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A call for improving the Internal validity and the reporting of manual therapy trials self-labelled as pragmatic: A methodological review

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ABSTRACT

Objectives: This study provides further data from a review assessing methodological characteristics of pragmatic randomised controlled trials (pRCTs) published in manual therapy (MT). In this second part, we aim to assess the report, the risk of bias (RoB), and the relationship between these items and the pragmatism scores of the self-labelled pRCTs in the MT field.

Study Design and Setting: We searched MEDLINE and the Cochrane Central Register of Controlled Trials for pRCTs in the MT field from inception to January 2024. Two independent reviewers screened the trials using several CONSORT extensions and assessed them using the Cochrane Risk of Bias tool. We performed a descriptive analysis using frequencies and percentages and a relation analysis between the trials' pragmatism, their reporting, and their RoB.

Results: We included 39 self-labelled MT pRCTs. Compliance with CONSORT items was higher than 70% in one-third of the included trials (13/39) but varied across items. Performance and detection bias were the main threats to internal validity (we rated 90%, 35/39, and 77%; 30/39 of trials at high risk of bias, respectively). Selective reporting bias was unclear in almost half of the sample (46%; 18/39). No relation was found between the highly pragmatic attitude and good reporting except for CONSORT item 25 (Sources of funding and other support) (p=0,006). No relation was found between the RoB and the pragmatic attitude of the studies. The percentage of compliance with CONSORT items was higher in the trials with low RoB.

Conclusion: Pragmatic trials in MT have significant methodological limitations, and their reporting is suboptimal. Nonetheless, trials with less risk of bias had higher compliance with CONSORT items.

KEYWORDS

Pragmatic Clinical Trials, Musculoskeletal Manipulations, manual therapy, generalizability, CONSORT, Risk of Bias

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1. INTRODUCTION

Despite the recent surge in manual therapy (MT) research, numerous methodological flaws continue to be reported by authors in this field [1–7]. Achieving a balance between external and internal validity in trials is fundamental to all research fields [8]. This challenge in balancing external and internal validity has already been observed in RCTs evaluating Complex Interventions (CI) [9–12], particularly in the MT field [13,14]. Among other strategies, some have proposed a deeper focus on the pragmatic attitude of randomised controlled trials (RCTs) to overcome methodological deficiencies [9,10]. It should be noted that interest in pragmatic randomised controlled trials (pRCTs) has grown globally over the last few years [15,16]. Despite this, it remains unclear how this research design has been implemented in MT research. Previous findings from the current methodological review on the level of pragmatism in self-labelled pRCTs demonstrate that MT trials exhibit a moderately pragmatic approach (mean score of 3.5 on the PRECIS-2 tool) [17].

On the flip side, studies have consistently shown a strong correlation between the overall methodological quality of MT literature studies and the quality of their reporting [3,6,7,18,19]. Additionally, reporting plays a crucial role in pRCTs, serving both to justify an author's pragmatic approach and provide context for the trial's pragmatic attitude [15,20]. To enhance the reporting of pragmatic trials and focus on applicability, an extension of the CONSORT statement - the Consolidated Standards of Reporting Trials - has been developed [21]. Several studies have examined adherence to the CONSORT reporting guideline (RG) in rehabilitation RCTs [1,6]. Previous research has shown that high-impact rehabilitation journals do not mention RG use, and a high percentage of those who claimed to use an RG did not do so appropriately [22]. Specifically, in MT RCTs, it was concluded that the quality of reporting has not improved over time. The quality of reporting can directly influence the risk of bias assessment, which is crucial for estimating the treatment effect. In this regard, a recent review by Arienti et al. concluded that bias can influence the treatment effect in different directions [7].

To our knowledge, there has been no systematic evaluation of compliance with CONSORT items or the relationship between completeness of reporting and RoB of pRCTs.

We reported the pragmatic attitude of self-labelled pragmatic trials published in the MT field elsewhere [17]. The primary aim of this second paper is to assess the quality of reporting and internal validity of MT pRCTs. As a secondary objective, we examined the relation between the reporting and the risk of bias in conjunction with the pragmatism of the trials.

2. METHODS

2.1 Protocol registration

We conducted a review to describe and assess the methodological characteristics of pragmatic trials on MT interventions. We reported the review according to the PRISMA guidelines [23] (Supplementary file 1). We prospectively registered the protocol in the Open Science Framework (DOI 10.17605/OSF.IO/WKEPZ).

2.2 Eligibility criteria

We included RCT reports with the words 'effectiveness' (related to an intervention), 'pragmatic' or 'naturalistic' (related to the methodological design) in either the title or abstract. [16,24]. The eligible resources must comprise either one or a combination of

manual techniques, including soft tissue techniques, joint mobilisations or manipulations, massage, myofascial release, nerve manipulation, strain/counterstrain, and acupressure. No limitations have been imposed with regard to population, comparators, or outcome measures. Experimental interventions delivered through electrotherapy, kinesiotaping, dry needling, acupuncture, drugs, active exercises or a combination of therapies not involving MT intervention were excluded from the study. Additionally, articles not written in English, protocols and poster/conference presentations were also excluded.

2.3 Search strategy

We conducted an extensive search of MEDLINE and the Cochrane Central Register of Controlled Trials from inception to January 2024. Our search strategy integrated controlled vocabulary with search terms pertinent to the field of MT and the design of interest (Supplementary file 2). The search strategy was designed by an experienced methodologist who is a member of our research team (IS).

2.4 Study selection

We imported the records into Rayyan software (www.rayyan.org) [25]. After removing duplicate entries, two reviewers (SR, GA) screened the references independently based on their titles and abstracts and resolved disagreements through discussion. For this paper, only the effectiveness studies self-described as pragmatic in the title and/or abstract were included.

2.5 Data collection process

Two independent reviewers (SR and one additional reviewer from GA, RN, JB, DH, CF and JP) extracted data from the included studies and resolved any disagreements by consensus. The extraction data form was designed by three authors (SR, GA, GU) and was used to collect data. After piloting five studies, the data extraction form was revised to incorporate suggestions from all reviewers to improve consistency. The team was also provided with a guideline for reviewers (Supplementary file 3).

2.6. Data items

The data extraction included the following elements:

1. Quality of report: all items from the CONSORT reporting guideline and the extension for pragmatic trials and non-pharmacological interventions were included [26–28].
2. Risk of Bias: RoB Cochrane tool [29]

Other items included in the data extraction have been assessed and reported elsewhere [17]. They included the bibliometric identification elements, the intent of the trial, the rationale of the intervention given by the authors, the experimental and control interventions and the pragmatism of the trials with the PRECIS-2 tool (Supplementary file 3).

2.7 Data analysis

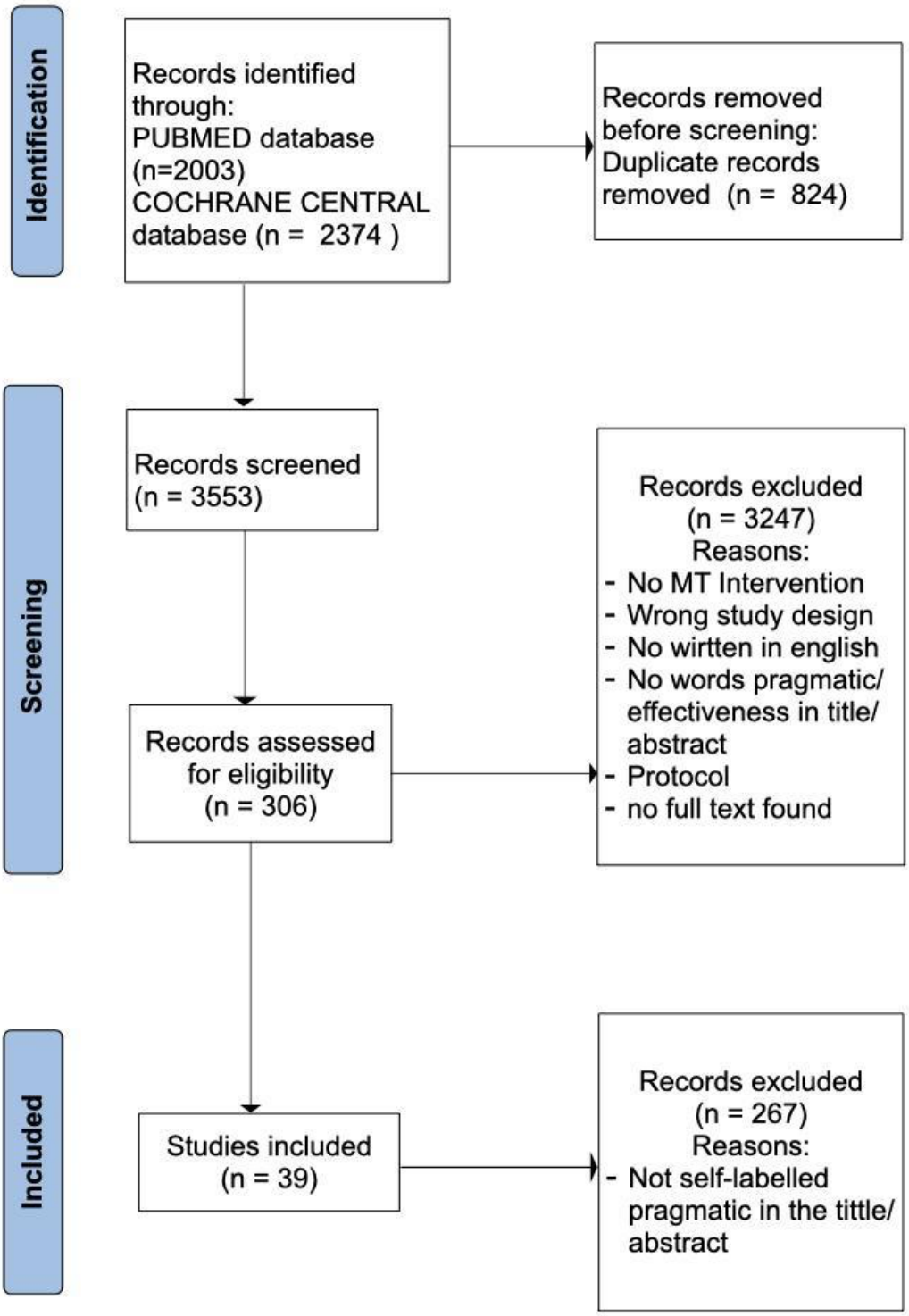
A descriptive analysis was undertaken on the categorical variables, and the findings were displayed as absolute and relative frequencies. The quantitative variables were described in terms of mean and standard deviation. Ordinal variables were defined by median and interquartile range. Chi-square was employed for categorical variables, and Kruskal-Wallis was used for ordinal variables to compare variables. We conducted a post-hoc analysis using Mann-Whitney test for Kruskal-Wallis. We compared in a post-hoc analysis the CONSORT results between two periods (before 2009 and after 2011 Additionally, we used the Spearman test to examine the correlation between CONSORT and RoB tools and the pragmatic attitude. Findings regarding the pragmatic attitude have been recently published elsewhere [17]. We explored the link between these results and the reporting and RoB of pRCTs. The significance level was set at 5% (alpha = 0.05). All data were analysed with IBM-SPSS (V26.0) software.

3. RESULTS

3.1 Study selection

After the removal of duplicate references, the search identified 3553 articles. After screening the title, abstract, and full-text disponibility, the final sample comprised 306 studies. Among these, 39 were identified as self-labelled pragmatic in the title and/or abstract, whereas 267 were ‘effectiveness’ Randomized Controlled Trials (RCTs) not self-labelled as pragmatic. Subsequently, for the purpose of this study, 39 self-identified pragmatic randomised controlled trials were included after screening [30–68]. Figure 1 provides the PRISMA diagram, and the identity elements of the included studies are presented in Table 1.

209 Figure 1. PRISMA flowchart (Reproduced with permission from Roura et al. 2024 [17]
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213 Table 1. Identity elements of the included studies
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STUDIES INCLUDED	Publication Year	Number of participants	Condition treated	Intervention type	PRECIS-2 SCORE
Lee et al.[30]	2021	108	Nonspecific Chronic Neck Pain	Chuna manual therapy	3.4
Nguyen, et al.[31]	2021	61	Lateral Ankle Sprains	Mulligan	2.7
Groisman et al.[32]	2019	90	Non-specific chronic neck pain	Osteopathic treatment	3.9
Wilkey A et al.[33]	2008	30	Chronic low-back pain	Chiropractic treatment	2.9
Finch P et al.[34]	2014	15	Multiple sclerosis	Massage therapy	3.9
Griswold et al.[35]	2015	22	Mechanical neck pain	Spinal manipulation	3.1
Cross et al.[36]	2010	527	Chronic obstructive pulmonary disease	Manual chest physiotherapy	4.1
Poole et al.[37]	2007	243	Chronic low back pain	Reflexology	3.2
Sharp et al.[38]	2010	183	Breast cancer	Reflexology	4
Stochkendahl et al.[39]	2012	115	Acute musculoskeletal chest pain	Chiropractic manipulative therapy	3.5
Goertz et al.[40]	2013	91	Acute Low Back Pain	Chiropractic manipulative therapy	3.1
Attias et al.[41]	2018	164	Surgical Procedures	Reflexology	3.6
Park et al.[42]	2020	194	Non-Acute Lower Back Pain	Chuna manipulative therapy	3.8
Hay et al.[43]	2005	402	Back pain	Manual therapy	4

Dissing et al.[44]	2018	238	Back and/or neck pain	Chiropractic manipulative therapy	3.6
Wyatt et al.[45]	2011	142	Cerebral palsy	Cranial osteopathy	3.8
Goertz et al.[46]	2018	750	Low Back Pain	Chiropractic treatment	4.3
Castien et al.[47]	2011	82	Chronic tension-type headache	Manual therapy	3.7
Dziedzic et al.[48]	2005	350	Neck Disorders	Manual therapy	4.5
Mafetoni et al.[49]	2015	156	Labor and cesarean	Acupressure	3.7
Miller et al.[50]	2012	104	Infant colic	Chiropractic manipulative therapy	3.3
Walach et al.[51]	2003	29	Chronic pain	Massage	4.4
Harper et al.[52]	2019	102	Low back pain	Fascial manipulation	3.9
Bergman et al.[53]	2010	150	Shoulder complaints	Manipulative therapy	4.2
Groeneweg et al.[54]	2017	181	Non-specific neck pain	Manual therapy	3.9
Hoving et al.[55]	2006	183	Neck Pain	Manual therapy/Physical therapy	4.3
Lilje et al.[56]	2010	78	Outpatients on orthopedic waiting lists	Naprapathic manual therapy	3.9
Schwerla et al.[57]	2015	80	Postpartum Low Back Pain	Osteopathy	3.9
Williams et al.[58]	2003	201	Spinal pain	Spinal manipulation	3.7

Gemmell et al.[59]	2010	47	Sub-acute non-specific neck pain	SpInal manipulation	3.1
Castro-Sánchez et al.[60]	2016	62	Chronic nonspecific low back pain	Spinal manipulation/functional technique	3.3
Evans et al.[62]	2018	185	Low back pain	Spinal manipulation	3.3
Bronfort et al.[61]	2014	192	Chronic back-related leg pain	Spinal manipulation	3.3
Georgoudis et al.[63]	2017	44	Tension-type headache	Myofascial release	2.4
Skillgate et al.[64]	2010	409	Back and neck pain	Naprapathy	3.2
Eklund et al.[65]	2018	328	Recurrent and persistent low back pain	Chiropractic care	4.8
Lim et al.[66]	2016	60	Non-acute low back pain	Chuna manual therapy	3.1
Kim et al.[67]	2022	70	Whiplash Injuries	Osteopathic treatment	4.6
Lynen et al.[68]	2022	132	Gastroesophageal Reflux Disease	Chuna manual therapy	3.4

3.2 Characteristics and pragmatism of trials

The main characteristics of our sample and the pragmatism of the MT pRCTs are summarised in Table 2 and reported extensively elsewhere [17]. The mean PRECIS-2 score was 3.5. Collectively, they showed a moderately pragmatic attitude. The wheel PRECIS-2 tool diagram is represented in Figure 2. A summary of the PRECIS-2, CONSORT and RoB assessment for each included paper can be found in supplementary file 4.

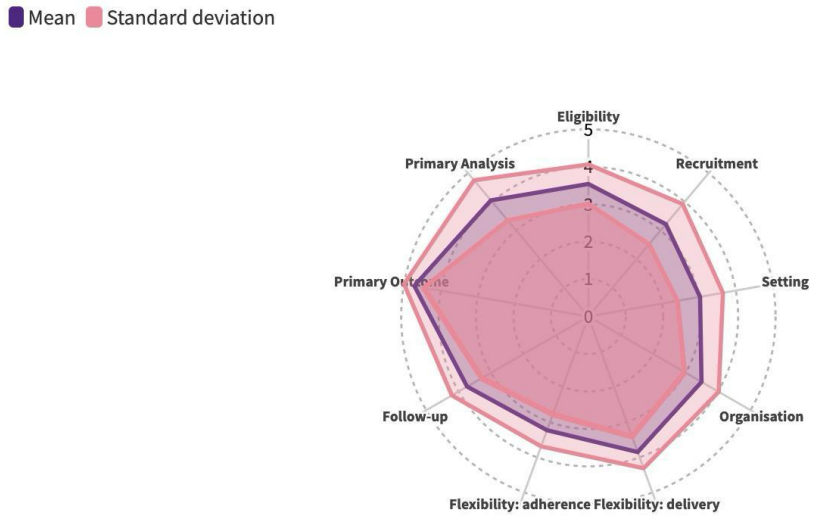
Table 2. Main characteristics of pRCTs in MT

Number of participants (Mean)		169,23 (SD=150,7)
N of participants		Per cent (n**)
<50		15% (6)
51-100		23% (9)
101-200		38% (15)
>201		23% (9)
EXPERIMENTAL INTERVENTION		
Combination of non-protocolised ***techniques***		54% (21)
Isolated non-protocolised ***technique***		15% (6)
Protocol of a combination of ***techniques***		13% (5)
Combination of non-protocolised ***therapies***		10% (4)
Protocol of an isolated ***technique***		5% (2)
Protocol of a combination of ***therapies***		2% (1)
CONTROL INTERVENTION		
2 arms	test treatment vs other active intervention	31% (12)
	test treatment vs placebo	2% (1)
	test treatment vs usual care	33% (13)
	test treatment vs no intervention	13% (5)
3 arms	test treatment vs 2 other active interventions	5% (2)
	test treatment vs 1 other intervention and 1 placebo	2% (1)
	test treatment vs 1 intervention and 1 usual care	10% (4)
	test treatment vs 1 other intervention and 1 no intervention	2% (1)
BLINDING (YES)		
Participants		8% (3)
Therapists		0% (0)
Outcome assessors		69% (27)
Statistician		43% (17)
SETTING		
Multicentric		56% (22)

Unicentric	33% (13)
Unclear report	10% (4)
FOLLOW-UP	
No follow-up	18% (7)
<2 weeks	0% (0)
2-4 weeks	2% (1)
4-12 weeks	10% (4)
3-6 months	18% (7)
6-12 months	20% (8)
>1 year	26% (10)
Individualised*	5% (2)

*Two studies used an individualised follow-up (trials assessing how many weeks patients remained pain-free)
** N of studies =39

Figure 2. Wheel diagram showing the mean PRECIS-2 score of the included studies.



3.3 CONSORT assessment items

Forty-one per cent (16/39) of the trials declared being reported according to the CONSORT statement. Still, only one study [36] reported their findings adhering to the CONSORT extension for pragmatic trials. One out of three trials of the sample complied with more than 70% of CONSORT items (13/39), between 50% to 70% in 49% of the

trials (19/39) and lower than 50% of the CONSORT items in 13% of the sample (5/39). Compliance of reporting varied across as seen in Table 3, and some items varied depending on whether they were published before or after the CONSORT statement publication (Supplementary file 5). The data analysis from the pre-and post-CONSORT periods indicates that the reporting of several items improved after the publication of the CONSORT tool (see supplementary file 5 for details). However, this improvement does not impact the final analysed reporting result for each item. The items reported by all the included trials were a structured abstract (1b), clear eligibility criteria (4a) and statistical methods (12a). Regarding the CONSORT extension for pragmatic trials, all the items were reported in more than 72% (28/39) of the cases except for item 5d (extra resources added to usual settings to implement the intervention). Although the description of the intervention for each study group (item 5a) was good in more than 70% (28/39) of the trials, the authors did not sufficiently report details of the intervention, such as different components of the intervention, the standardisation or individualisation of the intervention and the additional sources to resemble clinical practice. Moreover, less than 20% (7/39) of the trials reported whether and how the adherence of participants or care providers was assessed. Furthermore, items 'harms' and 'trial registration number and where the protocol can be assessed' were not reported in almost 50% (16/39) of the sample. Thirty per cent (12/39) of the trials did not report strategies to limit bias when blinding was not possible, mechanisms to implement the random sequence allocation, the way in which the sample size was calculated or the setting where the data was collected. Twenty-five per cent (10/39) of the trials did not report the generalisability of the trial results or explain why blinding was not possible.

Table 3. Percentage of studies across each item of the CONSORT checklist for non-pharmacological interventions and the extension for pragmatic trials, in MT trials (N=39)

ITEM	**Studies with the item reported**	
	N	**%**
1. TITLE AND ABSTRACT		
1a.Identification as a randomised trial in the title	33	85
1b.Structured summary of trial design, methods, results, and conclusions	39	100
2. BACKGROUND		
2a.Scientific background and explanation of the rationale **Describe the health or health service problem that the intervention is intended to address and other interventions that may commonly be aimed at this problem	37	95
2b.Specific objectives or hypotheses	38	98

METHODS		
3. TRIAL DESIGN		
3a.Description of trial design (e.g. parallel, factorial) including allocation ratio	27	69
3b.Important changes to methods after trial commencement (such as eligibility criteria), with reasons	7	18
4. PARTICIPANTS		
4a.Eligibility criteria for participants *When applicable, eligibility criteria for centres and for care providers **Eligibility criteria should be explicitly framed to show the degree to which they include typical participants and/or, where applicable, typical providers (e.g. nurses), institutions (e.g. hospitals), communities (or localities e.g. towns) and settings of care (e.g. different healthcare financing systems)	39	100
4b. Settings and locations where the data were collected	29	74
5. INTERVENTIONS		
5a.The interventions for each group with sufficient details to allow replication, including how and when they were actually administered *Precise details of both the experimental treatment and comparator	28	72
5b.*Description of the different components of the interventions and, when applicable, description of the procedure for tailoring the interventions to individual participants	21	54
5c.*Details of whether and how the interventions were standardised	22	56
5d.**Describe extra resources added to (or resources removed from) usual settings in order to implement the intervention. Indicate whether efforts were made to standardise the intervention or whether the intervention and its delivery were allowed to vary between participants, practitioners or study sites	15	38
5e.*Details of whether and how adherence of care providers to the protocol was assessed or enhanced	7	17
5f.*Details of whether and how adherence of participants to interventions was assessed or enhanced	6	15
6. OUTCOMES		
6a.Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed **Explain why the chosen outcomes and, when relevant, the length of follow-up are considered important to those who will use the results of the trial	38	97
6b. Any changes to trial outcomes after the trial commenced, with reasons	3	8
7. SAMPLE SIZE		
7a. How sample size was determined **If calculated using the smallest difference considered important by the target decision-maker audience (the minimally important difference), then report where this difference was obtained	29	74

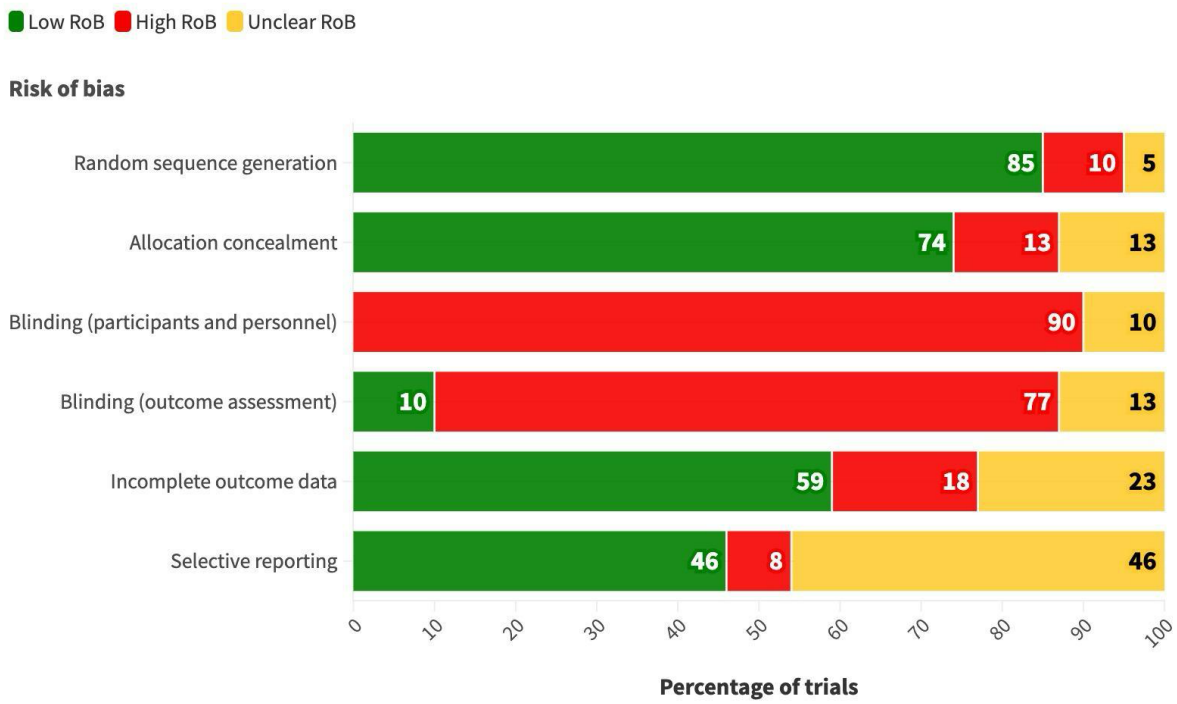
7b.When applicable, explanation of any interim analyses and stopping guidelines	2	5
8. SEQUENCE GENERATION		
8a.The method used to generate the random allocation sequence	35	90
8b.Type of randomisation; details of any restriction (such as blocking and block size)	30	77
9. ALLOCATION CONCEALMENT		
9. The mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	28	72
10. IMPLEMENTATION		
10. Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	26	67
11. BLINDING		
11a.*If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how **If blinding was not done, or was not possible, explain why	30	77
11b. If relevant, a description of the similarity of interventions	23	59
11c.*If blinding was not possible, description of any alternative attempts to limit bias	27	69
12. STATISTICAL METHODS		
12a.Statistical methods used to compare groups for primary and secondary outcomes *When applicable, details of whether and how the clustering by care providers or centres was addressed	39	100
12b. Methods for additional analyses, such as subgroup analyses and adjusted analyses	21	54
RESULTS		
13. PARTICIPANTS FLOW (a diagram is strongly recommended)		
13a.For each group, the numbers of participants who were randomly assigned, received the intended treatment and were analysed for the primary outcome *The number of care providers or centres performing the intervention in each group and the number of patients treated	34	87
13b. For each group, losses and exclusions after randomisation, together with reasons	34	87
13c.*For each group, the delay between randomisation and the initiation of the intervention	5	13
13d. Details of the experimental treatment and comparator as they were implemented	4	10
14. RECRUITMENT		

14a.Dates defining the periods of recruitment and follow-up	29	74
14b.Why the trial ended or was stopped	37	95
15. BASELINE DATA		
15. A table showing baseline demographic and clinical characteristics for each group *When applicable, a description of care providers (case volume, qualification, expertise, etc.) and centres (volume) in each	37	95
16. NUMBERS ANALYSED		
16. For each group, the number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	35	90
17. OUTCOMES AND ESTIMATION		
17a. Estimated effect size and its precision (such as 95% confidence interval)	36	92
17b. For binary outcomes, the presentation of both absolute and relative effect sizes is recommended	10	26
18. ANCILLARY ANYALYSIS		
18. Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing prespecified from exploratory	15	38
19. HARMS		
19.All significant harms or unintended effects in each group	22	56
DISCUSSION		
20. Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses *In addition, take into account the choice of the comparator, lack of or partial blinding, and unequal expertise of care providers or centres in each group	31	79
21. Generalizability (external validity, applicability) of the trial findings *Generalizability (external validity) of the trial findings according to the intervention, comparators, patients, and care providers and centres involved in the trial **Describe key aspects of the setting which determined the trial results. Discuss possible differences in other settings where clinical traditions, health service organisation, staffing, or resources may vary from those of the trial	29	74
22. Interpretation consistent with results, balancing benefits and harms and considering other relevant evidence	32	82
23.Registration number and name of trial registry	25	64
24. Where the full trial protocol can be accessed, if available	23	59
25. Sources of funding and other support (such as supply of drugs), role of funders	32	82

*Items from the CONSORT extension for non-pharmacological interventions

**Items from the CONSORT extension for pragmatic trials

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273 3.4 Risk of Bias assessment
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275 The overall risk of bias is summarised in Figure 3. Performance and detection bias were
276 the domains with a higher risk of bias (scored high in 90%, 35/39 and 77%; 30/39 of
277 included trials, respectively). Reporting bias was unclear in almost half of the sample
278 (46%; 18/39). Supplementary file 6 contains a table showing the complete RoB
279 assessment.
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281 Figure 3. Risk of Bias assessment (n=39)
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286 3.6 Relationship between the pragmatism, the quality of reporting and the RoB
287
288 The results recently published about the pragmatic attitude of the MT pRCTs [17]
289 revealed that 61% (24/39) of the studies were moderately pragmatic, 36% (14/39) highly
290 pragmatic, and 3% (1/37) slightly pragmatic. No relation was found between the highly
291 pragmatic attitude and good reporting except for CONSORT item 25 (Sources of funding
292 and other support) (p=0,005). Similarly, no relation was found between the RoB and the
293 pragmatic attitude of the studies.
294
295 A comparison of the studies with a low vs high/unclear RoB according to the compliance
296 with CONSORT items is provided in Table 3. The results showed that the percentage of
297 compliance with CONSORT items was higher in the trials with low RoB in the following

domains: Random sequence generation, allocation concealment, incomplete outcome data, and selective reporting. The comparison between RoB and each CONSORT item is shown in Supplementary File 5.

Table 4. Comparison between studies with low vs high/unclear RoB according to the compliance with CONSORT items

Domais	Number of studies with a high/unclear risk of bias	% Compliance in CONSORT	Number of studies with a low risk of bias	% Compliance in CONSORT	P-value
Random sequence generation	7	46.7 (42.8-51.1)	32	68.9 (62.2-78.8)	<0.001
Allocation concealment	11	48.9 (46.2-58.9)	28	68.9 (64.4-78.9)	<0.001
Blinding (participants and personnel)	39	66.7 (56.7-73.3)	0	-	-
Blinding (outcome assessment)	33	66.7 (57.8-77.8)	6	67.8 (58.4-68.9)	0.598
Incomplete outcome data	17	64.4 (46.7-68.9)	22	68.9 (60.5-81.1)	0.049
Selective reporting	22	58.9 (47.3-66.7)	17	73.3 (68.9-82.2)	<0.001

Note: Data are presented as median and interquartile range. The number of studies in the low risk of bias or high/unclear risk of bias category varies in each domain of the RoB tool.

4. DISCUSSION

This review described methodological and reporting features among self-labelled pRCTs in MT. It was found that the reporting is suboptimal in MT pRCTs. Performance and detection biases are present in MT pRCTs, mostly due to the intrinsic difficulties of MT interventions to manage blinding. Moreover, half of the sample showed unclear selective

reporting. A relation was found between trials with low RoB and compliance with CONSORT RG.

Certain considerations about reporting specific features from pragmatic studies are worth mentioning. About 40% of the sample declared adherence to any reporting guideline. Only one trial [36] reported using the CONSORT extension for pragmatic trials [69]. This suggests that its usage may not be prevalent despite recommendations within the field [70]. The overall report was suboptimal. These results align with those of other authors assessing the reporting of RCTs in MT [1] and rehabilitation [6]. However, reporting items in the methods and results sections were slightly better reported in our sample, e.g. sample size description, randomisation and sequence allocation, and results description (flowchart).

Certain considerations about specific, pragmatic reporting features are worth mentioning. A significant cornerstone for understanding a trial's pragmatism is how the intervention has been performed and its characteristics. This is particularly relevant in a non-pharmacological complex intervention such as MT [71]. In our sample, general compliance with item 5 of CONSORT (Interventions) was generally poor. Research in this area has previously identified the problem of inadequate reporting of interventions and lack of improvement over time [1]. Although general descriptions of the interventions were provided, details such as the procedure for tailoring the intervention to individual participants and how the adherence of participants and providers was assessed were present in less than half of the sample. These points are relevant in pRCTs and essential to understanding the study context for readers unfamiliar with the intervention and ensuring the intervention's reproducibility [72]. A protocolised intervention (because of the trial requirements) avoids biases and facilitates and allows trial replication [73]. However, it contraposes MT interventions that require a person-centred approach. The treatment can differ between patients because of the high variation among the same condition. For example, non-specific lumbar pain can have multiple aetiology depending on each patient, thus requiring individual approaches for each person and different manual techniques according to the evolution of the condition [74]. Although MT interventions in pRCTs might be performed at the therapist's discretion, reporting the information about how the intervention will be tailored to individual participants will facilitate trial replication and directly increase the methodological quality of the trial [73,75]. In fact, this item (tailoring of the intervention) is included in the TIDIER guideline. However, no studies mentioned using the TIDIER checklist [76] or other reporting tools to describe the intervention. Despite several calls to improve the reporting of the intervention [76–78], a recent overview of reviews of healthcare research reports found that it was inadequate [79]. The comprehensive reporting of any research intervention in clinical trials is essential to assess the relevance of the findings in the context of routine practice [71,80].

Our sample showed good reporting of the way in which blinding was used and the strategies used to limit the bias when blinding was not possible. This is highly recommended in the CONSORT extension for non-pharmacological trials [28,81] and the CONSORT extension for pragmatic trials [69]. However, due to the difficulties in implementing effective blinding strategies in MT trials [73,75], our RoB assessment found performance and detection biases in almost the entire sample. This fact, which is very common in MT literature [73,75,82], greatly affects the perceived quality of any RCT and the credibility of the results. In the face of this situation, some authors could question the usefulness of the RoB tool to assess the quality of the trial evaluating a complex non-drug intervention such as MT, especially if the trial has been designed with a clear, pragmatic attitude and follows their premises. In fact, whether blinding should be performed in pRCTs is a subject of discussion [83–85]; instead, open-label trials and masking the external assessor alternatives have been proposed to resemble clinical practice better [82]. Moreover, patient-reported outcomes constitute a key feature of pRCTs. However, if patients have not been blinded, masking the outcome assessors becomes impossible, leading again to some sort of bias. The IMMPACT statement recently published about research objectives and considerations on pragmatic trials of pain intervention proposed different strategies to limit bias in pRCTs, such as nonblinded comparative effectiveness trials, blinding to study hypothesis, Zelen designs or use of data capture systems for patient-reported outcomes [20].

Additionally, there is an urgent call for MT pRCTs to register research protocols and to report whether the protocol exists and where it is to be found. Reporting bias was unclear in half of our sample for this reason.

Looking at the reporting and RoB assessment results, we concur that good reporting is necessary to assess the risk of bias in trials properly. This is essential to determine whether any bias influences the interventions' treatment effect [7]. In fact, in MT and physical rehabilitation, recent meta-research studies have shown a high correlation between good reporting and the quality of the studies [1,6]

5. STRENGTHS AND LIMITATIONS

While our sample may not be comprehensive in covering all MT modalities, it does include all pRCTs published in the MT field from inception to January 2024.

We recognise that the reviewer group was sizeable, which could have contributed to heterogeneity in the data extraction process and influenced the outcomes. To reduce this limitation, we conducted a pilot of the data extraction form and had extensive

discussions on the ratings prior to commencing the study. Additionally, all reviewers were paired with the IP to discuss the scores and minimise subjectivity. To describe the pragmatism of the included studies, we have used the methodology described by other authors in their studies [16,86–92]. While this methodology lacks scientific validation, the authors deemed it worthwhile to replicate it to facilitate a comparison between manual therapy and other healthcare disciplines. Using available tools to assess the risk of bias in designs with the particularities of a pragmatic trial remains a challenge. However, it is important to emphasize that the most widely accepted approaches for conducting this assessment include domains that have empirically been shown to impact the internal validity of studies. Moreover, we conducted the review in accordance with the main methodological guidelines of Cochrane. The interest to assess the health research methodology is evolving. The homogenization and consensus in the methodological proposals for this type of study [93,94] should enable their implementation in a systematic and rigorous manner.

6. CONCLUSIONS

The standards of the reporting are suboptimal in MT pRCTs. Also, such studies are commonly affected by performance and detection bias due to the difficulties related to blinding strategies. Overall, neither the quality of the reporting nor the RoB is related to a higher or lower pragmatic attitude. Trials with low RoB have shown higher compliance with CONSORT reporting guidelines.

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Sònia Roura: Conceptualization, Methodology, Investigation, Writing - original draft, Writing - review & editing. Gerard Alvarez: Conceptualization, Methodology, Investigation, Writing - review & editing. David Hohenschurz-Schmidt: Investigation, Writing - review & editing. Ivan Solà: Supervision, Investigation, Writing - review & editing. Rodrigo Núñez-

Cortés: Methodology, Investigation, Writing - review & editing. Javier Bracchiglione: Methodology, Investigation, Writing - review & editing. Carles Fernández-Jané: Investigation. Jules Phalip: Investigation. Ignasi Gich: Formal analysis, Writing - review & editing. Mercè Sitjà-Rabert: Writing - review & editing. Gerard Urrutia: Conceptualization, Methodology, Supervision, Writing - review & editing.

ABBREVIATIONS

MT	Manual Therapy
pRCT	Pragmatic Randomised Controlled Trial
RoB	Risk of Bias
CI	Complex Intervention
RG	Reporting Guideline

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