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Methodological quality of randomized controlled trials of home-based rehabilitation in knee osteoarthritis: A cross-sectional survey

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All procedures in this study involving human participants were performed in accordance with the 1964 Helsinki Declaration and its later amendments.

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No conflict of interest was declared by the authors.

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Abstract

Background/Aim: This study aimed to evaluate the methodological quality of randomized controlled trials (RCTs) that examine home-based rehabilitation (HBR) trials for knee osteoarthritis (KOA) using the Physiotherapy Evidence Database (PEDro) scale and the nine methodology-related items of the Consolidated Standards of Reporting Trials (CONSORT) 2010 statement.

Methods: Three electronic databases were scanned from baseline to October 10, 2021. Two reviewers independently evaluated the articles according to the two inclusion criteria: (1) in individuals diagnosed with KOA, at least one group received home-based rehabilitation as a study intervention and (2) at least one group received a comparison intervention or no intervention. The methodological quality of the included studies (n=22) was assessed using the PEDro scale and nine items of the CONSORT 2010 statement.

Results: Among 1557 RCTs, 22 studies that fulfilled our criteria were included in the review. The mean PEDro scale score was 5.77 (1.54). This result reflects moderate methodological quality. Concealed allocation (6; 27.3%), blinding of subjects (4; 18.2%), and (0; 0.0%) of therapists associated with the methodological quality were not reported in most studies. An author's expertise in epidemiology and/or statistics was 0.78 points (95% confidence interval [CI] 0.11–1.44), the multicenter study 0.94 points (95% CI: 0.19–1.68), and a one-unit increase in the total score of the CONSORT statement led to an increase in methodological quality of 0.55 points (95% CI: 0.34–0.76).

Conclusion: The methodological quality of most RCTs examining HBR in KOA that we included in our systematic review was moderate. The adherence of journals and authors to CONSORT checklists in reporting of studies may lead to an improvement in the methodological quality of future published studies.

Keywords: knee osteoarthritis, remote rehabilitation, PEDro scale, CONSORT statement, quality of methodological

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Introduction

Osteoarthritis (OA) is a very common rheumatic disease in older adults and affects the hips and knees most frequently the weight-bearing joints [1]. The global burden of knee osteoarthritis (KOA) is increasing in most countries, and it is expected that this burden will continue to increase with the aging populations in most countries. Raising the awareness of the population and policymakers about the risk factors of KOA and the importance and benefits of its management and the provision of adequate health care to patients with OA is recommended to manage the future burden of this condition [2]. In addition, the effectiveness of exercise therapy in KOA patients is supported by strong evidence with reduced potential harms and beneficial effects on overall health compared to other KOA treatments (such as analgesia or surgery) [3,4]. In light of this evidence, the inclusion of exercise therapy among the primary treatments offered for all people with KOA will help reduce future burden and cost [5].

Exercise leads to a significantly reduction in pain and improvements in function, performance, and quality of life in people with KOA [6]. Both rehabilitation programs, whether clinical-based or home-based exercises, provide these benefits for people with KOA [7,8]. Home-based exercise programs have the advantages of being inexpensive and require little or no equipment compared to clinic-based exercise programs [9]. In addition to these advantages, the progression of coronavirus disease 2019 as an epidemic worldwide created difficulties in healthcare services and has brought home-based rehabilitation (HBR) to the forefront even more than in previous years [10].

However, whether practicing home or clinic-based exercises, an appropriate exercise protocol is required to maximize the benefits of these exercises [11]. While creating these exercise protocols, the results of evidence-based practices are used in addition to clinical experience [12]. Randomized controlled trials (RCTs) are the gold standard for evaluating the results of clinical trials and are also valuable in clinical decision making in physiotherapy. However, the lack of methodological quality in such RCTs can make their results misleading. The methodology and findings of the published report must be clear, complete, and transparent for a study to accurately evaluate the results and benefits to patients [13,14].

Today, home-based exercises are at the forefront of treatment in patients with KOA. RCTs results are important when prescribing these exercise programs within the framework of evidence-based practices. However, no studies have examined the quality of methodological of RCTs related to HBR in patients with KOA. This study aimed to evaluate the methodological quality based on the PEDro scale and the methodology-related items of the CONSORT 2010 statement of RCTs that were used to examine HBR trials for KOA.

Materials and methods

The Preferred Reporting Items for Systemic Reviews and Meta-analyses (PRISMA) statement was used to guide the reporting of this review [15].

Study selection

We included RCTs released in English before October 10, 2021. The inclusion criteria of our study consisted of several parameters: (1) the participants in the articles had been diagnosed with knee osteoarthritis regardless of the stage and did not undergo any previous surgery related to knee osteoarthritis (such as total knee arthroplasty), (2) received home-based rehabilitation in at least one group, and (3) received a comparison intervention in at least one group (such as inpatient/outpatient physical therapy and/or medical therapy) or (4) no intervention/placebo. In addition, RCTs were also excluded if the publications were only in abstract form or were incomplete.

Data sources and search strategy

The search was conducted in PubMed, Cochrane Central Register of Controlled Trials (CENTRAL), and Web of Science using a combination of keywords such as ((((random[Title/Abstract]) OR random* [Title/Abstract]) OR randomized[Title/Abstract])) AND ((home-based [Title/Abstract]) AND rehabilitation[Title/Abstract]) OR exercise[Title/Abstract])) AND English[lang]). The search results were screened using titles and abstracts. The reference lists of included trials and review articles on the topic of home-based exercise in KOA were also manually reviewed to identify any additional trials for inclusion.

Study process

All articles obtained in electronic databases with relevant keywords were downloaded to EndNote X7.7 software, and both authors independently excluded duplicate articles using this software. The scanning of the remaining articles then occurred again. Scanning was done first according to the title, then as abstract. When an article title related to the subject that we examined was seen, it was evaluated in terms of abstract suitability. If the relevance was not sufficiently understood in the abstract, a separate file was created to examine the full text. After the two authors independently conducted this search, the third author was consulted when any discrepancy in the selected articles was found. The reason for exclusion was noted for each study that was found unsuitable during screening and was not included in the study.

Data collection

We used 11 items on the PEDro scale to evaluate the methodological quality of the articles. The Physiotherapy Evidence Database (PEDro) is one of the most comprehensive databases indexing randomized controlled trials that examine physiotherapy interventions [16]. In addition, the trials in the database are graded on the PEDro scale according to their methodological quality with a total of 0 to 10 points without including the first item in the scoring [17]. PEDro makes it easy for physical therapists to access high-quality research. Thus, the PEDro database provides an important source of information that supports evidence-based clinical practice in physiotherapy [18].

Higher scores on the PEDro scale reflect increased methodological quality [19]. PEDro score of 9 to 10 points were accepted as “excellent”, 6 to 8 points “good”, 4 to 5 points “moderate”, and studies below 4 points are considered “poor” quality [20]. The PEDro scale was evaluated independently by two authors, and in case of inconsistency, the third author was

consulted and the problem was resolved through discussion. Items of the PEDro scale downloaded from the PEDro website are presented in table 1 [21].

Table 1: PEDro Scale

1. Eligibility criteria were specified;
2. Subjects were randomly allocated to groups (in a crossover study, subjects were randomly allocated an order in which treatments were received);
3. Allocation was concealed;
4. The groups were similar at baseline regarding the most important prognostic indicators;
5. There was blinding of all subjects;
6. There was blinding of all therapists who administered the therapy;
7. There was blinding of all assessors who measured at least 1 key outcome;
8. Measures of at least 1 key outcome were obtained from >85% of the subjects initially allocated to groups;
9. All subjects for whom outcome measures were available received the treatment or control condition as allocated, or where this was not the case, data for at least 1 key outcome were analyzed by intention to treat;
10. The results of between-group statistical comparisons are reported for at least 1 key outcome;
11. The study provides both point measures and measures of variability for at least 1 key outcome.

The Consolidated Standards of Reporting Trials (CONSORT) statement was created in 1996 to standardize the reporting of RCTs [14], and the most recently updated guide was published in 2010 [13]. The last version of the CONSORT Statement consists of a 25-item checklist and flowchart that includes examination of different aspects such as the design, analysis, and interpretation of RCTs [22]. The CONSORT statement aims to help researchers design trials and guide referees and editors in the evaluation of articles. Thus, it is predicted that the clarity and transparency of the published trials can possibly be increased [13,14,22].

Based on the methodology of a previous study, nine methodology-related items of the CONSORT statement were used alongside PEDro to assess the methodological quality of the articles included in our study. Both discussions between the authors and use of the method from a previous study were effective on which CONSORT statement items should be included in our study. The methodological quality of the articles eligible for the study was evaluated independently by both authors using these two scales. Discrepancies in scoring were resolved in consultation with the third author. The nine CONSORT items are presented in table 2 [23].

We examined the websites of the journals to check whether the articles were edited according to the CONSORT statement of the journal in which they were published. In addition, we examined whether the authors in all studies were affiliated with the epidemiology or statistics departments of different academic institutions. If any of the authors in the studies had a relationship with these sections, we coded it as yes, and if no such a relationship existed, we coded it as no.

We gathered the study characteristics of each RCT included in our study under several headings: (1) first author's name, (2) article title, (3) journal name, (4) journal impact factor, (5) number of authors, (6) sample size, (7) number of groups (two arms or more than two arms), (8) length of follow up, (9) funding source, and (10) number of primary results.

Table 2: Nine CONSORT Items

1. Identification as a randomized trial in the title (CONSORT item 1a): The authors must use the word “randomized” in the title. This helps to ensure that the trial report was properly indexed in databases and easily identifiable by readers. This criterion was rated as yes (coded as 1) or no (coded as 0).
2. Number of randomized participants (CONSORT item 4a): This item refers to the number of participants initially allocated to groups. Larger sample size increases the probability of the article as greater external validity and increases statistical precision. The number of randomized participants was extracted from the methods section. This was coded as 1 for the number of randomized participants specified and 0 if not specified.
3. How sample size was determined (CONSORT item 7a): Authors must have identified how the sample size was calculated, so that the trial report would have a high probability to detect a clinically important difference. Trials fulfilled this criterion if the authors stated that a sample size calculation was performed prospectively and were coded as 1. Retrospective calculations were not considered and were coded as 0 along with articles which did include a sample size calculation.
4. Locations where the data were collected (CONSORT item 4b): This information was important to judge the applicability and the generalizability of the trial results. Social, economic, cultural, or environmental aspects can affect the external validity. The country was extracted from the methods section, and in the absence of this information we assumed that the trial took place in the country of the first author of the trial. We collapsed the countries into regions (ie, Africa, Asia, Europe, North America, Oceania, South America, missing). In the case of multicenter trials, we recorded the number of centers involved. In the absence of this information, the trial was considered to be a single-center trial. Multicenter trials were coded as 1, and single-center trials were coded as 0.
5. Number of primary outcomes (CONSORT item 6a): Trials may have 1 primary outcomes. The other outcomes of interest are secondary outcomes. We used the following keywords (or variants of these) to determine if 1 primary outcomes were specified: primary outcomes, main outcomes, major outcomes, or end point. The number of primary outcomes was recorded. Articles which specified primary outcomes were coded as 1, whereas those which did not were coded as 0.
6. Statistical adjustment for multiple primary outcomes (CONSORT Item 12b): This adjustment is necessary to avoid a false-positive result (type 1 error). This information was extracted from the statistical analysis section, and the following key-words (or variants of these) were used: adjustment for primary outcomes, Bonferroni, Tukey, or Duncan. This criterion was rated as yes (coded as 1) or no (coded as 0).
7. Participant flow diagram (CONSORT item 13a): A diagram describing the number of participants in each treatment group, those who actually received the treatment, those who were excluded, and those who were analyzed for the primary outcomes should be presented. We did not consider flowcharts of the trial design. This criterion was rated as yes (coded as 1) or no (coded as 0).
8. Clinical trial registration (CONSORT item 23): The trial must have been registered in a public domain to avoid selection bias. We did not check if the registration was prospective or not. This information was solely based on the trial report. This criterion was rated yes (the trial was registered; coded as, 1) or no (if there was no explicit evidence of registration; coded as 0).
9. Funding sources (CONSORT item 25): Trials can receive various types of funding. Trials that received funding from scientific agencies are more likely to have better quality because they were peer reviewed prior to the inception of the trial. In contrast, trials funded by the private sector may have conflicts of interest and may have bias. This criterion was rated as yes (coded as 1) or no or not reported (both coded as 0).

Statistical analysis

Descriptive statistics of included studies, including number and percentage were defined for dichotomous data, and continuous variables were defined as the mean (standard deviation [SD]) when they fulfilled the conditions of normal distribution, and as the median with the interquartile range (IQR) when they did not.

Studies that fulfilled each item of the PEDro and CONSORT statement were assigned one point, and those that did not were assigned zero points. In addition, the median (IQR) calculation was performed for the categorical variables in the CONSORT statement.

To examine the relationship between reporting quality and study characteristics, we identified five factors based on reports of studies in the literature [23–26]. Next, our authors discussed which of the relevant factors better fits our hypothesis. Our discussion resulted in five factors, including RCT in the title (yes versus no), total score for the 9-item CONSORT statement (continuous variable), author's affiliation with an epidemiology and/or statistics department (yes versus no), multi-center study (yes versus no), and sample size (sample size ≤60 versus >60). Included were categorized according to the median of sample sizes.

Table 3: Characteristics of the 22 RCTs included in our study.

Article No	First Author	Journal Name	Year	Journal Impact Factor	Number of authors	Sample Size	Number of groups (2 arms and >2 arms)	Length of follow up (week)	Number of center (n)	Funding Source *	PEDro Score (0-10 point)	CONSORT Statement Score (0-9 point)
1	O'Reilly et al	Annals of the rheumatic diseases.	1999	16.102	3	191	2	24	2	1	7	7
2	Thomas et al.	BMJ	2002	30.223	6	786	6	104	3	1	7	8
3	Bruce et al.	BMC musculoskeletal disorders	2012	2.002	6	41	3	14	2	2	5	7
4	Tunay et al.	Acta Orthop Traumatol Turc	2010	1.121	3	60	2	6	1	4	5	3
5	Thomas et al.	Arthritis Care & Research	2005	4.056	6	786	6	104	3	1	6	6
6	Aoki et al.	Journal of Physical Therapy Science	2009	-	6	36	2	12	4	4	5	3
7	Rogers et al.	South African Journal of Sports Medicine.	2011	-	5	12	2	8	3	2	3	4
8	Rogers et al.	Journal of sports science & medicine	2012	1.806	4	44	4	8	3	2	5	6
9	Chaipinyo et al.	Australian Journal of Physiotherapy	2009	5.440	2	48	2	4	1	1	7	8
10	Brismee et al.	Clinical Rehabilitation	2007	2.599	10	41	2	18	1	1	6	7
11	Baker et al.	The Journal of rheumatology	2001	-	6	46	2	16	2	1	7	7
12	Bennell et al.	Arthritis Care & Research	2017	4.056	14	168	2	72	7	1	9	7
13	Bezalel et al.	Physiotherapy	2010	2.478	3	50	2	8	1	4	6	6
14	Gail et al.	Physical therapy	2005	3.140	9	134	2	8	3	4	8	7
15	McCarthy et al.	Rheumatology.	2004	5.606	6	214	2	52	1	1	6	7
16	Talbot et al.	Journal of the American Geriatrics Society	2003	4.180	4	34	2	24	1	1	4	6
17	Talbot et al.	The Journal of rheumatology.	2003	-	4	34	2	12	1	1	4	4
18	Çolak et al.	Rheumatology international.	2017	1.984	10	78	2	6	2	1	6	7
19	Bennell et al.	Osteoarthritis and Cartilage	2020	4.793	9	128	2	12	3	1	8	9
20	Oh, Seung et al.	Aging Clinical and Experimental Research.	2020	2.697	4	60	2	20	2	4	4	4
21	Evcik et al.	Rheumatology international.	2002	1.984	2	90	3	12	2	4	4	3
22	Kawasaki et al.	Journal of Orthopaedic Science.	2009	1.259	11	102	2	24	6	4	5	5

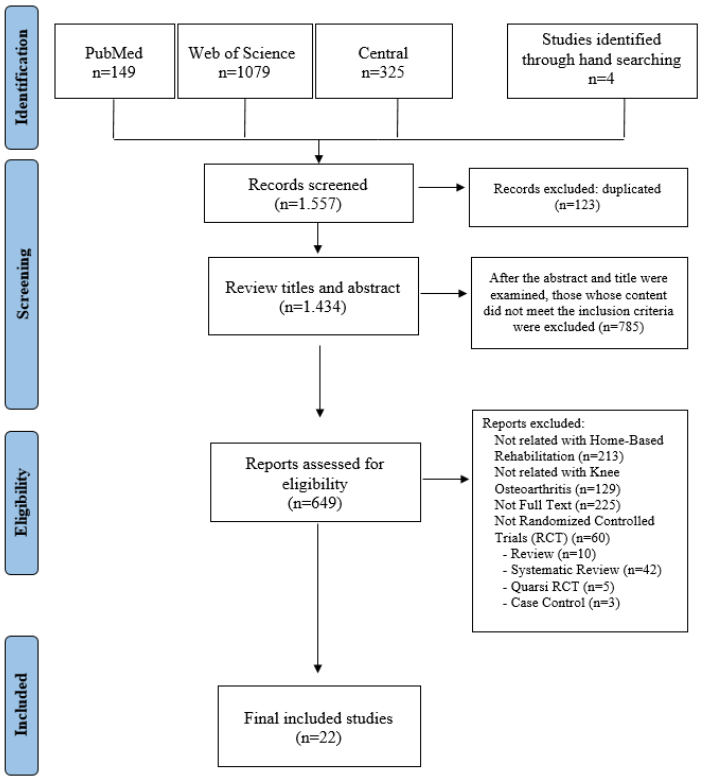
*** Funding Source:** Not-for-profit funding=1, For profit funding=2, Clearly stated, not funded=3, Not reported=4

We used univariable and multivariable linear regression analyses to examine the association of methodological quality with the pre-specified variables. We checked that the scores fulfilled the assumption of normality, collinearity, homogeneity of variance, normality of residuals, and variance inflation. To construct the regression model, we computed single predictive linear regression models between the dependent variable (total PEDro score) and each of the independent variables (identification as a randomized trial in the title, author's affiliation with a statistics and/or epidemiology department, number of centers, sample size, and total score for the 9-item CONSORT statement). We used the "Enter" analysis type in the regression analysis. We thought the model was complete when all variables reached a *P*-value of ≤0.05. Data were entered into an electronic database (Excel) and analyzed using statistical software (SPSS 22.0).

Results

According to our research strategy, the total number of studies obtained from databases was 1557. After title and abstract screening, 649 reports were found that were potentially available; upon reading the full texts, those who did not meet the inclusion criteria were excluded, and finally, 22 RCT reports were found to be eligible (Figure 1). Study characteristics are listed in table 3.

Figure 1: Flow diagram for searching and selection processes



These 22 RCTs were published between 1999 and 2020 among which 17 (77.3%) were two-arm trials, 12 (54.5%) were funded by not-for-profit funding agencies, and 13 (59.1%) were published in a journal that approved the CONSORT statement. Seventeen (77.3%) of the studies were graded based on the impact factor of the journal in which they were published, and the impact factor ranged between 1.121 and 30.223 (median 2.967). The sample sizes ranged from 12 to 786 (median: 60). The length of follow-up ranged from four to 104 weeks (median: 12 weeks). The median number of authors was six (IQR: 2–14) as shown in Table 4.

The overall mean total PEDro score was 5.77 (1.54). A small proportion of trials (six; 27.3%) reached a score of 6 to 8 points, indicating good quality [20]. Only one (4.5%) study achieved >9 points and was of very good quality [27].

Table 4: General characteristics of included Random Controlled Trials (RCTs)

Features of included RCTs	n=22, (%)
Sample size (Median [IQR])	
≤60 [a]	12 (54.5)
>60	10 (45.5)
Journal impact factor (Median [IQR])	
≤2.967 [a]	9 (40.9)
≥2.968	8 (36.4)
Journal has no impact factor	5 (22.7)
Number of arms	
2 arms	17 (77.3)
>2 arms	5 (22.7)
Length of follow up (Median [IQR])	
≤13 weeks [a]	11 (50.0)
>13 weeks	11 (50.0)
Sources of trial funding	
Not-for-profit funding	12 (54.5)
For profit funding	3 (13.6)
Clearly stated, not funded	0 (0.0)
Not reported	7 (31.8)
Published in a journal that endorses the CONSORT statement	
Yes	13 (59.1)
No	9 (40.9)
Number of authors (Median [IQR])	6 (2-14)

[a]: Median, IQR: interquartile range

Table 5 shows the percentage of trials that met each of the PEDro scale items. The following items of the PEDro scale were fulfilled in all studies, eligibility criteria in 22 (100.0%), statistical comparisons between groups in 22 (100.0%), and point measures and variability in 22 (100.0%). The least frequently fulfilled criteria were concealed allocation (6; 27.3%), blinding of subjects (4; 18.2%), and blinding of therapists (0; 0.0%). Details of the scoring of the included studies based on each item of the PEDro scale can be found in table 6.

According to the analysis of nine items of the CONSORT statement (table 7), only 12 trials (54.5%) included the definition as a randomized study in the title. Half of the trials showed (11; 50.0%) how sample size was determined. Most of the trials (15; 68.2%), conducted multicenter research. Regarding the region of the trial, the Asian continent had the highest trial rate (8; 36.4%), followed by North America (7; 31.8%), and Europe (5; 22.7%). More than half (15; 68.2%) of the trials identified a primary outcome (s). Only nine trials (40.9%) were statistically adjusted for primary results, and very few trials recorded research protocols (4; 18.2%).

Table 5: Percentage of articles meeting each Physiotherapy Evidence Database (PEDro) item (n=22)

PEDro Item	n (%)
1. Eligibility criteria and source of subjects	22 (100.0)
2. Random allocation	21 (95.5)
3. Concealed allocation	6 (27.3)
4. Baseline comparability	20 (90.9)
5. Subject blinding	4 (18.2)
6. Therapist blinding	0 (0.0)
7. Assessor blinding	10 (45.5)
8. >85% follow-up	11 (50.0)
9. Intention-to-treat analysis	10 (45.5)
10. Between-group comparisons	22 (100.0)
11. Point measures and variability	22 (100.0)
Total PEDro scale score mean (SD)	5.77 (1.54)

SD: Standard deviation

Table 7: Characteristics of articles according to the CONSORT statement items

Item	n (%)	Median (IQR)
Identification as a randomized trial in the title	12 (54.5)	
Number of randomized participants		
Reported	22 (100.0)	
Sample size		60 (102)
How the sample size was determined reported	11 (50.0)	
Locations where the data were collected		
Multicenter trials	15 (68.2)	
Number of trial centers		2 (2)
Continent where trial was conducted		
Europe	5 (22.7)	
North America	7 (31.8)	
Asia	8 (36.4)	
Oceania	2 (9.1)	
South America	0 (0.0)	
Africa	0 (0.0)	
Missing	0 (0.0)	
Number of primary outcomes		
Primary outcome(s) identified	15 (68.2)	
Number of primary outcomes		1 (3)
Statistical adjustment for multiple primary outcomes	9 (40.9)	
Participant flow diagram	17 (77.3)	
Clinical trial registration	4 (18.2)	
Funding sources	15 (68.2)	

Median, IQR: interquartile range

The final multivariate model is presented in table 8. The three independent variables were found to be associated with an increase in the total PEDro scale score. An author's expertise in epidemiology and/or statistics produced an increase in the score of 0.78 points (95% confidence interval [CI] 0.11-1.44), a multi-center study produced an increase in the score by 0.94 points (95% CI: 0.19–1.68), and each unit increase of the total score of the CONSORT statement produced an increase in the total PEDro score of 0.55 points (95% CI: 0.34–0.76). The multivariate model explains 78% of the total variance of the PEDro score (R^2: 0.780).

Table 8: Univariate and multivariate models of factors that may be associated with the PEDro total score

Variables	Univariable Analysis Coefficient (95% CI)	*P*-value	Multivariable analysis Coefficient (95% CI)	*P*-value
Identification as a randomized trial in the title				
yes vs no [ref]	1.87 (0.85–2.88)	<0.001	0.37 (–0.38–1.14)	0.332
Total score for the 9-item CONSORT statement	0.65 (0.41–0.90)	<0.001	0.55 (0.34–0.76)	<0.001
Author's affiliation to statistics or epidemiology department				
yes vs no [ref]	1.33 (0.15–2.52)	0.026	0.78 (0.11–1.44)	0.021
Center				
multicenter vs single center [ref]	0.92 (–0.37–2.21)	0.162	0.94 (0.19–1.68)	0.013
Sample size				
>60 vs ≤60 [ref]	1.33 (0.19–2.46)	0.021	0.26 (–0.45–0.98)	0.471

[ref]: reference level

Table 6: PEDro scores of included studies

Study	Random allocation	Concealed allocation	Groups similar at baseline	Participant blinding	Therapist blinding	Assessor blinding	<15% dropouts	Intention-to-treat analysis	Between-group difference reported	Point estimate and variability reported	Total (0 to 10)
O'Reilly et al. (1999) [39]	Y	Y	Y	N	N	N	Y	Y	Y	Y	7
Thomas et al. (2002) [40]	Y	N	Y	N	N	Y	Y	Y	Y	Y	7
Bruce et al. (2012) [41]	Y	N	Y	N	N	Y	N	N	Y	Y	5
Tunay et al. (2010) [42]	Y	N	Y	N	N	N	Y	N	Y	Y	5
Thomas et al. (2005) [43]	Y	N	N	Y	N	N	Y	Y	Y	Y	6
Aoki et al. (2009) [44]	Y	N	Y	N	N	Y	N	N	Y	Y	5
Rogers et al. (2011) [45]	Y	N	N	N	N	N	N	N	Y	Y	3
Rogers et al. (2012) [46]	Y	N	Y	Y	N	N	N	N	Y	Y	5
Chaipinyo et al. (2009) [47]	Y	Y	Y	N	N	Y	Y	N	Y	Y	7
Brismee et al. (2007) [48]	Y	N	Y	N	N	Y	N	N	Y	Y	6
Baker et al. (2001) [49]	Y	N	Y	Y	N	N	Y	Y	Y	Y	7
Bennell et al. (2017) [23]	Y	Y	Y	Y	N	Y	Y	Y	Y	Y	9
Bezalel et al. (2010) [50]	Y	N	Y	N	N	Y	N	Y	Y	Y	6
Deyle et al. (2005) [51]	Y	Y	Y	N	N	Y	Y	Y	Y	Y	8
McCarthy et al. (2004) [52]	Y	N	Y	N	N	Y	Y	N	Y	Y	6
Talbot et al. (2003) [53]	Y	N	Y	N	N	N	N	N	Y	Y	4
Talbot et al. (2003) [54]	Y	N	Y	N	N	N	N	N	Y	Y	4
Çolak et al. (2017) [55]	Y	Y	Y	N	N	N	N	Y	Y	Y	6
Bennell et al. (2020) [56]	Y	Y	Y	N	N	Y	Y	Y	Y	Y	8
Oh, Seung et al. (2020) [57]	Y	N	Y	N	N	N	N	N	Y	Y	4
Evcik et al. (2002) [58]	N	N	Y	N	N	N	Y	N	Y	Y	4
Kawasaki et al. (2009) [59]	Y	N	Y	N	N	N	N	Y	Y	Y	5

Discussion

This study is the first to investigate the quality of RCTs for HBR for KOA patients using the CONSORT statement 2010 and the PEDro scale. We included 22 studies that fulfilled our criteria. The overall methodological quality of these studies was suboptimal. Associated factors of higher PEDro scale score included the total CONSORT statement score, an author's statistical and/or epidemiological expertise, and/or multi-center execution of the study.

The methodological quality of RCTs in our study was moderate [20]. The total PEDro score of the previous study examining the quality of RCTs related to musculoskeletal conditions was also similar to our results with a the mean score of 5.27 (1.63) [23]. In addition, in another study of methodological quality in physiotherapy subdisciplines, the mean total PEDro score of studies in the musculoskeletal discipline was 5.08 (1.72) and was also consistent with our results [24].

In our review, we identified common methodological flaws regarding quality. Most of the studies we included did not report or underreported some features related to reporting methodological quality (concealed allocation, blinding, intention to treat, power analysis) according to CONSORT checklists. Articles with low methodological quality tend to exaggerate treatment effects and have a high risk of bias [28,29].

Concealed allocation associated with methodological quality was reported in only a few of the studies we investigated (six; 27.3%). In the previous quality reporting study, it was shown that the item of the least reported PEDro scale was concealed allocation [24,30]. Gonzalez et al [23] reported similar results (438; 31.2%). However, studies reporting this item more frequently have been published [25,26]. With these results, it was shown that studies examining HBR in KOA can both reduce the risk of bias and contribute to the methodological quality by reporting concealed allocation in compliance with CONSORT checklists.

Another item associated with the methodological quality is the intention to treatment (ITT) analysis, which describes the participation of individuals in the study in the analysis of their group even if they do not receive intervention. Thus, this parameter contributes to the external validity of the trials [31]. However, ITT was reported in almost half of the studies we included. ITT was reported more frequently in our study than in other studies [23,24,32,33]. However, this analysis was still inadequate in RCTs examining HBR in KOA. In order to ensure external validity of studies examining HBR in KOA, to increase their methodological quality, and to ensure the reliability of their results, ITT analyses following CONSORT checklists should be performed.

Also, blinding is associated with methodological quality. However, in the studies we included, blinding (subject, therapist, and assessors) was not at an optimal level. These results were similar to the results of the study reporting blinding

in the field of physiotherapy [34, 35]. Very few of the studies we reviewed reported blinding of subjects (four; 18.2%). This result was similar to Gonzalez et al. (161; 11.5%) [23]. In a study examining the quality of chiropractic RCTs, blinding of subjects was reported more frequently (16; 46.0%) [25]. Also, no blinding of the therapists was reported in any of the studies included in our study. This situation was similar to reports from studies examining blinding [23,34]. It should be emphasized that RCTs in the field of physiotherapy may be extremely difficult in terms of therapist blinding. In addition, blinding of the assessors can be applied to any study using simple procedures [24], but studies we included reported that this process was used in only about half. In the light of this information, even if it is difficult for therapists to be blinded in studies examining HBR for KOA, methodological quality can be improved by ensuring blinding of the assessors.

It is important to calculate the sample size correctly to obtain the correct results in RCTs. Excessively large sample selection may increase the cost; on the contrary, an excessively small sample size may lead to studies with low power [36]. However, the method by which the sample size was obtained was reported in only half of the studies we included. In previous studies, how the sample was found was not sufficiently reported [23,26,33,36]. On the contrary, more than half of the articles included in the study by Karpouzis et al. [25] provided information on the way in which the sample size was found. In addition, studies reporting that the quality increases as the sample size increases have been published [25,26]. However, for this purpose, we determined that sample size was not an associated factor with methodological quality in our study. Jia et al. [26]. also reached similar conclusions in their study. Thus, although we found that it was not related to methodological quality in the HBR studies in KOA, we think that performing power analyses and reporting information about the methods used to obtain these analyses were done may have an impact on the methodological quality so that the sample size in future studies in this area can be obtained at a sufficient level.

Based on our results, 12 RCTs (54.5%) included the designation as a randomized study in the title. Jia et al. [26]. reported that more than half of the RCTs in the title in studies that they examined presented results similar to our results. However, Gonzales et al. [23] showed that 626 (44.6%) expressions of RCT were less reported in titles. In the same study, they showed that inadequate reporting of RCT expression affects study quality. However, in our study, we observed that the inclusion of the RCT expression in the title did not affect methodological quality. One of the reasons that we could not find the expression of study design in the title as a determining factor associated with good methodological quality may be due to the higher frequency of expression of study type in the titles of the studies included in our study compared to the data examined in previous reviews.

Most of the studies we reviewed had received funding. A similar situation was reported in previous studies [23,26,33]. RCTs that receive funding are published in journals that have higher impact factors than RCTs that do not receive or specify this information, have a larger sample size, and better methodological quality [33,37]. The source of the funds was unclear in most studies. Future studies that examine HBR in KOA, if they are to receive funding, can improve methodological quality by using this funding for either the blinding of assessors or obtaining a larger sample size [24].

In our regression analysis, we observed a higher total CONSORT scale score yielded higher the methodological quality. RCTs published in journals requiring CONSORT compliance had higher scores on the PEDro scale [23,33]. However, the number of those who requested compliance with the CONSORT checklist from the journals published by the studies we included was 13 (59.1%). The use of reporting checklists (such as CONSORT statement) is mandatory in all journals, and journal referees and journal editors emphasize that the methodological quality can be improved by using the CONSORT statement during the review process [23,38]. If the CONSORT statement compliance of RCTs of HBR for KOA increases, the methodological quality may also increase. Another factor associated with the methodological quality of the studies we included was that the authors were experts in epidemiology and/or statistics. Authors with expertise in epidemiology and/or statistics are generally associated with higher quality studies. The results of our study also support this information, and we observed that methodologically higher quality studies are produced when one or more of the authors had statistical or epidemiological information. The last factor affecting the methodological quality in our study was that the studies were multi-center. Multi-center studies are of higher quality than single-center studies [26].

Our review has some limitations. Our review focused on three different databases, which are the most comprehensive databases of RCTs of physical therapy interventions [16]. However, we did not include the PEDro database, which is another comprehensive database in this field, and we only reviewed full-text articles published in English, so we acknowledge that we may have missed some RCTs for HBR in KOA. In addition, the choice of tools and methods used to assess the quality of RCTs will likely affect the rating of methodological quality. Therefore, in our study, we chose the PEDro scale, which was designed to assess the quality of RCTs in physical therapy interventions [17]. Our last limitation is that we did not include all 25 reporting items listed in the CONSORT checklist. However, the reason we did not include all items was that the same items evaluating the methodological quality on the PEDro scale were also included in the CONSORT statement. Therefore, based on an earlier study [23], we selected nine items from the CONSORT statement that did not match the PEDro scale items.

Conclusion

The reporting of most of the RCTs examining HBR in KOA, which we included in our study, was of low to medium quality. Among the items related to methodological quality, especially the blinding and concealed allocation items, most were insufficiently reported in many studies. The increase in the total CONSORT score, the author's expertise in statistics and/or epidemiology, and a multicenter study were associated with the methodological quality. Journals can improve the quality of studies by requiring adherence to CONSORT checklists in their

reporting so that readers, healthcare providers, and researchers can access more accurate, unbiased, and reliable results.

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