Template for Randomized Trials-Based on:  
EQUATOR- CONSORT

Checklist, please refer to <https://www.equator-network.org/reporting-guidelines/consort/> for more information. Please mark N/A where the questions are not applicable, however, the study should meet most if not all of the criteria below.

Title

Identified as randomized in the title

Comments:

Abstract

Structure and summary of trial design, methods, results and conclusions

Comments:

Introduction - Background and Objectives

Scientific Background, and significance of conducting the research, including rationale

Specific Objectives/Hypothesis/Aims

Page number:

Comments:

Methods

Trial design to include: Participants, inclusion and exclusion criteria, sample size calculations, and setting

Page number:

Comments:

IRB approval

Page number:

Comments:

Interventions and groups

Interventions and groups, how groups were selected, blinding and randomization methods. Time period for recruitment and follow up

Page numbers:

Comments:

Defined outcomes

Defined outcomes pre-specified outcome measures, how and when they were assessed. Defined length of the study.

Page number:

Comments:

Statistical methods

Statistical methods comparing groups for primary and secondary outcomes, are they appropriate for the study

Page number:

Comments:

Results

For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analyzed for the primary outcome. Any losses or exclusions, along with reasons.

Page number:

Comments:

Table

Table showing baseline demographics, and clinical characteristic of the each group

Page number, table number

Comments:

Numbers Analyzed

Numbers analyzed-For each group, number of participants included in each analysis and whether the analysis was by original assigned groups

Page numbers (table or graph numbers if applicable)

Comments:

Primary and secondary outcome

For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval). Results of any other, secondary analyses if undertaken

Page numbers (table or graph numbers if applicable)

Comments:

Harms/unintended consequences

All important harms or unintended effects in each group. If not applicable, please enter “NA”

Page numbers (table or graph numbers if applicable)

Comments:

Discussion

Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence

Page numbers:

Comments:

Generalizability

Generalizability (external validity, applicability) of the trial findings

Page number:s

Comments:

Trial limitations

Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses

Page number:

Comments:

Future research recommendation

Page number:

Comments:

Funding source

Page number:

Comments:

Any Additional Comments