SPIRIT 2025 Checklist

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Scope: Standard Protocol Items: Recommendations for Interventional Trials.

Reference: See `source/archetypes/spirit-2025.yml` for canonical link and provenance.

Instructions

- Use the boxes to confirm each reporting item.
- Add reviewer notes under each section as needed.

Administrative information

- ☐ **1. Title:** Descriptive title that identifies the study as a randomised trial, the interventions, the trial acronym, and the SPIRIT item this protocol is based on.
- ☐ **2. Trial registration:** Trial identifier and registry name. If not yet registered, name of intended registry.
- ☐ **3. Protocol version:** Date and version identifier.
- ☐ **4. Funding:** Sources and types of financial, material, and other support.
- ☐ **5. Roles and responsibilities:** Names, affiliations, and roles of protocol contributors.

Introduction

- ☐ **6. Background and rationale:** Description of research question and justification for undertaking the trial, including summary of relevant studies.
- ☐ **7. Objectives:** Specific objectives or hypotheses.

Methods: Participants, interventions, and outcomes

- ☐ **8. Trial design:** Description of trial design including type of trial, allocation ratio, and framework.
- ☐ **9. Study setting:** Description of study settings.
- ☐ **10. Eligibility criteria:** Inclusion and exclusion criteria for participants.
- ☐ **11. Interventions:** Interventions for each group with sufficient detail to allow replication.
- ☐ **12. Outcomes:** Primary, secondary, and other outcomes.

Methods: Assignment of interventions (for controlled trials)

- ☐ **13. Allocation:** Sequence generation, concealment mechanism, and implementation.
- ☐ **14. Blinding (masking):** Who will be blinded and how.

Methods: Data collection, management, and analysis

- ⍰ **15. Data collection methods:** Plans for assessment and collection of outcome, baseline, and other trial data.
- ⍰ **16. Data management:** Plans for data entry, coding, security, and storage.
- ⍰ **17. Statistical methods:** Statistical methods for analysing primary and secondary outcomes.

Methods: Monitoring

- ⍰ **18. Data monitoring:** Plans for data monitoring.
- ⍰ **19. Harms:** Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct.
- ⍰ **20. Auditing:** Frequency and procedures for auditing trial conduct.

Ethics and dissemination

- ⍰ **21. Research ethics approval:** Plans for seeking research ethics committee/institutional review board approval.
- ⍰ **22. Protocol amendments:** Plans for communicating important protocol modifications to relevant parties.
- ⍰ **23. Consent or assent:** Who will obtain informed consent or assent from potential trial participants or authorized surrogates, and how.
- ⍰ **24. Confidentiality:** How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial.
- ⍰ **25. Declaration of interests:** Financial and other competing interests for principal investigators for the overall trial and each study site.
- ⍰ **26. Access to data:** Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators.
- ⍰ **27. Ancillary and post-trial care:** Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation.
- ⍰ **28. Dissemination policy:** Plans for investigators and sponsors to authors and other stakeholders to share trial results.
- ⍰ **29. Authorship eligibility:** Guidelines for authorship eligibility for trial publications.
- ⍰ **30. Reproducibility:** Plans for sharing of original data and statistical code.

Appendices

- ⍰ **31. Informed consent materials:** Model consent form and other related documentation given to participants and authorized surrogates.

- ⍰ **32. Biological specimens:** Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable.

Notes

Provenance

- Source: See sidecar metadata in `source/archetypes/spirit-2025.yml`
- Version: 2025
- License: CC-BY-4.0