CONSORT 2010 Checklist

Section/Topic	Item No.	Checklist item	Reported on page No.
Title and abstract	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, conclusions	1
Introduction	2a	Scientific background and rationale	1–2
	2b	Specific objectives or hypotheses	2
Methods	3a	Trial design including allocation ratio	2
	3b	Important changes to methods after commencement	N/A
	4a	Eligibility criteria	3
	4b	Settings and locations	2
	5	Interventions	2
	6a	Primary and secondary outcomes	2–3
	6b	Changes to outcomes	N/A
	7a	Sample size	2
	7b	Interim analyses	N/A
	8a	Sequence generation	2
	8b	Type of randomisation	2
	9	Allocation concealment	2
	10	Implementation	N/A
	11a	Blinding	2
	11b	Similarity of interventions	N/A
	12a	Statistical methods	3
	12b	Additional analyses	NR
Results	13a	Participant flow	4 (Fig.1)
	13b	Losses/exclusions	4 (Fig.1)
	14a	Recruitment	2
	14b	Trial ended/stopped	NR
	15	Baseline data	3
	16	Numbers analysed	3–4
	17a	Outcomes and	6–8

		estimation	
	17b	Binary outcomes	N/A
	18	Ancillary analyses	N/A
	19	Harms	6, 9
Discussion	20	Limitations	9
	21	Generalisability	9
	22	Interpretation	9
Other information	23	Registration	2
	24	Protocol availability	-
	25	Funding	9