|  |
| --- |
| **Table 1: The ORBIT classification system for missing or complete outcome reporting in benefit outcomes** |
| **Classification** | **Description** | **Level of reporting** | **Risk of bias\*** |
| ***Clear that the outcome was measured and analysed*** |
| **A** | Trial report states that outcome was analysed but only reports that result was not significant (typically stating p-value>0.05). | Partial | High Risk |
| **B** | Trial report states that outcome was analysed but only reports that result was significant (typically stating p-value<0.05). | Partial | No Risk |
| **C** | Trial report states that outcome was analysed but insufficient data were presented for the trial to be included in meta-analysis or to be considered to be fully tabulated. | Partial | Low Risk |
| **D** | Trial report states that outcome was analysed but no results reported. | None | High Risk |
| ***Clear that the outcome was measured*** |
| **E** | Clear that the outcome was measured. Judgment says outcome ***likely*** to have been analysed but not reported because of non-significant results. | None | High Risk |
| **F** | Clear that the outcome was measured. Judgment says outcome ***unlikely*** to have been analysed. | None | Low Risk |
| ***Unclear whether the outcome was measured*** |
| **G** | Not mentioned but clinical judgment says likely to have been measured and analysed but not reported on the basis of non-significant results. | None | High Risk |
| **H** | Not mentioned but clinical judgment says unlikely to have been measured at all. | None | Low Risk |
| ***Clear that the outcome was not measured*** |
| **I** | Clear that the outcome was not measured. | NA | No Risk |

\*Risk of bias arising from the lack of inclusion of non-significant results when a trial was excluded from a meta-analysis or not fully reported in a review because the data were unavailable.

|  |  |
| --- | --- |
| **Table 2: The ORBIT II classification system for missing or complete outcome reporting in harm outcomes** |  |
| **Classification** | **Description** | **Level of reporting** | **Risk of bias\*** |
| **Explicit specific harm outcome: measured and compared across treatment****groups** |  |  |
| **P1** | States outcome analysed but reported only that p-value>0.05. | Partial | High Risk |
| **P2** | States outcome analysed but reported only that p-value<0.05. | Partial | High Risk |
| **P3** | Insufficient reporting for meta-analysis or full tabulation. | Partial | Low Risk |
| **Explicit specific harm outcome: measured but not compared across****treatment groups** |  |  |
| **Q** | Clear that outcome was measured and clear outcome was not compared. | NA | No risk |
| **Explicit specific harm outcome: measured, not clear whether compared or****not across treatment groups** |  |  |
| **R1** | Clear that outcome was measured but no results reported. | None | High Risk |
| **R2** | Result reported globally across all groups. | None | High Risk |
| **R3** | Result reported from some groups only. | None | High Risk |
| **Specific harm outcome not explicitly mentioned: clinical judgment says likely measured and likely compared across treatment groups** |  |  |
| **S1** | Only pooled adverse events reported (could include specific harm outcome). | None | High Risk |
| **S2** | No harms mentioned or reported.  | None | High Risk |
| **Specific harm outcome not explicitly mentioned: clinical judgment says likely measured but no events** |  |  |
| **T1** | Specific harm not mentioned but all other specific harms fully reported. | None | Low Risk |
| **T2** | No description of specific harms. | None | Low Risk |
| **Specific harm outcome not explicitly mentioned, clinical judgment says unlikely measured** |  |  |
| **U** | No harms mentioned or reported. | None | Low Risk |
| **Explicit the specific harm outcome was not measured** |  |  |
| **V** | Report clearly specifies that data on the specific harm of interest was not measured. | NA | No Risk |

\*Bias would occur if specific harm had been measured, but data were presented or suppressed in a way that would mask the harm profile of particular interventions.

**Table 3 Outcome matrix for epilepsy review with ORBIT classifications**

| Study ID(author, date of publication) |  |  | Review primary benefit outcome | Review secondary outcomes | Review harm outcomes |
| --- | --- | --- | --- | --- | --- |
| Sample size (Topiramate)  | Sample Size (Placebo)  | 50% reduction in seizure frequency | Seizure freedom | Treatment withdrawal\* | Dizziness | Headache | Nausea/vomiting | Paraesthesias | Weight loss | Fatigue | Somnolence | Concentration impairment | Speech difficulty | Thinking abnormally | Ataxia |
| Ben-Menachem 1996 | 28 | 28 | http://ctrc.liv.ac.uk/orbit/assets/images/icons/tick.png | http://ctrc.liv.ac.uk/orbit/assets/images/icons/cross.pngE | http://ctrc.liv.ac.uk/orbit/assets/images/icons/tick.png | http://ctrc.liv.ac.uk/orbit/assets/images/icons/tick.png | http://ctrc.liv.ac.uk/orbit/assets/images/icons/tick.png | http://ctrc.liv.ac.uk/orbit/assets/images/icons/cross.pngR1 | http://ctrc.liv.ac.uk/orbit/assets/images/icons/tick.png | http://ctrc.liv.ac.uk/orbit/assets/images/icons/tick.png | http://ctrc.liv.ac.uk/orbit/assets/images/icons/tick.png | http://ctrc.liv.ac.uk/orbit/assets/images/icons/cross.pngR1 | http://ctrc.liv.ac.uk/orbit/assets/images/icons/tick.png | http://ctrc.liv.ac.uk/orbit/assets/images/icons/cross.pngR1 | http://ctrc.liv.ac.uk/orbit/assets/images/icons/cross.pngR1 | http://ctrc.liv.ac.uk/orbit/assets/images/icons/cross.pngR1 |
| Elterman 1999 | 41 | 45 | http://ctrc.liv.ac.uk/orbit/assets/images/icons/tick.png | http://ctrc.liv.ac.uk/orbit/assets/images/icons/tick.png | http://ctrc.liv.ac.uk/orbit/assets/images/icons/tick.png | http://ctrc.liv.ac.uk/orbit/assets/images/icons/cross.pngR1 | http://ctrc.liv.ac.uk/orbit/assets/images/icons/cross.png R1 | http://ctrc.liv.ac.uk/orbit/assets/images/icons/cross.png R1 | http://ctrc.liv.ac.uk/orbit/assets/images/icons/cross.png R1 | http://ctrc.liv.ac.uk/orbit/assets/images/icons/tick.png | http://ctrc.liv.ac.uk/orbit/assets/images/icons/tick.png | http://ctrc.liv.ac.uk/orbit/assets/images/icons/tick.png | http://ctrc.liv.ac.uk/orbit/assets/images/icons/tick.png | http://ctrc.liv.ac.uk/orbit/assets/images/icons/cross.png R1 | http://ctrc.liv.ac.uk/orbit/assets/images/icons/cross.png R1 | http://ctrc.liv.ac.uk/orbit/assets/images/icons/cross.png R1 |
| Faught 1996 | 136 | 45 | http://ctrc.liv.ac.uk/orbit/assets/images/icons/tick.png | http://ctrc.liv.ac.uk/orbit/assets/images/icons/cross.pngE | http://ctrc.liv.ac.uk/orbit/assets/images/icons/tick.png | http://ctrc.liv.ac.uk/orbit/assets/images/icons/tick.png | http://ctrc.liv.ac.uk/orbit/assets/images/icons/tick.png | http://ctrc.liv.ac.uk/orbit/assets/images/icons/cross.pngR1 | http://ctrc.liv.ac.uk/orbit/assets/images/icons/tick.png | http://ctrc.liv.ac.uk/orbit/assets/images/icons/cross.pngR1 | http://ctrc.liv.ac.uk/orbit/assets/images/icons/tick.png | http://ctrc.liv.ac.uk/orbit/assets/images/icons/tick.png | http://ctrc.liv.ac.uk/orbit/assets/images/icons/cross.pngR1 | http://ctrc.liv.ac.uk/orbit/assets/images/icons/cross.pngR1 | http://ctrc.liv.ac.uk/orbit/assets/images/icons/tick.png | http://ctrc.liv.ac.uk/orbit/assets/images/icons/tick.png |
| Guberman 2002 | 171 | 92 | http://ctrc.liv.ac.uk/orbit/assets/images/icons/tick.png | http://ctrc.liv.ac.uk/orbit/assets/images/icons/tick.png | http://ctrc.liv.ac.uk/orbit/assets/images/icons/tick.png | http://ctrc.liv.ac.uk/orbit/assets/images/icons/tick.png | http://ctrc.liv.ac.uk/orbit/assets/images/icons/cross.pngR1 | http://ctrc.liv.ac.uk/orbit/assets/images/icons/cross.pngR1 | http://ctrc.liv.ac.uk/orbit/assets/images/icons/tick.png | http://ctrc.liv.ac.uk/orbit/assets/images/icons/tick.png | http://ctrc.liv.ac.uk/orbit/assets/images/icons/tick.png | http://ctrc.liv.ac.uk/orbit/assets/images/icons/tick.png | http://ctrc.liv.ac.uk/orbit/assets/images/icons/tick.png | http://ctrc.liv.ac.uk/orbit/assets/images/icons/cross.pngR1 | http://ctrc.liv.ac.uk/orbit/assets/images/icons/cross.pngR1 | http://ctrc.liv.ac.uk/orbit/assets/images/icons/cross.pngR1 |
| Korean 1999 | 91 | 86 | http://ctrc.liv.ac.uk/orbit/assets/images/icons/tick.png | http://ctrc.liv.ac.uk/orbit/assets/images/icons/tick.png | http://ctrc.liv.ac.uk/orbit/assets/images/icons/tick.png | http://ctrc.liv.ac.uk/orbit/assets/images/icons/tick.png | http://ctrc.liv.ac.uk/orbit/assets/images/icons/tick.png | http://ctrc.liv.ac.uk/orbit/assets/images/icons/tick.png | http://ctrc.liv.ac.uk/orbit/assets/images/icons/cross.pngR1 | http://ctrc.liv.ac.uk/orbit/assets/images/icons/tick.png | http://ctrc.liv.ac.uk/orbit/assets/images/icons/cross.pngR1 | http://ctrc.liv.ac.uk/orbit/assets/images/icons/tick.png | http://ctrc.liv.ac.uk/orbit/assets/images/icons/cross.pngR1 | http://ctrc.liv.ac.uk/orbit/assets/images/icons/tick.png | http://ctrc.liv.ac.uk/orbit/assets/images/icons/cross.pngR1 | http://ctrc.liv.ac.uk/orbit/assets/images/icons/tick.png |
| Privitera 1996 | 143 | 47 | http://ctrc.liv.ac.uk/orbit/assets/images/icons/tick.png | http://ctrc.liv.ac.uk/orbit/assets/images/icons/cross.pngE | http://ctrc.liv.ac.uk/orbit/assets/images/icons/tick.png | http://ctrc.liv.ac.uk/orbit/assets/images/icons/tick.png | http://ctrc.liv.ac.uk/orbit/assets/images/icons/tick.png | http://ctrc.liv.ac.uk/orbit/assets/images/icons/cross.pngR1 | http://ctrc.liv.ac.uk/orbit/assets/images/icons/tick.png | http://ctrc.liv.ac.uk/orbit/assets/images/icons/cross.pngQ | http://ctrc.liv.ac.uk/orbit/assets/images/icons/tick.png | http://ctrc.liv.ac.uk/orbit/assets/images/icons/tick.png | http://ctrc.liv.ac.uk/orbit/assets/images/icons/tick.png | http://ctrc.liv.ac.uk/orbit/assets/images/icons/cross.pngR1 | http://ctrc.liv.ac.uk/orbit/assets/images/icons/tick.png | http://ctrc.liv.ac.uk/orbit/assets/images/icons/tick.png |
| Rosenfeld 1996 | 167 | 42 | http://ctrc.liv.ac.uk/orbit/assets/images/icons/tick.png | http://ctrc.liv.ac.uk/orbit/assets/images/icons/circle.pngC | http://ctrc.liv.ac.uk/orbit/assets/images/icons/tick.png | http://ctrc.liv.ac.uk/orbit/assets/images/icons/tick.png | http://ctrc.liv.ac.uk/orbit/assets/images/icons/cross.pngR1 | http://ctrc.liv.ac.uk/orbit/assets/images/icons/tick.png | http://ctrc.liv.ac.uk/orbit/assets/images/icons/cross.pngR1 | http://ctrc.liv.ac.uk/orbit/assets/images/icons/cross.pngR1 | http://ctrc.liv.ac.uk/orbit/assets/images/icons/tick.png | http://ctrc.liv.ac.uk/orbit/assets/images/icons/tick.png | http://ctrc.liv.ac.uk/orbit/assets/images/icons/cross.pngR1 | http://ctrc.liv.ac.uk/orbit/assets/images/icons/cross.pngR1 | http://ctrc.liv.ac.uk/orbit/assets/images/icons/tick.png | http://ctrc.liv.ac.uk/orbit/assets/images/icons/tick.png |
| Sharief 1996 | 23 | 24 | http://ctrc.liv.ac.uk/orbit/assets/images/icons/tick.png | http://ctrc.liv.ac.uk/orbit/assets/images/icons/tick.png | http://ctrc.liv.ac.uk/orbit/assets/images/icons/tick.png | http://ctrc.liv.ac.uk/orbit/assets/images/icons/cross.pngR1 | http://ctrc.liv.ac.uk/orbit/assets/images/icons/tick.png | http://ctrc.liv.ac.uk/orbit/assets/images/icons/cross.pngR1 | http://ctrc.liv.ac.uk/orbit/assets/images/icons/cross.pngR1 | http://ctrc.liv.ac.uk/orbit/assets/images/icons/tick.png | http://ctrc.liv.ac.uk/orbit/assets/images/icons/tick.png | http://ctrc.liv.ac.uk/orbit/assets/images/icons/tick.png | http://ctrc.liv.ac.uk/orbit/assets/images/icons/tick.png | http://ctrc.liv.ac.uk/orbit/assets/images/icons/tick.png | http://ctrc.liv.ac.uk/orbit/assets/images/icons/cross.pngR1 | http://ctrc.liv.ac.uk/orbit/assets/images/icons/cross.pngR1 |
| Tassinari 1996 | 30 | 30 | http://ctrc.liv.ac.uk/orbit/assets/images/icons/tick.png | http://ctrc.liv.ac.uk/orbit/assets/images/icons/tick.png | http://ctrc.liv.ac.uk/orbit/assets/images/icons/tick.png | http://ctrc.liv.ac.uk/orbit/assets/images/icons/tick.png | http://ctrc.liv.ac.uk/orbit/assets/images/icons/tick.png | http://ctrc.liv.ac.uk/orbit/assets/images/icons/tick.png | http://ctrc.liv.ac.uk/orbit/assets/images/icons/cross.pngR1 | http://ctrc.liv.ac.uk/orbit/assets/images/icons/tick.png | http://ctrc.liv.ac.uk/orbit/assets/images/icons/tick.png | http://ctrc.liv.ac.uk/orbit/assets/images/icons/tick.png | http://ctrc.liv.ac.uk/orbit/assets/images/icons/tick.png | http://ctrc.liv.ac.uk/orbit/assets/images/icons/cross.pngR1 | http://ctrc.liv.ac.uk/orbit/assets/images/icons/tick.png | http://ctrc.liv.ac.uk/orbit/assets/images/icons/cross.pngR1 |
| Yen 2000 | 23 | 23 | http://ctrc.liv.ac.uk/orbit/assets/images/icons/tick.png | http://ctrc.liv.ac.uk/orbit/assets/images/icons/cross.pngE | http://ctrc.liv.ac.uk/orbit/assets/images/icons/tick.png | http://ctrc.liv.ac.uk/orbit/assets/images/icons/cross.pngS1 | http://ctrc.liv.ac.uk/orbit/assets/images/icons/tick.png | http://ctrc.liv.ac.uk/orbit/assets/images/icons/tick.png | http://ctrc.liv.ac.uk/orbit/assets/images/icons/tick.png | http://ctrc.liv.ac.uk/orbit/assets/images/icons/tick.png | http://ctrc.liv.ac.uk/orbit/assets/images/icons/cross.pngT1 | http://ctrc.liv.ac.uk/orbit/assets/images/icons/cross.pngS1 | http://ctrc.liv.ac.uk/orbit/assets/images/icons/cross.pngT1 | http://ctrc.liv.ac.uk/orbit/assets/images/icons/cross.pngT1 | http://ctrc.liv.ac.uk/orbit/assets/images/icons/cross.pngT1 | http://ctrc.liv.ac.uk/orbit/assets/images/icons/cross.pngT1 |
| Zhang 2011 | 46 | 40 | http://ctrc.liv.ac.uk/orbit/assets/images/icons/tick.png | http://ctrc.liv.ac.uk/orbit/assets/images/icons/tick.png | http://ctrc.liv.ac.uk/orbit/assets/images/icons/tick.png | http://ctrc.liv.ac.uk/orbit/assets/images/icons/cross.pngS1 | http://ctrc.liv.ac.uk/orbit/assets/images/icons/tick.png | http://ctrc.liv.ac.uk/orbit/assets/images/icons/cross.pngT1 | http://ctrc.liv.ac.uk/orbit/assets/images/icons/tick.png | http://ctrc.liv.ac.uk/orbit/assets/images/icons/tick.png | http://ctrc.liv.ac.uk/orbit/assets/images/icons/tick.png | http://ctrc.liv.ac.uk/orbit/assets/images/icons/cross.pngT1 | http://ctrc.liv.ac.uk/orbit/assets/images/icons/cross.pngT1 | http://ctrc.liv.ac.uk/orbit/assets/images/icons/tick.png | http://ctrc.liv.ac.uk/orbit/assets/images/icons/cross.pngT1 | http://ctrc.liv.ac.uk/orbit/assets/images/icons/cross.pngT1 |
| Excluded Study: Reason for exclusion “did not look at the outcome of interest: 50% or greater reduction in seizure frequency, treatment withdrawal or side effects.” |
| Coles 1999 | 52 | 51 | http://ctrc.liv.ac.uk/orbit/assets/images/icons/cross.pngE | http://ctrc.liv.ac.uk/orbit/assets/images/icons/cross.pngE | http://ctrc.liv.ac.uk/orbit/assets/images/icons/cross.pngG | http://ctrc.liv.ac.uk/orbit/assets/images/icons/cross.pngS2 | http://ctrc.liv.ac.uk/orbit/assets/images/icons/cross.pngS2 | http://ctrc.liv.ac.uk/orbit/assets/images/icons/cross.pngS2 | http://ctrc.liv.ac.uk/orbit/assets/images/icons/cross.pngS2 | http://ctrc.liv.ac.uk/orbit/assets/images/icons/cross.pngS2 | http://ctrc.liv.ac.uk/orbit/assets/images/icons/cross.pngS2 | http://ctrc.liv.ac.uk/orbit/assets/images/icons/cross.pngS2 | http://ctrc.liv.ac.uk/orbit/assets/images/icons/cross.pngS2 | http://ctrc.liv.ac.uk/orbit/assets/images/icons/cross.pngS2 | http://ctrc.liv.ac.uk/orbit/assets/images/icons/cross.pngS2 | http://ctrc.liv.ac.uk/orbit/assets/images/icons/cross.pngS2 |

\* In epilepsy, treatment withdrawal reflects both benefit/harm, i.e. withdrawal from treatment due to recurrent seizures on treatment (lack of benefit) and/or withdrawal due to adverse events (harm).

 indicates full reporting  indicates not reported – not clear whether measured or not  indicates partial reporting  not measured