Appendix F. Risk-of-Bias Tables

Table F1. Risk of bias observational studies

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| --- | --- | --- | --- | --- | --- | --- |
| **Author, Year** | **Groups** | **Masked****Statistical Analysis** | **Attrition** | **Miscellaneous** | **Outcomes** | **Risk of Bias****Notes Explaining Risk of Bias** |
| Carlier, 199822Prospective study design?No | Groups recruited from same source population?YesBoth groups recruited over same time period?Yes% completed treatment100% | Attempt to mask outcome assessors?YesDifferences between groups taken into account in statistical analysis?YesConfounding adequately accounted for either through study design or statistical analysis?Yes | Overall attrition ≥20%?NoDifferential attrition ≥15%?No | I/E criteria equally applied in both groups?YesTime of follow-up equal in both groups?Yes | Outcome measures equal, valid and reliable?YesMethod of Handling DropoutsNAAny participants who started the trial excluded from analysis?No | HighRisk of recall bias because no data available until 8 months after trauma. High risk of selection bias and confounding from subjects’ self-selection to treatment groups. |
| Eid, 200123Prospective study design?Yes | Groups recruited from same source population?NoBoth groups recruited over same time period?Yes% completed treatmentNR | Attempt to mask outcome assessors?UnclearDifferences between groups taken into account in statistical analysis?UnclearConfounding adequately accounted for either through study design or statistical analysis?Unclear | Overall attrition ≥20%?NRDifferential attrition ≥15%?NR | I/E criteria equally applied in both groups?UnclearTime of follow-up equal in both groups?Yes | Outcome measures equal, valid and reliable?YesMethod of Handling DropoutsNAAny participants who started the trial excluded from analysis?NR | HighCohort study with a small sample size. No reported adjustment for confounders. Further risk of bias assessment impossible due to inadequate reporting of methods. |

Table F1. Risk of bias observational studies (continued)

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| --- | --- | --- | --- | --- | --- | --- |
| **Author, Year** | **Groups** | **Masked****Statistical Analysis** | **Attrition** | **Miscellaneous** | **Outcomes** | **Risk of Bias****Notes Explaining Risk of Bias** |
| Foa, 199524Prospective study design?Yes | Groups recruited from same source population?YesBoth groups recruited over same time period?Yes% completed treatment100% | Attempt to mask outcome assessors?YesDifferences between groups taken into account in statistical analysis?YesConfounding adequately accounted for either through study design or statistical analysis?No | Overall attrition ≥20%?NRDifferential attrition ≥15%?NR | I/E criteria equally applied in both groups?YesTime of follow-up equal in both groups?Yes | Outcome measures equal, valid and reliable?YesMethod of Handling DropoutsUnclearAny participants who started the trial excluded from analysis?No | HighNonrandomized study with small sample size (N = 20). Attrition data NR. High risk of selection bias and confounding: participants matched on some variables but not all, and timing of outcomes differed by group. |
| Frappell-Cooke, 201025Prospective study design?Yes | Groups recruited from same source population?YesBoth groups recruited over same time period?Yes% completed treatment100% | Attempt to mask outcome assessors?NRDifferences between groups taken into account in statistical analysis?YesConfounding adequately accounted for either through study design or statistical analysis?Unclear | Overall attrition ≥20%?YesDifferential attrition ≥15%?Yes | I/E criteria equally applied in both groups?YesTime of follow-up equal in both groups?Yes | Outcome measures equal, valid and reliable?YesMethod of Handling DropoutsUnclearAny participants who started the trial excluded from analysis?No | HighNonrandomized study with high overall (24%) and differential (43%) attrition. Completers analysis only. |

Table F1. Risk of bias observational studies (continued)

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| --- | --- | --- | --- | --- | --- | --- |
| **Author, Year** | **Groups** | **Masked****Statistical Analysis** | **Attrition** | **Miscellaneous** | **Outcomes** | **Risk of Bias****Notes Explaining Risk of Bias** |
| Gelpin, 199626Prospective study design?Yes | Groups recruited from same source population?YesBoth groups recruited over same time period?Yes% completed treatmentOverall: NAG1: 69%G2: NA | Attempt to mask outcome assessors?UnclearDifferences between groups taken into account in statistical analysis?YesConfounding adequately accounted for either through study design or statistical analysis?No | Overall attrition ≥20%?NRDifferential attrition ≥15%?NR | I/E criteria equally applied in both groups?YesTime of follow-up equal in both groups?Yes | Outcome measures equal, valid and reliable?YesMethod of Handling DropoutsUnclearAny participants who started the trial excluded from analysis?Unclear | HighUnclear if only completers analysis used. Large risk of selection bias because administration of benzodiazepines based on clinician’s evaluation of efficacy, side effects, distress level, and other characteristics like severity of trauma. Specific drug of choice (either alprazolam or clonazepam) administered in nonsystematic way. High risk of bias given likely effect of these issues on results because of small sample size (n=26). |

Table F1. Risk of bias observational studies (continued)

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| --- | --- | --- | --- | --- | --- | --- |
| **Author, Year** | **Groups** | **Masked****Statistical Analysis** | **Attrition** | **Miscellaneous** | **Outcomes** | **Risk of Bias****Notes Explaining Risk of Bias** |
| Grainger, 199721Prospective study design?Yes | Groups recruited from same source population?YesBoth groups recruited over same time period?Yes% completed treatmentNR | Attempt to mask outcome assessors?UnclearDifferences between groups taken into account in statistical analysis?NAConfounding adequately accounted for either through study design or statistical analysis?Unclear | Overall attrition ≥20%?NRDifferential attrition ≥15%?NR | I/E criteria equally applied in both groups?YesTime of follow-up equal in both groups?Yes | Outcome measures equal, valid and reliable?MixedMethod of Handling DropoutsNAAny participants who started the trial excluded from analysis?Unclear | HighOnly 29% of participants receiving at least 1 session of EMDR included in analysis because only participants completing both baseline and posttreatment assessments analyzed. Inclusion criteria unclear (other than surviving Hurricane Andrew) and may have been established after treatment given to survivors. Unclear if only completers analysis used: only waitlist group completers reported. Unclear how late some participants might have first received treatment. |

Table F1. Risk of bias observational studies (continued)

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| **Author, Year** | **Groups** | **Masked****Statistical Analysis** | **Attrition** | **Miscellaneous** | **Outcomes** | **Risk of Bias****Notes Explaining Risk of Bias** |
| Jotzo, 200527Prospective study design?Yes | Groups recruited from same source population?NoBoth groups recruited over same time period?No% completed treatmentNR | Attempt to mask outcome assessors?UnclearDifferences between groups taken into account in statistical analysis?YesConfounding adequately accounted for either through study design or statistical analysis?Unclear | Overall attrition ≥20%?NRDifferential attrition ≥15%?NR | I/E criteria equally applied in both groups?YesTime of follow-up equal in both groups?Unclear | Outcome measures equal, valid and reliable?YesMethod of Handling DropoutsNRAny participants who started the trial excluded from analysis?Unclear | HighNo baseline PTSD data collected. Information about attrition, ITT, blinding, or confounding largely unavailable. |
| Krauseneck, 201028Prospective study design?Yes | Groups recruited from same source population?YesBoth groups recruited over same time period?Yes% completed treatmentOverall: 84%G1: NRG2: NR | Attempt to mask outcome assessors?UnclearDifferences between groups taken into account in statistical analysis?YesConfounding adequately accounted for either through study design or statistical analysis?Yes | Overall attrition ≥20%?NoDifferential attrition ≥15%?NR | I/E criteria equally applied in both groups?YesTime of follow-up equal in both groups?Yes | Outcome measures equal, valid and reliable?YesMethod of Handling DropoutsNRAny participants who started the trial excluded from analysis?No | HighHigh risk of bias based primarily on unmeasured potential confounders: 1) Beta-blockers apparently administered postoperatively in Germany "according to a standard protocol"; 2) May be important clinical reasons for not giving beta-blockers to some patients (e.g., preoperative characteristics, such as history of asthma or COPD or postoperative course such as bradycardia, that could indicate illness severity after surgery;  |

Table F1. Risk of bias observational studies (continued)

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| --- | --- | --- | --- | --- | --- | --- |
| **Author, Year** | **Groups** | **Masked****Statistical Analysis** | **Attrition** | **Miscellaneous** | **Outcomes** | **Risk of Bias****Notes Explaining Risk of Bias** |
| Krauseneck, 201028 (continued) |  |  |  |  |  | 3) No discussion of how these potential confounders related to risk of PTSD symptoms. |
| Peres, 201129Prospective study design?Yes | Groups recruited from same source population?YesBoth groups recruited over same time period?Yes% completed treatmentNR | Attempt to mask outcome assessors?UnclearDifferences between groups taken into account in statistical analysis?UnclearConfounding adequately accounted for either through study design or statistical analysis?Unclear | Overall attrition ≥20%?NRDifferential attrition ≥15%?NR | I/E criteria equally applied in both groups?NoTime of follow-up equal in both groups?Yes | Outcome measures equal, valid and reliable?YesMethod of Handling DropoutsNAAny participants who started the trial excluded from analysis?Unclear | HighNot randomized, and attrition and number of subjects included in analysis NR. Impossible to determine similarity of original groups. Unclear how statistical analyses were conducted. |

Table F1. Risk of bias observational studies (continued)

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| --- | --- | --- | --- | --- | --- | --- |
| **Author, Year** | **Groups** | **Masked****Statistical Analysis** | **Attrition** | **Miscellaneous** | **Outcomes** | **Risk of Bias****Notes Explaining Risk of Bias** |
| Peris, 201130Prospective study design?No | Groups recruited from same source population?YesBoth groups recruited over same time period?No% completed treatmentNR | Attempt to mask outcome assessors?NoDifferences between groups taken into account in statistical analysis?YesConfounding adequately accounted for either through study design or statistical analysis?No | Overall attrition ≥20%?YesDifferential attrition ≥15%?Yes | I/E criteria equally applied in both groups?YesTime of follow-up equal in both groups?Yes | Outcome measures equal, valid and reliable?YesMethod of Handling DropoutsNAAny participants who started the trial excluded from analysis?NR | HighNonrandomizated study with high overall (44%) and differential (16%) attrition. Study groups evaluated at two different time periods.Outcome assessment not blinded. |
| Richards, 200131Prospective study design?Yes | Groups recruited from same source population?YesBoth groups recruited over same time period?Unclear% completed treatmentNR  | Attempt to mask outcome assessors?NoDifferences between groups taken into account in statistical analysis?NoConfounding adequately accounted for either through study design or statistical analysis?No | Overall attrition ≥20%?YesDifferential attrition ≥15%?No | I/E criteria equally applied in both groups?YesTime of follow-up equal in both groups?Yes | Outcome measures equal, valid and reliable?YesMethod of Handling DropoutsCompleters analysisAny participants who started the trial excluded from analysis?Unclear | HighHigh overall attrition (50%). Unclear whether control group was concurrent. |

Table F1. Risk of bias observational studies (continued)

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| --- | --- | --- | --- | --- | --- | --- |
| **Author, Year** | **Groups** | **Masked****Statistical Analysis** | **Attrition** | **Miscellaneous** | **Outcomes** | **Risk of Bias****Notes Explaining Risk of Bias** |
| Rothbaum, 200832Prospective study design?Yes | Groups recruited from same source population?YesBoth groups recruited over same time period?No% completed treatment100% | Attempt to mask outcome assessors?UnclearDifferences between groups taken into account in statistical analysis?NRConfounding adequately accounted for either through study design or statistical analysis?No | Overall attrition ≥20%?YesDifferential attrition ≥15%?No | I/E criteria equally applied in both groups?YesTime of follow-up equal in both groups?Yes | Outcome measures equal, valid and reliable?YesMethod of Handling DropoutsCompleters analysisAny participants who started the trial excluded from analysis?NR | HighNonrandomized study with small sample size (n=10). High overall attrition (20%). Completers analysis only. Possible statistically significant between-group differences at baseline (e.g., age, sex). No attempts to adjust for potential confounding from participants’ trauma histories and whether previous traumas from adulthood or childhood. Participants not screened for ASD or PTSD at baseline when eligibility assessed. |

Table F1. Risk of bias observational studies (continued)

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| --- | --- | --- | --- | --- | --- | --- |
| **Author, Year** | **Groups** | **Masked****Statistical Analysis** | **Attrition** | **Miscellaneous** | **Outcomes** | **Risk of Bias****Notes Explaining Risk of Bias** |
| Vaiva, 200333Prospective study design?Yes | Groups recruited from same source population?YesBoth groups recruited over same time period?Yes% completed treatmentOverall: 89%G1: 81%G2: 100% | Attempt to mask outcome assessors?YesDifferences between groups taken into account in statistical analysis?YesConfounding adequately accounted for either through study design or statistical analysis?No | Overall attrition ≥20%?NRDifferential attrition ≥15%?NR | I/E criteria equally applied in both groups?YesTime of follow-up equal in both groups?Yes | Outcome measures equal, valid and reliable?YesMethod of Handling DropoutsNAAny participants who started the trial excluded from analysis?NR | HighAttrition data NR and unclear how attrition handled in analysis. No baseline PTSD symptom data collected. Risk of selection bias due to participant self-selection into treatment groups, which is not addressed in analysis. |
| Vijayakumar, 200834Prospective study design?Yes | Groups recruited from same source population?YesBoth groups recruited over same time period?Yes% completed treatmentNR | Attempt to mask outcome assessors?NoDifferences between groups taken into account in statistical analysis?YesConfounding adequately accounted for either through study design or statistical analysis?No | Overall attrition ≥20%?NRDifferential attrition ≥15%?NR | I/E criteria equally applied in both groups?YesTime of follow-up equal in both groups?Yes | Outcome measures equal, valid and reliable?NoMethod of Handling DropoutsOtherAny participants who started the trial excluded from analysis?Unclear | HighAttrition rates and method of handling dropouts NR. PTSD measure piloted for this study, but no validity data provided. Only one statistically significant baseline difference (illiteracy) taken into account in statistical analysis. Outcome assessors not blinded. |

Abbreviations: COPD = chronic obstructive pulmonary disease; EMDR = Eye movement desensitization and reprocessing therapy; G = group; I/E = inclusion/exclusion; N = number of participants; NR = not reported; PTSD = posttraumatic stress disorder; RCT = randomized controlled trial