# Additional file 3: Consort checklist

***Supplementary Table 3:*** *Consort checklist*

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| 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 | Page 1 |
| 1b | Structured summary of pilot trial design, methods, results, and conclusions (for specific guidance see CONSORT abstract extension for pilot trials) | Page 2 |
| Introduction |
| Background and objectives | 2a | Scientific background and explanation of rationale for future definitive trial, and reasons for randomised pilot trial | Pages 4-5 |
| 2b | Specific objectives or research questions for pilot trial | Page 5 |
| Methods |
| Trial design | 3a | Description of pilot trial design (such as parallel, factorial) including allocation ratio | Page 5 |
| 3b | Important changes to methods after pilot trial commencement (such as eligibility criteria), with reasons | Pages 6-7 |
| Participants | 4a | Eligibility criteria for participants | Pages 6-7 |
| 4b | Settings and locations where the data were collected | Pages 5-6 |
|  | 4c | How participants were identified and consented | Pages 6-7 |
| Interventions | 5 | The interventions for each group with sufficient details to allow replication, including how and when they were actually administered | Pages 8-9 |
| Outcomes | 6a | Completely defined prespecified assessments or measurements to address each pilot trial objective specified in 2b, including how and when they were assessed | Pages 10-12 |
| 6b | Any changes to pilot trial assessments or measurements after the pilot trial commenced, with reasons | Page 7 |
|  | 6c | If applicable, prespecified criteria used to judge whether, or how, to proceed with future definitive trial | Pages 12, 23-25 (Table 6) |
| Sample size | 7a | Rationale for numbers in the pilot trial | Page 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 | NA |
| 8b | Type of randomisation(s); details of any restriction (such as blocking and block size) | NA |
| Allocationconcealmentmechanism | 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 | NA |
| Implementation | 10 | Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions | NA |
| Blinding | 11a | If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how | NA |
| 11b | If relevant, description of the similarity of interventions | NA |
| Statistical methods | 12 | Methods used to address each pilot trial objective whether qualitative or quantitative | Page 12 |
| 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 4 |
| 13b | For each group, losses and exclusions after randomisation, together with reasons | NA |
| Recruitment | 14a | Dates defining the periods of recruitment and follow-up | Pages 12, 14, 20 |
| 14b | 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 objective, number of participants (denominator) included in each analysis. If relevant, these numbersshould be by randomised group | Page 21 |
| Outcomes and estimation | 17 | For each objective, results including expressions of uncertainty (such as 95% confidence interval) for anyestimates. If relevant, these results should be by randomised group | Page 21 |
| Ancillary analyses | 18 | Results of any other analyses performed that could be used to inform the future definitive trial | NA |
| Harms | 19 | All important harms or unintended effects in each group (for specific guidance see CONSORT for harms) | NA |
|  | 19a | If relevant, other important unintended consequences | NA |
| Discussion |
| Limitations | 20 | Pilot trial limitations, addressing sources of potential bias and remaining uncertainty about feasibility | Page 28 |
| Generalisability | 21 | Generalisability (applicability) of pilot trial methods and findings to future definitive trial and other studies | Page 28 |
| Interpretation | 22 | Interpretation consistent with pilot trial objectives and findings, balancing potential benefits and harms, andconsidering other relevant evidence | Page 29 |
|  | 22a | Implications for progression from pilot to future definitive trial, including any proposed amendments | Pages 26-28 |
| Other information |  |
| Registration | 23 | Registration number for pilot trial and name of trial registry | Page 3 |
| Protocol | 24 | Where the pilot trial protocol can be accessed, if available | Page 5 |
| Funding | 25 | Sources of funding and other support (such as supply of drugs), role of funders | Page 30 |
|  | 26 | Ethical approval or approval by research review committee, confirmed with reference number | Page 30 |