CONSORT 2010 Checklist

Section/Topic	Item	CONSORT 2010 checklist item	Reported in manuscript (page; line nos.)
Title and abstract			
	1a	Identification as a randomised trial in the title	p.1; lines 1–2
	1b	Structured summary of trial design, methods, results, and conclusions	p.2; lines 11–35 (Abstract)
Introduction — Background and objectives			
	2a	Scientific background and explanation of rationale	p.3; lines 38–62
	2b	Specific objectives or hypotheses	p.3–4; lines 63–70 (primary hypothesis stated lines 65–68)
Methods — Trial design			
	3a	Description of trial design (such as parallel, factorial) including allocation ratio	p.4; lines 72–80 (parallel-group, 1:1)
	3b	Important changes to methods after trial commencement, with reasons	p.4; lines 75–76
Methods — Participants			
	4a	Eligibility criteria for participants	p.4–5; lines 81–97 (esp. 82–87)
	4b	Settings and locations where the data were collected	p.4; lines 72–75
Methods — Interventions			
	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	p.5; lines 98–114
Methods — Outcomes			
	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when assessed	p.5–6; lines 115–135
	6b	Any changes to trial outcomes after the trial commenced, with reasons	p.4; lines 75–76 (general statement only)
Methods — Sample size			
	7a	How sample size was determined	p.6; lines 142–148 (also flagged in Limitations, lines 359–362)
	7b	Explanation of any interim analyses and stopping guidelines, when applicable	p.4; line 75
Methods — Randomisation: Sequence generation			
	8a	Method used to generate the random allocation sequence	p.6–7; lines 149–155
	8b	Type of randomisation; details of any restriction (blocking, block size)	p.6–7; lines 149–155 (stratified, unblocked — explicitly stated)
Methods — Randomisation: Allocation concealment mechanism			
	9	Mechanism used to implement the allocation sequence, and steps to conceal it until assignment	p.7; lines 156–158 (SNOSE)

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Methods — Randomisation: Implementation			
	10	Who generated the sequence, who enrolled participants, and who assigned participants to interventions	p.7; lines 159–164
Methods — Blinding			
	11a	If done, who was blinded after assignment to interventions, and how	p.7; lines 165–170
	11b	If relevant, description of the similarity of interventions	p.7 line 166; p.15 lines 373–375
Methods — Statistical methods			
	12a	Statistical methods used to compare groups for primary and secondary outcomes	p.7; lines 171–181
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	p.8; lines 182–196
Results — Participant flow (diagram recommended)			
	13a	For each group, numbers randomly assigned, receiving intended treatment, and analysed for the primary outcome	p.8; lines 198–206; Fig. 1 (p.23 legend, p.24 image)
	13b	For each group, losses and exclusions after randomisation, with reasons	p.4–5 lines 81–97 (pre-randomisation exclusions); p.8 lines 198–206 (none post-randomisation); Fig. 1
Results — Recruitment			
	14a	Dates defining the periods of recruitment and follow-up	p.4 lines 72–75; p.6 lines 128–129; p.8 lines 198–206
	14b	Why the trial ended or was stopped	p.6; lines 142–148
Results — Baseline data			
	15	A table showing baseline demographic and clinical characteristics for each group	p.8–9 lines 207–219; Table 1 (p.20)
Results — Numbers analysed			
	16	For each group, number of participants included in each analysis, and whether by original assigned groups	p.8 lines 189–192 (ITT statement); lines 198–206; Fig. 1
Results — Outcomes and estimation			
	17a	For each primary/secondary outcome, results for each group and the estimated effect size and precision	p.9–10 lines 229–260; Table 3 (p.22)
	17b	For binary outcomes, presentation of both absolute and relative effect sizes recommended	p.9 lines 229–236 (RD and RR for GTR); Table 3
Results — Ancillary analyses			
	18	Results of any other analyses, incl. subgroup and adjusted analyses, distinguishing pre-specified from exploratory	p.9–11 lines 237–270 (incl. case-mix standardization, lines 242–246); Suppl. Table S1 (p.26), Suppl. Fig. S2 (p.27)
Results — Harms			
	19	All important harms or unintended effects in each group	p.10; lines 252–260; Table 3

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Discussion — Limitations			
	20	Trial limitations, addressing sources of potential bias, imprecision, and multiplicity of analyses	p.15; lines 358–378 (Limitations)
Discussion — Generalisability			
	21	Generalisability (external validity, applicability) of the trial findings	p.12 lines 279–284; p.15 lines 369–378
Discussion — Interpretation			
	22	Interpretation consistent with results, balancing benefits and harms, considering other evidence	p.12–14 lines 272–357 (esp. 296–309); Conclusions lines 346–357
Other information — Registration			
	23	Registration number and name of trial registry	p.2 lines 32–33 (Abstract); p.4 lines 78–80 (Methods)
Other information — Protocol			
	24	Where the full trial protocol can be accessed, if available	p.16; lines 389–392 (Declarations – Protocol)
Other information — Funding			
	25	Sources of funding and other support; role of funders	p.16; lines 380–381 (Declarations – Funding)