



CONSORT 2010 checklist of information to include when reporting a pilot or feasibility randomized trial in a journal or conference abstract

| Item | Description | Reported on line number |
|--------------------|---|-------------------------|
| Title | Identification of study as randomised pilot or feasibility trial | 8 |
| Authors * | Contact details for the corresponding author | 16 |
| Trial design | Description of pilot trial design (e.g. parallel, cluster) | 32 |
| Methods | | |
| Participants | Eligibility criteria for participants and the settings where the pilot trial was conducted | 34 |
| Interventions | Interventions intended for each group | 35 |
| Objective | Specific objectives of the pilot trial | 38 |
| Outcome | Pre-specified assessment or measurement to address the pilot trial objectives** | 38 |
| Randomization | How participants were allocated to interventions | 36 |
| Blinding (masking) | Whether or not participants, care givers, and those assessing the outcomes were blinded to group assignment | 37 |
| Results | | |
| Numbers randomized | Number of participants screened and randomised to each group for the pilot trial objectives** | 42 |
| Recruitment | Trial status† | n/a |
| Numbers analysed | Number of participants analysed in each group for the pilot objectives** | 45 |
| Outcome | Results for the pilot objectives, including any expressions of uncertainty** | 47 |
| Harms | Important adverse events or side effects | n/a |
| Conclusions | General interpretation of the results of pilot trial and their implications for the future definitive trial | 50 |
| Trial registration | Registration number for pilot trial and name of trial register | 56 |
| Funding | Source of funding for pilot trial | 57 |

Citation: Eldridge SM, Chan CL, Campbell MJ, Bond CM, Hopewell S, Thabane L, et al. CONSORT 2010 statement: extension to randomised pilot and feasibility trials. *BMJ*. 2016;355.

**this item is specific to conference abstracts*

***Space permitting, list all pilot trial objectives and give the results for each. Otherwise, report those that are a priori agreed as the most important to the decision to proceed with the future definitive RCT.*

†For conference abstracts.



CONSORT 2010 checklist of information to include when reporting a pilot or feasibility trial*

| Section/Topic | Item No | Checklist item | Reported on page No |
|----------------------------------|---------|---|---------------------|
| Title and abstract | | | |
| | 1a | Identification as a pilot or feasibility randomised trial in the title | 1 |
| | 1b | Structured summary of pilot trial design, methods, results, and conclusions (for specific guidance see CONSORT abstract extension for pilot trials) | 2 |
| Introduction | | | |
| Background and objectives | 2a | Scientific background and explanation of rationale for future definitive trial, and reasons for randomised pilot trial | 3,4 |
| | 2b | Specific objectives or research questions for pilot trial | 4 |
| Methods | | | |
| Trial design | 3a | Description of pilot trial design (such as parallel, factorial) including allocation ratio | 5,7 |
| | 3b | Important changes to methods after pilot trial commencement (such as eligibility criteria), with reasons | 9 |
| Participants | 4a | Eligibility criteria for participants | 5 |
| | 4b | Settings and locations where the data were collected | 5 |
| | 4c | How participants were identified and consented | 6,7,Figure 1 |
| Interventions | 5 | The interventions for each group with sufficient details to allow replication, including how and when they were actually administered | 5, Table 1 |
| Outcomes | 6a | Completely defined prespecified assessments or measurements to address each pilot trial objective specified in 2b, including how and when they were assessed | 6, Table 2 |
| | 6b | Any changes to pilot trial assessments or measurements after the pilot trial commenced, with reasons | N/a |
| | 6c | If applicable, prespecified criteria used to judge whether, or how, to proceed with future definitive trial | Table 2 |
| Sample size | 7a | Rationale for numbers in the pilot trial | 6 |
| | 7b | When applicable, explanation of any interim analyses and stopping guidelines | 8 |
| Randomisation: | | | |
| Sequence generation | 8a | Method used to generate the random allocation sequence | N/a |
| | 8b | Type of randomisation(s); details of any restriction (such as blocking and block size) | 7 |
| 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 | N/a |

| | | | |
|--|-----|---|-------------|
| Implementation | 10 | Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions | N/a |
| Blinding | 11a | If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how | 7 |
| | 11b | If relevant, description of the similarity of interventions | Table 1 |
| Statistical methods | 12 | Methods used to address each pilot trial objective whether qualitative or quantitative | 8 |
| Results | | | |
| Participant flow (a diagram is strongly recommended) | 13a | 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 | Figure 2 |
| | 13b | For each group, losses and exclusions after randomisation, together with reasons | 9, Figure 2 |
| Recruitment | 14a | Dates defining the periods of recruitment and follow-up | 8 |
| | 14b | Why the pilot trial ended or was stopped | 8 |
| Baseline data | 15 | A table showing baseline demographic and clinical characteristics for each group | Table 3 |
| Numbers analysed | 16 | For each objective, number of participants (denominator) included in each analysis. If relevant, these numbers should be by randomised group | 9, 10 |
| Outcomes and estimation | 17 | 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 | N/a |
| Ancillary analyses | 18 | Results of any other analyses performed that could be used to inform the future definitive trial | N/a |
| Harms | 19 | All important harms or unintended effects in each group (for specific guidance see CONSORT for harms) | 9 |
| | 19a | If relevant, other important unintended consequences | N/a |
| Discussion | | | |
| Limitations | 20 | Pilot trial limitations, addressing sources of potential bias and remaining uncertainty about feasibility | 12 |
| Generalisability | 21 | Generalisability (applicability) of pilot trial methods and findings to future definitive trial and other studies | 12 |
| Interpretation | 22 | Interpretation consistent with pilot trial objectives and findings, balancing potential benefits and harms, and considering other relevant evidence | 13 |
| | 22a | Implications for progression from pilot to future definitive trial, including any proposed amendments | 13 |
| Other information | | | |
| Registration | 23 | Registration number for pilot trial and name of trial registry | 4 |
| Protocol | 24 | Where the pilot trial protocol can be accessed, if available | 4 |
| Funding | 25 | Sources of funding and other support (such as supply of drugs), role of funders | 3 |
| | 26 | Ethical approval or approval by research review committee, confirmed with reference number | 4 |

Citation: Eldridge SM, Chan CL, Campbell MJ, Bond CM, Hopewell S, Thabane L, et al. CONSORT 2010 statement: extension to randomised pilot and feasibility trials. *BMJ*. 2016;355.

*We strongly recommend reading this statement in conjunction with the CONSORT 2010, extension to randomised pilot and feasibility trials, Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.
