

Brazilian Journal of Physical Therapy



https://www.journals.elsevier.com/brazilian-journal-of-physical-therapy

SYSTEMATIC REVIEW

Assessment of description and implementation fidelity of clinical trials involving exercise-based treatment in individuals with rotator cuff tears: a scoping review



Larissa Pechincha Ribeiro^a, Francisca Curiel-Montero^b, Daiana Priscila Rodrigues-de-Souza^{b,c}, Paula Rezende Camargo^{a,*}, Francisco Alburquerque-Sendín^{b,c}

^a Laboratory of Analysis and Intervention of the Shoulder Complex, Department of Physical Therapy, Universidade Federal de São Carlos, São Carlos, SP, Brazil

^b Department of Nursing, Pharmacology and Physical Therapy, Universidad de Córdoba, Córdoba, Spain

^c Maimonides Biomedical Research Institute of Cordoba (IMIBIC), Córdoba, Spain

Received 1 December 2022; received in revised form 13 March 2024; accepted 27 March 2024 Available online 11 April 2024

KEYWORDS	Abstract
Refront of the second s	 Abstract Background: For evidence-based practice, clinicians and researchers can rely on well-conducted randomized clinical trials that exhibit good methodological quality, provide adequate intervention descriptions, and implementation fidelity. Objective: To assess the description and implementation fidelity of exercise-based interventions in clinical trials for individuals with rotator cuff tears. Methods: A systematic search was conducted in PubMed, Embase, CINAHL, LILACS, Cochrane Library, Web of Science, SCOPUS and SciELO. Randomized clinical trials that assessed individuals with rotator cuff tears confirmed by imaging exam were included. All individuals must have received an exercise-based treatment. The methodological quality was scored with the Physiotherapy Evidence Database (PEDro) scale. The Template for Intervention Description and Replication (TIDieR) checklist and the National Institutes of Health Behaviour Change Consortium (NIHBCC) were used to assess intervention description and implementation fidelity, respectively. Results: A total of 13 studies were included. Despite their adequate methodological quality, the description of the intervention was poor with TIDieR scores ranging from 6 to 15 out of 24 total points. The TIDieR highest-scoring item was item 1 (brief name) that was reported in all studies. Considering fidelity, only one of the five domains of NIHBCC (i.e., treatment design) reached just over 50%.

* Corresponding author at: Departamento de Fisioterapia, Universidade Federal de São Carlos, Rodovia Washington Luiz, Km 235, CEP:13.565-905, São Carlos, SP, Brazil.

E-mail: prcamargo@ufscar.br (P.R. Camargo).

https://doi.org/10.1016/j.bjpt.2024.101062

1413-3555/© 2024 Associação Brasileira de Pesquisa e Pós-Graduação em Fisioterapia. Published by Elsevier España, S.L.U. All rights reserved.

Conclusion: Exercise-based interventions used in studies for individuals with rotator cuff tears are poorly reported. The description and fidelity of the intervention need to be better reported to assist clinical decision-making and support evidence-based practice.

© 2024 Associação Brasileira de Pesquisa e Pós-Graduação em Fisioterapia. Published by Elsevier España, S.L.U. All rights reserved.

Introduction

Shoulder pain is a very common condition in the general population and may affect up to 66.7% of the population over a lifetime.¹ Rotator cuff related shoulder pain, which includes rotator cuff tears, is one of the most frequent diagnoses.²⁻⁴ Current evidence shows that surgical approaches are not superior to conservative approaches, and that exercise-based treatment should be considered as a first-line option.^{5,6}

The effectiveness of exercise-based interventions in individuals with rotator cuff tears has been previously reported. $^{5-7}$ It is therefore timely to assess the description and implementation fidelity of clinical trials investigating exercise-based interventions for rotator cuff tears. Incomplete reporting of interventions may prevent clinicians and researchers to promptly replicate these interventions in clinical practice and future trials.

The Template for Intervention Description and Replication (TIDieR) can be used to improve the description of interventions and their implementation. The TIDieR checklist was created in 2014 to improve reporting of interventions in clinical trials.^{8,9} This checklist contains 12 items that cover information about how a treatment is delivered, the equipment and the level of training needed, and the dose and intensity used in the program, among others.¹⁰ In addition to providing a detailed description of an intervention, implementation fidelity of the intervention is another aspect that may improve reliability and internal validity of the study, as it involves the knowledge of the fidelity between what was prescribed compared to what was performed as an intervention in the trial.¹¹ If studies do not provide enough and adequate details about the intervention, the findings may be under or overestimated, resulting in misleading interpretations and hindering reproducibility for researchers and clinicians.¹² The National Institutes of Health Behaviour Change Consortium (NIHBCC)¹³ was created to assess the implementation fidelity and improve the clarity and quality of reporting interventions. This tool evaluates the full treatment implementation model that consists of treatment delivery, receipt, and enactment.^{14,15} Ideally, clinicians and researchers should be able to replicate evidence-based exercises to treat individuals with shoulder pain and rotator cuff tear. Therefore, it is important that studies not only have low risk of bias, but also provide information about materials, infrastructure, dosage, possible modifications made in the treatment, and appropriate implementation fidelity.

The objective of this study was to assess the description and implementation fidelity of exercise-based interventions in clinical trials for individuals with rotator cuff tears. We expected to highlight possible gaps for clinicians and researchers.

Methods

Registration and research question

This scoping review was previously registered in Open Science Framework on March 31, 2022 (https://osf.io/xv3cq). The Preferred Reporting Items for Systematic reviews and Meta-Analyses Extension for Scoping Review (PRISMA-ScR) guideline was followed.¹⁶

Data sources and search

A systematic search was conducted in 8 electronic databases (PubMed, Embase, CINAHL, LILACS, Cochrane Library, Web of Science, SCOPUS and SciELO) from their inception to June 2023. These databases, including regional ones, were searched in an attempt to conduct a comprehensive search and identify as much relevant evidence as possible. A search strategy was developed by combining relevant keywords. All keywords were searched independently and then combined using relevant Boolean terms. Randomized clinical trials were selected and no other limits were used (Supplementary material).

Study eligibility

In this review, inclusion criteria were determined based on the "PCC" mnemonic which stands for Population, Concept, and Context.¹⁷ Population: Individuals with a partial or fullthickness rotator cuff tear confirmed by imaging exam. The tear size was not taken into consideration as long as the articles did not exclusively include a population with massive and irreparable rotator cuff tears. Concept: The target population included individuals who received an exercisebased treatment in any study arm. Exercise-based interventions were considered when any type of exercise was applied alone or as a component of a rehabilitation program, which could also include other therapeutic modalities such as electrotherapy, medication, pain education, injection, and other interventions combined with exercise. Context: This scoping review focused on randomized clinical trials (RCT).

Studies that involved participants with shoulder pain and other diagnoses, for example an isolated tendinopathy in rotator cuff muscles or bursitis (mixed population), shoulder instability, and/or frozen shoulder were excluded. Retrospective studies, cohort studies, case studies, clinical commentaries, recommendation papers, and consensus statements were also excluded.

Data extraction

Two independent reviewers (LPR and FCM) performed the selection process and a third reviewer (FAS) was consulted for consensus in case of any disagreement. Articles were

analyzed with the assistance of the StArt program (copyright_version) designed by the Universidade Federal de São Carlos (Brazil). The titles were initially screened and those that clearly did not fit the eligibility criteria were excluded. The abstracts of the selected titles were analyzed for inclusion according to the study design, participants, and interventions. Finally, the full texts of potentially relevant articles were analyzed for inclusion. Reference lists from included full-text articles and retrieved systematic reviews were also screened for additional relevant publications.

Data items

To characterize the articles, information about the year of publication, number of participants, diagnosis, type of injury, and outcomes evaluated in each article was collected. Furthermore, all articles were assessed according to the scale and checklists below.

Methodological quality assessment

All studies were scored with the Physiotherapy Evidence Database (PEDro) scale, which is a tool that evaluates the risk of bias and completeness of statistical reporting of trial reports for interventional studies in physical therapy.¹⁸ PEDro is a reliable tool and the items are scored as yes (1) or no (0). It consists of 11 items, but it is important to note that item 1 is not scored.¹⁹ Thus, the possible maximum score is 10 points. If an item was not clearly described or unclear, no points were awarded. The scoring can be classified as "poor" (less than 4 points), "fair" (4-5 points), "good" (6-8 points), and "excellent" (9-10 points).²⁰ The scores of the studies already indexed and scored in the PEDro database were used. Methodological quality assessment of studies not indexed in PEDro was performed by two independent reviewers (LPR and FCM). Any inconsistency in the rating was solved by a third reviewer (FAS).

TIDieR checklist

The TIDieR checklist consists of 12 items: (1) brief name, (2) why, (3) what materials, (4) what procedures, (5) who provided, (6) how, (7) where, (8) when and how much, (9) tailoring, (10) modifications, (11) how well (planned), and (12) how well (actual).⁸ Each item was scored using the following criteria: reported (2), partially reported (1), not reported (0). The range of score varies from 0 to 24 points. This tool is valid and used to improve description of interventions in clinical trials.^{12,21–23} The TIDier assessment was performed by two independent reviewers (LPR and FCM) and inconsistencies in rating were solved by a third reviewer (FAS).

NIHBCC checklist

The NIHBCC checklist has five domains: (1) treatment design, (2) training of providers, (3) treatment delivery, (4) treatment receipt and (5) treatment enactment.²⁴ In general, the checklist helps to understand how the intervention was designed, as well as if and how healthcare professionals were trained, how the treatment was delivered to the patient, how the patient received it, and the execution of what was proposed. The NIHBCC assessment was performed by the same researchers (LPR and FCM). Each item was scored using the following criteria: reported (2), partially

reported (1), not reported (0) and NA, when "not applicable". In the treatment design domain, there is a total of six questions. The maximum and minimum scores depend on the number of intervention groups. Specifically, when the study includes more than two treatment groups, the score can reach higher values because it requires evaluating the information from each group. The maximum score in the training of providers domain was 14 points with seven questions, treatment delivery was 18 points with nine questions, treatment receipt was 10 points with five questions, and treatment enactment was 4 points with only two questions.²⁴ This checklist was previously used in other studies involving exercise intervention.^{12,25}

Synthesis of results

Extracted data were organized in Microsoft Excel (Microsoft Corporation, Redmond, WA) where scores and percentages were calculated. The scale and checklist's items were classified in a consensus forum between LPR and FMC.

Results

Our database search identified 4400 articles. Thirteen studies fulfilled the criteria for inclusion with a total of 900 participants. A flow chart with the selection process is shown in Fig. 1. The characteristics of the included studies are provided in Table 1. Two follow-up studies reporting secondary analyses for different time points from the same trial in separate publications, $^{26-29}$ were merged and presented in this review as a single study. 30,31

Among the included studies, the oldest article was published in 2010, and the most recent ones were published in 2021. Most studies included individuals with partial-thickness tears rather than full-thickness rotator cuff tears, and the mechanism of injury varied but was mostly not reported. Several approaches were used in the management of individuals with rotator cuff tears. In addition to exercises, the treatment also involved injection therapy, manual therapy, electrotherapy, and shoulder surgical procedures. The outcome measures used to assess effectiveness were highly variable. Shoulder function and pain were evaluated in all studies (n = 13), but using different tools. Muscle strength (n = 6), 30,31,35,39,40,42 range of motion (n = 8), 30-32,35,37,39,40,42radiological outcomes (n = 3),^{29,35,40} pressure pain threshold (n = 1),³³ and satisfaction $(n = 2)^{33,36}$ were also evaluated in some studies. Psychosocial $(n = 3)^{30,35,38}$ and psychological $(n = 2)^{33,37}$ factors were assessed in a few studies. The mean PEDro score was, on average, 6.2/10 (standard deviation [SD]: 1.3) indicating a good methodological quality of the articles included (Table 1).

The TIDieR scores are provided in Table 2. The average score across all studies on the TIDieR was 10.4/24 (SD: 2.6) points, ranging from 6 to 15 points. The percentage regarding each TIDieR item checklist varied from 7.6% (lowest value achieved) to 100% (highest value achieved) and are presented in Table 3. All studies (n = 13) provided information about the first item (brief name that provided the name or a phrase that described the intervention). Few studies reported

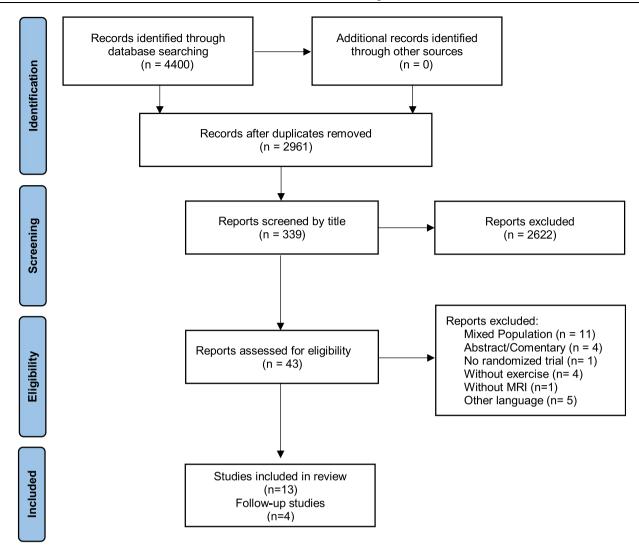


Fig. 1 Flow chart of the selection process.

possible adaptations in the management $(n = 4)^{26,27,30,40}$ and adherence $(n = 2)^{32,35}$ to the program (Table 3).

Regarding implementation fidelity across the NIHBCC scale, the overall fidelity score across all the studies (n = 13) of each domain ranged from 0.5 to 51.2%. The highest score was for treatment design domain that reached 51.2%, and the lowest scores were in the domains of training of providers and treatment enactment, which scored 0.5% and 3.8%, respectively. The treatment delivery and treatment enactment also achieved low final scores, 20.8% and 3.8%, respectively. The overall score of all studies with the five domains taken together was 27.4%. All information about NIHBCC score is presented in Table 4 with the score of each article.

Discussion

This review evaluated the description and implementation fidelity of exercise-based interventions included in clinical trials for individuals with rotator cuff tears. Our findings show these clinical trials showed good methodological quality, but the description and fidelity of the intervention were poorly reported. Clinicians and researchers may face challenges when attempting to replicate and implement the interventions due to insufficient available information.

Most of the included clinical trials were published in 2018 or after. Even after the publication of the TIDieR checklist in 2014, few items were properly reported in more recent studies, making it difficult to replicate the intervention. Interventions performed in individuals with rotator cuff tear were highly variable. Studies compared exercises versus surgery, 30,31,35,39,40 different exercises modalities³⁶ or exercises associated with manual therapy^{33,37} or electro-therapy³⁸ and also injectable therapies. ^{32,34,41,42}

The average quality of the included studies was considered "good" based on an overall mean score greater than 6 points on the PEDro scale.⁴³ While the PEDro scale is a valid tool to assess the methodological quality of clinical trials,⁴⁴ and the studies are of good quality, the lack of information hinders the implementation of the intervention. Full treatment description would allow replication of the intervention,⁸ while incomplete information creates a barrier in the implementation of potential effective treatments.¹⁰ The results of this study show a lack of information about interventions because the low total TIDieR scores indicate a lack of information even in those

Article	Year of Publication	Population	Diagnosis	Atraumatic, Traumatic or Both	Intervention	Outcomes	PEDro Scale
Hajivandi <i>et al³²</i>	2021	n = 96	Full-thickness rotator cuff degenerative tear	Atraumatic	EBT + CSI x EBT x CSI	VAS, ROM, DASH	4/10
Sadikoglu <i>et al³³</i>	2021	n = 46	Partial-thickness rotator cuff tears	-	Ischemic compression + EBT x IASTM + EBT	DASH, ASES, VAS, ROM, PPT, HADS and Global Rating of Change scale	7/10
Centeno <i>et al³⁴</i>	2020	n = 25	Partial or full-thickness rota- tor cuff tear	-	EBT x Injection	DASH, NPS, SANE	6/10
Ranebo et al ³⁵	2020	n = 58	Full-thickness rotator cuff tear	Traumatic	Surgery x EBT	CSM, strength, WORC, NRS, MRI	8/10
Türkmen et al ³⁶	2020	n = 33	Partial-thickness rotator cuff tear	-	EBT (video) x EBT-(super- vised)	ROM, VAS, DASH, ASES, PCS- 12, MCS-12, Global Rating of Change scale	7/10
Akbaba <i>et al³⁷</i>	2019	n = 53	Partial-thickness rotator cuff tears	-	Myofascial trigger points + EBT x EBT	VAS, ROM, DASH, ASES, and HAD	8/10
Vrouva <i>et al³⁸</i>	2019	n = 42	Partial-thickness rotator cuff tear	-	TENS + EBT x MENS + EBT	SPADI, NRS, EQ-5D	6/10
Kim et al ³⁹	2018	n = 78	Partial-thickness rotator cuff tears	Atraumatic	Immediate repair x delayed repair after EBT	ASES, CSM, ROM, VAS, repair integrity	4/10
Heerspink <i>et al⁴⁰</i>	2015	n = 56	Full-thickness rotator cuff tear	Atraumatic	Surgery x EBT	CMS, DSST, VAS Radiologic Outcome	6/10
Ilhanli <i>et al</i> ⁴¹	2015	n = 70	Partial-thickness supraspina- tus tear	-	Platelet-rich plasma x EBT	ROM, VAS, DASH	5/10
Kukkonen et al ^{28,29,31}	2014, 2015 and 2021	n = 180	Symptomatic supraspinatus tendon tear comprising < 75% of the tendon	Atraumatic	EBT x Acromioplasty + EBT x Repair + acromioplasty + EBT	CSM	7/10
Gialanella <i>et al⁴²</i>	2011	n = 60	Full-thickness rotator cuff tear	-	Single injection x Two injec- tions x EBT	VAS, CMS	5/10
Moonsmayer et al ^{26,27,30}	2010, 2014 and 2019	<i>n</i> = 103	Symptomatic small or medium-sized partial-thick- ness tears of the rotator cuff	Both	Surgery x EBT	CMS, ASES score, SF-36	8/10

ASES, American Society of Shoulder and Elbow Surgeons; CMS, Constant-Murley Score; CSI, corticosteroid injections; DASH, Disabilities of Arm, Shoulder and Hand; DSST, Dutch Simple Shoulder Test; EBT, exercise-based treatment; EQ-5D, EuroQoL Questionnaire; IASTM, instrument-assisted soft tissue mobilization; NPS, numerical pain scale; NRS, numerical rating scale; ROM, range of Motion; SANE, Single Assessment Numeric Evaluation; SF-12, Short Form 12; SPADI, Shoulder Pain and Disability Index; VAS, visual analogic scale.

Article	ltem	Item	Item	ltem	Item	ltem	Item	ltem	Item	ltem	ltem	Item	TIDieR score
Article	1	2	3	4	5	6	7	8	9	10	11	12	TIDIER Score
Hajivandi <i>et al</i> ³⁶													10/24 (41.6%)
Sadikoglu <i>et al</i> ³⁸													11/24 (45.8%)
Centeno et al42													10/24 (41.6%)
Ranebo et al ³³													15/24 (62.5%)
Türkmen <i>et al</i> ³⁹													14/24 (58.3%)
Akbaba <i>et al</i> ³⁷													10/24 (41.6%)
Vrouva <i>et al</i> 40													7/24 (29.1%)
Kim <i>et a</i> l ³⁴													9/24 (37.5%)
Heerspink et al ³²													13/24 (54.1%)
Ilhanli <i>et al</i> 41													8/24 (33.3%)
Kukkonen <i>et al</i> ^{28,29,31}													12/24 (50%)
Gialanella and Prometti ³⁵													6/24 (25%)
Moonsmayer et al ^{26,27,30}													10/24 (41.6%)

 Table 2
 Template for Intervention Description and Replication (TIDieR) score, score of each item and total score, for the included studies.

Score for item 1 to 12 and overall TIDieR score. Green, item was reported (2 points); yellow, item was partially reported (1 point); red, item was not reported (0 point).

Table 3	Overall score and percentage of studies reporting items from Template for Intervention Description and Replication
(TIDieR) o	:hecklist (<i>n</i> = 13).

Item	Overall score	%
1. Provide the name or a phrase that describes the intervention.	26	100%
2. Describe any rationale, theory, or goal of the elements essential to the intervention.	25	96. 1%
3. Materials: Describe any physical or informational materials used in the intervention, including those provided to participants or used in intervention delivery or in training of intervention providers. Provide information on where the materials can be accessed (e.g. online appendix, URL).	16	61.5%
4. Procedures: Describe each of the procedures, activities, and/or processes used in the inter- vention, including any enabling or support activities.	15	57.7%
For each category of intervention provider (e.g. psychologist, nursing assistant), describe their expertise, background and any specific training given.	11	42.3%
6. Describe the modes of delivery (e.g. face-to-face or by some other mechanism, such as inter- net or telephone) of the intervention and whether it was provided individually or in a group.	9	34.6%
7. Describe the type(s) of location(s) where the intervention occurred, including any necessary infrastructure or relevant features.	8	30.7%
Describe the number of times the intervention was delivered and over what period of time including the number of sessions, their schedule, and their duration, intensity or dose.	13	50%
9. If the intervention was planned to be personalised, titrated or adapted, then describe what, why, when, and how.	3	11.5%
10. If the intervention was modified during the course of the study, describe the changes (what, why, when, and how).	2	7.6%
11. Planned: If intervention adherence or fidelity was assessed, describe how and by whom, and if any strategies were used to maintain or improve fidelity, describe them.	3	11.5%
12. Actual: If intervention adherence or fidelity was assessed, describe the extent to which the intervention was delivered as planned.	2	7.6%

Article	Treatment design	Training of providers	Treatment delivery	Treatment receipt	Treatment enactment	Overall score
Hajivandi <i>et al</i> ³²	65.0% (26/40)	0% (0/14)	16.6% (3/18)	0% (0/10)	0% (0/4)	33.7% (29/86)
Sadikoglu <i>et al</i> ³³	68.8% (22/32)	7.4% (1/14)	16.6% (3/18)	0% (0/10)	0% (0/4)	33.3% (26/78)
Centeno et al ³⁴	34.3% (11/32)	0% (0/14)	16.6% (3/18)	0% (0/10)	0% (0/4)	17.9% (14/78)
Ranebo et al ³⁵	59.3% (19/32)	0% (0/14)	55.5% (10/18)	0% (0/10)	0% (0/4)	37.1% (29/78)
Türkmen <i>et al</i> ³⁶	71.8% (23/32)	0% (0/14)	38.8% (7/18)	60% (6/10)	50% (2/4)	48.7% (38/78)
Akbaba <i>et al</i> ³⁷	59.4% (19/32)	0% (0/14)	27.7% (5/18)	0% (0/10)	0% (0/4)	30.8% (24/78)
Vrouva <i>et al</i> ³⁸	53.1% (17/32)	0% (0/14)	5.5% (1/18)	0% (0/10)	0% (0/4)	23.1% (18/78)
Kim <i>et a</i> l ³⁹	28.1% (9/32)	0% (0/14)	11.1% (2/18)	0% (0/10)	0% (0/4)	14.1% (11/78)
Heerspink <i>et al</i> ⁴⁰	53.1% (17/32)	0% (0/14)	22.2% (4/18)	0% (0/10)	0% (0/4)	26.9% (21/78)
Ilhanli <i>et al</i> ⁴¹	46.8% (15/32)	0% (0/14)	11.1% (2/18)	0% (0/10)	0% (0/4)	21.8% (17/78)
Kukkonen <i>et al</i> ^{28,29,31}	30% (12/40)	0% (0/14)	11.1% (2/18)	20% (2/10)	0% (0/4)	18.6% (16/86)
Gialanella <i>et al</i> ⁴²	45% (18/40)	0% (0/14)	33.3% (6/18)	0% (0/10)	0% (0/4)	27.9% (24/86)
Moonsmayer <i>et al</i> ^{26,27,30}	50% (16/32)	0% (0/14)	5.5% (1/18)	0% (0/10)	0% (0/4)	21.8% (17/78)
Average score	51.2%	0.5%	20.8%	6.1%	3.8%	27.4%

Table 4 The National Institutes of Health Behaviour Change Consortium (NIHBCC) sco	Table 4
---	---------

studies recently published.^{32–39,45} Missing information included treatment duration, dose, intensity, intervention planning, and modifications, as well as patient adherence to the program.

Clinicians treating individuals with shoulder pain and rotator cuff tears, researchers conducting trials with this population and also for policymakers interested in implementing evidence-based interventions may face challenges when trying to use interventions included in this review. Patients may not adhere to exercise interventions or opt for other approaches such as surgical procedure, medications, or injectable therapies due to a lack of clarity about, for instance, exercise progression or adaptations. Our findings are in agreement with other studies involving physical therapy treatment in patients with hip osteoarthritis,²² femoroacetabular impingement syndrome,⁴⁶ subacromial pain syndrome,¹² hamstring strain,²¹ Achilles tendon rupture,⁴⁷ and preoperative patient program for orthopaedic surgerv48 where researchers also need to improve the quality of reporting interventions.

In general, the evaluation of fidelity of studies involving individuals with rotator cuff tear was low. As in previous studies,^{12,25} the lowest scored domain was training of providers, meaning that no detailed information about how the training was conducted, the assessment of skill acquisition, and whether any specific characteristics were encouraged or avoided during the sessions. Non-significant results of a treatment can potentially be attributed to ineffectiveness of an intervention or also by providers with inadequate training and monitoring.²⁴ In addition, the patient's skills during the exercises should be assessed and informed. It is also important to minimize the chances of the patient not performing or performing the exercise incorrectly when not supervised.

A clinical trial is often considered a high-impact publication. However, detailing the implementation process is essential to understand possible barriers and facilitators of an intervention program. Over the years, authors have been striving to minimize bias and improve the methodological quality of clinical trials.⁴⁹ However, improving the quality of information is also important, and can impact the ability to replicate the intervention, especially in clinical practice. Although it is easier to think about the importance of designing and delivering the treatment, it is also necessary to train professionals, and to understand how the patient receives and executes the intervention. Therefore, future studies need to improve the quality of reporting interventions, and scientific journals should request authors to report each step of the intervention more clearly, facilitating its replication and implementation. It is possible that improving the understanding and execution of the exercise program leads to greater adherence to treatment. Through good fidelity delivery, it is possible to improve evidence-based practice and assist the clinicians in decision making.⁵⁰

Limitations

This study has some limitations. Some of the items of the NIHBCC may have influenced the final score. For instance, the item regarding the method to ensure dose equivalence between intervention groups was rated as "not applicable" in all articles, which removes this item from the final score in the treatment design domain. In contrast, for studies comparing similar exercises without the addition of other modalities or treatments this item was relevant and included in the final score. In addition, it is possible that the authors may have provided an item, as for example, advice or education, but did not mention that in the manuscript. There are no methods to weight or infer if it was done unless it was explicitly mentioned, resulting in a reduction of the total score.

Conclusion

Exercise-based treatment in individuals with rotator cuff tears presents poor description and fidelity of the interventions. More information about the infrastructure, adaptations during the treatment and adherence are needed to improve the description of the treatment. In addition, information about provider training is essential. Future studies should improve the treatment description and fidelity in attempt to facilitate implementation by clinicians, researchers, and policymakers and replication of the study.

Data sharing

All data relevant to the study are included in the article or are available as supplementary material.

This project was funded by Coordenação de Aperfeiçoamento de Pessoal de Nível Superior (CAPES), Conselho Nacional de Desenvolvimento Científico e Tecnológico (CNPq) (144436/2019-1) and Erasmus+ (63350-MOB-00143). The funders had no role in study design, data analysis, decision to publish, or preparation of the manuscript.

Conflicts of interest

The authors declare no conflicts of interest.

Supplementary materials

Supplementary material associated with this article can be found in the online version at doi:10.1016/j.bjpt.2024. 101062.

References

- Luime J, Koes B, Hendriksen I, et al. Prevalence and incidence of shoulder pain in the general population; a systematic review. *Scand J Rheumatol.* 2004;33(2):73–81. https://doi.org/ 10.1080/03009740310004667.
- Ludewig PM, Kamonseki DH, Staker JL, Lawrence RL, Camargo PR, Braman JP. Changing our diagnostic paradigm: movement system diagnostic classification. *Int J Sports Phys Ther.* 2017;12 (6):884–893. https://doi.org/10.26603/ijspt20170884.
- McClure PW, Michener LA. Staged approach for rehabilitation classification: shoulder disorders (STAR-shoulder). *Phys Ther.* 2015;95(5):791–800. https://doi.org/10.2522/ptj.20140156.
- Lewis J. Rotator cuff related shoulder pain: assessment, management and uncertainties. *Man Ther.* 2015;23:57–68. https:// doi.org/10.1016/j.math.2016.03.009.
- Ryösä A, Laimi K, Äärimaa V, Lehtimäki K, Kukkonen J, Saltychev M. Surgery or conservative treatment for rotator cuff tear: a meta-analysis. *Disabil Rehabil*. 2017;39(14):1357–1363. https://doi.org/10.1080/09638288.2016.1198431.
- Piper CC, Hughes AJ, Ma Y, Wang H, Neviaser AS. Operative versus nonoperative treatment for the management of full-thickness rotator cuff tears: a systematic review and meta-analysis. J Shoulder Elbow Surg. 2018;27(3):572–576. https://doi.org/ 10.1016/j.jse.2017.09.032.
- 7. Kuhn JE, Dunn WR, An Q, et al. Effectiveness of physical therapy in treating atraumatic full thickness rotator cuff tears. a multicenter prospective cohort study. J Shoulder Elbow Surg. 2013;22(10):1371–1379. https://doi.org/10.1016/j. jse.2013.01.026.
- Hoffmann TC, Glasziou PP, Boutron I, et al. Better reporting of interventions: template for intervention description and replication (TIDieR) checklist and guide. *BMJ (Online)*. 2014;348 (March):1–12. https://doi.org/10.1136/bmj.g1687.
- 9. Leite MN, Hoffmann TC, Helal L, Umpierre D, Yamato TP. Helping to know about the intervention: the Template for Intervention Description and Replication (TIDieR) checklist is now

available in Brazilian Portuguese. *Braz J Phys Ther.* 2023;27(1). https://doi.org/10.1016/j.bjpt.2023.100483.

- Yamato T, Maher C, Saragiotto B, et al. The TIDieR checklist will benefit the physical therapy profession. J Orthopaed Sports Phys Ther. 2016;46(6):402–404. https://doi.org/10.2519/ jospt.2016.0108.
- Borrelli B, Sepinwall D, Bellg AJ, et al. A new tool to assess treatment fidelity and evaluation of treatment fidelity across 10 years of health behavior research. J Consult Clin Psychol. 2005;73 (5):852–860. https://doi.org/10.1037/0022-006X.73.5.852.
- Ribeiro DC, Spiers K, Thomas L, et al. Monitoring, implementation and reporting of interventions in a selection of trials assessing exercise therapy for the management of shoulder subacromial pain : a cross- sectional investigation. *BMJ Open*. 2021;11(2): e044462. https://doi.org/10.1136/bmjopen-2020-044462.
- Bellg AJ, Resnick B, Minicucci DS, et al. Enhancing treatment fidelity in health behavior change studies: best practices and recommendations from the NIH Behavior Change Consortium. *Health Psychol*. 2004;23(5):443–451. https://doi.org/10.1037/ 0278-6133.23.5.443.
- Lichstein KL, Riedel BW, Grieve R. Fair tests of clinical trials: a treatment implementation model. *Adv Behav Res Ther.* 1994;16 (1):1–29. https://doi.org/10.1016/0146-6402(94)90001-9.
- 15. Ginsburg LR, Hoben M, Easterbrook A, Anderson RA, Estabrooks CA, Norton PG. Fidelity is not easy! Challenges and guidelines for assessing fidelity in complex interventions. *Trials*. 2021;22 (1):1–13. https://doi.org/10.1186/s13063-021-05322-5.
- Tricco AC, Lillie E, Zarin W, et al. PRISMA extension for scoping reviews (PRISMA-ScR): checklist and explanation. *Ann Intern Med.* 2018;169(7):467–473. https://doi.org/10.7326/M18-0850.
- Peters MDJ, Godfrey C, McInerney P, Munn Z, Tricco AC, Khalil H. Chapter 11: scoping reviews (2020 version). JBI Manual Evid Synth. 2020. https://doi.org/10.1891/9780826152268.0012.
- Moseley AM, Rahman P, Wells GA, et al. Agreement between the Cochrane risk of bias tool and Physiotherapy Evidence Database (PEDro) scale: a meta-epidemiological study of randomized controlled trials of physical therapy interventions. *PLoS One*. 2019;14 (9):1–16. https://doi.org/10.1371/journal.pone.0222770.
- Maher CG, Sherrington C, Herbert RD, Moseley AM, Elkins M. Reliability of the PEDro scale for rating quality of randomized controlled trials. *Phys Ther.* 2003;83(8):713–721. https://doi. org/10.1093/ptj/83.8.713.
- Cashin AG, McAuley JH. Clinimetrics: Physiotherapy Evidence Database (PEDro) scale. J Physiother. 2020;66(1):59. https:// doi.org/10.1016/j.jphys.2019.08.005.
- Breed R, Opar D, Timmins R, Maniar N, Banyard H, Hickey J. Poor reporting of exercise interventions for hamstring strain injury rehabilitation: a scoping review of reporting quality and content in contemporary applied research. J Orthopaed Sports Phys Ther. 2022;52(3):130–141. https://doi.org/10.2519/jospt.2022.10641.
- Burgess LC, Wainwright TW, James KA, von Heideken J, Iversen MD. The quality of intervention reporting in trials of therapeutic exercise for hip osteoarthritis: a secondary analysis of a systematic review. *Trials*. 2021;22(1):1–10. https://doi.org/10.1186/ s13063-021-05342-1.
- Pool J, Maissan F, de Waele N, Wittink H, Ostelo R. Completeness of the description of manipulation and mobilisation techniques in randomized controlled trials in neck pain; a review using the TiDieR checklist. *Musculoskelet Sci Pract*. 2020;45: 102098. https://doi.org/10.1016/J.MSKSP.2019.102098.
- Borrelli B. The assessment, monitoring, and enhancement of treatment fidelity in public health clinical trials. J Public Health Dent. 2011;71(1):S52–S63. https://doi.org/10.1111/j.1752-7325.2011.00233.x.
- 25. Toomey E, Currie-Murphy L, Matthews J, Hurley DA. Implementation fidelity of physiotherapist-delivered group education and exercise interventions to promote self-management in people

with osteoarthritis and chronic low back pain: a rapid review Part II. *Man Ther.* 2015;20(2):287–294. https://doi.org/10.1016/j.math.2014.10.012.

- 26. Moosmayer S, Lund G, Seljom US, et al. Tendon repair compared with physiotherapy in the treatment of rotator cuff tears: a randomized controlled study in 103 cases with a five-year followup. J Bone Joint Surg - Am Vol. 2014;96(18):1504–1514. https://doi.org/10.2106/JBJS.M.01393.
- Moosmayer S, Lund G, Seljom US, et al. At a 10-year follow-up, tendon repair is superior to physiotherapy in the treatment of small and medium-sized rotator cuff tears. J Bone Joint Surg - Am Vol. 2019;101(12):1050–1060. https://doi.org/10.2106/JBJS.18.01373.
- Kukkonen J, Joukainen A, Lehtinen J, et al. Treatment of nontraumatic rotator cuff tears: a randomized controlled trial with two years of clinical and imaging follow-up. *The J Bone Joint Surg Am.* 2015;97(21):1729–1737.
- Kukkonen J, Ryösä A, Joukainen A, et al. Operative versus conservative treatment of small, nontraumatic supraspinatus tears in patients older than 55 years: over 5-year follow-up of a randomized controlled trial. J Shoulder Elbow Surg. 2021;30 (11):2455–2464. https://doi.org/10.1016/j.jse.2021.03.133.
- 30. Moosmayer S, Lund G, Seljom U, et al. Comparison between surgery and physiotherapy in the treatment of small and medium-sized tears of the rotator cuff: a randomised controlled study of 103 patients with one-year follow-up. J Bone Joint Surg - Ser B. 2010;92 (1):83–91. https://doi.org/10.1302/0301-620X.92B1.22609.
- **31.** Kukkonen J, Joukainen A, Lehtinen J, et al. Treatment of nontraumatic rotator cuff tears: a randomised controlled trial with one-year clinical results. *Bone Joint J*. 2014;96-B(1):75–81.
- Hajivandi S, Dachek A, Salimi A, et al. Comparison of the separate and combined effects of physiotherapy treatment and corticosteroid injection on the range of motion and pain in nontraumatic rotator cuff tear: a randomized controlled trial. Adv Orthop. 2021:1–7. https://doi.org/10.1155/2021/678945.
- Sadikoglu BA, Akbaba YA, Taskiran H. Effects of ischemic compression and instrument-assisted soft tissue mobilization techniques in trigger point therapy in patients with rotator cuff pathology: randomized controlled study. *Somatosens Mot Res.* 2022;39 (1):70–80. https://doi.org/10.1080/08990220.2021.2005015.
- 34. Centeno C, Fausel Z, Stemper I, Azuike U, Dodson E. A randomized controlled trial of the treatment of rotator cuff tears with bone marrow concentrate and platelet products compared to exercise therapy: a midterm analysis. Stem Cells Int. 2020;2020:1–10. https://doi.org/10.1155/2020/5962354.
- Ranebo MC, Björnsson Hallgren HC, Holmgren T, Adolfsson LE. Surgery and physiotherapy were both successful in the treatment of small, acute, traumatic rotator cuff tears: a prospective randomized trial. J Shoulder Elbow Surg. 2020;29 (3):459–470. https://doi.org/10.1016/j.jse.2019.10.013.
- 36. Türkmen E, Analay Akbaba Y, Altun S. Effectiveness of videobased rehabilitation program on pain, functionality, and quality of life in the treatment of rotator cuff tears: a randomized controlled trial. J Hand Ther. 2020;33(3):288–295. https://doi. org/10.1016/j.jht.2019.08.004.
- Akbaba YA, Mutlu EK, Altun S, Turkmen E, Birinci T, Celik D. The effectiveness of trigger point treatment in rotator cuff pathology: a randomized controlled double-blind study. J Back

Musculoskelet Rehabil. 2019;32(3):519-527. https://doi.org/ 10.3233/BMR-181306.

- Vrouva S, Batistaki C, Paraskevaidou E, et al. Comparative study of pain relief in two non-pharmacological treatments in patients with partial rotator cuff tears: a randomized trial. *Anesth Pain Med*. 2019;9(2):e88327. https://doi.org/10.5812/aapm.88327.
- 39. Kim YS, Lee HJ, Kim JH. When should we repair partial-thickness rotator cuff tears? after 6-month period of nonsurgical treatment. Am J Sports Med. 2018;46(5):1091–1096. https:// doi.org/10.1177/0363546518757425.
- Heerspink FOL, van Raay JJAM, Koorevaar RCT, et al. Comparing surgical repair with conservative treatment for degenerative rotator cuff tears: a randomized controlled trial. J Shoulder Elbow Surg. 2015;24(8):1274–1281. https://doi.org/10.1016/ j.jse.2015.05.040.
- Ilhanli I, Guder N, Gul M. Platelet-rich plasma treatment with physical therapy in chronic partial supraspinatus tears. *Iran Red Crescent Med J.* 2015;17(9). https://doi.org/10.5812/ircmj.23732.
- Gialanella B, Prometti P. Effects of corticosteroids injection in rotator cuff tears. *Pain Med.* 2011;12(10):1559–1565. https:// doi.org/10.1111/j.1526-4637.2011.01238.x.
- Foley NC, Teasell RW, Bhogal SK, Speechley MR. Stroke rehabilitation evidence-based review. *Methodology*. 2003;10(1):1–7.
- 44. de Morton NA. The PEDro scale is a valid measure of the methodological quality of clinical trials: a demographic study. Aust J Physiother. 2009;55(2):129–133. https://doi.org/10.1016/ S0004-9514(09)70043-1.
- 45. McCambridge AB, Nasser AM, Mehta P, Stubbs PW, Verhagen AP. Has reporting on physical therapy interventions improved in 2 decades? an analysis of 140 trials reporting on 225 interventions. J Orthopaed Sports Phys Ther. 2021;51(10):503–509. https://doi.org/10.2519/jospt.2021.10642.
- 46. Reiman MP, Boyd J, Ingel N, Reichert A, Westhoven M, Peters S. There is limited and inconsistent reporting of postoperative rehabilitation for femoroacetabular impingement syndrome: a scoping review of 169 studies. J Orthopaed Sports Phys Ther. 2020;50 (5):252–258. https://doi.org/10.2519/jospt.2020.9189.
- Christensen M, Zellers JA, Kjær IL, Silbernagel KG, Rathleff MS. Resistance exercises in early functional rehabilitation for achilles tendon ruptures are poorly described: a scoping review. J Orthopaed Sports Phys Ther. 2020;50(12):681–691. https:// doi.org/10.2519/jospt.2020.9463.
- 48. Furtado R, MacDermid JC, Ziebart C, Bryant D, Faber KJ. Preoperative patient education programs for orthopaedic surgery: what do the programs include? how are they delivered? what are the knowledge gaps? a scoping review of 46 studies. J Orthopaed Sports Phys Ther. 2022;52(9):572–585. https://doi.org/10.2519/jospt.2022.10614.
- 49. Vinkers CH, Lamberink HJ, Tijdink JK, et al. The methodological quality of 176,620 randomized controlled trials published between 1966 and 2018 reveals a positive trend but also an urgent need for improvement. *PLoS Biol.* 2021;19(4):1–16. https://doi.org/10.1371/journal.pbio.3001162.
- Toomey E, Hardeman W. Addressing intervention fidelity within physical therapy research and clinical practice. J Orthopaed Sports Phys Ther. 2017;47(12):895–898. https://doi.org/ 10.2519/jospt.2017.0609.