



Study Protocol Article Template

Title

Metadata

Funding

Competing interests

Data availability

Abstract

Must include the trial/study registration number where applicable

Introduction

Explain the rationale for the study, the hypotheses it is designed to test, and what new evidence it is anticipated to provide. Appropriate previous literature should be referenced.

Materials and Methods

Should include:

- the aim, design and setting of the study
- The sample size, inclusion and exclusion criteria
- the characteristics of participants and how the sample will be selected and, where applicable, randomization and blinding. Or, a description of how materials will be selected for the study and used
- a description of all processes, interventions, comparisons
- what outcomes will be measured, when and how
- data management plans
- safety considerations, if applicable
- the type of data and statistical analyses planned

- ethical considerations and declarations
- the status and timeline of the study

Discussion

Include discussion of any issues involved in performing the study that are not covered in other sections. These can include:

- limitations of the study design
- dissemination plans
- how amendments to the study, including termination, will be dealt with

Authors' contributions

Acknowledgements

Supporting Information

Might include checklists e.g. PRISMA-P, SPIRIT

References