**Randomized clinical trial evaluation checklist**

**Study identification** (*Include author, title, year of publication, journal title)*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Title and abstract** | | | | |
| **Statements** | **Yes** | **No** | **Not clear** | **Comments** |
| Identification as a randomised trial in the title |  |  |  |  |
| Structured summary of trial design, methods, results, and conclusions |  |  |  |  |
| **Introduction** | | | | |
| Scientific background and explanation of rationale |  |  |  |  |
| Specific objectives or hypotheses |  |  |  |  |
| **Methods** | | | | |
| Description of trial design (such as parallel, factorial) |  |  |  |  |
| Eligibility criteria for participants |  |  |  |  |
| Settings and locations where the data were collected |  |  |  |  |
| The interventions for each group with sufficient details, including how and when they were actually administered |  |  |  |  |
| Completely defined primary and secondary outcome measures, including how and when they were assessed |  |  |  |  |
| Method used to generate the random allocation sequence |  |  |  |  |
| Blindness after assignment to interventions |  |  |  |  |
| Statistical methods used to compare groups for primary and secondary outcomes |  |  |  |  |
| **Results** | | | | |
| For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analyzed for the primary outcome |  |  |  |  |
| For each group, losses and exclusions after randomisation, together with reasons |  |  |  |  |
| A table showing baseline demographic and clinical characteristics for each group |  |  |  |  |
| All important harms or unintended effects in each group |  |  |  |  |
| **Discussion** | | | | |
| Trial limitations, addressing sources of potential bias |  |  |  |  |
| **Other information** | | | | |
| Registration number and name of trial registry |  |  |  |  |
| Sources of funding and other support (such as supply of drugs), role of funders |  |  |  |  |
| References are satisfactory and updated |  |  |  |  |