

Quality of reporting matched interventions for non-specific neck pain in randomised controlled trials and its association with trial outcomes: A secondary analysis of a systematic review

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Quality of reporting matched interventions for nonspecific neck pain in randomised controlled trials and its association with trial outcomes: A secondary analysis of a systematic review

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TITLE: Quality of reporting matched interventions for non-specific neck pain in randomised controlled trials and its association with trial outcomes: A secondary analysis of a systematic review.

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ABSTRACT

Background: Variable levels of intervention fidelity and quality of intervention delivery may contribute to inconsistent findings on the effectiveness of matched or stratified care. We sought to investigate this for randomised controlled trials (RCT) of matched versus unmatched physical therapy interventions for non-specific neck pain (NSNP): an area in which our previous systematic review demonstrated there were highly heterogeneous effect estimates.

Exercise and manual therapy are recommended for managing non-specific neck pain (NSNP), but most randomised controlled trials (RCT) have not identified specific subgroups that might respond best to each intervention. Although matched exercise was found to be superior to unmatched interventions in the short term, high heterogeneity in effectiveness estimates and variable levels of intervention fidelity and quality of delivery may contribute to inconsistent findings on the effectiveness of matched or stratified care. **Objectives:** To assess the quality of intervention reporting and its relationship to treatment effect estimates in RCTs comparing matched versus unmatched exercise or manual therapy interventions for NSNP.

Design: Secondary analysis of a recently published systematic review with meta-analysis. (n=24 RCTs).

Methods: For all included RCTs, independent reviewers rated the quality of intervention reporting using the TIDieR checklist. Meta-regression was used to assess the direction and magnitude of association between TIDieR scores and treatment effect estimates (standardised mean difference of change scores) for short-term pain and disability outcomes.

Results: The items related to intervention fidelity were not adequately reported. Materials used, intervention provider, location and modification were inconsistently reported. Poorer quality of intervention reporting was associated with larger treatment effect estimates in short-term pain and disability in favour of matched interventions.

Conclusions: Trials with inadequate intervention reporting may exaggerate overestimate the benefits of matched physical therapy exercise or manual therapy treatments for NSNP. The lack of insufficient information to judge intervention fidelity in this field reinforces the need for better guidance on this specific aspect of study design, conduct, and reporting.

CONTRIBUTION OF THE PAPER:

- Reporting of intervention fidelity in trials comparing matched versus unmatched exercise or manual therapy in non-specific neck pain is sub-optimal.
- Trials with poorer quality completeness of intervention reporting tend to favour matched interventions

KEYWORDS:

neck pain, matched interventions, manual therapy, exercise

1. INTRODUCTION

Neck pain is a complex condition leading to significant pain, disability and economic impact(1). In 2020, it impacted 203 million people, and by 2050, this number is expected to rise by 32.5% to 269 million (2). It was estimated that in 2020, neck pain impacted 203 million individuals, with a higher age-standardized prevalence observed in women compared to men (1). By 2050, it is anticipated that the global incidence of neck pain will rise by 32.5%, affecting an estimated 269 million people (2). More than 90% of patients with non-traumatic neck pain do not have serious pathologies or neurological signs and symptoms and are classified as patients with non-specific neck pain (NSNP) (3).

Exercise and manual therapy are recommended in the management of NSNP, but most randomized controlled trials (RCTs) assessed single treatments without identifying specific subgroups that might respond best to each intervention (4). A tailored approach matching the intervention to individual patients' specific signs and symptoms has been advocated as a way to improve treatment outcomes (5). Our A previous systematic review of 24 22 RCTs comparing treatments matched to a clinical assessment with similar but unmatched treatments, found that matched exercise was superior to unmatched intervention at short-term, but this was not the case for matched manual therapy. However, the estimates of effectiveness displayed high heterogeneity, precluding definitive conclusions (6). In a recent editorial, Foster et al. raise one possible explanation why RCTs may fail to detect superior outcomes from matched interventions: lack of intervention fidelity (7). Judging intervention fidelity relies on full and transparent reporting of the matched and unmatched interventions. The Template for Intervention Description and Replication

(TIDieR) was introduced in 2014 aiming to prompt authors to not only describe interventions in sufficient detail, but to encourage full and transparent reporting of any tailoring and modification of interventions and assessment of intervention fidelity. Accurate judgment of intervention fidelity requires comprehensive and transparent reporting, and the Template for Intervention Description and Replication (TIDieR) aims to facilitate by encouraging detailed descriptions and full disclosure of any tailoring, modifications, and fidelity assessments (8). The TIDieR checklist has revealed that most clinical trials on exercise and manual therapy for chronic neck pain lack sufficient reporting, limiting the reproducibility of these interventions in both clinical practice and research (9,10). While there is evidence that incomplete reporting is a common issue in RCTs investigating exercise or manual therapy for patients with NSNP, no previous studies have explored whether more complete reporting and higher intervention fidelity are more likely to yield clinical effectiveness findings that favour matched over unmatched interventions. Therefore, this secondary analysis aimed to apply the TIDieR checklist to RCTs of matched treatments for NSNP to evaluate the completeness of intervention descriptions, including fidelity, and to explore whether more comprehensive reporting and higher fidelity are linked to clinical effectiveness favouring matched interventions.

2. METHODS

This secondary analysis involved the independent rating of the quality completeness of intervention reporting using the TIDieR checklist and meta-regression analysis applied to 27 22 RCTs identified in a recently published systematic review and meta-analysis of matched versus unmatched physical therapy interventions for non-specific neck pain (6). **2.1 Information sources and search strategy**

A previous systematic review and meta-analysis included 27 RCTs of matched treatments for NSNP using a registered search strategy across seven databases from inception to January 2023, with the protocol registered in PROSPERO (CRD42021297163) (6). The included studies were RCTs investigating patients with NSNP, where the experimental group received matched treatments based on clinical presentation, evidence-based assessment, or patient preference, the control group received similar but unmatched treatments, and pain or disability were reported as outcome measures. Detailed information on matching processes and intervention characteristics and fidelity may not be provided in primary results papers but in related articles and protocols. Therefore, for all included trials, we sought to identify trial protocols in international trial registers, such as

clinicalTrial.gov, ISRCTN, International Clinical Trials Registry Platform (ICTRP), and European Union Clinical Trial Register. Additionally, we searched for related publications, including articles describing intervention development, training, or delivery for the trial, using unique trial registry numbers (where available), keywords/author searches, and citation reference searches. Therefore for all included trials, in addition to the main trial findings publication we sought to identify trial protocols in international trial registers (e.g. clinicalTrial.gov, ISRCTN, International Clinical Trials Registry Platform (ICTRP), European Union Clinical Trial Register), and related publications (e.g. articles describing intervention development, training, or delivery for the trial) using unique trial registry number (where available, keywords/author search, citation reference searches).

2.2 Data collection

To assess the quality and completeness of the intervention arm of the RCTs and matching criteria described we used the 12-item TIDieR checklist (11). The TIDieR checklist outlines essential items for describing interventions in sufficient detail to allow replication. These include: the intervention's name; its rationale, theory, or goal; physical or informational materials used provided to participants or intervention providers; procedures involved; the background and specific training of intervention providers; modes of delivery, whether individual or group; locations where the intervention occurred; the number of sessions, their schedule, duration, intensity, or dose, and the period over which they were delivered; details on personalization or adaptation of the intervention; any modifications made during the study; assessment of intervention adherence or fidelity, including strategies to maintain or improve fidelity; and the extent to which the intervention was delivered as planned. All items were scored with a three-point Likert scale with the categories: not reported (0), partially reported (1) and adequately reported (2). For example, if the authors did not specify any planned or actual strategies to assess adherence, the last two items were rated as not reported (0). If compliance with an exercise program was assessed using a diary but the data were not clearly reported, adherence was rated as partially reported (1). Conversely, if the logbook data were clearly presented, adherence was rated as adequately reported (2). This created a summary score ranging from 0 to 24, with 24 indicating excellent reporting (12). The key items regarding planned and actual fidelity assessment, were evaluated as suggested by Borrelli et al. This entailed clear planning and reporting of intervention dose, frequency, duration and number of sessions, details of intervention deliverers' experience and training, treatment manuals or training sessions, participants' understanding assessment of intervention, and monitoring of patient's homeprograms through recorded diaries. Two reviewers (PM and SM) independently assessed the studies and differences were discussed until consensus was reached. If no consensus was reached, a third reviewer (GP) was consulted.

2.3 Analysis

We used simple descriptive statistics and plots to summarise the completeness of reporting for each TiDieR item across all RCTs and TIDieR total for each RCT. To explore the study-level association between quality and completeness of intervention description and clinical effectiveness estimate, we performed meta-regression analyses with the TIDieR summary score (0-24) as the covariate of interest for two treatment effect outcomes, the standardised mean difference (SMD) in change scores for short-term pain, and the SMD in change scores for short-term disability. Short-term outcomes were defined as outcome measured up to, or including, 3 months post-intervention. Intermediate-term outcomes were excluded from the meta-regression analysis due to the recommendation against conducting meta-regression with fewer than ten studies (13). We used randomeffects meta-regression with restricted maximum likelihood estimation and Knapp-Hartung variance estimator which is preferred in situations with a small number of studies and high heterogeneity (14). Meta-regression findings were displayed using bubble plots and summarised as beta coefficients with 95% confidence intervals. Where bubble's size indicated study weight, the x-axis represented TIDieR score, the y-axis showing the SMD in change score, while regression's line slope indicated the direction and strength of the association.

3. RESULTS

Of the 27 identified studies, three were not included in the meta-analyses due to mixed or different interventions (15–17) and two studies with incomplete data were excluded after attempts to obtain additional information were unsuccessful (18,19). Consequently, of the remaining 22 studies, 11 were included in the manual therapy meta-analysis (18–30), 12 in the exercise meta-analysis (27,31–41), with one study included in both meta-analyses (27) (Fig 1). 11 studies assessed matched manual therapy (19–25,27–30,42), 13 assessed matched exercise (18,27,32–38,40,41,43,44), and three assessed different or mixed interventions (15–17).

Identification

Records identified from Databases (n = 9516) Records removed *before screening*: Duplicate records removed (n = 4284)



Fig. 1 Prisma flow diagram. * one study was included in both meta-analyses.

3.1 TIDieR Checklist Assessment

The characteristics of the included trials, including sample size, intervention and control, and the number and duration of interventions, are presented in table 1. Table 2 presents the TIDieR checklist items scores for each study, while figure 2 shows the completeness of reporting for each TIDieR checklist item across the 24 22 included RCTs. The items that were most commonly reported adequately were the name of the intervention (100% of RCTs), the rationale (100%), the number, duration and dose of the intervention (100%) and the tailoring criteria or criterion (96%), the procedure (96%), the modes of the delivery (87%), and the materials (74%). The items least likely to be reported adequately were 'planned for adherence or fidelity' (17%) and 'actual adherence or fidelity' (4%). Four studies (37,38,41,43) adopted exercise diary to record patients' adherence to the exercise programmes, while no trial investigating manual therapy reported any fidelity assessment strategy.

Table 2. Characteristics of the included studies

	Participants	Interventions	Sessions	Follow-ups	Outcome
Aquino et al. 2009	<mark>48, age 18-65years,</mark> chronic NSNP	<u>Matched group</u> : manual mobilization of symptomatic level (n=24)	1 session	Immediately post-	<mark>Pain (NRS)</mark>
				intervention	

		Unmatched group: manual mobilization of random level (n=24)			
Schomacher 2009	126, neck pain, symptoms changing with selective neck movements	<u>Matched group</u> : manual mobilization of symptomatic level (n=59) <u>Unmatched group</u> : manual mobilization of random level (n=67)	1 session	Immediately post- intervention	<mark>Pain (NRS)</mark>
Joshi et al. 2020	42, neck pain, 18-60 years, cervico- thoracic movement dysfunction	<u>Matched group</u> : manual mobilization of C7-T1 (n=21) <u>Unmatched group</u> : manipulation T3-T6 (n=21)	1 session	Immediately post- intervention	<mark>Pain (NRS)</mark>
Karas et al. 2014	39, neck pain, 18-60 years	<u>Matched group</u> : supine thoracic manipulation at limited segment (n=19) <u>Unmatched group</u> : seated thoracic global manipulation (n=20)	1 session	Immediately post- intervention	<mark>Pain (NRS)</mark>
Martìnez-Segura et al. 2006	70, mechanical neck pain for more than 1 month, positive lateral gliding test (limitation C3-C5)	<u>Matched group</u> : cervical manipulation at limited segment (n=34) <u>Unmatched group</u> : cervical mobilization held for 30" similar to the manipulation without thrust (n=37)	1 session	Immediately post- intervention	Pain (VAS)
Puentedura et al. 2011	24, 18-60 years, NDI>20%, CPR for thoracic manipulation ⁺	<u>Matched group</u> : cervical manipulation at limited segment plus exercise (n=14) <u>Unmatched group</u> : thoracic global manipulation plus exercise (n=10)	5 sessions over 2 weeks	<mark>4 weeks, 6</mark> months	<mark>Pain (NRS)</mark>
Karas et al. 2018	<mark>69, mechanical neck</mark> pain, 18-60 years	<u>Matched group</u> : supine thoracic manipulation at limited segment in the direction of the movement limitation (n=34) <u>Unmatched group</u> : supine thoracic manipulation at limited segment in the	1 session	Immediately post- intervention	Pain (NRS) Disability (NDI)
Cleland et al. 2010	140, neck pain, 18-	opposite direction of the movement limitation (n=35) <u>Matched group</u> : 3 manipulations to mid-	<mark>5 sessions</mark>	<mark>4 weeks, 6</mark>	Pain (NRS)
	60 years, NDI>20%, CPR for thoracic manipulation⁺	thoracic spine plus specific exercise, CPR+ (n=33) <u>Unmatched group</u> : 3 manipulations to mid-thoracic spine plus specific exercise, CPR- (n=27)	over 4 weeks	months	<mark>Disability</mark> (NDI)
Kanlayanaphotporn et al. 2009	60, unilateral neck pain, VAS at rest>2	<u>Matched group</u> : cervical unilateral postero-anterior cervical mobilisation (n=30) <u>Unmatched group</u> : cervical random mobilisation (n=30)	1 session	Immediately post- intervention	Pain (VAS)
Kanlayanaphotporn et al. 2014	60, central or bilateral neck pain, VAS at rest>2	Matched group: cervical central postero- anterior cervical mobilisation (n=30) Unmatched group: cervical random mobilisation (n=30)	1 session	Immediately post- intervention	<mark>Pain (VAS)</mark>
Lagoutaris et al. <mark>2020</mark>	20, acute neck pain, 18-60 years, 2 <vas<7< th=""><th><u>Matched group</u>: pragmatic cervical mobilisation (n=10) <u>Unmatched group</u>: C1-2 and T1-2 unilateral mobilisation (n=10)</th><th>1 session</th><th>48 hours after intervention</th><th>Pain (VAS) Disability (NDI)</th></vas<7<>	<u>Matched group</u> : pragmatic cervical mobilisation (n=10) <u>Unmatched group</u> : C1-2 and T1-2 unilateral mobilisation (n=10)	1 session	48 hours after intervention	Pain (VAS) Disability (NDI)
Andersen et al. 2008	48, chronic neck pain, women, repetitive work task, tightness and tenderness of upper trapezius	Matched group: Specific neck/shoulder strength training neck/shoulder (n=18) <u>Unmatched group</u> : general aerobic training (n=16) Other group: no treatment (n=14)	3 sessions per week over 10 weeks	10 weeks, 5 months	Pain (VAS)
Cleland et al. 2010	140, neck pain, 18- 60 years, NDI>20%, CPR for thoracic manipulation [*]	<u>Matched group</u> : Stretching and strengthening CPR+ (n=29) <u>Unmatched group</u> : Stretching and strengthening, CPR- (n=25)	<mark>5 sessions</mark> over 4 weeks	<mark>4 weeks, 6</mark> months	Pain (NRS) Disability (NDI)
<mark>lm et al. 2016</mark>	15, chronic neck pain, shoulder flexion>130°, CVA < 14°	Matched group: scapular stabilization exercises (n=8) Unmatched group: relaxation exercises	12 sessions over 4 weeks	<mark>4 weeks</mark>	Disability
Kang et al. 2021	32, neck pain, 20-60 years, VAS>4, CVA<53°	<u>Matched group</u> : scapular stabilization and thoracic extension exercise (n=16) <u>Unmatched group</u> : cervical stabilization and stretching exercises (n=16)	18 sessions over 6 weeks	<mark>6 weeks</mark>	Pain (NRS) Disability (NDI)
Lee et al. 2016	46, chronic neck pain, 18-60 years, NDI>20, limited upper cervical and	Matched group: deep neck flexors strengthening and stretching exercises (n=15) Unmatched group: active mobility	30 sessions over 10 weeks	10 weeks	Pain (NRS)
	thoracic spine in flexion/extension	exercises (n=15) Other group: manual therapy, deep neck flexors strengthening and stretching exercises (n=16)			(NDI)

Petersen et al. 2012	72, neck pain	<u>Matched group</u> : pragmatic manual therapy plus movement direction specific exercise (n=36)	1 session	4 days after intervention	Pain (NRS) Disability	
		Unmatched group: pragmatic manual therapy plus general exercises (n=36)			(NDI)	
Jull et al. 2007	58, chronic neck pain, abnormal joint position sense	Matched group: proprioceptive training exercise (n=28) Unmatched group: deep neck flexors strengthening exercises (n=30)	<mark>6 sessions</mark> over 6 weeks	<mark>7 weeks</mark>	Pain (NRS) Disability (NDI)	
Kjellman et al. 2002	77, neck pain provoked by active/sustained movement, foraminal test, upper limb tension test	Matched group: mechanical diagnosis and therapy criteria (n=28) <u>Unmatched group</u> : general exercises (n=23) Other group: ultrasound (n=26)	16 sessions over 8 weeks	8 weeks, 6 months, 12 months	Pain (NRS) Disability (NDI)	

Table 1. Score of the TIDieR checklist where 0=not reported, 1=partially reported,2=adequately reported. MT= manual therapy,EX= exercise.

	<mark>1.</mark>	2.	<mark>3.</mark>	4.	<mark>5.</mark>	<mark>6.</mark>	7.	<mark>8.</mark>	9.	10.	<mark>11.</mark>	<mark>12.</mark>	_
	Interve ntion	Ratio nale	Mater ials	Proced ures	Provi der	Mod es	Locat ion	Numbe	Tailor ind	Modifica tions	Planne d	Actual adhere	Tot al
	- Haon	naic		urco	uci	00		duratio	^{in ig}		adhere	nce or	sco
								<mark>n, dose</mark>			nce or	fidelity	re
								ot interve			fidelity		
								ntion					
Aquino et al.,	<mark>2 MT</mark>	<mark>2</mark>	<mark>2</mark>	<mark>2</mark>	<mark>1</mark>	2	2	2	<mark>2</mark>	<mark>0</mark>	<mark>0</mark>	<mark>0</mark>	<mark>17</mark>
Cleland et	2 MT	2	2	1	2	2	2	2	2	2	0	0	19
<mark>al., 2010</mark>			- 2 -						- 2 -		_	- 2 -	
Joshi et al.,	<mark>2 MT</mark>	<mark>2</mark>	<mark>2</mark>	<mark>2</mark>	2	2	<mark>2</mark>	<mark>2</mark>	<mark>2</mark>	<mark>2</mark>	<mark>0</mark>	<mark>0</mark>	<mark>20</mark>
Z020 Karas et al	2 MT	2	1	2	2	2	2	2	2	2	0	0	19
2014												- 2 -	
Martìnez-	<mark>2 MT</mark>	<mark>2</mark>	<mark>2</mark>	2	1	<mark>2</mark>	<mark>2</mark>	<mark>2</mark>	<mark>2</mark>	<mark>0</mark>	<mark>0</mark>	<mark>0</mark>	<mark>17</mark>
al., 2006													
Puentedura	<mark>2 MT</mark>	<mark>2</mark>	2	2	1	<mark>2</mark>	<mark>2</mark>	<mark>2</mark>	<mark>2</mark>	<mark>0</mark>	<mark>0</mark>	<mark>0</mark>	<mark>17</mark>
et al., 2011 Karaa at al		0	4	0	-	<mark>0</mark>	<mark>0</mark>	<mark>0</mark>	2	<mark>0</mark>	0	0	10
2018		<u> </u>		4	~	2	<mark>4</mark>	<u> </u>	~	<mark>2</mark>	U	U	19
Kanlayanaph	<mark>2 MT</mark>	2	2	2	<mark>1</mark>	<mark>2</mark>	<mark>1</mark>	<mark>2</mark>	<mark>2</mark>	<mark>0</mark>	<mark>0</mark>	<mark>0</mark>	<mark>16</mark>
otporn et al.,													
2009 Kanlavanaph	2 MT	2	2	2	1	2	2	2	2	0	0	0	17
otporn et al.,										-			
2014 Sebemeeber	2 MT	2	0	2	2	2	4	2	0	0	0	0	47
2009		<u> </u>	<u> </u>	<u>~</u>	~	~	•	~	<u>~</u>	U	U	v	17
<mark>Lagoutaris et</mark>	<mark>2 MT</mark>	<mark>2</mark>	<mark>1</mark>	<mark>2</mark>	<mark>2</mark>	<mark>2</mark>	<mark>1</mark>	<mark>2</mark>	<mark>1</mark>	<mark>2</mark>	<mark>0</mark>	<mark>0</mark>	<mark>17</mark>
al. 2020 Abd El-		2	2	2	0	2	2	2	2	0	ο	ō	16
Azeim et al.,		~	~	<u> </u>	U	~	<u> </u>	~	<u> </u>	U U	U	<u>v</u>	10
<mark>2022</mark>		_	_	_		_		_		_	_		
Andersen et	2 EX	2	<mark>0</mark>	1	1	2	<mark>1</mark>	2	2	<mark>0</mark>	2	0	<mark>15</mark>
Arif et al.,	<mark>2 EX</mark>	2	2	2	0	<mark>1</mark>	<mark>2</mark>	2	<mark>2</mark>	2	0	0	<mark>17</mark>
2022		_	_	_	_	_	_	_	-	_	_	-	
Cleland et al.	2 EX	2	2	2	2	2	2	2	2	2	<mark>0</mark>	<mark>0</mark>	<mark>20</mark>
Giménez-	<mark>2 EX</mark>	2	<mark>2</mark>	2	<mark>1</mark>	<mark>2</mark>	<mark>1</mark>	<mark>2</mark>	<mark>2</mark>	<mark>2</mark>	<mark>2</mark>	<mark>0</mark>	<mark>20</mark>
Costa et al.,													
2022 Im et al		2	2	2	ο	ο	ο	2	2	Π	ο	D	12
2016		-	-	=	v	v	<u>v</u>	<u> </u>	-	<u>v</u>	<u>~</u>	<u>~</u>	14
Jull et al.,	<mark>2 EX</mark>	<mark>2</mark>	<mark>2</mark>	<mark>2</mark>	<mark>1</mark>	<mark>2</mark>	<mark>0</mark>	<mark>2</mark>	<mark>2</mark>	<mark>0</mark>	<mark>2</mark>	<mark>1</mark>	<mark>18</mark>
2007 Kang et al	2 FX	2	2	2	1	2	0	2	2	0	0	0	15
2021		-	-	-	-	-	<u>~</u>	-	-	<u>~</u>	<u>~</u>	<u>~</u>	
Kjellman &	<mark>2 EX</mark>	<mark>2</mark>	<mark>1</mark>	<mark>2</mark>	<mark>2</mark>	<mark>2</mark>	<mark>2</mark>	<mark>2</mark>	<mark>2</mark>	<mark>0</mark>	<mark>0</mark>	<mark>0</mark>	<mark>17</mark>
Oberg, 2002	I												

	Journal Pre-proof												
Lee et al., 2016 Petersen et al., 2015 Takasaki & Yamasaki, 2023	2 EX 2 EX 2 EX	2 2 2	2 0 2	2 2 2	1 1 0	1 2 2	0 0 0	2 2 2	2 2 2	0 2 2	0 2 0	0 2 0	14 19 16



Fig. 2 Quality Completeness of intervention reporting by TIDieR checklist item, for 27 22 RCTs of matched physical therapy interventions for NSNP.

3.2 Meta-Regression Analysis

Standardised mean difference of the change scores between matched and unmatched groups for pain and disability at short-term were moderated by TIDieR checklist summary score (figure 3 and 4). For both short-term pain and short-term disability outcomes, lower reporting quality was associated with greater SMD estimates in favour of matched interventions with slope coefficients 0.212 (95%CI: -0.009, 0.434), p=0.06, and 0.293 (95%CI: 0.083, 0.504), p=0.01 respectively. Findings indicated that inadequate reporting was associated with higher effect estimates for short-term pain and disability, favouring matched interventions.



Fig. 3 Meta-regression analysis to assess the impact of TIDieR summary scores on standardised mean difference (SMD) of pain at short-term.





4. DISCUSSION

This analysis of 24 22 RCTs comparing matched versus unmatched physical therapy interventions for NSNP found that poorer reporting of interventions was associated with larger effect estimates for short-term pain and disability in favour of matched treatment. Intervention reporting was often incomplete. Of particular relevance to the purpose of this review, items relating to intervention fidelity were the least likely to be adequately reported. In addition, materials used, intervention provider, location and modification were inconsistently reported across the studies.

Findings suggest poorer intervention reporting is associated with larger treatment effect estimates in favour of matched interventions. In other words, studies with poorer intervention reporting may yield over-optimistic findings on the superiority of matched physical therapy interventions in NSNP. Although the association between short-term pain and SMD did not reach statistical significance, our analysis emphasizes the effect size and uncertainty over rigid significance thresholds, offering a more nuanced understanding of the data (45). A similar correlation between poorly reporting exercise description and studies location and larger effect was found also in a systematic review investigating exercise in knee osteoarthritis (46). If reporting guality of clinical trials has an impact on effect size of interventions, the use of checklists such as the TIDieR should be recommended among authors, but also among journal editors, peer reviewer, ethics committees and funding agencies, to improve the quality of research (8). Due to the limited number of intermediate-term trials, the certainty of the correlation between poorer intervention reporting and larger treatment effect estimates favouring matched interventions is diminished. Nevertheless, in the longer term, the non-specific effects of musculoskeletal interventions, such as natural fluctuations in disease severity, regression to the mean, and spontaneous remission, might reduce the impact of specific and matched interventions (47).

The TIDieR checklist includes assessment of fidelity which is often poorly reported and assessed in clinical trials investigating exercise and manual therapy in NSNP (9,10). Fidelity assessment in clinical trials is a challenging process due to lack of specific tools to measure it and to missing data on adherence (48). Only one of the 24 clinical trials included in this secondary analysis reported adequately planning and actual assessment of fidelity (37). In a systematic review published in 2016, the reporting completeness of physiotherapy intervention trials was generally inadequate and commonly poorly described aspects included intervention materials, procedure details, tailoring, and intervention fidelity (8). Conversely, RCTs included in this secondary analysis generally contained an

adequate description of procedures and tailoring, perhaps reflecting their focus on evaluating matched interventions as opposed to Yamato's broader remit. However, our findings confirm the weakness of reporting related to fidelity to intended intervention. Treatment fidelity encompasses high quality in intervention delivery by ensuring clinician expertise and consistent dosing but also monitoring participant adherence to ensure adequate engagement with the intervention (49). High guality delivery requires that treatment deliverers develop competence in the treatment protocol (50). Within manual therapy studies the variability in the amount of clinical experience and qualifications may affect the skill levels of treatment providers (51). Nevertheless, only six out of 11 studies investigating matched versus unmatched manual therapy adequately reported enough details regarding intervention deliverers (21–24,27,30) and only two of the studies investigating matched versus unmatched exercise adequately reported physiotherapists background and experience (27,44). Furthermore, Cook et al. noted that even highly qualified and experienced treating physiotherapists should be trained to assess adherence to the research protocol to avoid drifts from intended interventions (49). Unfortunately, only four of the included studies reported a prior training of the treatment deliverers (23,27,30,44), but it should be observed that in the majority of the studies the researchers were also the treating physiotherapists, therefore, the necessity of a training might be questioned.

Evaluation of adherence to intended treatment was planned by four of the studies investigating matched versus unmatched exercise using diaries to record home exercise sessions (31,37,40,41), but only one study fully reported those data (37). Many clinical trials investigating exercise therapy for chronic neck pain failed to provide sufficient details on patient adherence (9). A recent systematic review exploring adherence to physiotherapy interventions, found that adherence to home-based programs was primarily assessed through self-reported diaries, which pose challenges as the sole measurement tool due to low completion rates and the potential for inaccurate recall and selfpresentation bias (52). In fact, missing data is one of the challenges to adequate fidelity assessment according to Ginsburg et al. (48). Regarding manual therapy, adherence and engagement to intervention involve physiotherapist-patient interaction and patients' expectation, and the assessment of these non-specific potential mediators of efficacy is recommended (49,51), but these were not considered in the studies included in this analysis. It is imperative that researchers conducting trials comparing matched and unmatched interventions urgently prioritize the rigorous reporting of treatment fidelity. This includes both adherence to planned treatment, and clinician fidelity, ensuring proper training of treatment providers. The lack of attention to these aspects might undermine the validity of clinical trial results, and without substantial improvements, the true effectiveness of tailored physiotherapy interventions will remain unclear. Future trials must incorporate robust methods to monitor and report fidelity to ensure that both the delivery and receipt of interventions are accurately reflected in research outcomes.

4.1 Strengths and weaknesses

A strength of this analysis was the inclusion of RCTs that selected patients according to clear clinical criteria, because it required that the studies had adequate tailoring procedure and a better description of the intervention. Another strength was that we conducted a meta-regression on more than 10 studies, following the Cochrane recommendation producing consistent findings for pain and disability at short-term follow up (13). The primary limitation of this secondary analysis is the lack of registration in any repository, which may result in selective reporting and hypothesizing after results are known, thereby distorting the evidence base and reducing the credibility of the findings (53). Another limitation of this secondary analysis was that we were unable to repeat the metaregression for longer-term assessment due to the paucity of studies with longer follow-ups. Furthermore, given the relatively small number of studies we did not investigate associations between any specific matching criteria and effect estimates. The scoring of TiDieR checklist was done by two independent raters with relatively few disagreements requiring a third rater. However, disagreements in materials used, modifications and planned or actual adherence or fidelity suggested greater potential for misclassification of these aspects of intervention description. It was observed that certain TIDieR checklist items, like intervention modifications and planned or actual fidelity assessment, may be subjective, leading to suggestions for modifications and clarifications to improve the checklists (54). Cotterill et al. noted the potential subjective nature of some TIDieR checklist items, such as modifications of intervention and planned or actual fidelity assessment, suggesting some modifications and clarifications to the checklists.

4.2 Future recommendations

The TIDieR checklist might be utilized to ensure that all aspects of interventions on NSNP are thoroughly reported. Its use can enhance the replicability of studies and also the

confidence in the findings. As this report showed, poor reporting may increase the effect of certain interventions, while better reporting might temper these results.

Adequate treatment fidelity assessment is very important to allow proper evaluation of effect sizes of different interventions, but research in musculoskeletal physiotherapy may require better tools to assess the competency of treatment providers and the adherence to the intended intervention. Toomey et al. noted that the conceptualisation and the definition of fidelity need to be standardised and that novel assessment frameworks might be required. The development of reporting guideline for fidelity of non-drug, non-surgical interventions (ReFiND) is a promising initiative that aims to improve this key item in TIDieR checklist (55).

4.3 Implication for researchers and clinicians

Future trials should incorporate robust methods, such as the TIDieR checklist, to monitor and report fidelity, ensuring accurate reflection of intervention delivery and receipt in research outcomes. Otherwise, clinicians and researchers may find it challenging to replicate these interventions in clinical practice and subsequent studies. Nevertheless, musculoskeletal physiotherapy research may need better tools to assess provider competency and adherence to intended interventions. The ReFiND initiative aiming to improve fidelity reporting guidelines for non-drug, non-surgical interventions, might be a promising enhancement the TIDieR checklist (55). Clinicians should be aware that existing evidence does not strongly support the superiority of matched treatments over unmatched ones. Therefore, tailoring exercise or manual therapy to each patient's unique clinical characteristics does not appear necessary to improve management outcomes.

5. CONCLUSION

The majority of RCTs investigating interventions matched to clinical assessment compared to a similar unmatched intervention unmatched lacked adequate reporting according to the TIDieR checklist. The least inadequately reported items were description and actual implementation of strategies to assess adherence and fidelity. Our findings suggest that trials with inadequate intervention reporting may exaggerate overestimate the benefits of matched physical therapy exercise or manual therapy treatments for NSNP. However, the lack of sufficient information on intervention fidelity in most studies prevented any evaluation of whether poor intervention fidelity explains null findings in previous trials of matched versus unmatched interventions. The majority of trials in the current review were

published after the TIDieR checklist, adding further weight to ongoing initiatives to improve guidance on this specific aspect of trial design, conduct, and reporting.

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