Additional file 1. CONSORT 2010 Statement: extension to randomised pilot and feasibility trials

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 and Appendix (below)
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	3 & 4
2b	Specific objectives or hypotheses	Specific objectives or research questions for pilot trial	4
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	4
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	5
Participants:			
4a	Eligibility criteria for participants	NA	NA
4b	Settings and locations where the data were collected	NA	NA
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	NA	NA
Outcomes:			

6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	Completely defined pre-specified assessments or measurements to address each pilot trial objective specified in 2b, including how and when they were assessed	6
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, pre-specified criteria used to judge whether, or how, to proceed with future definitive trial	NA
Sample size:			
7a	How sample size was determined	Rationale for numbers in the pilot trial	5
7b	When applicable, explanation of any interim analyses and stopping guidelines		
Randomisation:			
Sequence generation:			
8a	Method used to generate the random allocation sequence		
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)	5
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	NA	NA
Implementation:			
10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	NA	NA
Blinding:			
11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	NA	NA
11b	If relevant, description of the similarity of interventions	NA	NA
Analytical methods:			
12a	Statistical methods used to compare group for primary and secondary outcomes	Methods used to address each pilot trial objective whether qualitative or quantitative	7 & 8
12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	NA	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	Figure 1. Schematic diagram of the pilot RCT
13b	For each group, losses and exclusions after randomisation, together with reasons	NA	NA
Recruitment:			
14a	Dates defining the periods of recruitment and follow-up	NA	NA
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	NA	NA
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 analyses should be by randomised group	Tables 2 and 3
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	Tables 2 and 3
17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	Not applicable	
Ancillary analyses:			
18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	Results of any other analyses performed that could be used to inform the future definitive trial	10 - 12
Harms:			
19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	NA	NA
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	14
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	15
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
22a		Implications for progression from pilot to future definitive trial including any proposed amendments	15
Other information			
Registration:			
23	Registration number and name of trial registry	Registration number for pilot trial and name of trial registry	Abstract
Protocol:			
24	Where the full trial protocol can be accessed, if available	Where the pilot trial protocol can be accessed, if available	Methods – Design
Funding:			
25	Sources of funding and other support (such as supply of drugs), role of funders	NA	NA
26		Ethical approval/research review committee approval confirmed with reference number	Methods - Ethics

Appendix: Revised version of example abstract for report of pilot trial

Item	Standard Checklist item	Extension for pilot trials	Reported
Title	Identification of study as randomised	Identification of study as randomised pilot trial	✓
Trial design	Description of the trial design (e.g. parallel, cluster, non-inferiority)	Description of pilot trial design (e.g. parallel, cluster)	✓
METHODS			
Participants	Eligibility criteria for participants and the settings where the data were collected	Eligibility criteria for participants and the settings where the pilot trial was conducted	✓
Interventions	Interventions intended for each group	*same*	✓
Objective	Specific objective or hypothesis	Specific objectives of the pilot trial	✓
Outcome	Clearly defined primary outcome for this report	Pre-specified assessment or measurement to address the pilot trial objective(s)	✓

Randomisation	How participants were allocated to interventions	*same*	✓
Blinding (masking)	Whether or not participants, care givers, and those assessing the outcomes were blinded to group assignment	*same*	✓
RESULTS			
Numbers randomised	Number of participants randomised to each group	Number of participants screened and randomised to each group for the pilot trial objective(s)[1]	✓
Recruitment	Trial status (for conference abstracts)	*same*	NA
Numbers analysed	Number of participants analysed in each group	Number of participants analysed in each group for the pilot objective(s)[1]	✓
Outcome	For the primary outcome, a result for each group and the estimated effect size and its precision	Results for the pilot objective(s), including any expressions of uncertainty	✓
Harms	Important adverse events or side-effects	*same*	NA
Conclusions	General interpretation of the results	General interpretation of the results of pilot trial and their implications for the future definitive trial	✓
Trial registration	Registration number and name of trial register	Registration number for pilot trial and name of trial register	✓
Funding	Source of funding	Source of funding for pilot trial	✓