RCT Risk of bias assessment: Fibromyalgia subgroup studies

Selection Bias	
Was method of randomization used to generate the sequence described in sufficient detail to assess whether it should produce comparable groups? (inadequate randomization?)	
Were all randomized participants analyzed in the group to which they were allocated?	
Were the groups similar at baseline regarding the most important prognostic indicators?	
Was method of treatment allocation adequate to keep treatment concealed until desired time?(inadequate allocation concealment)	
Risk of selection bias (inadequate randomization or allocation concealment):	**[Low, Unclear, High]**
Performance Bias	
Was the care provider blinded to the intervention?	Yes, no, NR
Were the participants blinded to the intervention?	Yes, no, NR
Nondrug interventions: Were interventions adequately defined so they could be replicated?	
Was the intended blinding effective?	
Risk of performance bias due to lack of participant and personnel blinding, intervention definition & fidelity to treatment?	**[Low, Unclear, High]**
Detection Bias	
Were the outcome assessors blinded to the intervention?	Yes, no, NR, NA
Was the scale/tool used to measure outcomes validated, reliable?	
Were co-interventions avoided?	
Was the timing of the outcome assessment similar in all groups?	
Were significance estimates for results appropriately corrected for multiple comparisons?	
Was study adequately powered – To detect main effects? To detect differences in subgroups?	
Risk of detection bias due to lack of outcome assessor blinding, measurement of outcomes, statistical analysis, low study power	**[Low, Unclear, High]**
Attrition Bias	
Was attrition lower than 20%? -overall -in subgroups	Y, N, NR, NR for SG %
Were reasons for incomplete/missing data adequately explained? (# assessed, # dropped out, # lost to follow-up)	
Were losses to followup also reported for subgroups?	
Was incomplete data handled appropriately?	

Risk of attrition bias due to amount, nature, or handling of incomplete outcome data?	**[Low, Unclear, High]**
Reporting Bias	
Were all outcomes reported in Results or were only select outcomes reported?	
Were results (in tables and/or text) reported for all randomized patients -for main outcomes? -for all outcomes? -for subgroups?	
What is the risk of reporting bias due to selective outcome reporting?	**[Low, Unclear, High]**
Other Sources of Bias	
Are there other risks of bias? If yes, describe them	
Additional subgroup items	
Was subgroup variable measured at baseline or after randomization?	
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 vs maybe (0.01<p<0.1) vs p<0.001 believable)	S-M-B vs NR -or text of "NS"
Is subgroup effect large?	
Is subgroup effect independent?	
Is the interaction effect consistent across similar outcomes in the study?	
Overall Risk of Bias Assessment by outcome(s)	**[Low, Moderate or High] and explanation (1-2 sentences)**

References:

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
2. Viswanathan M, Ansari M, Berkman N, et al. Assessing the Risk of Bias of Individual Studies in Systematic Reviews of Health Care Interventions. AHRQ. 2012.
3. Higgins JPT, Altman D, Sterne J. Chapter 8: Assessing risk of bias in included studies. In: Higgins JPT, Green S, eds. Cochrane Handbook for Systematic Reviews of Interventions: Version 5.1.0. The Cochrane Collaboration; 2011.