

CONSORT checklist of information to include when reporting a pilot trial*

| Section/topic and item No | Standard checklist item | Extension for pilot trials | Page No where item is reported |
|----------------------------|---|--|--------------------------------|
| Title and abstract | | | |
| 1a | Identification as a randomised trial in the title | Identification as a pilot or feasibility randomised trial in the title | 1 |
| 1b | Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts) | Structured summary of pilot trial design, methods, results, and conclusions (for specific guidance see CONSORT abstract extension for pilot trials) | 2-3 |
| Introduction | | | |
| Background and objectives: | | | |
| 2a | Scientific background and explanation of rationale | Scientific background and explanation of rationale for future definitive trial, and reasons for randomised pilot trial | 4 |
| 2b | Specific objectives or hypotheses | Specific objectives or research questions for pilot trial | 5 |
| Methods | | | |
| Trial design: | | | |
| 3a | Description of trial design (such as parallel, factorial) including allocation ratio | Description of pilot trial design (such as parallel, factorial) including allocation ratio | 5 |
| 3b | Important changes to methods after trial commencement (such as eligibility criteria), with reasons | Important changes to methods after pilot trial commencement (such as eligibility criteria), with reasons | 15 |
| Participants: | | | |
| 4a | Eligibility criteria for participants | | 5-6 |
| 4b | Settings and locations where the data were collected | | 5-7 |
| 4c | | How participants were identified and consented | 5 |
| Interventions: | | | |
| 5 | The interventions for each group with sufficient details to allow replication, including how and when they were actually administered | | 6 |
| Outcomes: | | | |
| 6a | Completely defined prespecified primary and secondary outcome measures, including how and when they were assessed | Completely defined prespecified assessments or measurements to address each pilot trial objective specified in 2b, including how and when they were assessed | 7 |
| 6b | Any changes to trial outcomes after the trial commenced, with reasons | Any changes to pilot trial assessments or measurements after the pilot trial commenced, with reasons | na |
| 6c | | If applicable, prespecified criteria used to judge whether, or how, to proceed with future definitive trial | 17-18 |

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|---|---|---|----------|
| Sample size: | | | |
| 7a | How sample size was determined | Rationale for numbers in the pilot trial | 8 |
| 7b | When applicable, explanation of any interim analyses and stopping guidelines | | na |
| Randomisation: | | | |
| Sequence generation: | | | |
| 8a | Method used to generate the random allocation sequence | | 6 |
| 8b | Type of randomisation; details of any restriction (such as blocking and block size) | Type of randomisation(s); details of any restriction (such as blocking and block size) | 6 |
| 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 | | 6 |
| Implementation: | | | |
| 10 | Who generated the random allocation sequence, enrolled participants, and assigned participants to interventions | | 6 |
| Blinding: | | | |
| 11a | If done, who was blinded after assignment to interventions (eg, participants, care providers, those assessing outcomes) and how | | 6-7 |
| 11b | If relevant, description of the similarity of interventions | | na |
| Analytical methods: | | | |
| 12a | Statistical methods used to compare groups for primary and secondary outcomes | Methods used to address each pilot trial objective whether qualitative or quantitative | 8-9 |
| 12b | Methods for additional analyses, such as subgroup analyses and adjusted analyses | Not applicable | na |
| 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 analysed for the primary outcome | For each group, the numbers of participants who were approached and/or assessed for eligibility, randomly assigned, received intended treatment, and were assessed for each objective | 9, Fig 1 |
| 13b | For each group, losses and exclusions after randomisation, together with reasons | | 9, Fig 1 |
| Recruitment: | | | |

| | | | |
|--------------------------|---|--|------------------------------|
| 14a | Dates defining the periods of recruitment and follow-up | | 9 |
| 14b | Why the trial ended or was stopped | Why the pilot trial ended or was stopped | na |
| Baseline data: | | | |
| 15 | A table showing baseline demographic and clinical characteristics for each group | | Table 1 |
| Numbers analysed: | | | |
| 16 | For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups | For each objective, number of participants (denominator) included in each analysis. If relevant, these numbers should be by randomised group | Table 2 9-13 |
| 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% confidence interval) | For each objective, results including expressions of uncertainty (such as 95% confidence interval) for any estimates. If relevant, these results should be by randomised group | Table 2 12-13, Fig 2,3 |
| 17b | For binary outcomes, presentation of both absolute and relative effect sizes is recommended | Not applicable | na |
| Ancillary analyses: | | | |
| 18 | Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing prespecified from exploratory | Results of any other analyses performed that could be used to inform the future definitive trial | 16 |
| Harms: | | | |
| 19 | All important harms or unintended effects in each group (for specific guidance see CONSORT for harms) | | 13 |
| 19a | | If relevant, other important unintended consequences | na |
| Discussion | | | |
| Limitations: | | | |
| 20 | Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses | Pilot trial limitations, addressing sources of potential bias and remaining uncertainty about feasibility | 15, 17 |
| Generalisability: | | | |
| 21 | Generalisability (external validity, applicability) of the trial findings | Generalisability (applicability) of pilot trial methods and findings to future definitive trial and other studies | 17-18 |
| Interpretation: | | | |
| 22 | Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence | Interpretation consistent with pilot trial objectives and findings, balancing potential benefits and harms, and considering other relevant evidence | 15-18 |
| 22a | | Implications for progression from pilot to future definitive trial, including any proposed amendments | |
| Other information | | | |

Registration:

23

Registration number and name of trial registry

Registration number for pilot trial and name of trial registry

3, 5

Protocol:

24

Where the full trial protocol can be accessed, if available

Where the pilot trial protocol can be accessed, if available

separate
file

Funding:

25

Sources of funding and other support (such as supply of drugs), role of funders

none

26

Ethical approval or approval by research review committee, confirmed with reference number

5

*Here a pilot trial means any randomised study conducted in preparation for a future definitive RCT, where the main objective of the pilot trial is to assess feasibility.