

Question	Response		Criteria	Justification
			Internal Validity	
1. Study design: prospective, retrospective or mixed?	Prospective	<input type="checkbox"/>	Outcome had not occurred when study was initiated; information was collected over time	
	Mixed	<input type="checkbox"/>	One group was studied prospectively; other(s) retrospectively	
	Retrospective	<input type="checkbox"/>	Analyzed data from past records, claims	
2. Were inclusion/exclusion criteria clearly stated?	Yes	<input type="checkbox"/>	Clearly stated	
	Partially	<input type="checkbox"/>	Some, but not all criteria stated or some not clearly stated.	
	No	<input type="checkbox"/>	Unclear	
3. Were baseline characteristics measured using valid and reliable measures and are they equivalent in both groups?	Yes	<input type="checkbox"/>	Valid measures, groups ~equivalent	
	No	<input type="checkbox"/>	Non-validated measures or nonequivalent groups	
	Uncertain	<input type="checkbox"/>	Could not be ascertained	
4. Were important variables known to impact the outcome(s) assessed at baseline?	Yes	<input type="checkbox"/>	Yes, most or all known factors were assessed	
	No	<input type="checkbox"/>	Critical factors are missing	
	Uncertain	<input type="checkbox"/>		
5. Is the level of detail describing the intervention adequate?	Yes	<input type="checkbox"/>	Intervention sufficiently described	
	Partially	<input type="checkbox"/>	Some of the above features.	
	No	<input type="checkbox"/>	Intervention poorly described	
6. Is the selection of the comparison group appropriate?	Yes	<input type="checkbox"/>	Other fibromyalgia patients with similar patient characteristics, severity and comorbid features	
7. Was the impact of a concurrent intervention or an unintended exposure that might bias results isolated?	Yes	<input type="checkbox"/>	By inclusion criteria, protocol or other means	
	Partially	<input type="checkbox"/>	Some were isolated, others were not	
	No	<input type="checkbox"/>	Important concurrent interventions were not isolated or prohibited	
8. Were there attempts to balance the allocation across groups? (e.g., stratification, matching or propensity scores)	Yes	<input type="checkbox"/>	<i>(If yes, what method was used?)</i>	
	No	<input type="checkbox"/>		
	Uncertain	<input type="checkbox"/>	Could not be ascertained	
9. Were outcomes assessors blinded?	Yes	<input type="checkbox"/>	Who assessed outcomes?	
	No	<input type="checkbox"/>		
	Uncertain	<input type="checkbox"/>	Not reported	
10. Were outcomes assessed using valid and reliable measures, and used consistently across all study participants?	Yes	<input type="checkbox"/>	Measures were valid and reliable (i.e., objective measure, validated scale/tool); consistent across groups	
	Partially	<input type="checkbox"/>	Some of the above features	
	No	<input type="checkbox"/>	None of the above features	
	Uncertain	<input type="checkbox"/>	Could not be ascertained.	
11. Was length of followup the same for all groups?	Yes	<input type="checkbox"/>		
	No	<input type="checkbox"/>		
	Uncertain	<input type="checkbox"/>	Could not be ascertained	
12. Did attrition result in	Yes	<input type="checkbox"/>	<i>(If yes, for which followup period(s)?)</i>	

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differences in group characteristics between baseline and followup?	No <input type="checkbox"/>		
	Uncertain <input type="checkbox"/>	Could not be ascertained	
13. If dissimilar baseline characteristics, does the analysis control for baseline differences between groups?	Yes <input type="checkbox"/>	What method?	
	No <input type="checkbox"/>		
	Uncertain <input type="checkbox"/>	Could not be ascertained	
14. Were confounding and/or effect modifying variables assessed using valid and reliable measures across all study participants?	Yes <input type="checkbox"/>		
	No <input type="checkbox"/>		
	Uncertain <input type="checkbox"/>	Could not be ascertained (i.e., retrospective designs where eligible at baseline could not be determined)	
	NA <input type="checkbox"/>	No confounders or effect modifiers included in the study.	
15. Were important confounding and effect modifying variables taken into account in design and/or analysis? (e.g., matching, stratification, interaction terms, multivariate analysis, or other statistical adjustment)	Yes <input type="checkbox"/>		
	Partially <input type="checkbox"/>	Some variables taken into account or adjustment achieved to some extent.	
	No <input type="checkbox"/>	Not accounted for or not identified.	
	Uncertain <input type="checkbox"/>	Could not be ascertained	
16. Are statistical methods used to assess the primary outcome appropriate to the data?	Yes <input type="checkbox"/>	Statistical techniques used must be appropriate to the data.	
	Partially <input type="checkbox"/>		
	No <input type="checkbox"/>		
	Uncertain <input type="checkbox"/>	Could not be ascertained	
17. Is there suggestion of selective outcome reporting?	Yes <input type="checkbox"/>	Not all prespecified outcomes reported, subscales not prespecified reported, outcomes reported incompletely	
	No <input type="checkbox"/>		
	Uncertain <input type="checkbox"/>	Could not be ascertained	
18. Was the funding source identified?	No <input type="checkbox"/>		
	Yes <input type="checkbox"/>	Who provided funding?	
	Uncertain <input type="checkbox"/>		
<b>Additional subgroup items<sup>1</sup></b>			
Was subgroup variable measured at baseline?			
Were subgroups pre-specified (a priori)?			
Was direction of subgroup effect on each/main outcome specified a priori? If so, was result consistent with it?			
Is subgroup effect significant? Skeptical $p > 0.01$ ; Maybe ( $0.01 < p < 0.1$ ) vs $p < 0.001$ believable)			
Is subgroup effect large?			
Is subgroup effect independent? (is another interaction significant that is a related variable?)			
Is the interaction effect consistent across similar outcomes in the study?			
Question	Response	Criteria	Justification
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<b>Overall Assessment</b>			
<b>Overall Risk of Bias assessment</b>	Low <input type="checkbox"/>	Results are believable taking study limitations into consideration	
	Moderate <input type="checkbox"/>	Results are probably believable taking study limitations into consideration	

Question	Response	Criteria	Justification
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	High <input type="checkbox"/>	Results are uncertain taking study limitations into consideration	

**Reference**

1. Sun X, Briel M, Walter SD, et al. Is a subgroup effect believable? Updating criteria to evaluate the credibility of subgroup analyses. *BMJ*. 2010;340:c117. PMID 2035401.