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, 199822  Prospective study design?  No | Groups recruited from same source population?  Yes  Both groups recruited over same time period?  Yes  % completed treatment  100% | Attempt to mask outcome assessors?  Yes  Differences between groups taken into account in statistical analysis?  Yes  Confounding adequately accounted for either through study design or statistical analysis?  Yes | Overall attrition ≥20%?  No  Differential attrition ≥15%?  No | I/E criteria equally applied in both groups?  Yes  Time of follow-up equal in both groups?  Yes | Outcome measures equal, valid and reliable?  Yes  Method of Handling Dropouts  NA  Any participants who started the trial excluded from analysis?  No | High  Risk 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, 200123  Prospective study design?  Yes | Groups recruited from same source population?  No  Both groups recruited over same time period?  Yes  % completed treatment  NR | Attempt to mask outcome assessors?  Unclear  Differences between groups taken into account in statistical analysis?  Unclear  Confounding adequately accounted for either through study design or statistical analysis?  Unclear | Overall attrition ≥20%?  NR  Differential attrition ≥15%?  NR | I/E criteria equally applied in both groups?  Unclear  Time of follow-up equal in both groups?  Yes | Outcome measures equal, valid and reliable?  Yes  Method of Handling Dropouts  NA  Any participants who started the trial excluded from analysis?  NR | High  Cohort 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, 199524  Prospective study design?  Yes | Groups recruited from same source population?  Yes  Both groups recruited over same time period?  Yes  % completed treatment  100% | Attempt to mask outcome assessors?  Yes  Differences between groups taken into account in statistical analysis?  Yes  Confounding adequately accounted for either through study design or statistical analysis?  No | Overall attrition ≥20%?  NR  Differential attrition ≥15%?  NR | I/E criteria equally applied in both groups?  Yes  Time of follow-up equal in both groups?  Yes | Outcome measures equal, valid and reliable?  Yes  Method of Handling Dropouts  Unclear  Any participants who started the trial excluded from analysis?  No | High  Nonrandomized 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, 201025  Prospective study design?  Yes | Groups recruited from same source population?  Yes  Both groups recruited over same time period?  Yes  % completed treatment  100% | Attempt to mask outcome assessors?  NR  Differences between groups taken into account in statistical analysis?  Yes  Confounding adequately accounted for either through study design or statistical analysis?  Unclear | Overall attrition ≥20%?  Yes  Differential attrition ≥15%?  Yes | I/E criteria equally applied in both groups?  Yes  Time of follow-up equal in both groups?  Yes | Outcome measures equal, valid and reliable?  Yes  Method of Handling Dropouts  Unclear  Any participants who started the trial excluded from analysis?  No | High  Nonrandomized 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, 199626  Prospective study design?  Yes | Groups recruited from same source population?  Yes  Both groups recruited over same time period?  Yes  % completed treatment  Overall: NA  G1: 69%  G2: NA | Attempt to mask outcome assessors?  Unclear  Differences between groups taken into account in statistical analysis?  Yes  Confounding adequately accounted for either through study design or statistical analysis?  No | Overall attrition ≥20%?  NR  Differential attrition ≥15%?  NR | I/E criteria equally applied in both groups?  Yes  Time of follow-up equal in both groups?  Yes | Outcome measures equal, valid and reliable?  Yes  Method of Handling Dropouts  Unclear  Any participants who started the trial excluded from analysis?  Unclear | High  Unclear 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, 199721  Prospective study design?  Yes | Groups recruited from same source population?  Yes  Both groups recruited over same time period?  Yes  % completed treatment  NR | Attempt to mask outcome assessors?  Unclear  Differences between groups taken into account in statistical analysis?  NA  Confounding adequately accounted for either through study design or statistical analysis?  Unclear | Overall attrition ≥20%?  NR  Differential attrition ≥15%?  NR | I/E criteria equally applied in both groups?  Yes  Time of follow-up equal in both groups?  Yes | Outcome measures equal, valid and reliable?  Mixed  Method of Handling Dropouts  NA  Any participants who started the trial excluded from analysis?  Unclear | High  Only 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, 200527  Prospective study design?  Yes | Groups recruited from same source population?  No  Both groups recruited over same time period?  No  % completed treatment  NR | Attempt to mask outcome assessors?  Unclear  Differences between groups taken into account in statistical analysis?  Yes  Confounding adequately accounted for either through study design or statistical analysis?  Unclear | Overall attrition ≥20%?  NR  Differential attrition ≥15%?  NR | I/E criteria equally applied in both groups?  Yes  Time of follow-up equal in both groups?  Unclear | Outcome measures equal, valid and reliable?  Yes  Method of Handling Dropouts  NR  Any participants who started the trial excluded from analysis?  Unclear | High  No baseline PTSD data collected. Information about attrition, ITT, blinding, or confounding largely unavailable. |
| Krauseneck, 201028  Prospective study design?  Yes | Groups recruited from same source population?  Yes  Both groups recruited over same time period?  Yes  % completed treatment  Overall: 84%  G1: NR  G2: NR | Attempt to mask outcome assessors?  Unclear  Differences between groups taken into account in statistical analysis?  Yes  Confounding adequately accounted for either through study design or statistical analysis?  Yes | Overall attrition ≥20%?  No  Differential attrition ≥15%?  NR | I/E criteria equally applied in both groups?  Yes  Time of follow-up equal in both groups?  Yes | Outcome measures equal, valid and reliable?  Yes  Method of Handling Dropouts  NR  Any participants who started the trial excluded from analysis?  No | High  High 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, 201129  Prospective study design?  Yes | Groups recruited from same source population?  Yes  Both groups recruited over same time period?  Yes  % completed treatment  NR | Attempt to mask outcome assessors?  Unclear  Differences between groups taken into account in statistical analysis?  Unclear  Confounding adequately accounted for either through study design or statistical analysis?  Unclear | Overall attrition ≥20%?  NR  Differential attrition ≥15%?  NR | I/E criteria equally applied in both groups?  No  Time of follow-up equal in both groups?  Yes | Outcome measures equal, valid and reliable?  Yes  Method of Handling Dropouts  NA  Any participants who started the trial excluded from analysis?  Unclear | High  Not 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, 201130  Prospective study design?  No | Groups recruited from same source population?  Yes  Both groups recruited over same time period?  No  % completed treatment  NR | Attempt to mask outcome assessors?  No  Differences between groups taken into account in statistical analysis?  Yes  Confounding adequately accounted for either through study design or statistical analysis?  No | Overall attrition ≥20%?  Yes  Differential attrition ≥15%?  Yes | I/E criteria equally applied in both groups?  Yes  Time of follow-up equal in both groups?  Yes | Outcome measures equal, valid and reliable?  Yes  Method of Handling Dropouts  NA  Any participants who started the trial excluded from analysis?  NR | High  Nonrandomizated study with high overall (44%) and differential (16%) attrition. Study groups evaluated at two different time periods.  Outcome assessment not blinded. |
| Richards, 200131  Prospective study design?  Yes | Groups recruited from same source population?  Yes  Both groups recruited over same time period?  Unclear  % completed treatment  NR | Attempt to mask outcome assessors?  No  Differences between groups taken into account in statistical analysis?  No  Confounding adequately accounted for either through study design or statistical analysis?  No | Overall attrition ≥20%?  Yes  Differential attrition ≥15%?  No | I/E criteria equally applied in both groups?  Yes  Time of follow-up equal in both groups?  Yes | Outcome measures equal, valid and reliable?  Yes  Method of Handling Dropouts  Completers analysis  Any participants who started the trial excluded from analysis?  Unclear | High  High 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, 200832  Prospective study design?  Yes | Groups recruited from same source population?  Yes  Both groups recruited over same time period?  No  % completed treatment  100% | Attempt to mask outcome assessors?  Unclear  Differences between groups taken into account in statistical analysis?  NR  Confounding adequately accounted for either through study design or statistical analysis?  No | Overall attrition ≥20%?  Yes  Differential attrition ≥15%?  No | I/E criteria equally applied in both groups?  Yes  Time of follow-up equal in both groups?  Yes | Outcome measures equal, valid and reliable?  Yes  Method of Handling Dropouts  Completers analysis  Any participants who started the trial excluded from analysis?  NR | High  Nonrandomized 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, 200333  Prospective study design?  Yes | Groups recruited from same source population?  Yes  Both groups recruited over same time period?  Yes  % completed treatment  Overall: 89%  G1: 81%  G2: 100% | Attempt to mask outcome assessors?  Yes  Differences between groups taken into account in statistical analysis?  Yes  Confounding adequately accounted for either through study design or statistical analysis?  No | Overall attrition ≥20%?  NR  Differential attrition ≥15%?  NR | I/E criteria equally applied in both groups?  Yes  Time of follow-up equal in both groups?  Yes | Outcome measures equal, valid and reliable?  Yes  Method of Handling Dropouts  NA  Any participants who started the trial excluded from analysis?  NR | High  Attrition 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, 200834  Prospective study design?  Yes | Groups recruited from same source population?  Yes  Both groups recruited over same time period?  Yes  % completed treatment  NR | Attempt to mask outcome assessors?  No  Differences between groups taken into account in statistical analysis?  Yes  Confounding adequately accounted for either through study design or statistical analysis?  No | Overall attrition ≥20%?  NR  Differential attrition ≥15%?  NR | I/E criteria equally applied in both groups?  Yes  Time of follow-up equal in both groups?  Yes | Outcome measures equal, valid and reliable?  No  Method of Handling Dropouts  Other  Any participants who started the trial excluded from analysis?  Unclear | High  Attrition 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