

BACKGROUND

- Complete reporting of interventions in research is required to ensure proper interpretation of results and scientific reproducibility
- In 2014, the Template for Intervention Description and Replication (TIDieR) checklist (consisting of twelve items) was created to aid stakeholders in comprehensively reporting interventions to ensure standards for reproducibility
- The completeness of intervention reporting using the TIDieR checklist has not been quantified in fibromyalgia RCTs

OBJECTIVE

To use the TIDieR checklist to 1) assess quality of reporting in fibromyalgia randomized-controlled trials (RCTs), 2) compare reporting between experimental and control groups, 3) determine predictor variables for better reporting.

METHODS

PROSPERO Registration #: CRD42020185788

Data Sources and Study Selection

- MEDLINE, EMBASE, Central, CINAHL, PEDro, AMED, PsycINFO, and PubMed were searched from January 2015 to July 2019 for any peer-reviewed RCT studying therapeutic interventions for fibromyalgia

Methodological Assessment

- Study quality was assessed using the Cochrane Risk of Bias 2.0 tool

Data synthesis and analysis

- For each trial, adherence to the TIDieR checklist was assessed separately for 1) experimental intervention groups, 2) control intervention groups, and 3) pooled intervention group
- For each group, adherence to each of the twelve TIDieR items was rated as zero (not reported), one (partially reported) or two (completely reported) and a composite TIDieR score was calculated
- Nonparametric related-samples Wilcoxin signed-rank test was used to compare adherence to each TIDieR item and composite score between groups
- Multiple linear regression was used to investigate the association between covariates (e.g. demographic variables and study quality) and composite TIDieR score from the pooled intervention group

- One-hundred RCTs yielding 129 experimental intervention groups and 79 control intervention groups were included
- Overall adherence to the TIDieR checklist was 71.0%, whereas experimental intervention group versus control intervention group adherence were 78.9% and 61.8% ($p < 0.001$), respectively

Table 1. Adherence of Experimental (n=129) vs. Control Groups (n=79)

TIDieR Item	Number of experimental groups (%)	Number of control groups (%)	P-value
1. "Name"			0.019
Full reporting	127 (98.4)	69 (87.3)	
Partial reporting	2 (1.6)	8 (10.1)	
No reporting	0	2 (2.5)	
2. "Rationale"			<0.001
Full reporting	126 (97.7)	44 (55.7)	
Partial reporting	3 (2.3)	27 (34.2)	
No reporting	0	8 (10.1)	
3. "Materials"			<0.01
Full reporting	92 (71.3)	30 (38.0)	
Partial reporting	22 (17.1)	24 (30.4)	
No reporting	15 (11.6)	25 (31.6)	
4. "Procedures"			0.348
Full reporting	84 (65.1)	41 (51.9)	
Partial reporting	41 (31.8)	29 (36.7)	
No reporting	4 (3.1)	9 (11.4)	
5. "Provider"			<0.01
Full reporting	76 (58.9)	27 (34.2)	
Partial reporting	15 (11.6)	7 (8.9)	
No reporting	38 (29.5)	45 (57.0)	
6. "Mode of Delivery"			0.037
Full reporting	81 (62.8)	37 (46.8)	
Partial reporting	39 (30.2)	20 (25.3)	
No reporting	9 (7.0)	22 (27.8)	
7. "Where"			0.062
Full reporting	54 (41.9)	21 (26.6)	
Partial reporting	35 (27.1)	19 (24.0)	
No reporting	40 (31.0)	39 (49.4)	
8. "Dosage"			<0.001
Full reporting	118 (91.5)	51 (64.6)	
Partial reporting	8 (6.2)	7 (8.9)	
No reporting	3 (2.3)	21 (26.6)	
9. "Tailoring"			0.317
Full reporting	20 (71.4)	4 (44.4)	
Partial reporting	11 (26.2)	3 (33.3)	
No reporting	1 (2.4)	2 (22.2)	
10. "Modifications"			N/A
Full reporting	1 (50.0)	1 (100.0)	
Partial reporting	0	0	
No reporting	1 (50.0)	0	
11. "How well – planned"			0.642
Full reporting	33 (25.6)	16 (20.3)	
Partial reporting	55 (42.6)	24 (30.4)	
No reporting	41 (31.8)	39 (49.4)	
12. "How well – actual"			0.336
Full reporting	106 (82.2)	67 (84.8)	
Partial reporting	17 (13.2)	9 (11.4)	
No reporting	6 (4.7)	3 (3.8)	

RESULTS

Figure 1. Percent Adherence versus TIDieR Item

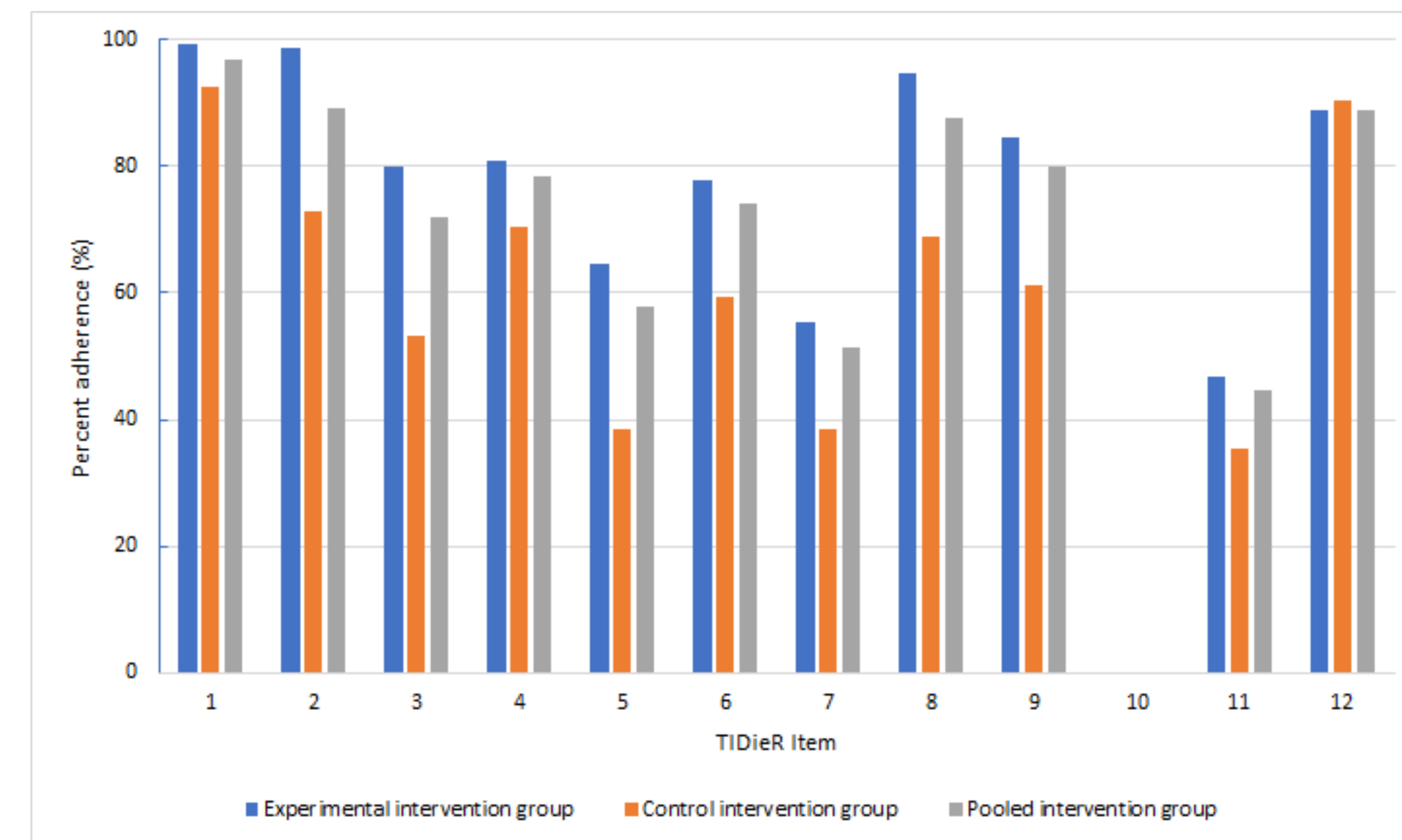


Table 2. Multiple Linear Regression ($p < 0.01$, $R^2_{adjusted} = 0.142$)

Predictor	Unstandardized B coefficient [95%CI]	P-value
Year published	0.0195 [0.001, 0.307]	0.046
Funding source – reported	0.157 [0.126, 0.188]	<0.001
Funding source – unreported	0.127 [0.091, 0.164]	<0.001
Randomization – low risk of bias	0.147 [0.105, 0.190]	<0.001
Randomization – some concerns of bias	0.079 [0.038, 0.119]	<0.001
Randomization – high risk of bias	0.059 [-0.011, 0.128]	0.096
Selective reporting – low risk of bias	0.160 [0.124, 0.196]	<0.001
Selective reporting – some concerns of bias	0.125 [0.091, 0.158]	<0.001

CONCLUSION

- Intervention-based fibromyalgia RCTs are moderately adherent to the TIDieR checklist since its publication in 2014
- Serious reporting deficiencies in how interventions are personalized over time exist
- Control groups are significantly underreported compared to experimental groups
- Trial registries could be restructured to incorporate TIDieR items, journals should continue to adopt the TIDieR checklist, and authors should be encouraged to use supplementary appendices or external protocols when faced with word limits