

Appendix D. Risk-of-Bias Assessment Form for Observational Studies

Author _____ Year _____ (PMID) _____ Reviewer _____

Question	Response	Criteria	Justification
Internal Validity			
1. Is the study design prospective, retrospective, or mixed?	Prospective <input type="checkbox"/>	Outcome has not occurred at the time the study is initiated and information is collected over time to assess relationships with the outcome.	
	Mixed <input type="checkbox"/>	Studies in which one group is studied prospectively and the other retrospectively.	
	Retrospective <input type="checkbox"/>	Analyzes data from past records.	
2. Are inclusion/exclusion criteria clearly stated?	Yes <input type="checkbox"/>		
	Partially <input type="checkbox"/>	Some, but not all, criteria stated or some not clearly stated.	
	No <input type="checkbox"/>		
3. Are baseline characteristics measured using valid and reliable measures and equivalent in both groups?	Yes <input type="checkbox"/>		
	No <input type="checkbox"/>		
	Uncertain <input type="checkbox"/>	Could not be ascertained.	
4. Is the level of detail describing the intervention adequate?	Yes <input type="checkbox"/>	Intervention described included adequate service details	
	Partially <input type="checkbox"/>	Some of the above features.	
	No <input type="checkbox"/>	None of the above features.	
5. Is the selection of the comparison group appropriate?	Yes <input type="checkbox"/>	Considering diagnostic assessment, other patient characteristics	
	Partially <input type="checkbox"/>		
	No <input type="checkbox"/>		
6. Did researchers isolate the impact from a concurrent intervention or an unintended exposure that might bias results?	Yes <input type="checkbox"/>	Accounted for concurrent informal care.	
	Partially <input type="checkbox"/>		
	No <input type="checkbox"/>		
7. Any attempt to balance the allocation between the groups (e.g., stratification, matching, propensity scores)?	Yes <input type="checkbox"/>	(If yes, what was used?)	
	No <input type="checkbox"/>		
	Uncertain <input type="checkbox"/>	Could not be ascertained.	
8. Were outcomes assessors blinded?	Yes <input type="checkbox"/>	Who were outcome assessors?	
	No <input type="checkbox"/>		
9. Are outcomes assessed using valid and reliable measures, implemented	Yes <input type="checkbox"/>	Measure valid and reliable (i.e., objective measures, well validated scale, provider report); and equivalent across groups.	

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consistently across all study participants?	Partially <input type="checkbox"/>	Some of the above features (partially validated scale)	
	No <input type="checkbox"/>	None of the above features (self-report, scales with lower validity, reliability); not equivalent across groups	
	Uncertain <input type="checkbox"/>	Could not be ascertained.	
10. Is the length of followup the same for all groups?	Yes <input type="checkbox"/>		
	No <input type="checkbox"/>		
	Uncertain <input type="checkbox"/>	Could not be ascertained.	
11. Did attrition result in a difference in group characteristics between baseline and followup?	Yes <input type="checkbox"/>	(Measurement period of interest if repeated measures)	
	No <input type="checkbox"/>		
	Uncertain <input type="checkbox"/>	Could not be ascertained (i.e. retrospective designs where eligible at baseline could not be determined)	
12. If baseline characteristics are not similar, does the analysis control for baseline differences between groups?	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)	
13. Are 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.	
14. Were the important confounding and effect modifying variables taken into account in the design and/or analysis (e.g., through 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	
15. Are the statistical methods used to assess the primary outcomes 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	

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16. Are reports of the study free of suggestion of selective outcome reporting?	Yes <input type="checkbox"/>		
	No <input type="checkbox"/>	Not all prespecified outcomes reported, subscales not prespecified reported, outcomes reported incompletely.	
	Uncertain <input type="checkbox"/>	Could not be ascertained.	
17. Funding source identified	No <input type="checkbox"/>		Industry, government, university, Foundation (funded by what money source?)
	Yes <input type="checkbox"/>	Who provided funding?	
	Uncertain <input type="checkbox"/>		
Overall Assessment			
18. Overall Risk of Bias assessment	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	
	High <input type="checkbox"/>	Results are uncertain taking study limitations into consideration	