**Supplemental Digital Content 1: JBI critical appraisal tool for randomized controlled trials**

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **RoB Assessor:** | | | | | | **Date of Appraisal:** | | | **Record Number:** | | | | | | | | | | | | |
| **Study Author:** | | | | | | **Study Title:** | | | **Study Year:** | | | | | | | | | | | | |
|  | | | | | |  | | |  | | | | | | | | | | | | |
| **Internal Validity** | | | | | | | | **Choice - Comments/Justification** | | **Yes** | **No** | | | **Unclear** | | | | **N/A** | | | |
| **Bias related to selection and allocation** | | | | | | | | | | | | | | | | | | | | | |
| **1** | **Was true randomization used for assignment of participants to treatment groups?** | | | | | | |  | |  |  | | |  | | | |  | | | |
| **2** | **Was allocation to treatment groups concealed?** | | | | | | |  | |  |  | | |  | | | |  | | | |
| **3** | **Were treatment groups similar at the baseline?** | | | | | | |  | |  |  | | |  | | | |  | | | |
| **Bias related to administration of intervention/exposure** | | | | | | | | | | | | | | | | | | | | | |
| **4** | **Were participants blind to treatment assignment?** | | | | | | |  | |  |  | | |  | | | |  | | | |
| **5** | **Were those delivering the treatment blind to treatment assignment?** | | | | | | |  | |  |  | | |  | | | |  | | | |
| **6** | **Were treatment groups treated identically other than the intervention of interest?** | | | | | | |  | |  |  | | |  | | | |  | | | |
| **Bias related to assessment, detection and measurement of the outcome** | | | | | | | | | | | | | | | | | | | | | |
| **7** | **Were outcome assessors blind to treatment assignment?** | | | | | | |  | | **Yes** | **No** | | | **Unclear** | | | | **N/A** | | | |
|  | **Outcome 1** | | | | | | |  | |  |  | | |  | | | |  | | | |
|  | **Outcome 2** | | | | | | |  | |  |  | | |  | | | |  | | | |
|  | **Outcome 3** | | | | | | |  | |  |  | | |  | | | |  | | | |
|  | **Outcome 4** | | | | | | |  | |  |  | | |  | | | |  | | | |
|  | **Outcome 5** | | | | | | |  | |  |  | | |  | | | |  | | | |
|  | **Outcome 6** | | | | | | |  | |  |  | | |  | | | |  | | | |
|  | **Outcome 7** | | | | | | |  | |  |  | | |  | | | |  | | | |
|  |  | | | | | | |  | |  |  | | |  | | | |  | | | |
| **8** | **Were outcomes measured in the same way for treatment groups?** | | | | | | |  | | **Yes** | **No** | | | **Unclear** | | | | **N/A** | | | |
|  | **Outcome 1** | | | | | | |  | |  |  | | |  | | | |  | | | |
|  | **Outcome 2** | | | | | | |  | |  |  | | |  | | | |  | | | |
|  | **Outcome 3** | | | | | | |  | |  |  | | |  | | | |  | | | |
|  | **Outcome 4** | | | | | | |  | |  |  | | |  | | | |  | | | |
|  | **Outcome 5** | | | | | | |  | |  |  | | |  | | | |  | | | |
|  | **Outcome 6** | | | | | | |  | |  |  | | |  | | | |  | | | |
|  | **Outcome 7** | | | | | | |  | |  |  | | |  | | | |  | | | |
|  |  | | | | | | |  | |  |  | | |  | | | |  | | | |
| **9** | **Were outcomes measured in a reliable way** | | | | | | |  | | **Yes** | **No** | | | **Unclear** | | | | **N/A** | | | |
|  | **Outcome 1** | | | | | | |  | |  |  | | |  | | | |  | | | |
|  | **Outcome 2** | | | | | | |  | |  |  | | |  | | | |  | | | |
|  | **Outcome 3** | | | | | | |  | |  |  | | |  | | | |  | | | |
|  | **Outcome 4** | | | | | | |  | |  |  | | |  | | | |  | | | |
|  | **Outcome 5** | | | | | | |  | |  |  | | |  | | | |  | | | |
|  | **Outcome 6** | | | | | | |  | |  |  | | |  | | | |  | | | |
|  | **Outcome 7** | | | | | | |  | |  |  | | |  | | | |  | | | |
|  |  | | | | | | |  | |  | | | | | | | | | | | |
| **Bias related to participant retention** | | | | | | | | | | | | | | | | | | | | | |
| **10** | **Was follow-up complete and if not, were differences between groups in terms of their follow-up adequately described and analyzed?** | | | | | | |  | |  | | | | | | | | | | | |
|  | **Outcome 1** | | | | | | |  | | **Yes** | **No** | | | | **Unclear** | | | **N/A** | | | |
|  |  | Result 1 | | | | | |  | |  |  | | |  | | | |  | | | |
|  |  | Result 2 | | | | | |  | |  |  | | |  | | | |  | | | |
|  |  | Result 3 | | | | | |  | |  |  | | |  | | | |  | | | |
|  | **Outcome 2** | | | | | | |  | | **Yes** | **No** | | | **Unclear** | | | | **N/A** | | | |
|  | Result 1 | | | | | |  | |  |  | | |  | | | |  | | | |
|  | Result 2 | | | | | |  | |  |  | | |  | | | |  | | | |
|  |  | Result 3 | | | | | |  | |  |  | | |  | | | |  | | | |
|  | **Outcome 3** | | | | | | |  | | **Yes** | **No** | | | **Unclear** | | | | **N/A** | | | |
|  |  | Result 1 | | | | | |  | |  |  | | |  | | | |  | | | |
|  |  | Result 2 | | | | | |  | |  |  | | |  | | | |  | | | |
|  |  | Result 3 | | | | | |  | |  |  | | |  | | | |  | | | |
|  | **Outcome 4** | | | | | | |  | | **Yes** | **No** | | | **Unclear** | | | | **N/A** | | | |
|  |  | Result 1 | | | | | |  | |  |  | | |  | | | |  | | | |
|  |  | Result 2 | | | | | |  | |  |  | | |  | | | |  | | | |
|  |  | Result 3 | | | | | |  | |  |  | | |  | | | |  | | | |
|  | **Outcome 5** | | | | | | |  | | **Yes** | **No** | | | **Unclear** | | | | **N/A** | | | |
|  |  | Result 1 | | | | | |  | |  |  | | |  | | | |  | | | |
|  |  | Result 2 | | | | | |  | |  |  | | |  | | | |  | | | |
|  |  | Result 3 | | | | | |  | |  |  | | |  | | | |  | | | |
|  | **Outcome 6** | | | | | | |  | | **Yes** | **No** | | | **Unclear** | | | | **N/A** | | | |
|  |  | Result 1 | | | | | |  | |  |  | | |  | | | |  | | | |
|  |  | Result 2 | | | | | |  | |  |  | | |  | | | |  | | | |
|  |  | Result 3 | | | | | |  | |  |  | | |  | | | |  | | | |
|  | **Outcome 7** | | | | | | |  | | **Yes** | **No** | | | **Unclear** | | | | **N/A** | | | |
|  |  | Result 1 | | | | | |  | |  |  | | |  | | | |  | | | |
|  |  | Result 2 | | | | | |  | |  |  | | |  | | | |  | | | |
|  |  | Result 3 | | | | | |  | |  |  | | |  | | | |  | | | |
|  |  |  | | | | | | | |  |  | | |  | | | |  | | | |
|  | **Statistical Conclusion Validity** | | | | | | | | |  |  | | |  | | | |  | | | |
| **11** | **Were participants analyzed in the groups to which they were randomized?** | | | | | | |  | |  | | | | | | | | | | | |
|  | **Outcome 1** | | |  | | | |  | | **Yes** | **No** | | | **Unclear** | | | | **N/A** | | | |
|  |  | Result 1 | | | | | |  | |  |  | | |  | | | |  | | | |
|  |  | Result 2 | | | | | |  | |  |  | | |  | | | |  | | | |
|  |  | Result 3 | | | | | |  | |  |  | | |  | | | |  | | | |
|  | **Outcome 2** | | |  | | | |  | | **Yes** | **No** | | | **Unclear** | | | | **N/A** | | | |
|  |  | Result 1 | | | | | |  | |  |  | | |  | | | |  | | | |
|  |  | Result 2 | | | | | |  | |  |  | | |  | | | |  | | | |
|  |  | Result 3 | | | | | |  | |  |  | | |  | | | |  | | | |
|  | **Outcome 3** | | |  | | | |  | | **Yes** | **No** | | | **Unclear** | | | | **N/A** | | | |
|  |  | Result 1 | | | | | |  | |  |  | | |  | | | |  | | | |
|  |  | Result 2 | | | | | |  | |  |  | | |  | | | |  | | | |
|  |  | Result 3 | | | | | |  | |  |  | | | | |  | | |  | | |
|  | **Outcome 4** | | | | | | |  | | **Yes** | **No** | | | | | **Unclear** | | | **N/A** | | |
|  |  | Result 1 | | | | | |  | |  |  | | | | |  | | |  | | |
|  |  | Result 2 | | | | | |  | |  |  | | | | |  | | |  | | |
|  |  | Result 3 | | | | | |  | |  |  | | | | |  | | |  | | |
|  | **Outcome 5** | | | | | | |  | | **Yes** | **No** | | | | | **Unclear** | | | **N/A** | | |
|  |  | Result 1 | | | | | |  | |  |  | | | | |  | | |  | | |
|  |  | Result 2 | | | | | |  | |  |  | | | | |  | | |  | | |
|  |  | Result 3 | | | | | |  | |  |  | | | | |  | | |  | | |
|  | **Outcome 6** | | | | | | |  | | **Yes** | **No** | | | | | **Unclear** | | | **N/A** | | |
|  |  | Result 1 | | | | | |  | |  |  | | | | |  | | |  | | |
|  |  | Result 2 | | | | | |  | |  |  | | | | |  | | |  | | |
|  |  | Result 3 | | | | | |  | |  |  | | | | |  | | |  | | |
|  | **Outcome 7** | | | | | | |  | | **Yes** | | **No** | | | | | **Unclear** | | **N/A** | | |
|  | Result 1 | | | | | |  | |  | |  | | | | |  | |  | | |
|  | Result 2 | | | | | |  | |  | |  | | | | |  | |  | | |
|  |  | Result 3 | | | | | |  | |  | |  | | | | |  | |  | | |
|  |  | | | | | | | | |  | |  | | | | |  | |  | | |
| **12** | **Was appropriate statistical analysis used?** | | | | | | |  | |  | |  | | | | |  | |  | | |
|  | **Outcome 1** | | | | | | |  | | **Yes** | | **No** | | | | | **Unclear** | | **N/A** | | |
|  |  | Result 1 | | | | | |  | |  | |  | | | | |  | |  | | |
|  |  | Result 2 | | | | | |  | |  | |  | | | |  | | | |  | |
|  |  | Result 3 | | | | | |  | |  | |  | | | |  | | | |  | |
|  | **Outcome 2** | | | | | | |  | | **Yes** | | **No** | | | | **Unclear** | | | | **N/A** | |
|  |  | Result 1 | | | | | |  | |  | |  | | | |  | | | |  | |
|  |  | Result 2 | | | | | |  | |  | |  | | | |  | | | |  | |
|  |  | Result 3 | | | | | |  | |  | |  | | | |  | | | |  | |
|  | **Outcome 3** | | | | | | |  | | **Yes** | | **No** | | | | **Unclear** | | | | **N/A** | |
|  |  | Result 1 | | | | | |  | |  | |  | | | |  | | | |  | |
|  |  | Result 2 | | | | | |  | |  | |  | | | |  | | | |  | |
|  |  | Result 3 | | | | | |  | |  | |  | | | |  | | | |  | |
|  | **Outcome 4** | | | | | | |  | | **Yes** | | **No** | | | | **Unclear** | | | | **N/A** | |
|  |  | Result 1 | | | | | |  | |  | |  | | | |  | | | |  | |
|  |  | Result 2 | | | | | |  | |  | |  | | | |  | | | |  | |
|  |  | Result 3 | | | | | |  | |  | |  | | | |  | | | |  | |
|  | **Outcome 5** | | | | | | |  | | **Yes** | | **No** | | | | **Unclear** | | | | **N/A** | |
|  |  | Result 1 | | | | | |  | |  | |  | | | |  | | | |  | |
|  |  | Result 2 | | | | | |  | |  | |  | | | |  | | | |  | |
|  |  | Result 3 | | | | | |  | |  | |  | | | |  | | | |  | |
|  | **Outcome 6** | | | | | | |  | | **Yes** | | **No** | | | | **Unclear** | | | | **N/A** | |
|  |  | Result 1 | | | | | |  | |  | |  | | | |  | | | |  | |
|  |  | Result 2 | | | | | |  | |  | |  | | | |  | | | |  | |
|  |  | Result 3 | | | | | |  | |  | |  | | | |  | | | |  | |
|  | **Outcome 7** | | | | | | |  | | **Yes** | | **No** | | | | **Unclear** | | | | **N/A** | |
|  |  | Result 1 | | | | | |  | |  | |  | | | |  | | | |  | |
|  |  | Result 2 | | | | | |  | |  | |  | | | |  | | | |  | |
|  |  | Result 3 | | | | | |  | |  | |  | | | |  | | | |  | |
|  |  | | | | | | |  | |  | | |  | | |  | | | | |  |
|  |  | | | | | | |  | | **Yes** | | | **No** | | | **Unclear** | | | | | **N/A** |
| **13** | **Was the trial design appropriate and any deviations from the standard RCT design (individual randomization, parallel groups) accounted for in the conduct and analysis of the trial?** | | | | | | |  | |  | | |  | | |  | | | | |  |
| **Overall appraisal:** | | | **Include:** | | **Exclude:** | | **Seek Further Info:** | | | | | | | | | | | | | | |
| **Comments:** | | | | | | | | | | | | | | | | | | | | | |