Checklist for Thesis with randomized clinical trials. **Clinical trials consort**

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| **Yes/No/NA** |  | **page** |
| **Title and abstract** | | |
|  | Identification as a randomised trial in the title |  |
|  | Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts) |  |
| **Introduction** | | |
|  | Scientific background and explanation of rationale |  |
| **Objectives** | | |
|  | Specific objectives or hypotheses |  |
| **Methods** | | |
| Trial design | | |
|  | Description of trial design (such as parallel, factorial) including allocation ratio |  |
|  | Important changes to methods after trial commencement (such as eligibility criteria), with reasons |  |
| Participants | | |
|  | Eligibility criteria for participants |  |
|  | Settings and locations where the data were collected |  |
| Interventions | | |
|  | The interventions for each group with sufficient details to allow replication, including how and when they were actually administered |  |
| Results | | |
|  | Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed |  |
|  | Any changes to trial outcomes after the trial commenced, with reasons |  |
| Sample size | | |
|  | How sample size was determined |  |
|  | When applicable, explanation of any interim analyses and stopping guidelines |  |
| Randomization | | |
|  | Method used to generate the random allocation sequence |  |
|  | Type of randomisation; details of any restriction (such as blocking and block size) |  |
|  | Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned |  |
|  | Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions |  |
|  | If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how |  |
|  | If relevant, description of the similarity of interventions |  |
| Statistical methods | | |
|  | Statistical methods used to compare groups for primary and secondary outcomes |  |
|  | Methods for additional analyses, such as subgroup analyses and adjusted analyses |  |
| **Results** | | |
| Participants | | |
|  | For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome |  |
|  | For each group, losses and exclusions after randomisation, together with reasons |  |
|  | Consider the use of a flow diagram |  |
| Recruitment | | |
|  | Dates defining the periods of recruitment and follow-up |  |
|  | Why the trial ended or was stopped |  |
| Baseline data | | |
|  | A table showing baseline demographic and clinical characteristics for each group |  |
| Numbers analyzed | | |
|  | For each group, number of participants (denominator) included in each analysis and whether the analysis was  by original assigned groups |  |
| Outcomes and estimation | | |
|  | For each primary and secondary outcome, results for each group, and the estimated effect size and its  precision (such as 95% confidence interval) |  |
|  | For binary outcomes, presentation of both absolute and relative effect sizes is recommended |  |
| Ancillary analysis | | |
|  | Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing  pre-specified from exploratory |  |
| Harms | | |
|  | All important harms or unintended effects in each group (for specific guidance see CONSORT for harms) |  |
| **Discussion** | | |
| Limitations | | |
|  | Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses |  |
| Interpretation | | |
|  | Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence |  |
| Generalizability | | |
|  | Generalizability (external validity, applicability) of the trial findings |  |
| **Other information** | | |
|  | Registration number and name of trial registry |  |
|  | Where the full trial protocol can be accessed, if available |  |
|  | Sources of funding and other support (such as supply of drugs), role of funders |  |

Based on “the CONSORT 2010 Explanation and Elaboration” for randomized clinical trials.

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| PhD Student signature |
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