### Additional file 4. 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                                                                      | N/A (The present study was not a randomised trial.) |
|                      | 1b      | Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts) | 3–4                 |
| **Introduction**     |         |                                                                                                                          |                     |
| Background and objectives | 2a | Scientific background and explanation of rationale                                                                     | 5–6                 |
|                      | 2b      | Specific objectives or hypotheses                                                                                       | 6                   |
| **Methods**          |         |                                                                                                                          |                     |
| Trial design         | 3a      | Description of trial design (such as parallel, factorial) including allocation ratio                                     | 6–7                 |
|                      | 3b      | Important changes to methods after trial commencement (such as eligibility criteria), with reasons                     | N/A                 |
| Participants         | 4a      | Eligibility criteria for participants                                                                                   | 7                   |
|                      | 4b      | Settings and locations where the data were collected                                                                   | 7                   |
| Interventions        | 5       | The interventions for each group with sufficient details to allow replication, including how and when they were actually administered | 8–10                |
| Outcomes             | 6a      | Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed      | 11–12               |
|                      | 6b      | Any changes to trial outcomes after the trial commenced, with reasons                                                 | N/A                 |
| Sample size          | 7a      | How sample size was determined                                                                                        | 7                   |
|                      | 7b      | When applicable, explanation of any interim analyses and stopping guidelines                                           | N/A                 |
| Randomisation:       |         |                                                                                                                          |                     |
| Sequence generation  | 8a      | Method used to generate the random allocation sequence                                                                  | N/A                 |
|                      | 8b      | Type of randomisation; details of any restriction (such as blocking and block size)                                   | N/A                 |
| Allocation concealment | 9    | 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 | N/A                 |
| Section       | Item | Description                                                                                                                                                                                                 | Page |
|---------------|------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------|
| Implementation| 10   | Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions                                                                                       | N/A  |
| Blinding      | 11a  | If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how                                                                 | N/A  |
|               | 11b  | If relevant, description of the similarity of interventions                                                                                                                                                  | N/A  |
| Statistical methods | 12a  | Statistical methods used to compare groups for primary and secondary outcomes                                                                                                                                     | 11   |
|               | 12b  | Methods for additional analyses, such as subgroup analyses and adjusted analyses                                                                                                                                               | 12   |
| Results       | 13a  | For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome                                                                   | N/A  |
|               | 13b  | For each group, losses and exclusions after randomisation, together with reasons                                                                                                                                  | N/A  |
| Recruitment   | 14a  | Dates defining the periods of recruitment and follow-up                                                                                                                                                           | 7    |
|               | 14b  | Why the trial ended or was stopped                                                                                                                                                                           | N/A  |
| Baseline data | 15   | A table showing baseline demographic and clinical characteristics for each group                                                                                                                                | 12, Table 1 (31) |
| Numbers analysed | 16  | For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups                                                                            | 7    |
| Outcomes and estimation | 17a | For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)                                                   | 13   |
|               | 17b  | For binary outcomes, presentation of both absolute and relative effect sizes is recommended                                                                                                                      | 13   |
| Ancillary analyses | 18  | Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory                                                                          | 13–14 |
| Harms         | 19   | All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)                                                                                                           | N/A  |
| Discussion    | 20   | Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses                                                                                                  | 15   |
| Generalisability | 21  | Generalisability (external validity, applicability) of the trial findings                                                                                                                                     | 18   |
| Interpretation | 22  | Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence                                                                                            | 14–18 |
| Other information | 23  | Registration number and name of trial registry                                                                                                                                                                  | 4    |
| Protocol      | 24   | Where the full trial protocol can be accessed, if available                                                                                                                                                     | N/A  |
| Funding       | 25   | Sources of funding and other support (such as supply of drugs), role of funders                                                                                                                                   | 20–21 |