# Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) Checklist

<table>
<thead>
<tr>
<th>Section/item</th>
<th>Item No</th>
<th>Description</th>
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<tbody>
<tr>
<td>Administrative information</td>
<td></td>
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</tr>
<tr>
<td>Title</td>
<td>1</td>
<td>Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym</td>
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<tr>
<td></td>
<td></td>
<td><em>A Pragmatic Multi-Centre Stepped Wedge Cluster Randomised Trial to Investigate the Effectiveness of Community-based Falls Prevention Programme for Older Adults with Falls Risk in Singapore: Protocol Paper</em></td>
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<tr>
<td>Trial registration</td>
<td>2a&amp;2b</td>
<td>Trial identifier and registry name. If not yet registered, name of intended registry.</td>
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<td></td>
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<td>All items from the World Health Organization Trial Registration Data Set.</td>
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<tr>
<td></td>
<td></td>
<td><em>ClinicalTrials.gov ID NCT04788251. Study progress has been updated to the registry, approved, and released in the registry on 03 January 2022. Link:</em></td>
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<tr>
<td>Protocol version</td>
<td>3</td>
<td>Date and version identifier</td>
</tr>
<tr>
<td></td>
<td></td>
<td><em>Not applicable.</em></td>
</tr>
<tr>
<td>Funding</td>
<td>4</td>
<td>Sources and types of financial, material, and other support</td>
</tr>
<tr>
<td></td>
<td></td>
<td><em>This work was supported by National Medical Research Council, Singapore, under National Innovation Challenge on Active and Confident Ageing (Award No.: MOH/NIC/F1/2017).</em></td>
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<tr>
<td>Roles and responsibilities</td>
<td>5a</td>
<td>Names, affiliations, and roles of protocol contributors</td>
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<tr>
<td></td>
<td></td>
<td><em>Refer to author lists and contribution statement.</em></td>
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<tr>
<td></td>
<td>5b</td>
<td>Name and contact information for the trial sponsor</td>
</tr>
<tr>
<td></td>
<td></td>
<td><em>National Medical Research Council, Singapore, under National Innovation Challenge on Active and Confident Ageing, NIC(PO): <a href="mailto:NIC_Ageing@moh.gov.sg">NIC_Ageing@moh.gov.sg</a></em></td>
</tr>
<tr>
<td>5c</td>
<td>Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities.</td>
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*Study sponsor and funders have no role in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication.* |

| 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). |

*There will be no independent Data Monitoring Committee for this trial. Both exercise interventions have relatively low risk as they have been widely implemented in other populations, and shown to reduce falls and to be safe to implement. Data Safety Monitoring Board will oversee the adverse events reporting.* |

### 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. |

*Refer to Introduction* |

6b | Explanation for choice of comparators |

*Refer to Introduction, and Method and Analysis: Control group* |

### Objectives

7 | Specific objectives or hypotheses |

*The study has two aims. First, we aim to evaluate the effectiveness of the intervention in reducing falls risk (measures of physical performance and fear of falling) for older adults with falls risk in Singapore. Second, we aim to evaluate the impact of the intervention on other health outcomes (falls, loneliness, health-related quality of life, subjective health, falls-related protective behaviours, falls-related healthcare utilisation and costs). We hypothesise that those who have received the intervention would have reduced falls risk (i.e. higher physical performance and lower fear of falling) and improved health outcomes compared to those who are wait list controls.*
| Trial design | 8 | Description of trial design including type of trial (e.g., parallel group, crossover, factorial, single group), allocation ratio, and framework (e.g., superiority, equivalence, noninferiority, exploratory)  
Refer to Method and Analysis: Trial Design and Setting |
|---|---|---|
| Methods: Participants, interventions, and outcomes | 9 | Study setting: Description of study settings (e.g., community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained  
Refer to Method and Analysis: Trial Design and Setting |
| | 10 | Eligibility criteria: Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (e.g., surgeons, psychotherapists)  
Refer to Method and Analysis: Participants |
| Interventions | 11a | Interventions for each group with sufficient detail to allow replication, including how and when they will be administered  
Refer to Method and Analysis: Intervention Condition |
| | 11b | Criteria for discontinuing or modifying allocated interventions for a given trial participant (e.g., drug dose change in response to harms, participant request, or improving/worsening disease)  
Refer to Method and Analysis: Intervention Condition and Adverse Events Reporting |
| | 11c | Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (e.g., drug tablet return, laboratory tests)  
Refer to Method and Analysis: Intervention |
| | 11d | Relevant concomitant care and interventions that are permitted or prohibited during the trial  
Refer to Participants: Eligibility criteria for participants |
| Outcomes | 12 | Primary, secondary, and other outcomes, including the specific measurement variable (e.g., systolic blood pressure), analysis metric (e.g., change from baseline, final value, time to event), method of aggregation (e.g., median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended  
Refer to Method and Analysis: Outcomes |
| 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)

Refer to Method and Analysis: Participant Timeline and Figure 2. |
| 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

Refer to Method and Analysis: Sample Size. |
| Recruitment | 15 | Strategies for achieving adequate participant enrolment to reach target sample size

Refer to Method and Analysis: Participant timeline – Recruitment. |

### Methods: Assignment of interventions (for controlled trials)

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<th>Allocation:</th>
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| 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

Refer to Method and Analysis: Assignment of Interventions – Allocation and Blinding |
| Allocation concealment mechanism | 16b | Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned

Refer to Method and Analysis: Assignment of Interventions – Allocation and Blinding |
| Implementation | 16c | Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions

Refer to Method and Analysis: Assignment of Interventions |
| Blinding (masking) | 17a | Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how

Refer to Method and Analysis: Assignment of Interventions – Allocation and Blinding |
| 17b | If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant’s allocated intervention during the trial  
*Refer to Method and Analysis: Assignment of Interventions – Allocation and Blinding* |
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<td><strong>Methods: Data collection, management, and analysis</strong></td>
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| **Data collection methods** | 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  
*Refer to Method and Analysis: Data collection, management, and quality assurance. Data collection forms are available upon request.* |
| 18b | Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols  
*Refer to Method and Analysis: Participants – Study Assessments.* |
| **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  
*Refer to Method and Analysis: Data collection, management, and quality assurance.* |
| **Statistical methods** | 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  
*Refer to Method and Analysis: Data analysis* |
| 20b | Methods for any additional analyses (eg, subgroup and adjusted analyses)  
*Refer to Method and Analysis: Data analysis* |
| 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)  
*Refer to Method and Analysis: Data analysis* |
<p>| <strong>Methods: Monitoring</strong> |  |  |</p>
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| Data monitoring          | 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.  
Refer to Method and Analysis: Data collection, management, and quality assurance. There will be no independent Data Monitoring Committee for this trial. Both exercise interventions have relatively low risk as they have been widely implemented in other populations, and shown to reduce falls and to be safe to implement. |
| Harms                    | 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  
Refer to Method and Analysis: Data collection, management, and quality assurance. |
| Auditing                 | 22   | Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct  
Refer to Method and Analysis: Adverse Events Reporting |
| Ethics and dissemination | 23   | Plans for seeking research ethics committee/institutional review board (REC/IRB) approval  
Refer to Ethics and Dissemination: Research Ethics Approval |
| Research ethics approval  | 24   | 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)  
Refer to Ethics and Dissemination: Protocol Amendments |
| Protocol amendments      | 25   | Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)  
Refer to Methods and Analysis: Participant Timeline – Consent |
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<tr>
<th>Appendix</th>
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| 26b      | Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable  
*Not applicable.* |
| 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  
*Refer to Method and Analysis: Data collection, management, and quality assurance.* |
| Declaration of interests | 28 Financial and other competing interests for principal investigators for the overall trial and each study site  
*No competing interests.* |
| Access to data | 29 Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators  
*Refer to Method and Analysis: Data collection, management, and quality assurance.* |
| 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  
*If participants follow the directions of the study team and they are physically injured due to the procedure given under the plan of this study, the Geriatric Education and Research Institute will compensate the medical expenses for the treatment of that injury.* |
| Dissemination policy | 31a Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (e.g., via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions  
*Refer to Ethics and Dissemination: Dissemination Policy* |
|              | 31b Authorship eligibility guidelines and any intended use of professional writers  
*Refer to Ethics and Dissemination: Dissemination Policy* |
|              | 31c Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code  
*Refer to Ethics and Dissemination: Dissemination Policy* |
| Appendices |             |
| Informed consent materials | 32 | Model consent form and other related documentation given to participants and authorised surrogates  

*Available upon request.* |

| 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  

*Not applicable.* |