

IMPORTANT CONSIDERATIONS FOR PTSD RESEARCH

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This document is designed to assist researchers in the design phase of their project to ensure that their resultant study will meet the required standards to be included in evidence-based clinical practice guidelines. To be included in such guidelines, studies are often assessed against a risk of bias analysis. The table below describes one such system, and it is based on the Agency for Healthcare Research, and Quality (AHRQ) Methods Guide for Comparative Effectiveness Reviews [1] and in the AHRQ Report 235 [2].

RISK OF BIASES (ROB)

Common design issues that lead to a high ROB are:



A poor reporting of randomization methods

Proper randomization reduces selection bias as participants begin the study. It is a crucial component of a high-quality RCT. It hinges on two steps: generation of an unpredictable allocation sequence and concealment of this sequence from the investigators who are enrolling participants into the treatment conditions.



Not having a care provider and patient/client masking

This does not apply in psychological treatment studies. However, would apply if you are comparing your psychological treatment with a medication treatment and a placebo control.



A poor description of the allocation concealment method

How was the person who allocated the patients kept separate to the allocation process.



Not conducting intent-to-treat (ITT) analyses

You can't only present the findings for people who only completed treatment. Those that did not complete the study must be included, and the process you went through to include them needs to be described and consistent with current statistical practices.



A poor reporting about the masking of the outcome assessors

The assessors need to take steps to ensure they don't inadvertently find out what treatment condition the patient was in.



Report over 20% overall attrition

Dropout overall must be lower than 20%



Report over 15% of differential attrition

The difference between any two treatment conditions in dropout should not be greater than 15%

When treating PTSD or Complex-PTSD, it is important to mention the percent of participants who met full criteria using a diagnosis instrument (e.g., CAPS-5).

The U.S. National Center for PTSD (NCPTSD) requested the AHRQ the exploration of an expanded ROB system to address concerns about transparency, reproducibility, and sensitivity of ROB assessment because the NCPTSD noted that most studies fall into the medium ROB category, and were concerned that final ratings were potentially inconsistently applied across raters due to lack of transparency and clarity in assessment methods.

If you want to know more about ROB assessment, you can read the RoB 2 Tool. Go to <https://tinyurl.com/yxqrop8q>

Other articles on risk if bias are the CONSORT guidelines. Go to: <https://tinyurl.com/lml7hq>

ROB Domain	ROB Assessment Elements		NOTES
Selection Bias	Was randomization adequate?	Yes	
		No	
		Unclear	
	Was allocation concealment adequate?	Yes	
		No	
		Unclear	
	Were groups similar at baseline?	Yes	
		No	
		Unclear	
	Intent-to-Treat (ITT) analyses was conducted?	Yes	
		No	
		Unclear	
Performance Bias	Care provider was masked?	Yes	
		No	
		Unclear	
	Patient was masked?	Yes	
		No	
		Unclear	
Detection Bias	Outcome assessor was masked?	Yes	
		No	
		Unclear	
Attrition	Overall attrition <20%	Yes	
		No	
		Unclear	
	Differential attrition <15%	Yes	
		No	
		Unclear	

References

1. Viswanathan M, Patnode CD, Berkman ND, et al. Assessing the Risk of Bias in Systematic Reviews of Health Care Interventions. *Methods Guide for Comparative Effectiveness Reviews*. (Prepared by the Scientific Resource Center under Contract No. 290-2012-0004-C). AHRQ Publication No. 17(18)-EHC036-EF. Rockville, MD: Agency for Healthcare Research and Quality; Dec 2017. www.effectivehealthcare.ahrq.gov/reports/final.cfm.
2. O'Neil ME, Cheney TP, Hsu FC, Carlson KF, Hart EL, Holmes RS, Murphy KM, Graham E, Cameron DC, Kahler J, Lewis M, Kaplan J, McDonagh MS. Pharmacologic and Nonpharmacologic Treatments for Posttraumatic Stress Disorder: An Update of the PTSD-Repository Evidence Base. *Comparative Effectiveness Review No. 235*. (Prepared by the Pacific Northwest Evidence-based Practice Center under Contract No. 290-2015-00009-I.) AHRQ Publication No. 20(21)-EHC029. Rockville, MD: Agency for Healthcare Research and Quality; November 2020. DOI: <https://doi.org/10.23970/AHRQEPCCER235>
3. Munder, T., & Barth, J. (2018). Cochrane's risk of bias tool in the context of psychotherapy outcome research. *Psychother Res*, 28(3), 347-355. doi:10.1080/10503307.2017.1411628

EXPANDED ROB

Missing data	Did the study use adequate methods for handling missing data?	Yes	
		No	
		Unclear	
Outcome measures	Were outcome measures equal, valid, and reliable?	Yes	
		No	
		Unclear	
Treatment fidelity	Did the study report adequate treatment fidelity (therapist adherence) based on measurement by independent raters?	Yes	
		No	
		Unclear	

A final note is that many researchers for psychotherapy studies often look at Treatment Implementation, which is assessing variables that can affect the quality of the therapy (see Munder and Bath, 2018). Things assessed include fidelity to protocol, therapist qualifications, and preference of the therapist for one treatment over another