[TITLE] The authors should provide a descriptive title that clearly identifies the study design, population, interventions, and, if applicable, trial acronym.

Authors:

[Include the names and affiliations of all authors]

Contact Details for Corresponding Author:

[Include the corresponding author's name, email address, and any other relevant contact information]

ABSTRACT [Maximum Length 300 Words]

[Provide a clear description of the trial design, e.g., Parallel, Cluster, Non-inferiority]

Background

- ☐ Clearly state the specific objective or hypothesis that your study aimed to address]
- ☐ The references should not be used in this section.

Methods

- ☐ Describe the criteria that participants had to meet in order to be included in the study.
- ☐ Specify the locations or settings where the data collection took place.
- ☐ Describe the interventions that were administered to the different groups in your study.
- ☐ Specify the primary outcome measure that was the focus of your study.
- ☐ Explain the method used for randomization, such as random number generation or a specific randomization software.
- ☐ Indicate whether blinding was employed in your study, and if so, who was blinded (participants, caregivers, outcome assessors) and to what extent

Results

- ☐ Specify the number of participants assigned to each experimental group.
- ☐ Indicate the current status of the trial (e.g., ongoing, completed, terminated, etc.).
- ☐ Specify the number of participants who completed the study and were included in the analysis for each group.
- ☐ Provide the specific results or findings for each experimental group.
- ☐ Include the estimated effect size (e.g., mean difference, odds ratio) and its precision (e.g., confidence interval) for the primary outcome.
- ☐ List any important adverse events or side-effects that were observed during the course of the study. Provide details such as the type of event, frequency, severity, and any actions taken.

Conclusion

- ☐ Provide a concise and clear interpretation of the results obtained in your study. Summarize the key findings and their implications in the context of your research question or hypothesis.

Trial Registration

- ☐ Include the registration number and the name of the trial register where your study was registered. This is important for transparency and to ensure the study's compliance with ethical and reporting standards.

  Example: ACTRN0000000000.

Funding

- ☐ Indicate the source(s) of funding that supported your research. This includes grants, institutional support, or any financial contributions. Be specific about the funding sources.

INTRODUCTION

☐ **Scientific Background and Explanation of Rationale:** Provide a brief overview of the scientific context and background that led to your study. Explain the rationale for conducting the research, including any gaps or knowledge deficiencies in the existing literature that your study aims to address.]

☐ **Specific Objectives or Hypothesis:** Clearly state the specific objectives or hypothesis of your study. Describe what you aim to achieve or investigate in your research.]

METHODS

☐ The methods section should mention six subtopics: trial design, participants, interventions, outcomes, sample size, and randomization-sequence generation.

Trial Design

☐ • Provide a clear description of the trial design, including whether it's parallel, factorial, or any other design, and specify the allocation ratio if applicable.

☐ • Describe any significant changes made to the trial design or methods after the trial started, and provide reasons for these changes.

Participants

☐ • List the criteria that participants had to meet in order to be eligible for the study.

☐ • Specify the settings and locations where data collection occurred.

Interventions

☐ Detail the interventions administered to each group, including the specifics of how and when they were administered. Provide sufficient information to allow replication.

Outcomes

☐ • List all primary and secondary outcome measures, specifying how and when they were assessed.

☐ • Describe any modifications made to the trial outcomes after the trial had begun and provide the reasons for these changes.

Sample Size

☐ • Explain the method used to calculate the required sample size for your study.

☐ • If applicable, explain whether interim analyses were conducted during the study and provide any predetermined stopping guidelines.

Randomization - Sequence Generation

☐ • Explain the method or approach used to create the random allocation sequence.

☐ • Specify the type of randomization employed (e.g., simple randomization, stratified randomization) and provide details of any restrictions, such as blocking and block size.

Randomization - Allocation Concealment Mechanism

☐ Describe the mechanism employed to conceal the random allocation sequence, such as the use of sequentially numbered containers. Explain any steps taken to ensure the sequence remained concealed until interventions were assigned.

Randomization – Implementation

☐ • Specify who generated the allocation sequence.

☐ • Describe who enrolled participants in the study

☐ • Explain who was responsible for assigning participants to their respective interventions.

Blinding

☐ • Indicate if blinding (masking) was implemented after participants were assigned to interventions. Specify who was blinded, such as participants, care providers, or outcome assessors, and describe how this was achieved

☐ • If relevant, provide details about the similarity of interventions, particularly in cases where blinding was utilized to ensure that participants and assessors remained unaware of group assignments.

Statistical Methods

☐ • Explain the statistical methods used to compare the groups for both primary and secondary outcomes. Include details of the statistical tests or analyses conducted.

☐ • Describe the methods used for any additional analyses, such as subgroup analyses or adjusted analyses, and explain their purpose.

RESULTS

Participant Flow Diagram (Strongly Recommended):

☐ Create a diagram for each group, illustrating the numbers of participants who underwent random assignment, received the intended treatment, and were included in the analysis for the primary outcome.

Participant Flow:

☐ • Document any losses and exclusions that occurred after randomization for each group.

☐ • Clearly state the reasons for these losses and exclusions.

Recruitment:

☐ • Define the specific dates that mark the start and end of the recruitment period.

☐ • Specify the follow-up duration if applicable.

Reason for Trial Termination:

- [ ] Explain why the trial ended or was prematurely stopped, providing a clear rationale.

Baseline Data:

- [ ] Prepare a table displaying baseline demographic and clinical characteristics for each group, ensuring that key variables are included.

Numbers Analyzed:

- [ ] • Report the number of participants included in each analysis for every group.
- [ ] • Specify whether the analysis was conducted based on the original assigned groups.

Outcomes and Estimation:

- [ ] • For both primary and secondary outcomes, present results for each group.
- [ ] • Include the estimated effect size along with its precision, typically expressed as a 95% confidence interval.
- [ ] • For binary outcomes, present both absolute and relative effect sizes as applicable.

Ancillary Analyses:

- [ ] • Report the results of any additional analyses performed, including subgroup analyses and adjusted analyses.
- [ ] • Clearly distinguish between pre-specified analyses and exploratory ones.

Harms:

- [ ] • Document all important harms or unintended effects that occurred in each group.
- [ ] • Follow specific guidance from CONSORT for reporting harms if available

DISCUSSION

Limitations:

- [ ] • Identify and discuss the limitations of the trial.
- [ ] • Address potential sources of bias that may have affected the study's results.
- [ ] • Highlight areas of imprecision in the data or analyses.
- [ ] • If relevant, acknowledge and address the issue of multiplicity of analyses, such as multiple comparisons or subgroup analyses.

Generalisability:

- [ ] • Assess and discuss the generalisability (external validity) of the trial findings.
- [ ] • Consider the extent to which the study results can be applied to broader populations, settings, or circumstances.
- [ ] • Examine the applicability of the findings to real-world clinical practice.

Interpretation:

- [ ] • Interpret the trial results in a manner that is consistent with the data presented.
- [ ] • Weigh the benefits and harms of the intervention or treatment under investigation.
- [ ] • Consider other relevant evidence from the literature or related studies when interpreting the findings.
- [ ] • Offer a balanced and reasoned interpretation of the study's implications for clinical practice or further research.

Other

- [ ] Provide information about where the full trial protocol can be accessed, if it is available.
- [ ] Ensure that readers have access to the detailed trial protocol for a more comprehensive understanding of the study's design, methods, and objectives.

Last Checks

- [ ] The resolution of the images used should be of high quality.
- [ ] Consent should be obtained from the patient for the use of images, and the source should be accurately referenced.
- [ ] The references used should not be older than 7 years.
- [ ] The tables used should be clear and informative.