CONSORT 2025 Checklist for the PROMOTE Trial

Section/topic	No	Item description	Reported on page Number/Line Number	Reported on Sections/Paragraph
Title and abstract				
Title and structured abstract	1a	**Identification as a randomised trial**	Page 1, Line 3; Line 26	Title; Abstract
	1b	**Structured summary of the trial design, methods, results, and conclusions**	Page 2, Lines 20-51	Abstract
Open science				
Trial registration	2	**Name of trial registry, identifying number (with URL) and date of registration**	Page 3, Lines 49-51	Abstract
Protocol and statistical analysis plan	3	**Where the trial protocol and statistical analysis plan can be accessed**	Page 12, Line 215	Methods Reference 26
Data sharing	4	**Where and how the individual de-identified participant data, statistical code, etc. can be accessed**	Page 23, Line 402	Declarations
Funding and conflicts of interest	5a	**Sources of funding and other support, and role of funders**	Page 23, Lines 405-414	Declarations,
	5b	**Financial and other conflicts of interest of the manuscript authors**	Page 23, Lines 403-404	Declarations
Introduction				
Background and rationale	6	**Scientific background and rationale**	Page 5, Lines 76-154	Background
Objectives	7	**Specific objectives related to benefits and harms**	Page 8, Lines 155-171	Background,
Methods				
Patient and public involvement	8	**Details of patient or public involvement in the design, conduct and reporting**	Not explicitly reported	(N/A)
Trial design	9	**Description of trial design including type of trial, allocation ratio, and framework**	Page 11, Lines 174-178; 191	Methods
Changes to trial protocol	10	**Important changes to the trial after it commenced**	Not reported	(N/A)
Trial setting	11	**Settings and locations where the trial was conducted**	Page 10, Lines 174-178	Methods
Eligibility criteria	12a	**Eligibility criteria for participants**	Page 10, Lines 179-181	Methods
	12b	**Eligibility criteria for sites and for individuals delivering the interventions**	Page 10, Lines 182-189; Line 203	Methods
Intervention and comparator	13	**Intervention and comparator with sufficient details to allow replication**	Page 10, Lines 197-215	Methods
Outcomes	14	**Prespecified primary and secondary outcomes, including measurement variables**	Page 12, Lines 220-223	Methods
Harms	15	**How harms were defined and assessed**	Not reported	(N/A)

Sample size	16a	**How sample size was determined, including assumptions**	Not reported in this manuscript	(N/A)
	16b	**Explanation of any interim analyses and stopping guidelines**	Not reported	(N/A)
Sequence generation	17a	**Who generated the random allocation sequence and the method used**	Page 10, Lines 191-193	Methods
	17b	**Type of randomisation and details of any restriction**	Page 10, Lines 191-192	Methods,
Allocation concealment	18	**Mechanism used to implement the random allocation sequence**	Line 193 (implied via independent statistician)	Methods,
Implementation	19	**Personnel access to random allocation sequence**	Page 10 , Lines 192-193	Methods
Blinding	20a	**Who was blinded after assignment to interventions**	Page 11, Lines 194-196	Methods
	20b	**If blinded, how blinding was achieved**	Page 11, Lines 194-196	Methods
Statistical methods	21a	**Statistical methods used to compare groups for primary and secondary outcomes**	Page 12, Lines 228-235	Methods
	21b	**Definition of who is included in each analysis**	Page 12, Lines 228-229	Methods
	21c	**How missing data were handled in the analysis**	Page 13, Lines 236-238	Methods
	21d	**Methods for any additional analyses (subgroup, sensitivity)**	Page 13, Lines 236-238	Methods
Results				
Participant flow	22a	**For each group, numbers assigned, received intervention, and analysed**	Page 13, Lines 248-251; Figure 1	Results
	22b	**For each group, losses and exclusions after randomisation**	Page 13, Lines 252-254; Figure 1	Results
Recruitment	23a	**Dates defining periods of recruitment and follow-up**	Page 11, Lines 175-176	Methods
	23b	**If relevant, why the trial ended or was stopped**	Not applicable	(N/A)
Intervention delivery	24a	**Intervention and comparator as they were actually administered**	Not fully detailed	(N/A)
	24b	**Concomitant care received during the trial**	Not reported	(N/A)
Baseline data	25	**A table showing baseline demographic and clinical characteristics**	Page 15, Table 1; Lines 259-267	Results
Outcomes & estimation	26	**Outcomes for each group, effect sizes, and precision (95% CI)**	Page 17, Table 2; Lines 268-284	Results
Harms	27	**All harms or unintended events in each group**	Not reported	(N/A)

Ancillary analyses	28	**Any other analyses performed (sensitivity)**	Page 17, Table 3; Lines 285-305	Results
Discussion				
Interpretation	29	**Interpretation consistent with results, balancing benefits and harms**	Page 19, Lines 306-376	Discussion
Limitations	30	**Trial limitations, addressing sources of bias, imprecision, generalisability**	Page 19, Lines 377-386	Discussion