## Table 1: CONSORT 2010 checklist of information to include when reporting a randomised trial (for a downloadable version of this checklist see Text S1 or the CONSORT website)\*

**Section/Topic Item**

**no.**

**Checklist Item Reported on**

**page no.**

Title and abstract

Introduction

Page 1 to 4

1a Identification as a randomised trial in the title

1b Structured summary of trial design, methods, results and conclusions (for

specific guidance see CONSORT for abstracts[21,31])

Background and objectives 2a Scientific background and explanation of rationale **page 5&6**

2b Specific objectives or hypotheses

Methods **Page 7**

Trial design 3a Description of trial design(such as parallel, factorial) including allocation ratio 3b Important charges to methods after trial commencement (such as eligibility

criteria), with reasons

Participations 4a Eligibility criteria for participants page 8

4b Settings and locations where the data were collected

Interventions 5 The interventions for each group with sufficient details to allow replication, page 9&10

including how and when they were actually administered

Outcomes a Completely defined pre-specified primary and secondary outcome measures, page8 &9

including how and when they were assessed

6b Any changes to trial outcomes after the trial commenced, with reasons

Sample size 7a How sample size was determined

7b When applicable, explanation of any interim analyses and stopping guidelines page 7

Randomisation page 9&10

Sequence generation 8a Method used to generate the random allocation sequence page 10

8b Type of randomisation, details of any restriction (such as blocking and block size)

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

Implementation 10 Who generated the random allocation sequence, who enrolled participants, and

who assigned participants to interventions page 10

Blinding 11a If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how **page 10**

11b If relevant, description of the similarity of interventions

Statistical methods 12a Statistical methods used to compare groups for primary and secondary page 10

outcomes

12b Methods for additional analyses, such as subgroup analyses and adjusted analyses

Results

Participant flow (a diagram is

strongly recommended)

page 11-13

13a For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for primary outcome

13b For each group, losses and exclusions after randomisation, together with reasons

Recruitment 14a Dates defining the periods of recruitment and follow-up page 8

14b Why the trial ended or was stopped

Baseline data 15 A table showing baseline demographic and clinical characteristics for each group Number analysed 16 For each group, number of participants (denominator) included in each ( analysis Yes- Table 1

and whether the analysis was by original assigned groups

Outcomes and estimation 17a For each primary and secondary outcomes, results for each group, and the

estimated effect size and its precision (such as 95% confidence interval)

17b For binary outcomes, presentation of both absolute and relative effect sizes in recommended

Ancillary analyses 18 Results of any other analyses perform, including subgroup analyses and

adjusted analyses, distinguishing pre-specified from exploratory

Harms 19 All important harms or unintended effects in each group (for specific guidance

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## Table 1: (Contd. )

**Section/Topic Item**

**no.**

**Checklist Item Reported on**

**page no.**

Discussion page 13-15

Limitations 20 Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses, page 14

Generalisability 21 Generalisability (external validity, applicability) of trial findings page 13-14

Interpretation 22 Interpretation consistent with results, balancing benefits and harms, and

considering other relevant evidence

Other information

Registration 23 Registration number and name of trial registry page 11

Protocol 24 Where the full trial protocol can be accessed, if available page 10

Funding 25 Sources of funding and other support (such as supply of drugs), role of funders page18