CONSORT 2010 checklist of information to include when reporting a pilot or feasibility trial: RECOVER TAVI Pilot*

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	P1 Title page
	1b	Structured summary of pilot trial design, methods, results, and conclusions (for specific guidance see CONSORT abstract extension for pilot trials)	P2,3 Abstract and 'Article Summary'
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale for future definitive trial, and reasons for randomised pilot trial	P3-4
	2b	Specific objectives or research questions for pilot trial	P3-4
Methods			
Trial design	3a	Description of pilot trial design (such as parallel, factorial) including allocation ratio	P5-6
	3b	Important changes to methods after pilot trial commencement (such as eligibility criteria), with reasons	P2,6 KCCQ
Participants	4a	Eligibility criteria for participants	P5
	4b	Settings and locations where the data were collected	P5,6
	4c	How participants were identified and consented	P5
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	P5
Outcomes	6a	Completely defined prespecified assessments or measurements to address each pilot trial objective specified in 2b, including how and when they were assessed	P6
	6b	Any changes to pilot trial assessments or measurements after the pilot trial commenced, with reasons	P2,6 KCCQ
	6c	If applicable, prespecified criteria used to judge whether, or how, to proceed with future definitive trial	Recruitment P7, Acceptability of Intervention

			P7,9,10
Sample size	7a	Rationale for numbers in the pilot trial	Statistical methods first para. Feasibility, not powered for outcome differences, P6
	7b	When applicable, explanation of any interim analyses and stopping guidelines	N/A
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	P5 para 2
	8b	Type of randomisation(s); details of any restriction (such as blocking and block size)	P5
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	P5
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	Independent investigator P5
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	Outcome assessor P5
	11b	If relevant, description of the similarity of interventions	N/A
Statistical methods	12	Methods used to address each pilot trial objective whether qualitative or quantitative	Statistics section P6
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	Flow chart Fig 1
	13b	For each group, losses and exclusions after randomisation, together with reasons	Flow chart text Fig 1
Recruitment	14a	Dates defining the periods of recruitment and follow-up	Participants P5, Recruitment Fig 2
	14b	Why the pilot trial ended or was stopped	Completed
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Table 1 and 4

Numbers analysed	16	For each objective, number of participants (denominator) included in each analysis. If relevant, these numbers should be by randomised group	Flow chart Fig 1, Results P7
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 small groups, not powered for outcome differences
Ancillary analyses	18	Results of any other analyses performed that could be used to inform the future definitive trial	KCCQ Sub-Study P6,18
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	No harms observed, adverse events section, P7
	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	Discussion P9
Generalisability	21	Generalisability (applicability) of pilot trial methods and findings to future definitive trial and other studies	Discussion P9
Interpretation	22	Interpretation consistent with pilot trial objectives and findings, balancing potential benefits and harms, and considering other relevant evidence	Discussion P9
	22a	Implications for progression from pilot to future definitive trial, including any proposed amendments	Future trial planning section P9
Other information			
Registration	23	Registration number for pilot trial and name of trial registry	NCT02921880 P1
Protocol	24	Where the pilot trial protocol can be accessed, if available	Attached Appendix 5
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	Funding P10
	26	Ethical approval or approval by research review committee, confirmed with reference number	LONDON 16/00/0687 p1