CONSORT **Checklist of items to include when reporting a randomized trial**

PAPER SECTION And topic	Item	Description	Reported on **Page #**
TITLE & ABSTRACT	1	How participants were allocated to interventions (*e.g.*, "random allocation", "randomized", or "randomly assigned").	• **P7** • **Primary manuscript (Lancet: 370:580-589, 2007)**
INTRODUCTION Background	2	Scientific background and explanation of rationale.	• **P4-5:** "Introduction"
METHODS Participants	3	Eligibility criteria for participants and the settings and locations where the data were collected.	• **P7** • **P9§1** • **Primary manuscript (Lancet: 370:580-589, 2007)**
Interventions	4	Precise details of the interventions intended for each group and how and when they were actually administered.	• **P7 §1** • **Primary manuscript (Lancet: 370:580-589, 2007)**
Objectives	5	Specific objectives and hypotheses.	• **P8**
Outcomes	6	Clearly defined primary and secondary outcome measures and, when applicable, any methods used to enhance the quality of measurements (*e.g.*, multiple observations, training of assessors).	• **P7§2** • **P9§1, 4 last lines** • **Primary manuscript (Lancet: 370:580-589, 2007)**
Sample size	7	How sample size was determined and, when applicable, explanation of any interim analyses and stopping rules.	• **P9§1**
Randomization -- Sequence generation	8	Method used to generate the random allocation sequence, including details of any restrictions (*e.g.*, blocking, stratification)	• **P7 §2** • **Primary manuscript (Lancet: 370:580-589, 2007)**
Randomization -- Allocation concealment	9	Method used to implement the random allocation sequence (*e.g.*, numbered containers or central telephone), clarifying whether the sequence was concealed until interventions were assigned.	• **P7 §2** • **Primary manuscript (Lancet: 370:580-589, 2007)**
Randomization -- Implementation	10	Who generated the allocation sequence, who enrolled participants, and who assigned participants to their groups.	• **P7 §2** • **Primary manuscript (Lancet: 370:580-589, 2007)**
Blinding (masking)	11	Whether or not participants, those administering the interventions, and those assessing the outcomes were blinded to group assignment. When relevant, how the success of blinding was evaluated.	• **P7 §2** • **Primary manuscript (Lancet: 370:580-589, 2007)**
Statistical methods	12	Statistical methods used to compare groups for primary outcome(s); Methods for additional analyses, such as subgroup analyses and adjusted analyses.	• **P7 §2** • **P 8** • **Primary manuscript (Lancet: 370:580-589, 2007)**
RESULTS Participant flow	13	Flow of participants through each stage (a diagram is strongly recommended). Specifically, for each group report the numbers of participants randomly assigned, receiving intended treatment, completing the study protocol, and analyzed for the primary	• **P9 §1** • **Primary manuscript (Lancet: 370:580-589, 2007)**

		outcome. Describe protocol deviations from study as planned, together with reasons.	
Recruitment	14	Dates defining the periods of recruitment and follow-up.	• **Primary manuscript (Lancet: 370:580-589, 2007)**
Baseline data	15	Baseline demographic and clinical characteristics of each group.	• **P9 §1** • **Primary manuscript (Lancet: 370:580-589, 2007)**
Numbers analyzed	16	Number of participants (denominator) in each group included in each analysis and whether the analysis was by "intention-to-treat". State the results in absolute numbers when feasible (*e.g.*, 10/20, not 50%).	• **P9 §1**
Outcomes and estimation	17	For each primary and secondary outcome, a summary of results for each group, and the estimated effect size and its precision (*e.g.*, 95% confidence interval).	• **P 9-10** • **Fig 1** • **Fig 2**
Ancillary analyses	18	Address multiplicity by reporting any other analyses performed, including subgroup analyses and adjusted analyses, indicating those pre-specified and those exploratory.	• **P7§2**
Adverse events	19	All important adverse events or side effects in each intervention group.	• **Primary manuscript (Lancet: 370:580-589, 2007)**
DISCUSSION Interpretation	20	Interpretation of the results, taking into account study hypotheses, sources of potential bias or imprecision and the dangers associated with multiplicity of analyses and outcomes.	• **P 11-14**
Generalizability	21	Generalizability (external validity) of the trial findings.	• **P 11-14**
Overall evidence	22	General interpretation of the results in the context of current evidence.	• **P 14**