## CONSORT 2010 checklist of information to include when reporting a randomised trial*

| Section/Topic          | Item No | Checklist item                                                                 | Reported on Page Number/Line Number | Reported on Section/Paragraph |
|------------------------|---------|---------------------------------------------------------------------------------|-------------------------------------|------------------------------|
| **Title and abstract** | 1a      | Identification as a randomised trial in the title                              | Page 1/line 1-3                     | Title/Para 1                  |
|                        | 1b      | Structured summary of trial design, methods, results, and conclusions (for specific guidance see Table 2) | Page 3-4/line 2-18,1-3              | Abstract/Para 1-4             |
| **Introduction**       | 2a      | Scientific background and explanation of rationale                             | Page 5-6/line 2-18,1-8              | Introduction/Para 1-2         |
|                        | 2b      | Specific objectives or hypotheses                                               | Page 6/line 9-18                    | Introduction/Para 3-4         |
| **Methods**            | 3a      | Description of trial design (such as parallel, factorial) including allocation ratio | Page 9/line 12-15                   | Methods/Par 7                 |
|                        | 3b      | Important changes to methods after trial commencement (such as eligibility criteria), with reasons | N/A                                 | no change                    |
| **Participants**       | 4a      | Eligibility criteria for participants                                           | Page 8-9/line 5-18, 1-3             | Methods/Par 2-4               |
|                        | 4b      | Settings and locations where the data were collected                           | Page 8/line 3-4                     | Methods/Par 1                 |
| **Interventions**      | 5       | The interventions for each group with sufficient details to allow replication, including how and when they were actually administered | Page 9-10/line 12-18,1-2            | Methods/Par 7                 |
| **Outcomes**           | 6a      | Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed | Page 13/line 2-4                    | Methods/Par 14                |
|                        | 6b      | Any changes to trial outcomes after the trial commenced, with reasons          | N/A                                 | no change                    |
| **Sample size**        | 7a      | How sample size was determined                                                  | Page 11/line 4-8                    | Methods/Par 12                |
|                        | 7b      | When applicable, explanation of any interim analyses and stopping guidelines    | Page 11/line 9-11                   | Methods/Par 13                |
| **Randomisation:**     | 8a      | Method used to generate the random allocation sequence                          | Page 9/line 15                      | Methods/Par 7                 |
|                        | 8b      | Type of randomisation; details of any restriction (such as blocking and block size) | N/A                                 | We do not stratify            |
| **Allocation concealment mechanism** | 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                                 | open -label study             |
| Implementation       | 10  | Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions | Page 8/line 3  
Page 9/line 14 | Methods/Par1,7 |
|----------------------|-----|-----------------------------------------------------------------------------------------------------------------|----------------|----------------|
| Blinding             | 11a | If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how | N/A            | open-label study |
|                      | 11b | If relevant, description of the similarity of interventions                                                      | N/A            | open-label study |
| Statistical methods  | 12a | Statistical methods used to compare groups for primary and secondary outcomes                                    | Page 13/line 6 | Methods/Par 15 |
|                      | 12b | Methods for additional analyses, such as subgroup analyses and adjusted analyses                                 | Page 13/line 5 | Methods/Par 15 |
| Results              | 13a | For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome | Page 14/line 3-6 | Results/Par 1  |
|                      | 13b | For each group, losses and exclusions after randomisation, together with reasons                                    | Page 14/line 3-6 | Results/Par 1  |
| Recruitment          | 14a | Dates defining the periods of recruitment and follow-up                                                          | Page 14/line 3 | Results/Par 1  |
|                      | 14b | Why the trial ended or was stopped                                                                              | Page 14/line 3-4 | Results/Par 1  |
| Baseline data        | 15  | A table showing baseline demographic and clinical characteristics for each group                                 | Page 14/line 6-8 | Results/Par 1  |
| Numbers analysed     | 16  | For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups | Page 14/line 5-6 | Results/Par 1  |
| 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) | Page 15/line 1-15 | Results/Par 3-4 |
|                      | 17b | For binary outcomes, presentation of both absolute and relative effect sizes is recommended                        | N/A            | This phase II study was |
| Ancillary analyses   | 18  | Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory | N/A            | These kinds of analyses had not been planned in |
| Harms                | 19  | All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)             | Page 16/line 6-12 | Results/Par 6  |
| Discussion           | 20  | Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses   | Page 20/line 12-17 | Discussion/Par 7 |
| Generalisability     | 21  | Generalisability (external validity, applicability) of the trial findings                                       | Page 17/line 2-7 | Discussion/Par 1 |
| Interpretation       | 22  | Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence      | Page 20-21/line18,1-2 | Discussion/Par 8 |
| Other information    | 23  | Registration number and name of trial registry                                                                   | Page 13/line 7-8 | Methods/Par15  |
Table 2 Items to include when reporting a randomized trial in a journal or conference abstract

| Item                | Description                                                                 | Reported on Page Number/Line Number | Reported on Section/Paragraph |
|---------------------|-----------------------------------------------------------------------------|-------------------------------------|------------------------------|
| Title               | Identification of the study as randomized                                    | Page 1/line 1-3                     | Title/Para 1                 |
| Authors *           | Contact details for the corresponding author                                 | Page 2/line 11-14                   | Title/Para 1                 |
| Trial design        | Description of the trial design (e.g. parallel, cluster, non-inferiority)    | Page 6/line 17-18                   | Introduction/Para 4          |
| Methods             |                                                                              |                                     |                              |
| Participants        | Eligibility criteria for participants and the settings where the data were collected | Page 8-9/line 3-18, 1-3             | Methods/Para 2-4             |
| Interventions       | Interventions intended for each group                                         | Page 9-10/line 12-18,1-2            | Methods/Para 7               |
| Objective           | Specific objective or hypothesis                                              | Page 12/line 15-17                  | Methods/Para 13              |
| Outcome             | Clearly defined primary outcome for this report                              | Page 12/line 14-15                  | Methods/Para 13              |
| Randomization       | How participants were allocated to interventions                              | Page 9/line 15                      | Methods/Para 7               |
| Blinding (masking)  | Whether or not participants, care givers, and those assessing the outcomes were blinded to group assignment | N/A                                 | open-label study             |
| Results             |                                                                              |                                     |                              |
| Numbers randomized  | Number of participants randomized to each group                               | Page 14/line 3-4                    | Results/Para 1               |
| Recruitment         | Trial status                                                                  | Page 14/line 3                      | Results/Para 1               |
| Numbers analysed    | Number of participants analysed in each group                                 | Page 14/line 4-6                    | Results/Para 1               |
| Outcome             | For the primary outcome, a result for each group and the estimated effect size and its precision | Page 15/line 14-16                  | Results/Para 4               |
| Harms               | Important adverse events or side effects                                      | Page 16/line 6-12                   | Results/Para 6               |
| Conclusions                        | General interpretation of the results | Page 17/line 2-7 | Discussion/Par 1 |
|----------------------------------|--------------------------------------|----------------|-----------------|
| Trial registration               | Registration number and name of trial register | Page 13/line 7-8 | Methods/Par15   |
| Funding                          | Source of funding                     | N/A            | This study had never been |

* this item is specific to conference abstracts

From: Hopewell S, Clarke M, Moher D, et al. CONSORT for reporting randomized controlled trials in journal and conference abstracts: explanation and elaboration. PLoS Med. 2008;5(1):e20

Article Information: http://dx.doi.org/10.21037/tlcr-20-721
*As the checklist was provided upon initial submission, the page number/line number reported may be changed due to copyediting and may not be referable in the published version. In this case, the section/paragraph may be used as an alternative reference.