasingly knowledge regarding the pathological and rehabilitative aspects of this condition, many patients remain symptomatic after 6-12 months.[3,4] Conservative therapy is considered the first line treatment for RCRP with exercise and various medications as main alternatives.[5] However, improvements seem to be modest when compared to natural history.[6] Nonetheless, in clinical practice, physiotherapists commonly adopt adjunct therapies alongside exercises with the expectancy to produce better outcomes, with a particular interest in musculoskeletal manipulations.[7]

Mobilisation with movement (MWM) is a form of musculoskeletal manipulation that targets painful and/or restricted movements.[8] It entails the use of an externally applied force to a joint segment, followed by an active movement towards a dysfunctional direction, with the aim to achieve a pain free range of motion. This external force might be applied with a therapeutic belt or with the hands. Since one of the main complaints made by people with RCRP is painful movements, MWM seems to be an appropriate form of treatment for this condition. A recent systematic review supports this argument and suggested that MWM procedures are associated with improvements in pain, motion and function in patients with shoulder problems.[9] However, none of the included studies had as comparator an exercise programme plus a sham MWM. Additionally, studies have consistently used only one form of MWM in one particular direction, not exploring all the possibilities available, and therefore, they might not reflect usual clinical practice for this form of musculoskeletal manipulation. The present study adopted a pragmatic use of MWM, meaning that different MWM possibilities could be applied amongst the participants of this clinical trial. Further details regarding the pragmatic application of MWM can be found in our protocol.[10]

Hence, the research question for this randomised, placebo-controlled, parallel clinical trial was: Is there a difference between MWM + exercises versus sham MWM + exercises in patients with rotator cuff related pain for function, pain, self-efficacy, range of motion and a global rating of change scale?

METHOD

The methods, procedures, outcome measures, for this clinical trial have been published elsewhere.[10] Shortly, participants aged between 18 and 65 who had atraumatic shoulder pain for more than 6 weeks' duration were invited to participate, and 59 were enrolled in the study. Participants were randomised with concealed allocation to two groups: MWM + exercises (MWM+E) or sham MWM + exercises (SMWM+E). The treatment phase of the study lasted 5 weeks, with two weekly, individualized sessions, of approximately 45 minutes each. Data collection occurred between mid-September 2020 and mid-October 2022, therefore not following the original study's schedule. This change in enrolment was conducted due to the COVID-19 pandemic. The same physiotherapist (RB) conducted both treatments and was blind to any outcome measure. A blind assessor (RD) conducted the active range of motion measurements (AROM) at both time points. The primary outcomes: Shoulder Pain and Disability Index (SPADI) and the numeric pain rating scale (NPRS) were collected in a self-reported manner at baseline (T0), end of treatment (T1) and follow-up (T2). The secondary outcomes: self-efficacy (SEFF) was collected at T0, T1 and T2, the AROM was collected at T0 and T1, and the global rating scale of change (GROC) was collected at T1 and T2. PPT and expectations will be analysed in a secondary study, as described previously in our study protocol.[10] The present trial is reported according to the CONSORT guidelines for randomised trials.[11]

Data analysis

A total sample of 70 participants was calculated a priori according to our protocol, using SPADI as our main outcome.[10] Nonetheless, the present study reports findings of 59 participants. An independent statistician blind to the differences between the treatment groups performed all analysis using a commercial software[a]. A generalized estimating equation (GEE) analysis was

conducted for SPADI, NPRS and SEFF.[12] The remaining statistical analysis were conducted as previously anticipated in our protocol.[10] Means were reported as standard error for GEE analysis and standard deviation for AROM. The analyses were conducted considering a statistically significant *p*-value of $\leq$ 0.05. The point estimates of effect were reported as mean difference and 95% confidence interval (95%CI). Effect sizes were calculated using Cohen effect size (0.2-0.5: small effect, 0.5-0.8: moderate effect, 0.8 or more: large effect) for the end of the treatment period and follow-up.

RESULTS

Compliance with the study protocol

All methodological aspects were conducted according to the protocol, with a few exceptions. First, due to the Covid-19 pandemic, the enrollment process was postponed from February 2020 to September 2020. Second, participants were only recruited from the study setting *Clínica Albrecht*, also due to the restrictions imposed by the sanitary situation at *Faculdades Integradas de Taquara*. Lastly, due to the reduced timeframe for the data collection phase of the study, we were able to enroll 59/70 (84%) of the sample size calculated. Therefore, the present study is an interim analysis.

Table 1
Clinical characteristics of participants enrolled in the study

Characteristic	MWM+E (n=29)	SMWM+E (n= 30)
Age (*yr*), mean (SD)	49 (10)	48 (10)
Gender, n female (%)	18 (62)	22 (73)
Duration of pain (m, median 25^{th}-75^{th})	10 (6.5-12)	9 (6-12)
Dominant side, right (%)	23 (79)	24(80)
BMI (Kg/m2), mean (SD)	29(4)	30(5)

MWM+E= mobilisation with movement + exercise; SMWM+E= sham mobilisation with movement + exercise group; yr = years; SD = standard deviation; m= months; BMI = body mass index.

Flow of participants through the study

Fifty-nine participants, with a mean age of 48 years (SD10) were randomly allocated to the MWM+E and the SMWM+E groups. Figure 1 illustrates the

recruitment process and the flow of participants through the study. There were three losses, one in the MWM+E group and two in the SMWM+E. Groups demonstrated similarity of data for all baseline clinical characteristics (table 1). Most participants were female and with a median duration of pain of 9.5 months.

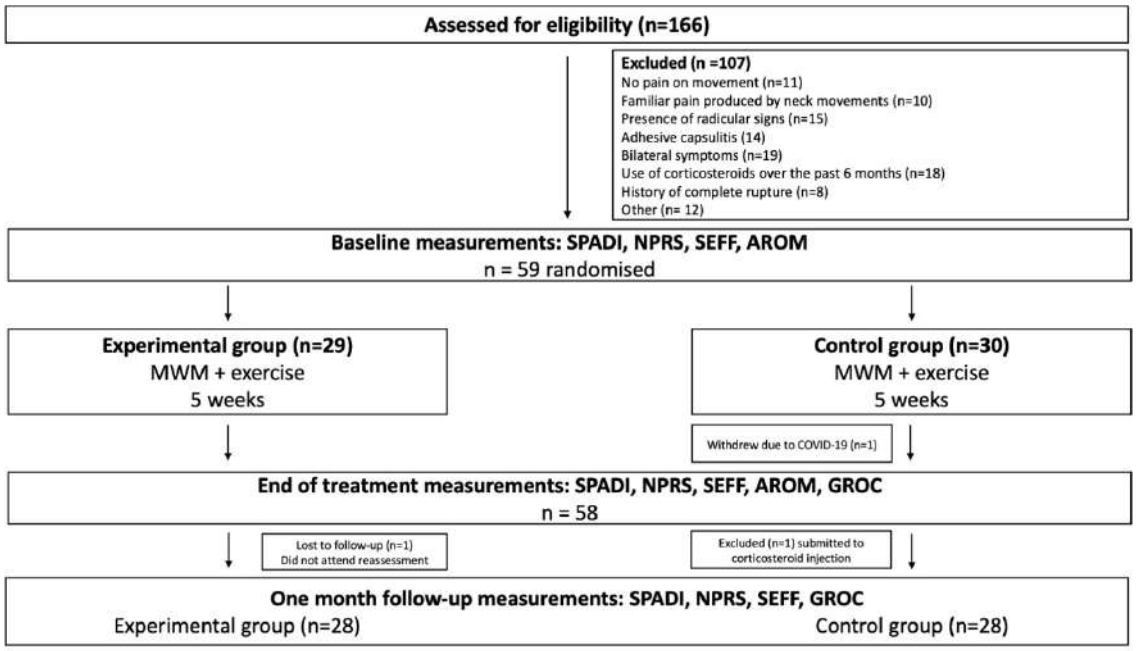


Figure 1. Recruitment process and flow of participants through study. SPADI = Shoulder Pain Disability Index; NPRS = numeric pain rating scale; SEFF = self-efficacy; AROM = active range of motion; GROC = global rating of change; MWM = mobilisation with movement; SMWM = sham mobilisation with movement.

Primary outcomes

Shoulder Pain and Disability Index

The GEE analysis demonstrated a significant group by time interaction ($p \leq 0.00$). A superior effect of the MWM+E group at the end of treatment was observed when compared to the SMWM+E. The mean between-group difference was 20 points ($p \leq 0.00$; 95%CI: -36 to -4), with a large effect size (d = 0.94). At the one-month follow-up, the non-statistically significant difference was of 9 points (p=1.00; 95%CI: -24 to 7). Table 2 presents further details.

Table 2

Disability and pain scores for both groups at each time point.

Outcome	MWM+E (n=29)	SMWM+E (n= 30)	Between-group difference, mean and 95%CI	P value	Effect size, Cohen *d*
SPADI total T0 (SE)	52 (4)	57(3)	-5 (-20 to 10)	1.00	---
SPADI total T1 (SE)	18 (3)	38(4)	-20 (-36 to -4)	0.00	0.94
SPADI total T2 (SE)	19 (4)	27(4)	-9 (-24 to 7)	1.00	---
NPRS *rest* T0 (SE)	3.9 (0.42)	5.3 (0.37)	-1.44 (-3.1 to 0.20)	0.15	---
NPRS *rest* T1 (SE)	1.3 (0.34)	2.7 (0.43)	-1.38 (-3 to 0.23)	0.18	---
NPRS *rest* T2 (SE)	0.83 (0.27)	2.1 (0.42)	-1.31 (-2.8 to 0.15)	0.13	---
NPRS *night* T0 (SE)	6.3 (0.30)	6.9 (0.33)	-.69 (-2 to 0.63)	1.00	---
NPRS night T1 (SE)	1.50 (0.37)	4.0 (0.44)	-2.5 (-4.2 to -0.8)	0.00	1.10
NPRS night T2 (SE)	1.18 (0.35)	2.9 (0.46)	-1.8 (-3.5 to -.09)	0.03	0.80
NPRS movement T0 (SE)	6.7 (0.32)	7,1 (0.33)	-.44 (-1.8 to 0.90)	1.00	---
NPRS movement T1 (SE)	1.8(0.39)	4.1 (0.40)	-2.3 (-4 to -0.70)	0.00	1.08
NPRS movement T2 (SE)	1.5 (0.34)	3.0 (0.36)	-1.5 (-2.9 to -0.5)	0.04	0.79

MWM+E= mobilisation with movement + exercise; SMWM+E= sham mobilisation with movement + exercise group; SPADI = shoulder pain and disability index; SE= standard error; T0 = baseline; T1 = end of treatment; T2 = follow-up; NRPS = numeric pain rating scale.

Numeric Pain Rating Scale

Resting pain: the GEE analysis indicated no group by time interaction ($p \geq 0.98$). Both groups observed a reduction in the resting pain levels from baseline to one-month follow-up (MWM+E, T0: 3.9, T1: 1.3, T2: 0.83; SMWM+E, T0: 5.3, T1: 2.7, T2: 2.1).

Night pain: the GEE analysis demonstrated a significant group by time interaction ($p \leq 0.01$). A statistically significant difference between-groups was observed at the end of treatment and one-month follow-up in favor of the MWM+E group. The mean between-group difference was 2.5 (95%CI: -4.2 to -0.8) at the end of treatment, and 1.78 (95%CI: -3.5 to -.09) at one-month follow-up. A large effect size was observed for T1 (*d=1.1)* and T2 (*d*=0.8).

Pain on movement: the GEE analysis indicated a significant group by time interaction (p≤0.00), with a statistically significant difference between-groups at the end of treatment and one-month follow-up in favor of the MWM+E group. The mean between-group difference was of 2.34 (95%CI: -4 to -0.70) at the end of treatment, and 1.50 (95%CI: -2.9 to -0.5) at one-month follow-up. A large effect size was observed for T1 (*d*=1.08) and a moderate effect size for T2 (*d*=0.79).

Secondary outcomes

Self-efficacy: GEE analysis demonstrated no group by time interactions for the pain (p≥0.10) or function (p≥0.32) domains. However, both groups demonstrated significant reductions across assessments (table 3).

Table 3
Self-efficacy for both groups at each time point.

Outcome	MWM+E (n=29)	SMWM+E (n= 30)	Between-group difference mean and 95% CI	P value
SEFF *pain* T0 (SE)	69 (3.6)	72 (2.6)	-2.3(-15 to 11)	1.00
SEFF *pain* T1 (SE)	89 (2.6)	80 (2.8)	9. (-2.1 to 20)	0.26
SEFF *pain* T2 (SE)	87 (3.1)	77 (3.5)	11 (-2.8 to 25)	0.30
SEFF *function* T0 (SE)	80 (2.9)	83 (2.1)	-2.6 (-13 to 7.8)	1.00
SEFF *function* T1 (SE)	91 (1.8)	90 (1.7)	1.3 (-6.1 to 8.7)	1.00
SEFF *function* T2 (SE)	91 (2.3)	87 (3.2)	4.2 (-7.5 to 16)	1.00

MWM+E= mobilisation with movement + exercise; SMWM+E= sham mobilisation with movement + exercise group; SEFF = self-efficacy; SE = standard error; T0 = baseline; T1 = end of treatment; T2 = follow-up.

Active range of motion

A statistically significant difference between-groups was observed in favor of the MWM+E for *flexion* by 20^0 (p≤0.00; 95%CI: 5.8-33), with a large effect size (*d*=1.0); for *abduction* by 24^0 (p≤0.01; 95%CI: 5.8 -30), with a large effect size (*d*=0.88); for *external rotation* by 9^0 (p≤0.02; 95%CI: 1-15) with a moderate effect size (*d*=0.74); and for *hand behind back* by 8^0 (p≤0.05; 95%CI: 2 - 18),

with a small effect size (*d*= 0.5). Table 4 provides further details regarding active range of motion measurements.

Perception of improvement (GROC)

End of treatment: 21 out of 29 (72%) participants in the MWM+E group rated GROC ≥ 5/7, while 26 out of 30 (87%) participants in the SMWM+E rated GROC ≥ 5/7. Three participants (5%) of the total sample, all from the MWM+E group, rated their perception of improvement as completely recovered (GROC 7/7).

Follow-up: 22 out of 29 (76%) participants in the MWM+E group rated GROC ≥ 5/7, while 20 out 30 (67%) participants in the SMWM+E rated GROC ≥ 5/7. Six participants (10%) of the total sample, all from the MWM+E group, rated their perception of improvement as completely recovered.

Table 4
Active pain free range of motion at baseline and end of treatment.

Outcome	MWM+E (n=29)	SMWM+E (n= 30)	Between-group difference (95% CI)	P value	Effect size, Cohen *d*
AROM *FLX* T0 (SD)	108 (6.8)	98 (6.8)	10 (-10 to 23)	0.15	---
AROM *FLX* T1 (SD)	163 (2.9)	143(4.4)	20 (5.8 to 33)	0.00	1.0
AROM *ABD* T0 (SD)	91 (7.2)	81 (5.8)	10 (-17 to 38)	0.16	---
AROM *ABD* T1 (SD)	142 (3.7)	118 (5.6)	24 (3 - 30)	0.01	0.88
AROM *ER* T0 (SD)	53 (17)	59 (12)	6 (-9 to 12)	0.70	---
AROM *ER* T1 (SD)	75 (14)	66 (10)	9 (1 - 15)	0.02	0.74
AROM HBB T0 (SD)	63 (26)	71 (15)	8 (-0.91 to 16)	0.25	---
AROM HBB T1 (SD)	89 (21)	81 (21)	8 (2 - 18)	0.05	0.5

MWM+E= mobilisation with movement + exercise; SMWM+E= sham mobilisation with movement + exercise group; T0= baseline; T1= end of treatment; AROM = active range of motion; SD= standard deviation; FLX = flexion; ABD = abduction; ER = external rotation; HBB = hand behind back.

DISCUSSION

The main findings of our research is that, in participants with atraumatic

chronic RCRP, the addition of MWM to a standard exercise programme provides superior benefits in disability, pain and active ROM, when compared to SMWM and exercise. However, for disability (SPADI) these benefits were only observed at the end of treatment and not at one month follow-up. Importantly, the superior short-term improvement in the SPADI scores in favor of the MWM+E (20 points) exceeds the minimal clinically important difference (MCID) of 8-13 points, suggested in the literature.[13] MWM+E also produced superior benefits for pain at night and during movement, at both reassessment periods. Also, the between-groups differences observed for pain at night (T1:2.5/10; T2:1.8/10) and during movement (T1:2,3/10; T2: 1.5/10) might also reach the MCID for patients with shoulder problems.[14] However, these benefits must be interpreted with caution, since the confidence intervals around the point estimates for function and pain imply uncertainty of clinical significance.

Considering the fact that the between and within-groups benefits observed were more significant at the end of treatment, it is plausible that adding MWM to an exercise regimen might accelerate improvements. A recent study in patients with distal radius fracture, also suggested that adding MWM to exercise and advice seems to accelerate recovery when compared to exercise and advice only.[15] Interestingly, when observing the improvements in function and pain in the present study, the MWM+E group showed a plateau behaviour after the end of treatment, while the SMWM+E group continued to improve afterwards for function by 10 points ($p \leq 0.00$; 95%CI: 19 to 1.6) and pain on movement by 1,13 points ($p \leq 0.00$; 95%CI -1.8 to -0.40). This finding corroborates with the fact the MWM might accelerate functional recovery that is sustained for, at least, one month.

Currently, we can only speculate about the mechanisms of action that might be responsible for the initial benefits of MWM. Theories suggest that a range of local effects, involving joint biomechanics[16], peripheral mechanoreceptors[17] and muscles[18] might be involved. Alternatively, neurophysiological mechanisms have also been considered as a potential explanation.[19,20,21] Nonetheless, one interesting aspect that our research raised, involves the pragmatic approach. Not all participants in the MWM+E group received and/or responded to the same MWM. This implies that a certain level of specificity when applying MWM is needed, otherwise it could be argued that

all participants would respond equally to the same procedure. This finding might suggest that the biomechanical input produced by the MWM procedure has a certain level of importance. For example, we observed that some participants needed the humeral head to be moved posteriorly, while others needed an anterior movement, in order to elevate their arm painlessly. Therefore, local aspects seemed to be relevant in order to bring about positive effects. Notwithstanding, it is likely that the mechanisms of action are more complex, and might well involve local and central effects.[21]

Patients with shoulder problems generally complain of pain and difficulties with performing various daily activities,[22] and many of these routinely performed activities have been measured accordingly.[23] Consequently, limitation of movement due to pain, restriction or avoidance behaviour might interfere directly with household or job tasks. MWM is a musculoskeletal manipulation that aims to restore pain free AROM,[8] and the findings of this study corroborates with this assumption. All AROM that reached between-groups statistical significance measured in this study exceeded the minimal detectable change suggested in the literature.[24–26] In addition, the clinically significant reduction in pain on movement observed in the MWM+E when compared to the SMWM+E seems to confirm the aforementioned procedure objective.

Research has pointed out to the importance of self-efficacy when considering the prognosis of patients with shoulder problems. Patients with low levels of SEFF are at greater risk of poor response to physiotherapy.[27] High levels of SEFF is considered a protective factor within health science, indicating less daily interference due to pain and greater perceived life management despite the pain experienced. Both groups demonstrated similar SEFF baseline levels, suggesting that it did not influence unequally other outcome measures at the end of treatment and follow-up. In line with other studies, the present investigation demonstrated improvements in self-efficacy scores in the short term,[28] but without a statistically significant difference between-groups. Therefore, despite the superior short-term effects on function, pain and AROM in the MWM+E group, this did not reflect on higher levels of self-efficacy for function and pain. In addition, the chronic pain self-efficacy scale does not have a cut-off value to rate an individual as possessing high or low self-efficacy,[29]

neither there are MCID values established. Thereupon, we cannot appraise the meaning of the higher levels of SEFF observed on both groups. Nonetheless, since SEFF seems to be an important prognostic factor for patients with RCRP, clinicians might be more interested in identifying early on in the rehabilitation phase those patients that present with low levels of SEFF. This might indicate a need for an approach that focuses more on behaviour change strategies.

Previous studies involving MWM in patients with shoulder problems have suggested positive effects on ROM, pain levels and function, similar to ours.[30,31,32] However, comparing the results from those studies with the present investigation is difficult, as several methodological aspects (clinical characteristics of participants enrolled, dosage and length of treatment, presence of co-treatments and different outcome measures) differ from ours. Notwithstanding, one particular characteristic deserves further consideration. The implementation of MWM in our cohort was pragmatic. The same participant could have received different forms of MWM throughout the period of treatment. According to a group of experts in the use of MWM, one of the most important factors when deciding to use it, or not, is the immediate response.[33] If a patient responds positively (e.g., increases pain free ROM), there is a greater chance that the procedure applied is beneficial, and therefore, could be used in that patient. However, this decision-making process is not always straightforward and a few attempts of different procedures might be needed, hence the pragmatic approach. Also, it has to be stated that, even after trialing different procedures, failure to observe positive results occurred in our cohort. Moreover, it could be the case, that during sessions, one movement (hand behind back) was the target of MWM, while on another occasion, the desired direction of movement was changed (flexion). The aforementioned studies all utilized only one specific form of MWM in their respective cohorts.

The decision to utilize a pragmatic application of MWM originates from the fact that patients with RCRP present movement difficulties in several directions, and the use of MWM has to take this clinical scenario into consideration. When taking into account the changes in ROM from previous studies, it becomes clear that the use of a single form of MWM might not be clinically relevant for all directions of movement. The use of an MWM for flexion, might be useful to increase pain free flexion mainly, not impacting significantly

on other movements,[30] the same applies for an MWM that aims to increase hand behind back.[32] Therefore, we understand that the manifold possibilities of MWM procedures for the shoulder region[8] should be adopted clinically in order to achieve more significant outcomes in other directions. The AROM changes in the present research appear to substantiate this assumption.

Musculoskeletal manipulations are commonly subjected to criticism due to the likely placebo effects involved and the lack of realistic placebo comparators in clinical trials.[34] We believe that our placebo advanced towards a credible sham procedure, since it involved the placement of the hands in the affected area, and followed the direction of movement chosen. This mimics the application of a "real" MWM. Furthermore, we adopted a three-point scale to verify blinding of participants regarding their treatment groups. Seventeen out of 29 (59%) participants in the MWM+E group considered themselves to be part of the experimental group, while 16/30 (53%) in the SMWM+E group judged themselves to be part of the experimental group. Therefore, the sham MWM applied did not seem to inform patients that they were part of the control group, and the procedure applied might have been considered a real part of the treatment package delivered.

The importance of exercise for patients with RCRP has been investigated in several studies with varying clinical results.[35,36] Up to date, it is difficult to decide upon which sort of exercise (rotator cuff *vs* scapular *vs* general; high *vs* low load) provides the best outcome. What seems to be important is exercising muscles around the shoulder joint. This research has highlighted the likely clinical benefits for function, pain and ROM as a result of the exercise programme implemented. It is difficult to attribute any significant benefit for the sham MWM applied, since only one patient in this group demonstrated a change in ROM that could be judged as significant. Thus, the improvements observed in the SMWM+E group are likely a result of the exercises regimen implemented. Furthermore, since the improvements in function were not significantly different at one-month follow-up and the significant differences in pain measures at one-month follow-up were lower than at the end of treatment, it might be argued that exercises might bring similar results when taking into account a longer period of reassessment.

Seventy percent or more of the participants in this study rated

themselves as improved by ≥ 5/7 when asked to assess their shoulder condition since the entry in the study and across assessment periods (GROC scale). Interestingly, despite the clinically and statistically significant superiority of the MWM+E group for disability, pain and AROM, more participants in the SMWM+E group rated the treatment received as successful (72% vs 87%, respectively). However, this was not observed at the end of treatment (76% vs 67%, respectively). Only 10% of the total sample rated themselves as completely recovered at one-month follow-up, highlighting the recalcitrant nature of this clinical presentation and/or participants enrolled.

A recent publication has highlighted the importance of providing information for refining clinical trials involving exercises, such as volume of treatment and safety.[37] We monitored the presence of adverse events on every treatment session and described the rationale behind the increase in the exercise regimen in our protocol.[10] There were 19 occurrences of side effects reports (9 in the MWM+E and 10 in the SMWM+E), 2 of them, both from the SMWMW+E group, lasted more than 24 hours. The vast majority of the adverse events reported, started between 30 minutes to 4 hours after the treatment session and none interfered with household or job-related activities. Consequently, we believe that the treatment delivered in this study is safe for patients, since the presence of adverse events were low, short lived, and did not impact on the daily living activities of the participants.

Several aspects involving the use of MWM in patients with RCRP might be investigated in future trials. For example, if a patient achieves a pain free ROM within a certain session, should further sets of the same procedure be applied with external resistance, since higher loads tend to produce more symptoms in patients with RCRP? Also, as MWM might be self-applied, would the effect on function and pain be the same as if the procedure was applied by a clinician? Third, would self-applied MWM procedures performed at home, in-between treatment sessions conducted by a clinician, produce greater effects, than only clinician applied procedures? Lastly, should future research involving MWM recruit only participants that respond positively to its application?

Clinicians should be aware of the limitations imposed by the current research. First, the eligibility criteria adopted probably included only a percentage of patients with shoulder problems presenting to health care

services. Second, the number of participants of this study represents 84% of the original sample size calculated. Hence, the final results might change. Third, our follow-up period was short, long-term results remains to be investigated.

We found that the use of MWM with exercise promotes clinical and statistically significant improvements in function, pain and ROM, at the end of treatment when compared to sham MWM and exercise. The improvements for pain measures are still present at one-month follow-up. It is possible that MWM accelerated these initial improvements, since most of the significant benefits were observed at the end of treatment. Thus, clinicians dealing with patients complaining of RCRP might consider applying MWM pragmatically, aiming to improve pain free AROM, together with an exercise programme, in order to hasten improvement.

REFERENCES

1. Picavet HSJ, Schouten JS a. G. Musculoskeletal pain in the Netherlands: prevalences, consequences and risk groups, the DMC(3)-study. *Pain*. 2003;102(1-2):167-178. doi:10.1016/s0304-3959(02)00372-x

2. Östör AJK, Richards CA, Prevost AT, Speed CA, Hazleman BL. Diagnosis and relation to general health of shoulder disorders presenting to primary care. *Rheumatology (Oxford)*. 2005;44(6):800-805. doi:10.1093/rheumatology/keh598

3. Karel YHJM, Verhagen AP, Thoomes-de Graaf M, et al. Development of a Prognostic Model for Patients With Shoulder Complaints in Physical Therapist Practice. *Phys Ther*. 2017;97(1):72-80. doi:10.2522/ptj.20150649

4. Cadogan A, Laslett M, Hing WA, McNair PJ, Coates MH. A prospective study of shoulder pain in primary care: prevalence of imaged pathology and response to guided diagnostic blocks. *BMC Musculoskelet Disord*. 2011;12:119. doi:10.1186/1471-2474-12-119

5. Doiron-Cadrin P, Lafrance S, Saulnier M, et al. Shoulder Rotator Cuff Disorders: A Systematic Review of Clinical Practice Guidelines and Semantic Analyses of Recommendations. *Arch Phys Med Rehabil*. 2020;101(7):1233-1242. doi:10.1016/j.apmr.2019.12.017

6. Dickinson RN, Ayers GD, Archer KR, et al. Physical therapy versus natural history in outcomes of rotator cuff tears: the Rotator Cuff Outcomes Workgroup (ROW) cohort study. *J Shoulder Elbow Surg*. 2019;28(5):833-838. doi:10.1016/j.jse.2018.10.001

7. Babatunde OO, Ensor J, Littlewood C, et al. Comparative effectiveness of treatment options for subacromial shoulder conditions: a systematic review and network meta-analysis. *Ther Adv Musculoskelet Dis*. 2021;13:1759720X211037530. doi:10.1177/1759720X211037530

8. Hing W, Hall T, Mulligan BR. *The Mulligan Concept of Manual Therapy: Textbook of Techniques*.; 2020.

9. Satpute K, Reid S, Mitchell T, Mackay G, Hall T. Efficacy of mobilization with movement (MWM) for shoulder conditions: a systematic review and meta-analysis. *J Man Manip Ther*. 2022;30(1):13-32. doi:10.1080/10669817.2021.1955181

10. Baeske R, Hall T, Silva MF. The inclusion of mobilisation with movement to a standard exercise programme for patients with rotator cuff related pain: a randomised, placebo-controlled protocol trial. *BMC Musculoskelet Disord*. 2020;21(1):744. doi:10.1186/s12891-020-03765-6

11. Boutron I, Moher D, Altman DG, Schulz KF, Ravaud P, CONSORT Group. Extending the CONSORT statement to randomized trials of nonpharmacologic treatment: explanation and elaboration. *Ann Intern Med*. 2008;148(4):295-309. doi:10.7326/0003-4819-148-4-200802190-00008

12. Guimarães LSP, Hirakata VN. Uso do Modelo de Equações de Estimações Generalizadas na Análise de Dados Longitudinais. *Revista HCPA*. 2013;32(4):503-511.

13. Roy JS, MacDermid JC, Woodhouse LJ. Measuring shoulder function: a systematic review of four questionnaires. *Arthritis Rheum*. 2009;61(5):623-632. doi:10.1002/art.24396

14. Hao Q, Devji T, Zeraatkar D, et al. Minimal important differences for improvement in shoulder condition patient-reported outcomes: a systematic review to inform a BMJ Rapid Recommendation. *BMJ Open*. 2019;9(2):e028777. doi:10.1136/bmjopen-2018-028777

15. Reid SA, Andersen JM, Vicenzino B. Adding mobilisation with movement to exercise and advice hastens the improvement in range, pain and function

after non-operative cast immobilisation for distal radius fracture: a multicentre, randomised trial. *J Physiother*. 2020;66(2):105-112. doi:10.1016/j.jphys.2020.03.010
16. Mulligan BR. *Manual Therapy: NAGS, SNAGS, MWMS, Etc*. 7th ed. Plane View Services Ltd; 2018.
17. Baeske R. Mobilisation with movement: a step towards understanding the importance of peripheral mechanoreceptors. *Physical Therapy Reviews*. 2015;20(5-6):299-305. doi:10.1080/10833196.2015.1121014
18. Yu IY, Kim SY, Kang MH. Strategies for controlling axial shoulder rotation change shoulder muscle activity during external rotation exercises. *J Shoulder Elbow Surg*. 2021;30(6):1230-1237. doi:10.1016/j.jse.2020.08.031
19. Paungmali A, O'Leary S, Souvlis T, Vicenzino B. Naloxone fails to antagonize initial hypoalgesic effect of a manual therapy treatment for lateral epicondylalgia. *J Manipulative Physiol Ther*. 2004;27(3):180-185. doi:10.1016/j.jmpt.2003.12.022
20. Paungmali A, O'Leary S, Souvlis T, Vicenzino B. Hypoalgesic and sympathoexcitatory effects of mobilization with movement for lateral epicondylalgia. *Phys Ther*. 2003;83(4):374-383.
21. Bialosky JE, Beneciuk JM, Bishop MD, et al. Unraveling the Mechanisms of Manual Therapy: Modeling an Approach. *J Orthop Sports Phys Ther*. 2018;48(1):8-18. doi:10.2519/jospt.2018.7476
22. Page MJ, O'Connor DA, Malek M, et al. Patients' experience of shoulder disorders: a systematic review of qualitative studies for the OMERACT Shoulder Core Domain Set. *Rheumatology (Oxford)*. Published online March 6, 2019:kez046. doi:10.1093/rheumatology/kez046
23. Namdari S, Yagnik G, Ebaugh DD, et al. Defining functional shoulder range of motion for activities of daily living. *J Shoulder Elbow Surg*. 2012;21(9):1177-1183. doi:10.1016/j.jse.2011.07.032
24. Kolber MJ, Vega F, Widmayer K, Cheng MSS. The reliability and minimal detectable change of shoulder mobility measurements using a digital inclinometer. *Physiother Theory Pract*. 2011;27(2):176-184. doi:10.3109/09593985.2010.481011
25. Satpute K, Hall T, Kumar S, Deodhar A. A new method of measuring shoulder hand behind back movement: Reliability, values in symptomatic and

asymptomatic people, effect of hand dominance, and side-to-side variability. *Physiother Theory Pract*. 2016;32(7):520-527. doi:10.1080/09593985.2016.1222041

26. Cools AM, De Wilde L, Van Tongel A, Ceyssens C, Ryckewaert R, Cambier DC. Measuring shoulder external and internal rotation strength and range of motion: comprehensive intra-rater and inter-rater reliability study of several testing protocols. *J Shoulder Elbow Surg*. 2014;23(10):1454-1461. doi:10.1016/j.jse.2014.01.006

27. Chester R, Khondoker M, Shepstone L, Lewis JS, Jerosch-Herold C. Self-efficacy and risk of persistent shoulder pain: results of a Classification and Regression Tree (CART) analysis. *Br J Sports Med*. 2019;53(13):825-834. doi:10.1136/bjsports-2018-099450

28. Martinez-Calderon J, Flores-Cortes M, Morales-Asencio JM, Fernandez-Sanchez M, Luque-Suarez A. Which Interventions Enhance Pain Self-efficacy in People With Chronic Musculoskeletal Pain? A Systematic Review With Meta-analysis of Randomized Controlled Trials, Including Over 12 000 Participants. *J Orthop Sports Phys Ther*. 2020;50(8):418-430. doi:10.2519/jospt.2020.9319

29. Anderson KO, Dowds BN, Pelletz RE, Edwards TW, Peeters-Asdourian C. Development and initial validation of a scale to measure self-efficacy beliefs in patients with chronic pain. *Pain*. 1995;63(1):77-83. doi:10.1016/0304-3959(95)00021-J

30. Delgado-Gil JA, Prado-Robles E, Rodrigues-de-Souza DP, Cleland JA, Fernández-de-las-Peñas C, Alburquerque-Sendín F. Effects of mobilization with movement on pain and range of motion in patients with unilateral shoulder impingement syndrome: a randomized controlled trial. *J Manipulative Physiol Ther*. 2015;38(4):245-252. doi:10.1016/j.jmpt.2014.12.008

31. Teys P, Bisset L, Vicenzino B. The initial effects of a Mulligan's mobilization with movement technique on range of movement and pressure pain threshold in pain-limited shoulders. *Man Ther*. 2008;13(1):37-42. doi:10.1016/j.math.2006.07.011

32. Satpute KH, Bhandari P, Hall T. Efficacy of Hand Behind Back Mobilization With Movement for Acute Shoulder Pain and Movement Impairment: A Randomized Controlled Trial. *J Manipulative Physiol Ther*. 2015;38(5):324-334. doi:10.1016/j.jmpt.2015.04.003

33. Baeske R, Silva MF, Hall T. The clinical decision making process in the use of mobilisation with movement - A Delphi survey. *Musculoskelet Sci Pract*. 2020;49:102212. doi:10.1016/j.msksp.2020.102212
34. Page MJ, Green S, McBain B, et al. Manual therapy and exercise for rotator cuff disease. *Cochrane Database Syst Rev*. 2016;(6):CD012224. doi:10.1002/14651858.CD012224
35. Gutiérrez-Espinoza H, Araya-Quintanilla F, Cereceda-Muriel C, Álvarez-Bueno C, Martínez-Vizcaíno V, Cavero-Redondo I. Effect of supervised physiotherapy versus home exercise program in patients with subacromial impingement syndrome: A systematic review and meta-analysis. *Phys Ther Sport*. 2020;41:34-42. doi:10.1016/j.ptsp.2019.11.003
36. Naunton J, Street G, Littlewood C, Haines T, Malliaras P. 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(9):1198-1216. doi:10.1177/0269215520934147
37. Hoogeboom TJ, Kousemaker MC, van Meeteren NL, et al. i-CONTENT tool for assessing therapeutic quality of exercise programs employed in randomised clinical trials. *Br J Sports Med*. 2021;55(20):1153-1160. doi:10.1136/bjsports-2019-101630

5 CONCLUSÃO GERAL

A mobilização com movimento é um procedimento de manipulação musculoesquelética que possui como objetivo a restauração da amplitude normal livre de dor. Desta forma, ela pode ser utilizada em diversas apresentações clínicas manejadas por fisioterapeutas, haja vista que disfunções relacionadas com o movimento é uma das principais queixas dos pacientes que procuram este profissional.

Embora o estado atual da ciência não possa explicar os mecanismos de ação da mobilização com movimento, diversas teorias têm sido propostas. Tais teorias podem ser divididas em dois grandes grupos: *efeitos locais* e *efeitos centrais.* No primeiro, acredita-se que o efeito biomecânico ocasionado pela mobilização com movimento altera a artrocinemática da articulação e/ou interfere no comportamento dos mecanorreceptores locais. Desta forma, o movimento disfuncional e doloroso torna-se assintomático. No segundo, entende-se que uma cascata de efeitos centrais, envolvendo centros cerebrais superiores, são estimulados através do contexto terapêutico envolvido nas mobilizações com movimentos. Como resultado disso, ocorre uma hipoalgesia supraespinhal, produzindo efeitos mais generalizados no sistema nociceptivo, melhorando assim, os sintomas dolorosos durante o movimento.

Os resultados desta tese indicam que a mobilização com movimento demonstrou ser clinicamente útil em duas importantes queixas de pacientes com dor no ombro relacionada com o manguito rotador: dor e restrição de amplitude de movimento livre de dor. O grupo que recebeu a mobilização com movimento obteve melhores resultados em desfechos de função, dor e movimento a curto prazo. Das diversas estratégias de tratamento recomendadas por guias de prática clínica atuais, exercícios aparecem como tratamento de primeira linha. Consequentemente, o seu uso em pacientes com disfunções dolorosas do ombro parece ser prioritário em grande parte destes pacientes. No entanto, tendo em vista as particularidades das mobilizações com movimento, o seu uso em conjunto com exercícios parece ser uma alternativa terapêutica plausível. Os resultados do estudo principal desta tese sugere tal fato.

Uma possibilidade plausível que pode ser observada ao se analisar os resultados da pesquisa clínica é o fato que o uso das mobilizações com movimento parece acelerar a melhora da amplitude de movimento, função e reduzir mais rapidamente os níveis álgicos em pacientes com dor no ombro relacionada com o manguito rotador. Este aspecto deve ser levado em consideração ao se manejar pacientes com dor relacionada com o manguito rotador, tendo em vista que vários destes pacientes podem permanecer sintomáticos por meses e, por vezes, obterem resultados terapêuticos não satisfatórios.

Apesar das inúmeras referências bibliográficas disponíveis e cursos de formação continuada nos procedimentos de mobilização com movimento, a vasta maioria dos estudos não refletem as nuances desta abordagem. O seu uso pode e deve ser adaptado para as necessidades de movimento específicas apresentadas pelos pacientes. Os estudos, de uma forma geral, utilizam apenas um procedimento de mobilização com movimento para uma determinada direção de movimento. Como resultado desta prática, observa-se melhoras naqueles movimentos tratados. No entanto, como o ombro é uma articulação que possui diversos eixos de movimento, é comum que pacientes com disfunções desta região apresentem queixas em diversas direções. Consequentemente, sob o ponto de vista clínico, torna-se necessário intervir de forma satisfatória em todas estas direções potencialmente acometidas.

Este aspecto da necessidade de individualização e tomada de decisão clínica em relação ao uso das mobilizações com movimento foi objeto de estudo durante o processo de doutoramento do doutorando responsável pela presente tese. O estudo foi publicado em outubro de 2020 no periódico científico *Musculoskeletal Science and Practice*, sob o título de *"The clinical decision making process in the use of mobilisation with movement – A Delphi survey"*.

Apesar dos resultados promissores, um aspecto que deve ser investigado adequadamente em pesquisas futuras é a responsividade ao uso de mobilização com movimento. Nem todos os participantes do grupo MWM+E responderam de forma positiva aos procedimentos aplicados. Alguns destes, responderam em tentativas subsequentes, porém nem todos. Desta forma, pesquisas envolvendo mobilização com movimento que apenas incluíssem

participantes responsivos ao seu uso, poderiam melhor informar os benefícios desta técnica em pacientes com dor no ombro relacionada com o manguito rotador.

Outro aspecto que poderia ser explorado sob o ponto de vista científico diz respeito a automobilização com movimento, ou seja, uma forma de mobilização com movimento que o próprio paciente aplica em si. Tal fato seria de grande valia social em ambientes de tratamento cujo o volume de pacientes é significativo. Isso acarretaria na não necessidade do fisioterapeuta estar envolvido nesta parte do tratamento e, ao mesmo tempo, poderia ser um instrumento valioso para aumentar a auto-eficácia de pacientes com dor no ombro com o manguito rotador.

Dois importantes adendos merecem ser comentados. *Primeiro*, o artigo 2 desta tese não recrutou o número total de participantes calculado no artigo 1. O autor e coautores da presente tese afirmam o interesse absoluto em continuar conduzindo a pesquisa até que todos os 70 pacientes sejam recrutados. Ressaltamos que faltam 16%, ou seja, a pesquisa se encontra dentro da margem estipulada para perdas amostrais de 20%. *Segundo*, conforme consta no artigo 1, alguns desfechos do artigo 2 serão analisados através de um estudo secundário. Neste, serão verificados se o uso das mobilizações com movimento em conjunto com exercício produz efeitos hipoálgicos diferentes da falsa mobilização com movimento em conjunto com exercícios. Outro aspecto que também será analisado neste estudo secundário é a expectativa em relação ao tratamento oferecido, como ela se comporta ao longo de um período curto de tratamento e sua correlação com desfechos funcionais (dor, função e amplitude de movimento.

6 IMPACTOS DO TRABALHO

Os resultados observados nas pesquisas realizadas possuem implicações *clínica*, *econômica*, *social* e *educacional*. A relevância *clínica* dos trabalhos realizados diz respeito ao acréscimo de informações relevantes ao estado atual da prática clínica em pacientes com dor no ombro relacionada com o manguito rotador. Serviços de reabilitação funcional podem considerar a inclusão de procedimentos de mobilização com movimento para acelerar a recuperação funcional de pacientes com disfunção no ombro. Ademais, a ausência de efeitos adversos significativos confere segurança clínica para sua utilização, deste que os preceitos adotados sejam respeitados.

Sob o ponto de vista *econômico*, o uso de mobilização com movimento pode conferir um processo de reabilitação mais acelerado, diminuindo a necessidade de um número maior de consultas. Tal nuance é importante, particularmente em ambientes cujo volume de pacientes é significativo. Ademais, uma vez que o aprendizado tenho ocorrido, a utilização desta modalidade de tratamento não necessita de instrumentos ou ferramentas onerosas para o profissional.

A relevância *social* dos produtos desta tese envolve dois aspectos. Primeiro, como a maior parte dos participantes da pesquisa são oriundos do sistema público de saúde, é possível que o atendimento recebido tenha sido mais precoce e individualizado. Segundo, tendo em vista que distintos profissionais de saúde tiveram participação em momentos variados da pesquisa, houve uma integração interdisciplinar significativa que promoveu a importância da fisioterapia no contexto estudado.

As implicações *educacionais* envolvem a importância da consumação dos resultados observados no contexto da prática baseada em evidências. Ademais, alguns dos autores envolvidos nas pesquisas são professores de graduação e/ou pós-graduação e, consequentemente, aspectos observados nas diferentes pesquisas são e serão discutidos com grupos de alunos.

APÊNDICES

APÊNDICE A

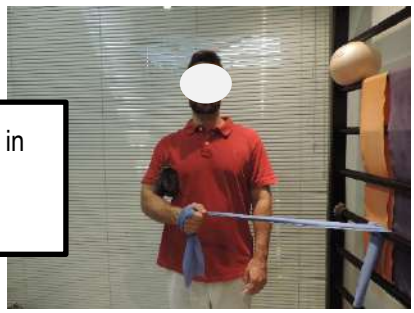
Additional file 1 – List of exercises

External rotation in side lying

Shoulder flexion in side lying

Shoulder protraction in supine

External rotation in standing



Internal rotation in standing

Punch-forwards in standing

Rowing in standing

Scapular retraction in standing

Shoulder elevation with co-contraction of external rotators

Shoulder elevation with co-contraction of internal rotators

Anterior shoulder stretch

Hand behind back stretch

Posterior shoulder stretch

APÊNDICE B

SHOULDER PAIN DISABILITY QUESTIONNAIRE – SPADI (versão brasileira)

Nome:_____**Data:** ____/____/____

Avaliação linha de base ( ) Término do período de tratamento ( ) *Follow-up* ( )

Por favor, coloque uma marca no número que melhor representa sua experiência durante a semana passada em relação ao seu problema do ombro.

ESCALA DE DOR: QUÃO GRAVE É A SUA DOR?

Por favor, circule o número que melhor descreva a sua dor, onde **0 = sem dor** e **10 = a pior dor que você possa imaginar.**

1.	Quando está no nível máximo?	0	1	2	3	4	5	6	7	8	9	10
2.	Quando deitado (a) sobre o lado afetado?	0	1	2	3	4	5	6	7	8	9	10
3.	Alcançando algo em uma prateleira?	0	1	2	3	4	5	6	7	8	9	10
4.	Tocando a parte posterior do pescoço?	0	1	2	3	4	5	6	7	8	9	10
5.	Empurrando algo com o braço afetado?	0	1	2	3	4	5	6	7	8	9	10

ESCALA DE INCAPACIDADE: QUANTA DIFICULDADE VOCÊ TEM?

Circule o número que melhor descreva sua experiência, onde **0 = sem dificuldade** e **10 = tão difícil que necessite de ajuda.**

1.	Lavando o cabelo?	0	1	2	3	4	5	6	7	8	9	10
2.	Lavando as costas?	0	1	2	3	4	5	6	7	8	9	10
3.	Colocando uma camiseta ou blusa pela cabeça?	0	1	2	3	4	5	6	7	8	9	10
4.	Colocando uma camisa com botões na frente?	0	1	2	3	4	5	6	7	8	9	10
5.	Colocando sua calça?	0	1	2	3	4	5	6	7	8	9	10
6.	Colocando um objeto em uma prateleira alta?	0	1	2	3	4	5	6	7	8	9	10
7.	Carregando um objeto pesado de 5.0 kg?	0	1	2	3	4	5	6	7	8	9	10
8.	Retirando algo do bolso de trás da calça?	0	1	2	3	4	5	6	7	8	9	10

SPADI DOR (soma das respostas/50) x 100.

SPADI INCAPACIDADE (soma das respostas/80) x 100.

SPADI TOTAL (soma das respostas/130) x 100.

APÊNDICE C

Escala visual numérica de dor

Nome:_____Data: ____/____/____

Avaliação linha de base ( ) Término do período de tratamento ( ) *Follow-up* ( )

Por favor, nos informe verbalmente o valor da sua dor máxima na últimas 24 horas. Sendo que **0 = sem dor** e **10 = máximo de dor imaginável**.

1. REPOUSO	0	1	2	3	4	5	6	7	8	9	10
2. NOITE	0	1	2	3	4	5	6	7	8	9	10
3. DURANTE OS MOVIMENTOS	0	1	2	3	4	5	6	7	8	9	10

APÊNDICE D

Escala de autoeficácia

Auto-eficácia para controle da dor (AED)

Nome:_____ **Data:** ____/____/____

Gostaríamos de saber de que maneira sua dor afeta você. Para cada pergunta circule o número que corresponde a quanta certeza você tem de poder realizar as tarefas mencionadas.

1. Quanta certeza você tem de que pode diminuir <u>um pouco</u> sua dor?

10	**20**	**30**	**40**	**50**	**60**	**70**	**80**	**90**	**100**
Muita incerteza				Moderada certeza					Muita certeza

2. Quanta certeza você tem de que pode continuar a realizar a maioria das suas atividades diárias?

10	**20**	**30**	**40**	**50**	**60**	**70**	**80**	**90**	**100**
Muita incerteza				Moderada certeza					Muita certeza

3. Quanta certeza você tem de que consegue impedir que a dor interfira com seu sono?

10	**20**	**30**	**40**	**50**	**60**	**70**	**80**	**90**	**100**
Muita incerteza				Moderada certeza					Muita certeza

4. Quanta certeza você tem de que consegue promover uma redução <u>pequena ou moderada</u> na sua dor?

10	**20**	**30**	**40**	**50**	**60**	**70**	**80**	**90**	**100**
Muita incerteza				Moderada certeza					Muita certeza

5. Quanta certeza você tem de que pode promover uma <u>grande</u> redução na sua dor?

10	**20**	**30**	**40**	**50**	**60**	**70**	**80**	**90**	**100**
Muita incerteza				Moderada certeza					Muita certeza

Auto-eficácia para funcionalidade (AEF)

Gostaríamos de conhecer sua autoconfiança para realizar algumas atividades diárias. Para cada pergunta, circule o número que corresponde a quanta certeza você tem de poder realizar as tarefas, sem ajuda de outras pessoas. Por favor considere aquilo que pode fazer no dia-a-dia, não atividades isoladas que exijam um esforço extraordinário.

Atualmente quanta certeza você tem que pode:

1. Caminhar 800 mestros em terreno plano?

10	20	30	40	50	60	70	80	90	100
Muita incerteza				Moderada certeza					Muita certeza

2. Levantar uma caixa pesando 5 quilos?

10	20	30	40	50	60	70	80	90	100
Muita incerteza				Moderada certeza					Muita certeza

3. Realizar um programa diário de exercícios a serem feitos em casa?

10	20	30	40	50	60	70	80	90	100
Muita incerteza				Moderada certeza					Muita certeza

4. Realizar os trabalhos de cuidados da casa?

10	20	30	40	50	60	70	80	90	100
Muita incerteza				Moderada certeza					Muita certeza

5. Fazer compras de supermercado ou de roupas?

10	20	30	40	50	60	70	80	90	100
Muita incerteza				Moderada certeza					Muita certeza

6. Participar de atividades sociais?

10	20	30	40	50	60	70	80	90	100
Muita incerteza				Moderada certeza					Muita certeza

7. Dedicar-se a passatempos ou atividades recreativas?

10	20	30	40	50	60	70	80	90	100
Muita incerteza				Moderada certeza					Muita certeza

8. Participar de atividades familiares?

10	20	30	40	50	60	70	80	90	100
Muita incerteza				Moderada certeza					Muita certeza

9. Realizar as tarefas de trabalho que você tinha antes do início da dor crônica? (para donas de casa, favor considerar as tarefas da casa como as tarefas de trabalho).

10	20	30	40	50	60	70	80	90	100
Muita incerteza				Moderada certeza					Muita certeza

APÊNDICE E

Escala de percepção da melhora geral (GROC)

Nome:_____

Término do período de tratamento ( ) **Follow-up ( )**

Com relação ao seu problema no ombro, como você avaliaria a sua condição desde a sua entrada no estudo?

Por favor, circule o valor que melhor retrata a sua resposta.

-7 EXTREMAMENTE PIOR

-6

-5

-4

-3

-2

-1

0 IGUAL

+1

+2

+3

+4

+5

+6

+7 COMPLETAMENTE RECUPERADO

APÊNDICE F

Escala de cegamento

Nome:_____ **Data:** ____/____/____

Por favor, assinale a alternativa que melhor responde a seguinte questão:

Em relação ao tratamento que você recebeu nestas cinco semanas, você entende que:
Recebeu o tratamento sob investigação nesta pesquisa ( )
Recebeu o tratamento controle ( )
Não sei ( )

ANEXOS

ANEXO A

Parecer do Comitê de Ética em Pesquisa da Universidade Federal de Ciências da Saúde de Porto Alegre

UNIVERSIDADE FEDERAL DE CIÊNCIAS DA SAÚDE DE PORTO ALEGRE

PARECER CONSUBSTANCIADO DO CEP

DADOS DO PROJETO DE PESQUISA

Título da Pesquisa: Efeitos da inclusão de mobilizações com movimento a um programa de exercícios terapêuticos em pacientes com dor no ombro relacionada com o manguito rotador.

Pesquisador: Marcelo Faria Silva
Área Temática:
Versão: 3
CAAE: 10534119.5.0000.5345
Instituição Proponente: Universidade Federal de Ciências da Saúde de Porto Alegre
Patrocinador Principal: Financiamento Próprio

DADOS DO PARECER

Número do Parecer: 3.528.946

Apresentação do Projeto:
O presente projeto de pesquisa almeja verificar se a inclusão de mobilizações com movimento (MWM) a um programa de exercícios acarreta em melhores resultados terapêuticos em pacientes com dor relacionada com o manguito rotador. Os participantes serão alocados aleatoriamente em dois diferentes grupos: grupo controle (exercícios e uma falsa MWM/placebo)ou grupo experimental (exercícios e MWM). O período de tratamento consistirá de cinco semanas, com duas sessões semanais de acompanhamento supervisionado e individualizado. Os desfechos primários são um questionário de incapacidade e dor, enquanto que os desfechos secundários são amplitude de movimento ativa, percepção da melhora geral e limiar de dor mecânica.

Objetivo da Pesquisa:
Objetivo Primário:
Investigar os efeitos do uso de MWM em conjunto com um programa de exercícios em pacientes com dor no ombro relacionada com o manguito rotador em desfechos de incapacidade funcional e níveis de dor.

Objetivo Secundário:
- Investigar os efeitos do uso pragmático de MWM em conjunto com um programa de exercícios terapêuticos nos níveis de incapacidade, investigada através de um questionário, imediatamente

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após o período de tratamento e no follow-up (quatro semanas).

- Investigar os efeitos do uso pragmático de MWM em conjunto com um programa de exercícios terapêuticos na dor em repouso, dor durante o movimento e dor noturna, avaliadas através de uma escala visual numérica de dor, imediatamente após o período de tratamento e no follow-up (quatro semanas).
- Investigar os efeitos do uso pragmático de MWM em conjunto com um programa de exercícios terapêuticos na percepção global de melhora subjetiva, mensurada através de uma escala tipo LIKERT, imediatamente após o período de tratamento e no follow-up (quatro semanas).
- Investigar os efeitos do uso pragmático de MWM em conjunto com um programa de exercícios terapêuticos nas amplitudes de movimento (ADM) ativa de flexão, abdução, rotação externa e mão nas costas, medidas através do uso de um inclinômetro, imediatamente após o período de tratamento e no follow-up (quatro semanas).
- Investigar os efeitos do uso pragmático de MWM em conjunto com um programa de exercícios terapêuticos no limiar de dor mecânica, avaliada através do uso de um algômetro, imediatamente após o período de tratamento e no follow-up (quatro semanas).
- Investigar se os efeitos do uso pragmático de MWM e falsa MWM se diferem ao serem utilizados em conjunto com um programa de exercícios terapêuticos nos níveis de incapacidade, dor, na percepção da melhora global subjetiva, na ADM ativa e no limiar de dor mecânica, imediatamente após o período de tratamento e no follow-up (quatro semanas).

Avaliação dos Riscos e Benefícios:

Riscos:

O presente projeto possui como procedimentos de intervenção exercícios, mobilização com movimento (MWM) e/ou falsa MWM. O programa de exercícios terapêuticos utilizados nesta investigação foi criado baseando-se em estudos prévios e, em recomendações gerais no manejo desta condição (LEWIS et al., 2015; LITTLEWOOD et al., 2015; MINTKEN et al., 2016; SHIRE et al., 2017). Caso ocorra a reprodução de sintomas durante a realização dos exercícios, tal fato será manejado da seguinte forma: um valor arbitrário de 5 (numa escala verbal numérica de dor, onde 0 - significa sem dor e 10 - máxima dor imaginável) será observado durante a execução dos mesmos, como regra geral. No entanto, o participante irá decidir qual o nível que ele (a) entenda ser o mais adequado. Tal fato proporciona uma individualização e torna o indivíduo pró-ativo na tomada de decisão. Assim, se ele(a) entenda que um nível 2 seja o máximo tolerável, isso será respeitado. Tal fato reduz as chances de reprodução de desconforto e adere a recomendações de estudos prévios. O uso de crioterapia será indicado caso ocorra a presença de algum desconforto.

A aplicação de mobilizações com movimento (MWM) e falsa MWM será realizada de acordo com as recomendações (MULLIGAN, 2010). Ou seja, o movimento será realizado somente até o início dos sintomas, caso houverem. Estudos prévios adotaram estas medidas e reportaram ausência de efeitos adversos.

Benefícios:
Por se tratar de uma pesquisa clínica, os participantes deste estudo se beneficiarão inicialmente de um processo meticuloso de avaliação baseado em recomendações provenientes da literatura científica específica. Com isso, o participante terá uma melhor compreensão da sua condição clínica. Além deste benefício, parte do tratamento proposto em ambos os grupos contempla a realização de exercícios, que é considerado atualmente como uma das melhores alternativas terapêuticas conservadora a ser utilizada em pacientes com dor no ombro relacionada com o manguito rotador. O uso de mobilização com movimento (MWM) e falsa MWM poderá acarretar em maiores benefícios relacionados a condição clínica do articipante.

Comentários e Considerações sobre a Pesquisa:
A pesquisa possui relevância acadêmica onde a intervenção de práticas fisioterapêuticas de baixo custo podendo trazer benefícios à população em estudo.

Considerações sobre os Termos de apresentação obrigatória:
Todos os termos de apresentação obrigatória foram apresentados.O termo de "Autorização de Trabalho de Conclusão na Rede Municipal de Saúde de São Leopoldo", assim como "Carta de Anuência", encontram-se devidamente assinado, porém sem data. Atentar para o preenchimento dos documentos em sua totalidade.

Recomendações:
Recomendamos, envio de notificação na PB para:
1) inclusão documentos na PB com preenchimento em sua totalidade;
2)Cronograma atualizado conforme informações desritas em "PB_Informações Básicas_do_Projeto", para que fique em acordo com datas propostas no "Cronograma", postado em 30/07/2019.

Recomendamos ainda que em próximas submissões ao CEP UFCSPA, envio de Projeto detalhado em formato .doc, conforme "Orientações e Documentos para Encaminhamento de Projetos para Análise do CEP via Plataforma Brasil", disponível em <https://www.ufcspa.edu.br/index.php/cep/encaminhamento-de-projeto-para-analise>.

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Conclusões ou Pendências e Lista de Inadequações:

Retirada do TCLE original assinado, na secretaria do CEP UFCSPA, para início da coleta de dados.

Considerações Finais a critério do CEP:

De acordo com o parecer do Relator.

Este parecer foi elaborado baseado nos documentos abaixo relacionados:

Tipo Documento	Arquivo	Postagem	Autor	Situação
Informações Básicas do Projeto	PB_INFORMAÇÕES_BÁSICAS_DO_PROJETO_1321887.pdf	31/07/2019 15:54:04		Aceito
Outros	CartaResposta.pdf	31/07/2019 15:49:15	RAFAEL BAESKE	Aceito
TCLE / Termos de Assentimento / Justificativa de Ausência	TCLE.pdf	31/07/2019 11:17:08	RAFAEL BAESKE	Aceito
Outros	AutorizacaoSecretariodeSaude.pdf	30/07/2019 10:28:45	RAFAEL BAESKE	Aceito
Outros	CartadeAnuenciaPrefeituradeSL.pdf	30/07/2019 10:25:16	RAFAEL BAESKE	Aceito
Cronograma	Cronograma.pdf	30/07/2019 10:18:57	RAFAEL BAESKE	Aceito
Projeto Detalhado / Brochura Investigador	projeto_detalhado.pdf	30/07/2019 10:18:27	RAFAEL BAESKE	Aceito
Outros	cartadeanuenciaFACCAT.pdf	30/05/2019 10:28:21	RAFAEL BAESKE	Aceito
Outros	ShoulderPainandDisabilityIndex.docx	28/03/2019 11:51:48	RAFAEL BAESKE	Aceito
Outros	TermodeCompromissoParaEntregadeRelatorio.pdf	28/03/2019 11:35:01	RAFAEL BAESKE	Aceito
Outros	Programadeexercicios.docx	28/03/2019 11:34:04	RAFAEL BAESKE	Aceito
Orçamento	Orcamento.docx	28/03/2019 11:33:38	RAFAEL BAESKE	Aceito
Outros	MaterialdeMarketing.docx	28/03/2019 11:33:30	RAFAEL BAESKE	Aceito
Outros	Fichadedadossociodemograficos.docx	28/03/2019 11:33:09	RAFAEL BAESKE	Aceito
Outros	Escalavisualnumericadedor.docx	28/03/2019 11:32:19	RAFAEL BAESKE	Aceito
Outros	Escaladepercepcaodamelhorageral.docx	28/03/2019 11:31:46	RAFAEL BAESKE	Aceito

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Continuação do Parecer: 3.528.946

Outros	Escalademonitoramentodeefeitosadversos.docx	28/03/2019 11:31:12	RAFAEL BAESKE	Aceito
Outros	Escaladecegamento.docx	28/03/2019 11:30:43	RAFAEL BAESKE	Aceito
Outros	CartadeAnuenciaClinicaALBRECHT.pdf	28/03/2019 11:29:31	RAFAEL BAESKE	Aceito
Outros	Avaliacaodasexpectativas.docx	28/03/2019 11:27:27	RAFAEL BAESKE	Aceito
Outros	Autoeficacia.docx	28/03/2019 11:27:03	RAFAEL BAESKE	Aceito
Folha de Rosto	Folha_de_Rosto_Plataforma_Brasil.pdf	28/03/2019 10:03:23	Marcelo Faria Silva	Aceito

Situação do Parecer:
Aprovado

Necessita Apreciação da CONEP:
Não

PORTO ALEGRE, 23 de Agosto de 2019

Assinado por:
Luciane Dalcanale Moussalle
(Coordenador(a))

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