# SPIRIT Checklist for *Trials*

| | | Reporting Item | Page and Line Number | Reason if not applicable |
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| **Administrative information** | | | | |
| Title | #1 | Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym | Line 1-2, Page 1 | |
| Trial registration | #2a | Trial identifier and registry name. If not yet registered, name of intended registry | Line 40-41, Page 2 | |
| Trial registration: data set | #2b | All items from the World Health Organization Trial Registration Data Set | n/a | The study protocol has been registered in Chinese Clinical Trial Registry. |
| Protocol version | #3 | Date and version identifier | Line 259-260, Page 10 | |
| Funding | #4 | Sources and types of financial, material, and other support | Line 274-275, Page 11 | |
| Roles and responsibilities: contributorship | #5a | Names, affiliations, and roles of protocol contributors | Line 4-5, Page 1 | |
| Roles and responsibilities: sponsor contact information | #5b | Name and contact information for the trial sponsor | n/a | This study does not have sponsors. |
| Roles and responsibilities: sponsor and funder | #5c | Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and | Line 274-275, Page 11 | |

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| | | the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities | | |
| Roles and responsibilities: committees | #5d | Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee) | Line 198-208, Page 8 | |
| **Introduction** | | | | |
| Background and rationale | #6a | Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention | Line 43-51, Page 2-3 | |
| Background and rationale: choice of comparators | #6b | Explanation for choice of comparators | Line 52-58, Page 3 | |
| Objectives | #7 | Specific objectives or hypotheses | Line 66-68, Page 3 | |
| Trial design | #8 | Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, non-inferiority, exploratory) | Line 72-73, Page 4 | |
| **Methods: Participants, interventions, and outcomes** | | | | |

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| Study setting | #9 | Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained | Line 72-80, Page 4 | |
| Eligibility criteria | #10 | Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists) | Line 93-101, Page 4-5 | |
| Interventions: description | #11a | Interventions for each group with sufficient detail to allow replication, including how and when they will be administered | Line 144-174, Page 6-7 | |
| Interventions: modifications | #11b | Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving / worsening disease) | Line 212-217, Page 9 | |
| Interventions: adherence | #11c | Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return; laboratory tests). Also relevant for non-pharmacological RCTs. | Line 203-205, Page 8 | |
| Interventions: concomitant care | #11d | Relevant concomitant care and interventions that are permitted or prohibited during the trial | Line 208-210, Page 8 | |
| Outcomes | #12 | Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), | Line 104-128, Page 5 | |

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| | | method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended | | |
| Participant timeline | #13 | Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure) | Line 222-223, Page 9 | |
| Sample size | #14 | Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations | Line 177-195, Page7- 8 | |
| Recruitment | #15 | Strategies for achieving adequate participant enrolment to reach target sample size | Line 220-223, Page 9 | |
| **Methods: Assignment of interventions (for controlled trials)** | | | | |
| Allocation: sequence generation | #16a | Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions | Line 132-136, Page 6 | |
| Allocation concealment mechanism | #16b | Mechanism of implementing the allocation sequence (eg, central telephone; sequentially | Line132-133, Page 6 | |

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| | | numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned | | |
| Allocation: implementation | #16c | Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions | Line 133-135, Page 6 | |
| Blinding (masking) | #17a | Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how | Line 139-140, Page 6 | |
| Blinding (masking): emergency unblinding | #17b | If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial | Line 140-141, Page 6 | |
| **Methods: Data collection, management, and analysis** | | | | |
| Data collection plan | #18a | Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol | Line 198-201, Page 8 | |
| Data collection plan: retention | #18b | Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who | Line 202-205, Page 8 | |

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| | | discontinue or deviate from intervention protocols | | |
| Data management | #19 | Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol | Line203-206, Page 8 | |
| Statistics: outcomes | #20a | Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol | Line 226-231, Page 9 | |
| Statistics: additional analyses | #20b | Methods for any additional analyses (eg, subgroup and adjusted analyses) | Line 226-231, Page 9 | |
| Statistics: analysis population and missing data | #20c | Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation) | Line 226-231, Page 9 | |
| **Methods: Monitoring** | | | | |
| Data monitoring: formal committee | #21a | Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed | Line 202-205, Page 8 | |

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| Data monitoring: interim analysis | #21b | Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial | Line 212-213, Page 9 | |
| Harms | #22 | Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct | Line 208-210, Page 8 | |
| Auditing | #23 | Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor | Line 216-217, Page 9 | |
| **Ethics and dissemination** | | | | |
| Research ethics approval | #24 | Plans for seeking research ethics committee / institutional review board (REC / IRB) approval including the committee's reference number (if applicable) | Line 88-91, Page 4 | |
| Protocol amendments | #25 | Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC / IRBs, trial participants, trial registries, journals, regulators) | Line 78-79, Page 4 | |
| Consent or assent | #26a | Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32) | Line 84-87, Page 4 | |

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| Consent or assent: ancillary studies | #26b | Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable | n/a | The subjects' data will not be used in other ancillary studies. |
| Confidentiality | #27 | 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 | Line 278-279, Page 11 | |
| Declaration of interests | #28 | Financial and other competing interests for principal investigators for the overall trial and each study site | n/a | The authors declare that they have no competing interests. |
| Data access | #29 | Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators | Line278-279, Page 11 | |
| Ancillary and post trial care | #30 | Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation | n/a | There is no provisions for compensation in this study. |
| Dissemination policy: trial results | #31a | Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions | Line 79-80, Page 4 | |
| Dissemination policy: authorship | #31b | Authorship eligibility guidelines and any intended use of professional writers | Line 268-271, Page 11 | |

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| Dissemination policy: reproducible research | #31c | Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code | Line277-279, Page 11 | |
| **Appendices** | | | | |
| Informed consent materials | #32 | Model consent form and other related documentation given to participants and authorised surrogates | Line281-284, Page 11 | |
| Biological specimens | #33 | 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 | n/a | This trial did not involve genetic or molecular testing. |