Online Resource 1. SPIRIT 2025 checklist: recommended items to address in a clinical trial protocol and related documents

Article: “Women in Action”: a multicomponent gender-sensitive intervention combining psychosocial factors, resistance training and nutrition in older women. A quasi-experimental feasibility study protocol

Journal: Aging Clinical and Experimental Research

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Note: the study is a non-randomised quasi-experimental study with covariate-adaptive minimisation; SPIRIT 2025 items on randomisation (21–24) are addressed by describing the allocation procedure actually used. Page numbers to be added after final formatting.

Item	Description	Section where addressed
1a	Title stating trial design, population, interventions, identified as protocol	Title page
1b	Structured summary including WHO Trial Registration Data Set items	Abstract; Methods: Study design (registry, identifier, ethics), Study setting, Participants, Intervention, Outcomes, Sample size; Declarations (sponsor, funding, data sharing)
2	Protocol version date and identifier	Methods: Study design (version 15 June 2026 approved by CEImPA; nature of subsequent editorial changes)
3a	Names, affiliations and roles of protocol contributors	Title page; Author contributions
3b	Name and contact of trial sponsor	Declarations: Sponsor; Title page (corresponding author)
3c	Role of sponsor and funders	Declarations: Sponsor; Funding
3d	Composition and roles of committees	Methods: Monitoring
4	Trial registry, number, URL, date	Abstract (last line); Methods: Study design; Declarations: Clinical trial registration
5	Access to protocol and statistical analysis plan	Methods: Study design
6	Data sharing	Data availability (individual participant data will not be shared)
7a	Funding sources	Funding
7b	Conflicts of interest	Declarations: Conflict of interest
8	Dissemination policy	Methods: Ethical considerations and dissemination; Declarations: Dissemination policy
9a	Background and rationale	Introduction (paragraphs 1–3)
9b	Choice of comparator	Introduction (paragraph 3); Methods: Control condition
10	Objectives	Introduction (last paragraph)
11	Patient and public involvement	Methods: Patient and public involvement (none; lay summaries to participants)
12	Trial design, allocation ratio, framework	Methods: Study design
13	Trial setting	Methods: Study setting
14a	Eligibility criteria for participants	Methods: Participants
14b	Eligibility criteria for sites and delivery staff	Methods: Participants (second paragraph); Study setting
15a	Intervention and comparator with sufficient detail	Methods: Intervention; Control condition; Tables 1–2; Online Resources 2–3 (TIDieR)
15b	Criteria for discontinuing or modifying intervention	Methods: Intervention (fourth paragraph)
15c	Strategies to improve and monitor adherence	Methods: Intervention (fourth paragraph)
15d	Concomitant care permitted or prohibited	Methods: Control condition
16	Outcomes: variable, metric, aggregation, time point	Methods: Outcomes and measures; Table 3
17	Harms: definition and assessment	Methods: Harms; Table 4 (adverse events, both arms)
18	Participant timeline	Methods: Study timeline; Table 4
19	Sample size and assumptions	Methods: Sample size calculation
20	Recruitment strategies	Methods: Sampling and recruitment
21a	Sequence generation: who and method	Methods: Group allocation and blinding (central minimisation by independent statistician)
21b	Type of randomisation; stratification factors	Methods: Group allocation and blinding (minimisation variables; biased-coin element)
22	Allocation concealment mechanism	Methods: Group allocation and blinding
23	Implementation: who enrols/assigns, access to sequence	Methods: Group allocation and blinding

24a	Who will be blinded	Methods: Group allocation and blinding (second paragraph)
24b	How blinding achieved	Methods: Group allocation and blinding (second paragraph)
24c	Unblinding circumstances	Not applicable (open intervention)
25a	Data collection methods and instruments; quality processes	Methods: Outcomes and measures; Data collection and management
25b	Retention and follow-up of discontinuers	Methods: Intervention (fourth paragraph); Data collection and management; Table 4 (self-reported attendance T1–T3)
26	Data management	Methods: Data collection and management
27a	Statistical methods for primary and secondary outcomes and harms	Methods: Statistical analysis; Harms
27b	Analysis population	Methods: Statistical analysis (all participants as allocated; per-protocol sensitivity)
27c	Missing data	Methods: Statistical analysis
27d	Additional analyses (subgroup, sensitivity)	Methods: Statistical analysis
28a	Data monitoring committee	Methods: Monitoring (none; rationale)
28b	Interim analyses and stopping guidelines	Methods: Monitoring (none); Outcomes and measures (progression criteria)
29	Trial monitoring	Methods: Monitoring
30	Research ethics approval	Methods: Study design; Declarations: Ethics approval
31	Protocol amendments	Methods: Ethical considerations and dissemination
32a	Consent: who and how	Methods: Ethical considerations and dissemination
32b	Ancillary studies consent	Methods: Ethical considerations and dissemination (none planned)
33	Confidentiality	Methods: Data collection and management
34	Ancillary and post-trial care; compensation	Methods: Ethical considerations and dissemination; Control condition

Reference: Chan A-W, Boutron I, Hopewell S et al (2025) SPIRIT 2025 statement: updated guideline for protocols of randomised trials. BMJ 389:e081477.