**CHECKLIST ITEMS**

**Extension Combination :**   Consort

**Item\_1 : TITLE & ABSTRACT**

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| **Consort** | **1a : Identification as a randomised trial in the title 1b : Structured summary of trial design, methods, results, and conclusions** | **1**  **6-16** |

**Item\_2 : INTRODUCTION Background and objectives**

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| **Consort** | **2a : Scientific background and explanation of rationale 2b : Specific objectives or hypotheses** | **4-5**  **5** |

**Item\_3 : METHODS Trial design**

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| **Consort** | **3a : Description of trial design (such as parallel, factorial) including allocation ratio 3b : Important changes to methods after trial commencement (such as eligibility criteria), with reasons** | **6**  **N/A** |

**Item\_4 : METHODS Participants**

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| **Consort** | **4a : Eligibility criteria for participants 4b : Settings and locations where the data were collected** | **5-6**  **5** |

**Item\_5 : METHODS Interventions**

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| **Consort** | **5 : The interventions for each group with sufficient details to allow replication, including how and when they were actually administered** |  |

**Item\_6 : METHODS Outcomes**

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| **Consort** | **6a : Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed 6b : Any changes to trial outcomes after the trial commenced, with reasons** | **5-11**  **N/A** |

**Item\_7 : METHODS Sample size**

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| **Consort** | **7a : How sample size was determined 7b : When applicable, explanation of any interim analyses and stopping guidelines** |  |

**Item\_8 : METHODS Randomisation : Sequence generation**

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| **Consort** | **8a : Method used to generate the random allocation sequence 8b : Type of randomisation; details of any restriction (such as blocking and block size)** | **5**  **6** |

**Item\_9 : METHODS Randomisation : Allocation concealment mechanism**

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| **Consort** | **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** | **6** |

**Item\_10 : METHODS Implementation**

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| **Consort** | **10 : Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions** | **6** |

**Item\_11 : METHODS Blinding**

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| **Consort** | **11a : If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how 11b : If relevant, description of the similarity of interventions** | **6**  **6** |

**Item\_12 : METHODS Statistical methods**

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| **Consort** | **12a : Statistical methods used to compare groups for primary and secondary outcomes 12b : Methods for additional analyses, such as subgroup analyses and adjusted analyses** | **10**  **N/A** |

**Item\_13 : RESULTS Participant flow (a diagram is strongly recommended)**

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| **Consort** | **13a : For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome 13b : For each group, losses and exclusions after randomisation, together with reasons** | **11**  **11** |

**Item\_14 : RESULTS Recruitment**

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| **Consort** | **14a : Dates defining the periods of recruitment and follow-up 14b : Why the trial ended or was stopped** | **5**  **N/A** |

**Item\_15 : RESULTS Baseline data**

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| **Consort** | **15 : A table showing baseline demographic and clinical characteristics for each group** | **Table 1** |

**Item\_16 : RESULTS Numbers analysed**

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| **Consort** | **16 : For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups** | **Table 2-5** |

**Item\_17 : RESULTS Outcomes and estimation**

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| **Consort** | **17a : For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval) 17b : For binary outcomes, presentation of both absolute and relative effect sizes is recommended** | **Table 2-5, Figure 1-4**  **N/A** |

**Item\_18 : RESULTS Ancillary analyses**

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| **Consort** | **18 : Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory** | **N/A** |

**Item\_19 : RESULTS Harms**

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| **Consort** | **19 : All important harms or unintended effects in each group** | **11** |

**Item\_20 : DISCUSSION Limitations**

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| **Consort** | **20 : Trial limitations; addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses** |  |

**Item\_21 : DISCUSSION Generalisability**

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| **Consort** | **21 : Generalisability (external validity, applicability) of the trial findings** |  |

**Item\_22 : DISCUSSION Interpretation**

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| **Consort** | **22 : Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence** |  |

**Item\_23 : OTHER INFORMATION Registration**

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| **Consort** | **23 : Registration number and name of trial registry** |  |

**Item\_24 : OTHER INFORMATION Protocol**

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| **Consort** | **24 : Where the full trial protocol can be accessed, if available** |  |

**Item\_25 : OTHER INFORMATION Funding**

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| **Consort** | **25 : Sources of funding and other support (such as supply of drugs), role of funders** |  |

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| **REFERENCES :** |
| **Consort** | Schulz KF, Altman DG, Moher D, for the CONSORT Group. CONSORT 2010 Statement: updated guidelines for reporting parallel group randomised trials. Ann Int Med 2010;152.  Moher D, Hopewell S, Schulz KF, Montori V, Gtzsche PC, Devereaux PJ, Elbourne D, Egger M, Altman DG, for the CONSORT Group. CONSORT 2010 Explanation and Elaboration: updated guidelines for reporting parallel group randomised trial. BMJ 2010; 340: c869. |