## Table1 Checklist for Reporting of Multi-Arm Parallel-Group Randomized Trials: Extension of the CONSORT 2010 Statement[a]

| Section/Topic | Item No | Item | Reported on Page Number/Line Number | Reported on Section/Paragraph |
|---|---|---|---|---|
| **Title and abstract** | | | | |
| | 1a | Identification as a multi-arm randomized trial in the title or an indication of the number of treatment groups that the participants were randomly assigned to | Page1,2/line2-4,31-32 | Title,Abstract/Para2 |
| | 1b | Structured summary of trial design, methods, results, and conclusions (for specific guidance see *Table 2*)<br>**(Specification of the number of treatment groups; details of any groups added or dropped)** | Page2/line26-47 | Abstract/Para1-4 |
| **Introduction** | | | | |
| Background and objectives | 2a | Scientific background and explanation of rationale<br>**(Rationale for using a multi-arm design)** | Page3/line51-74 | Introduction/Para1-2 |
| | 2b | Specific objectives or hypotheses<br>**(Specification of the research question referring to all of the treatment groups**<br>**Clear statement of all hypotheses to be tested and the primary comparisons involved)** | Page3,4/line74-76 | Introduction/Para2 |
| **Methods** | | | | |
| Trial design | 3a | Description of trial design (such as parallel, factorial) including allocation ratio<br>**(Specification of the number of treatment groups)** | Page4,5/line82-83,96-102 | Methods/Para1 |
| | 3b | Important changes to methods after trial commencement (such as eligibility criteria), with reasons<br>**(Details of any treatment groups added or dropped (if relevant), with reasons, and/or changes to the allocation ratio)** | N/A | N/A |
| Participants | 4a | Eligibility criteria for participants | Page4/line85-90 | Methods/Para1 |
| | 4b | Settings and locations where the data were collected | Page4/line83-85 | Methods/Para1 |
| Interventions | 5 | The interventions for each group with sufficient details to allow replication, including how and when they were actually administered | Page4,5/line83,96-108 | Methods/Para1,2 |
| Outcomes | 6a | Completely defined prespecified primary and secondary outcome measures, including how and when they were assessed | Page5,6/line108-138 | Methods/Para2,3 |
| | 6b | Any changes to trial outcomes after the trial commenced, with reasons | N/A | N/A |

| | | | | |
|---|---|---|---|---|
| Sample size | 7a | How sample size was determined<br>**(Planned sample size with details of how it was determined for each primary comparison)** | N/A | N/A |
| | 7b | When applicable, explanation of any interim analyses and stopping guidelines | N/A | N/A |
| Randomization: | | | | |
| Sequence generation | 8a | Method used to generate the random allocation sequence | Page4/line91-95 | Methods/Para1 |
| | 8b | Type of randomization; details of any restriction, such as blocking and block size | Page4/line91 | Methods/Para1 |
| Allocation concealment mechanism | 9 | 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 | Page4/line93-95 | Methods/Para1 |
| Implementation | 10 | Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions | Page4/line92-95 | Methods/Para1 |
| Blinding | 11a | If applicable, who was blinded after assignment to interventions (eg, participants, care providers, individuals assessing outcomes) and how | Page4/line95-96 | Methods/Para1 |
| | 11b | If relevant, description of the similarity of interventions | Page5/line105-108 | Methods/Para2 |
| Statistical methods | 12a | Statistical methods used to compare groups for primary and secondary outcomes<br>**(Explicitly state if no adjustments for multiplicity were applied; if adjustments were applied, state the method used)** | Page6,7/line140-150 | Methods/Para4 |
| | 12b | Methods for additional analyses, such as subgroup analyses and adjusted analyses | Page6,7/line140-150 | Methods/Para4 |
| **Results** | | | | |
| Participant flow (a diagram is strongly recommended) | 13a | For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analyzed for the primary outcome | Page4,5,22/line96-102,425 | Methods/Para1/Figure1 |
| | 13b | For each group, losses and exclusions after randomization with reasons included | Page5,22/line102-104,425 | Methods/Para1/Figure1 |
| Recruitment | 14a | Dates defining the periods of recruitment and follow-up<br>**[If periods of recruitment and follow-up are different across treatment groups (eg, groups were added or dropped), the periods of recruitment and follow-up, reason(s) for the differences, and any statistical implications should be described]** | Page 4/line83 | Methods/Para1 |
| | 14b | Why the trial ended or was stopped | N/A | N/A |
| Baseline data | 15 | A table showing baseline demographic and clinical characteristics for each group | Page7,8/line156-164 | Results/Para1/Table1 |

| | | | | |
|---|---|---|---|---|
| Numbers analyzed | 16 | For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups | Page7-14,22/line156-228,425 | Results/Para1-7/Figure1/Table1-6 |
| Outcomes and estimation | 17a | For each primary and secondary outcome, results for each group, and the estimated effect size and its precision, such as 95% CI<br>**(Results for each prespecified comparison of treatment groups)** | Page8-14,23,24/line166-228,440,460 | Results/Para2-7/Figure2,3/Table2-6 |
| | 17b | For binary outcomes, presentation of both absolute and relative effect sizes is recommended | Page12-13/line210-216 | Results/Para6/Table5 |
| Ancillary analyses | 18 | Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing prespecified from exploratory | Page8-10,23,24/line166-182,440,460 | Results/Para2/Figure1,2/Table2 |
| Harms | 19 | All important harms or unintended effects in each group (for specific guidance, see CONSORT for harms)[8] | Page12-13/line210-216 | Results/Para6/Table5 |
| **Discussion** | | | | |
| Limitations | 20 | Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses | Page17/line306-316 | Discussion/Para8 |
| Generalizability | 21 | Generalizability (external validity, applicability) of the trial findings | Page15-16/line265-296 | Discussion/Para5-7 |
| Interpretation | 22 | Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence | Page15-17/line265-296,31 | Discussion/Para5-7/Conclu |
| **Other information** | | | | |
| Registration | 23 | Registration number and name of trial registry | | |
| Protocol | 24 | Where the full trial protocol can be accessed, if available | Page18/line340-342 | DataSharingStatement |
| Funding | 25 | Sources of funding and other support (such as supply of drugs), role of funders | Page17/line325-326 | FundingStatement |

[a] It is strongly recommended that this checklist is read in conjunction with the CONSORT 2010 Statement Explanation and Elaboration for important clarification on the items

From: Juszczak E, Altman DG, Hopewell S, Schulz K. Reporting of Multi-Arm Parallel-Group Randomized Trials: Extension of the CONSORT 2010 Statement. JAMA. 2019;321(16):1610-1620

## Table 2 Items to include when reporting a randomised trial in a journal abstract

| Item | Description | Reported on Page Number/Line Number | Reported on Section/Paragraph |
|---|---|---|---|
| Authors | Contact details for the corresponding author | Page1/line21-25 | TitlePage |
| Trial design | Description of the trial design (such as parallel, cluster, non-inferiority) | Page2/line31 | Abstract/Para2 |
| **Methods** | | | |
| Participants | Eligibility criteria for participants and the settings where the data were collected | Page2/line32-33 | Abstract/Para2 |
| Interventions | Interventions intended for each group | Page2/line32 | Abstract/Para2 |
| Objective | Specific objective or hypothesis | Page2/line28-30 | Abstract/Para1 |
| Outcome | Clearly defined primary outcome for this report | Page2/line35-37 | Abstract/Para2 |
| Randomisation | How participants were allocated to interventions | Page2/line31 | Abstract/Para2 |
| Blinding (masking) | Whether participants, care givers, and those assessing the outcomes were blinded to group assignment | Page2/line31 | Abstract/Para2 |
| **Results** | | | |
| Numbers randomised | Number of participants randomised to each group | Page2/line33-35 | Abstract/Para2 |
| Recruitment | Trial status | Page2/line31-32 | Abstract/Para2 |
| Numbers analysed | Number of participants analysed in each group | Page2/line33-35 | Abstract/Para2 |
| Outcome | For the primary outcome, a result for each group and the estimated effect size and its precision | Page2/line38-42 | Abstract/Para3 |
| Harms | Important adverse events or side effects | N/A | N/A |
| Conclusions | General interpretation of the results | Page2/line43-45 | Abstract/Para4 |
| Trial registration | Registration number and name of trial register | | |
| Funding | Source of funding | Page17/line325-326 | FundingStatement |

From: CONSORT Group website. http://www.consort-statement.org. Accessed May 29, 2012.

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*As the checklist was provided upon initial submission, the page number/line number reported may be changed due to copyediting and may not be referable in the published version. In this case, the section/paragraph may be used as an alternative reference.