CONSORT2019

1a. Title: Identification as a randomised trial in the title	
1b. Abstract Structured summary of trial design, methods, results, and conclusions	Page 2
2a. Background Scientific background and explanation of rationale	Page 3
2b. Objectives Specific objectives or hypotheses	Page 4 Paragraph 2
3a. Trial Design Description of trial design (such as parallel, factorial) including allocation ratio	Page 4 Paragraph 3
3b. Changes to trial design Important changes to methods after trial commencement (such as eligibility criteria), with reasons	N/A
4a. Participants Eligibility criteria for participants	Page 4 Paragraph 4
4b. Study settings Settings and locations where the data were collected	Page 4 Paragraph 4
5. Interventions The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	Page 6 Paragraph 3-4
6a. Outcomes Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	Page 6 Paragraph 5
6b. Changes to outcomes Any changes to trial outcomes after the trial commenced, with reasons	N/A
7a. Sample size How sample size was determined	Page 4 Paragraph 4

7b. Interim analyses and stopping guidelines When applicable, explanation of any interim analyses and stopping guidelines **8a. Randomisation: sequence generation** Method used to generate the random allocation sequence	N/A
8b. Randomisation: type Type of randomisation; details of any restriction (such as blocking and block size)	Page 5 Paragraph 1
9. Randomisation: allocation concealment mechanism 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	Page 5 Paragraph 1
10. Randomisation: implementation Who generated the allocation sequence, who enrolled participants, and who assigned participants to interventions	Page 10 Paragraph 4
11a. Blinding If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	N/A
11b. Similarity of interventions If relevant, description of the similarity of interventions	N/A
12a. Statistical methods Statistical methods used to compare groups for primary and secondary outcomes	Page 8 Paragraph 2
12b. Additional analyses Methods for additional analyses, such as subgroup analyses and adjusted analyses	N/A
13a. Participant Flow For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	Page 5 Paragraph 1

13b. Losses and exclusions For each group, losses and exclusions after randomisation, together with reasons	Page 4 Paragraph 4 (diagram 1)
14a. Recruitment Dates defining the periods of recruitment and follow-up	Page 6 Paragraph 2
14b. Reason for stopped trial Why the trial ended or was stopped	N/A
15. Baseline Data A table showing baseline demographic and clinical characteristics for each group	Page 8 Paragraph 3
16. Numbers analysed For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	Page 4 Paragraph 4 (diagram 1)
17a. Outcomes and estimation For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	Page 8 Paragraph 4
17b. Binary outcomes For binary outcomes, presentation of both absolute and relative effect sizes is recommended	N/A
18. Ancillary analyses Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	N/A
19. Harms All important harms or unintended effects in each group	N/A
20. Limitations Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	Page 5 Paragraph 4

21. Generalisability Generalisability (external validity, applicability) of the trial findings	Page 10 Paragraph 1
22. Interpretation Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	Page 9-10 Paragraph 2-1
23. Registration Registration number and name of trial registry	Page 2 Paragraph 5
24. Protocol Where the full trial protocol can be accessed, if available	Page 10 Paragraph 8
25. Funding	Page 8 Paragraph 7