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

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Abstract

Background

After menopause, women lose muscle strength and physical function at an accelerated rate, and gender-related barriers such as internalised stereotypes, caregiving roles and ageism further limit their participation in resistance training. Interventions combining resistance training, nutrition education and psychosocial components addressing these barriers are scarce.

Aims

The principal aim is to evaluate the feasibility, implementation fidelity and acceptability of the “Women in Action” programme in community settings. The secondary aim is to estimate its preliminary effects on the two primary outcomes, handgrip strength and lower-limb strength and physical performance (Short Physical Performance Battery), and on body composition, dietary behaviour and psychosocial variables in women aged 55–75 years.

Methods

Quasi-experimental, two-arm, mixed-methods study in the Principality of Asturias, Spain. Insufficiently active women (n = 214) will be allocated by covariate-adaptive minimisation to a 16-week programme (two supervised multicomponent exercise sessions per week and eight fortnightly psychoeducational and nutrition workshops) or to a passive control group. Assessments will take place at baseline, week 8, week 16 and 3 months after the intervention. Quantitative data will be analysed with linear mixed-effects models and integrated with thematic analysis of focus groups.

Discussion

The study will show whether the programme can be delivered as planned and accepted by participants, and will provide effect-size estimates to inform a subsequent trial.

Conclusions

This protocol describes a replicable, gender-sensitive multicomponent intervention for older women and the procedures for its evaluation under real-world community conditions.

Trial registration

ClinicalTrials.gov NCT07860424, first posted on 6 October 2026.

Introduction

Older women are among the least physically active groups in the population. The World Health Organization (WHO) recommends 150–300 min/week of moderate-intensity aerobic activity, or 75–150 min/week of vigorous activity or an equivalent combination, together with muscle-strengthening activity on at least two days [1]; globally, insufficient aerobic activity is more prevalent in women than in men (31.7% vs 23.4%) [2], and the gap widens with age. The barriers reported by older women are not only physical: fear of injury and limited resources in rural areas coexist with traditional roles and age- and gender-related stereotypes that discourage participation [3, 4], and experimental work shows that stereotype-related messages change how older adults perceive exercise [5]. Any programme that aims to increase physical activity in this group therefore has to address the sociocultural determinants of participation, not only the exercise prescription.

Resistance training is the intervention of choice against the age-related loss of muscle strength and function [6, 7] and improves strength in healthy postmenopausal women [8]. Yet strength has been culturally coded as masculine, and this perception is associated with body-related self-stigma and self-exclusion from strength-based exercise among women [9, 10], so the population that would benefit most is the one least likely to take it up. Nutrition is the second pillar: adherence to the Mediterranean diet is associated with physical resilience in older adults [11], and in people with sarcopenic obesity around retirement age adding protein to exercise reduces fat mass further than exercise alone [12], although whether education changes dietary behaviour in this population remains to be shown. The third pillar is psychosocial: qualitative evidence links psychological needs and motivation to older adults' participation in physical activity [13], cross-sectional data relate agency, autonomy and physical self-efficacy to exercising in women [14], and improvements in body image and self-reported activity have been described after strength training in midlife and older rural women [15]; however, exercise empowerment remains inconsistently operationalised in intervention studies [16]. Multicomponent programmes such as Vivifrail improve functional capacity in frail or pre-frail older adults [17], and exercise improves physical function in residential care [18], but these programmes were not designed for community-dwelling women and do not address the gender-specific barriers that condition their engagement. To our knowledge, no protocol has combined supervised resistance training, nutrition-focused behavioural education and psychoeducation on gender stereotypes, personal agency and body perception within a single intervention for women in the postmenopausal and early older-age period.

“Women in Action” was designed to fill this gap. It is a 16-week multicomponent programme delivered in community settings by exercise, nutrition and psychology professionals, framed within an intersectional, gender-sensitive approach, and described with the level of detail needed for replication. Because the programme will run at several community venues with fixed timetables, randomisation at the individual level is not feasible; a passive control group under usual lifestyle was therefore chosen as comparator, since no comparable programme is available to this population in the study area. Evidence from non-randomised intervention studies can contribute to evidence synthesis provided that confounding and

other risks of bias are addressed explicitly [19], and the design incorporates covariate-adaptive allocation, concealed assignment and adjusted analysis for that purpose.

The principal aim of the study is to evaluate the feasibility, implementation fidelity and acceptability of the programme in community settings. The secondary aim is to estimate, in insufficiently active women aged 55–75 years, the effect of the 16-week programme compared with usual lifestyle on the two registered primary outcomes, handgrip strength and lower-limb strength and physical performance measured with the Short Physical Performance Battery (SPPB), analysed as change from baseline to week 16, and on body composition, dietary behaviour and psychosocial outcomes. It is hypothesised that, compared with the control group, intervention participants will show a greater increase in handgrip strength between baseline and week 16 (first primary contrast) and a greater improvement in SPPB score (second, hierarchically ordered primary contrast), together with favourable changes in body composition, Mediterranean diet adherence, personal agency and empowerment, physical self-concept and exercise self-efficacy, and a reduction in ageing- and exercise-related stereotypes; these secondary outcomes will be analysed as estimates with confidence intervals rather than as confirmatory tests. Harms will be recorded systematically.

Methods

Study design

This will be a quasi-experimental, two-arm (intervention vs passive control), parallel, longitudinal study with four assessment points: baseline (T0), mid-intervention (T1, week 8), post-intervention (T2, week 16) and follow-up (T3, 3 months after the end of the intervention). A qualitative component (focus groups with intervention participants) is embedded in a convergent mixed-methods design [20]. The study framework is exploratory, with feasibility as the main aim and preliminary effectiveness as the secondary aim, drawing on the feasibility principles of the CONSORT extension for randomised pilot and feasibility trials, adapted here to a non-randomised design [21]. The protocol follows the SPIRIT 2025 recommendations [22] (checklist in Online Resource 1), the TREND statement for non-randomised evaluations [23] and the TIDieR checklist for the description of the intervention [24].

The study was approved by the Research Ethics Committee of the Principality of Asturias (CEImPA, Central University Hospital of Asturias; reference no. 2026.307; protocol version dated 15 June 2026; approval dated 7 July 2026) and was registered prospectively in ClinicalTrials.gov (NCT07860424; protocol record WIA-2026-01; first posted on 6 October 2026) before the enrolment of the first participant. The present manuscript introduces only changes in wording and presentation with respect to the approved protocol. The full protocol is available through this publication and the registry record; the statistical analysis plan will be completed before database lock and deposited in the registry.

Patient and public involvement

Patients and members of the public were not involved in the design of this protocol, the intervention or the choice of outcomes. Participants and partner organisations will receive lay summaries of the results.

Study setting

The study will take place in community settings of the Principality of Asturias (northern Spain): municipal sports facilities, community and healthcare centres, women's associations in urban and rural municipalities, and the sports facilities of the University of Oviedo. Recruitment will be carried out through approximately 10–15 community sites; the intervention will be delivered in eight to nine groups of 12–15 women at those sites with suitable facilities. Recruitment is scheduled to begin between January and February 2027.

Participants

Women will be eligible if they: (a) are aged 55–75 years; (b) live in the Principality of Asturias; (c) are insufficiently active, defined as not meeting the WHO recommendation (< 150 moderate-equivalent min/week of aerobic activity, computed as moderate minutes plus twice the vigorous minutes, and/or fewer than two muscle-strengthening sessions per week) and/or reporting low adherence to previously prescribed or self-initiated exercise routines, screened with the Global Physical Activity Questionnaire (GPAQ) [25] for aerobic activity and a separate question on the weekly frequency of muscle-strengthening activity; (d) report exposure to gender-related stereotypes associated with physical activity, recorded through a structured question in the digital screening questionnaire (no cut-off score is applied, and the Aging Stereotypes and Exercise Scale is used as an outcome measure, not as an eligibility instrument); (e) have medical clearance for supervised moderate-to-vigorous exercise; (f) are willing to complete all assessments; and (g) give written informed consent. Exclusion criteria are: medical conditions contraindicating supervised exercise; severe cognitive impairment limiting participation; concurrent participation in structured resistance training; and any condition preventing the safe performance of handgrip strength or Short Physical Performance Battery (SPPB) tests. Menopausal status (perimenopause, early or late postmenopause according to STRAW + 10 criteria [26]), use of menopausal hormone therapy, corticosteroids and calcium/vitamin D or other supplements will be recorded at baseline and used as covariates.

Exercise sessions will be supervised by professionals holding a university degree in Sport and Exercise Science (or physiotherapy with specialisation in exercise prescription) and documented experience in resistance training with older or clinical populations. Before the study they will complete a training programme covering technique and progression for women of this age, monitoring of training load, safety procedures and the gender-sensitive, body-positive approach of the programme. Workshops will be delivered by a psychologist and an educational psychologist with experience in women's health and by a registered dietitian-nutritionist.

Sampling and recruitment

A non-probability convenience sample will be recruited. Eligible women who respond to a multichannel community campaign (sports and healthcare centres, women's associations, third-sector organisations, municipal active-ageing services, local media and social networks) will be enrolled consecutively at each site until the target sample of 214 is reached; the recruitment period will be extended if necessary. Recruitment will be carried out simultaneously for both arms and will precede allocation. Because the sample is not probabilistic, no claim of statistical representativeness of the regional population is made. To describe potential selection bias, the numbers of women approached, screened, eligible, enrolled and allocated will be recorded by site and presented in a participant flow diagram, and the sociodemographic and health profile of the enrolled sample will be compared descriptively with regional data for women aged 55–75 years.

Group allocation and blinding

Participants will be allocated to the intervention group (IG) or the control group (CG) by covariate-adaptive minimisation [27] with a random element. Because logistical constraints can determine assignment, the overall allocation procedure is not fully randomised, and the study is reported as quasi-experimental. For each participant, a statistician independent of recruitment and assessment will: (1) identify the group/venue configurations that are logistically feasible for her, based only on travel distance and timetable availability; (2) calculate, for each feasible assignment, the imbalance that would result across the balancing variables (age, menopausal status, GPAQ activity level, SPPB score, ageing- and exercise-related stereotypes score, socioeconomic status and urban/rural residence; equal weights; sum-of-variances method); and (3) assign the participant to the group that minimises imbalance with probability 0.8 and to the alternative group with probability 0.2. When only one option is feasible, allocation will be deterministic and recorded as logistically constrained; the proportion of such allocations will be reported. Allocation will be generated centrally with a pre-specified algorithm and concealed from enrolling staff until the baseline assessment has been completed. Baseline comparability will be checked before the intervention starts, and residual imbalance will be handled by covariate adjustment.

Participants and the professionals delivering the intervention will not be blinded. Outcome assessors will be different from delivery staff and blinded to allocation whenever feasible; participants will be asked not to reveal their group during assessments, and data analysts will work with coded group labels. Where assessor blinding cannot be guaranteed (e.g. small venues), this will be documented and reported.

Intervention

The intervention lasts 16 weeks and is delivered according to a written manual prepared following TIDieR [24], available from the corresponding author. Each week includes two supervised exercise sessions

(50–60 min, non-consecutive days); every second week, participants also attend a 90-min group workshop (eight workshops in total; Table 1).

Exercise sessions consist of warm-up (5–8 min), resistance training (20–25 min), interval-based cardiorespiratory conditioning (8–15 min, depending on phase), balance training (8–10 min) and cool-down (5–7 min), organised in three phases of increasing load and complexity (Table 2; detailed prescription in Online Resource 2). Resistance training comprises six to eight multi-joint exercises (squat, row, press, deadlift, step-up and combinations), two to three sets of 7–10 repetitions, progressing from 40–50% to 60–70% of the one-repetition maximum (1RM) [7, 28, 29]; 1RM will be estimated from submaximal repetitions to fatigue at the start of each phase. As velocity-measuring devices will not be available at all venues, load will be prescribed with the level-of-effort method, i.e. the repetitions performed in relation to the maximum achievable with that load [30], and the prescribed repetitions will be kept below the estimated maximum so that sets end before failure. Velocity loss is related to acute neuromuscular fatigue [31], and a monitored 10% velocity-loss threshold has improved strength and functional capacity in older adults [32]; without velocity measurement, the present prescription cannot verify that a specific threshold is reached. Perceived exertion will be recorded with the OMNI-RES scale [33]. Cardiorespiratory conditioning uses functional work/active-recovery intervals monitored by heart-rate reserve (chest-strap or optical monitors; resting and age-predicted maximal heart rate, adjusted for rate-limiting medication) and the Borg CR-10 scale; interval training has been applied safely in older adults [34], although this specific prescription has not been validated. This block (16–30 min/week) does not by itself meet the WHO aerobic recommendation; participants will be encouraged to accumulate additional lifestyle activity, recorded by self-report. Balance training progresses from static tasks on a wide base to dynamic, dual-task and perturbation exercises [35, 36].

Workshops use experiential methods (guided reflection, case analysis, role-play, transfer tasks). Four workshops are psychoeducational (gender stereotypes and sociocultural barriers; body perception and ageing; personal agency and decision-making; life skills), three address psychonutrition (emotional eating; Mediterranean diet; meal planning) and the final session integrates both strands. The first workshop, on gender stereotypes, is co-educational: male relatives, partners or community members are invited to take part in a structured discussion on stereotypes affecting men and women and on shared responsibility for equality in physical activity settings. These men are not study participants: they will sign a separate consent limited to their attendance, will not be assessed, and their records will be kept apart from participant data. Women may decline the co-educational format without consequence.

Loads, volume and exercise selection will be individualised to functional capacity. The exercise prescription will be reduced or paused in case of musculoskeletal complaints, cardiovascular symptoms or at the participant's request, and the participant will be withdrawn from exercise if a physician advises it, while remaining in the assessment schedule. Attendance will be recorded by delivery staff at every session and reported separately for exercise sessions (attended/32) and workshops (attended/8); participants will also complete a brief self-report of weekly attendance and out-of-session activity at T1, T2 and T3. Participants attending at least 80% of exercise sessions (26 of 32) will be considered to have

received the intervention as planned. Delivery staff will complete a fidelity log after each session (content delivered, deviations, engagement, contextual factors), which the principal investigators will review monthly. Flexible timetables, reminders and a supportive, non-judgemental group climate will be used to promote retention.

Control condition

The CG will maintain their usual lifestyle during the 16-week intervention and the 3-month follow-up and will complete the same assessments at the same time points. At the end of the study they will receive written healthy-lifestyle recommendations and an individual report of their results. Participation in other structured exercise, nutrition or psychological programmes will be discouraged in both arms and recorded at each assessment, together with changes in medication or supplements.

Table 1
Weekly structure and content of the 16-week “Women in Action” intervention

Weeks	Workshop (90 min, fortnightly; facilitator)	Exercise sessions (2/week, 50–60 min)
1–2	W1 Gender stereotypes and sociocultural barriers; co-educational session open to men (psychologist and educational psychologist)	Phase 1: familiarisation with movement patterns; single-joint resistance exercises; low-intensity intervals; basic balance and postural control
3–4	W2 Body perception and ageing; physical self-perception (psychologist and educational psychologist)	Phase 1: technical consolidation; progression of basic strength; longer intervals; static balance
5–6	W3 Emotional eating and emotional regulation (dietitian-nutritionist)	Phase 2: load increase; multi-joint exercises; higher interval intensity; dynamic and proprioceptive balance
7–8	W4 Personal agency, decision-making and body-related stigma (psychologist and educational psychologist)	Phase 2: multi-joint and functional exercises; greater interval demands; dynamic postural control. T1 assessment
9–10	W5 Mediterranean diet (dietitian-nutritionist)	Phase 2: consolidation of functional strength; progressive cardiorespiratory intensity; integrated balance
11–12	W6 Life skills: intrapersonal and interpersonal competencies (psychologist and educational psychologist)	Phase 3: integration of functional patterns; maintenance of intervals; complex functional balance
13–14	W7 Meal planning and autonomous dietary decisions (dietitian-nutritionist)	Phase 3: integrated functional strength, endurance, trunk stability and dynamic balance
15–16	W8 Consolidation and transfer; autonomous maintenance plan (all facilitators)	Phase 3: functional integration and transfer to daily living. T2 assessment

Workshops take place in the morning and exercise sessions in the afternoon of the same week

Table 2
Programming of the exercise component by phase

Component / variable	Phase 1 (weeks 1–4)	Phase 2 (weeks 5–10)	Phase 3 (weeks 11–16)
Resistance training: exercises per session / sets / repetitions	6–7 / 2 / 7–10	7–8 / 2–3 / 7–10	6–8 / 2–3 / 7–10
Resistance training: intensity (%1RM); level of effort (repetitions performed [maximum possible])	40–50%; 7–10 (18–25)	50–60%; 7–10 (14–20)	60–70%; 7–10 (10–15)
Resistance training: inter-set rest	90 s	120 s	150–180 s
Cardiorespiratory conditioning: duration; work/active recovery; intensity (%HRR; RPE CR-10)	8–10 min; 45 s/45 s; 50–60%; 3–4	10–12 min; 60 s/60 s; 70–80%; 4–5	12–15 min; 60 s/40 s; 85–90%; 5–6
Balance training: duration; work/rest; difficulty	8–10 min; 20–30 s/20–30 s; wide base, static balance, mobility	8–10 min; 20–30 s/20–30 s; narrow base, changes of direction, proprioception	8–10 min; 20–30 s/20–30 s; dual tasks, controlled perturbations

1RM one-repetition maximum, HRR heart-rate reserve, RPE rating of perceived exertion. Two sessions per week in all phases. Within each range, the repetitions performed are set below the estimated maximum for the load so that sets do not reach failure

Outcomes and measures

Outcomes are organised in three tiers (Table 3). Feasibility outcomes correspond to the principal aim and will be judged against pre-specified progression criteria: recruitment of at least 80% of the target sample within 2 months of the start of recruitment, retention of at least 75% at T3, median attendance of at least 70% of exercise sessions, and no serious adverse event attributable to the intervention. Failure to meet a criterion will lead to modification of the protocol rather than to abandonment of the programme. Two primary outcomes are registered: handgrip strength, a measure used in the assessment of low muscle strength and sarcopenia [6], and lower-limb strength and physical performance measured with the SPPB, a composite of balance, 4-m gait speed and five-times chair-stand tests used to identify functional limitation in older adults [37]. Handgrip strength is the first outcome in the testing hierarchy and the basis of the sample size calculation; the SPPB total score is the second, and its continuous components (gait speed and chair-stand time) will also be analysed to limit ceiling effects. Secondary outcomes include body composition by bioelectrical impedance analysis (fat mass, fat-free mass and skeletal muscle mass, together with body mass index and estimated basal metabolic rate),

Mediterranean diet adherence measured with the 14-item MEDAS questionnaire [38] complemented by a 3-day estimated dietary record (energy and protein intake, BEDCA food composition database), personal agency and empowerment (ESAGE-Sp-19 [39], validated in Spanish university students, with personal agency as a second-order factor and self-confidence, internal control and empowerment as first-order factors), physical self-concept (CAF-MAY, 30 items in five dimensions [40]), exercise self-efficacy (nine-item Self-Efficacy for Exercise scale [41], scored as the sum of items, 0–90) and ageing- and exercise-related stereotypes (12-item Aging Stereotypes and Exercise Scale, ASES, with three subscales [42]). No validated Spanish version of the ASES has been identified; a cross-cultural adaptation (forward and back translation, expert panel, cognitive pre-testing) will be completed before the study [43], its scoring rules will be fixed in the scoring manual before enrolment, and its internal consistency and structure will be examined in the study sample. The ASES measures beliefs about ageing and exercise rather than gender stereotypes as such; the gendered dimension will be explored in the focus groups.

Table 3
Outcomes, instruments, analysis metrics and time points

Tier	Outcome	Instrument / source	Analysis metric; summary measure	Time points
Feasibility (principal aim)	Recruitment (first 2 months), retention (T3), attendance and adherence (exercise sessions /32; workshops /8), acceptability, fidelity, adverse events, logistical feasibility, assessment completion	Recruitment, attendance, fidelity and adverse-event logs; satisfaction questionnaire	Proportions with 95% CI; medians	Continuous during intervention; T2 (acceptability); T3 (retention)
Primary (1st in hierarchy)	Handgrip strength (kg), dominant hand, best of three attempts	Hydraulic hand dynamometer, standardised seated protocol	Change T0–T2; adjusted difference in means between groups (95% CI)	T0, T1, T2, T3
Primary (2nd in hierarchy)	Lower-limb strength and physical performance: SPPB total score (0–12); five-times chair-stand time (s) and 4-m gait speed (m/s) as continuous components	SPPB	Change T0–T2; adjusted difference in means between groups (95% CI)	T0, T1, T2, T3
Secondary: body composition	Fat mass, fat-free mass, skeletal muscle mass; BMI (kg/m²); estimated basal metabolic rate (kcal/day)	Bioelectrical impedance analysis; stadiometer and scale	Change from baseline; means	T0–T3
Secondary: dietary behaviour	Mediterranean diet adherence (0–14); energy (kcal/day) and protein (g/kg/day) intake	MEDAS (interview); 3-day dietary record	Change from baseline; means; proportion with ≥ 2-point increase in MEDAS	T0–T3 (MEDAS); T0, T2 (record)
Secondary: psychosocial	Personal agency and empowerment; physical self-concept; exercise self-efficacy; ageing- and exercise-related stereotypes	ESAGE-Sp-19; CAF-MAY; SEE; ASES (Spanish adaptation)	Change from baseline; means	T0–T3

Tier	Outcome	Instrument / source	Analysis metric; summary measure	Time points
Secondary: qualitative	Experience of stereotypes, body perception, emotional safety, empowerment, barriers and facilitators	Focus groups (IG subsample)	Themes; joint display with quantitative results	T2, T3
Covariates	Age; menopausal status; baseline activity (GPAQ); socioeconomic status; urban/rural residence; hormone therapy, corticosteroids, supplements; social desirability	Sociodemographic and clinical questionnaire; GPAQ	—	T0

ASES Aging Stereotypes and Exercise Scale, BIA bioelectrical impedance analysis, BMI body mass index, CAF-MAY Physical Self-Concept Questionnaire for Older Adults, CI confidence interval, ESAGE-Sp-19 Personal Agency and Empowerment Scale, GPAQ Global Physical Activity Questionnaire, IG intervention group, MEDAS Mediterranean Diet Adherence Screener, SEE Self-Efficacy for Exercise scale, SPPB Short Physical Performance Battery

Harms

Adverse events will be recorded systematically in both arms. At every session the supervisor will note on a standard form any musculoskeletal complaint, fall or near-fall, cardiovascular symptom or other event, graded by severity (mild, moderate, severe) and relationship with the intervention (related, possibly related, unrelated); events outside sessions, and all events in the CG, will be asked about at each assessment up to T3. Serious adverse events (e.g. fracture, hospitalisation) will be reported to the principal investigators within 24 h and to the ethics committee, and will lead to a review of the participant's continued involvement. Harms will be summarised by arm as the number of events and the number of participants with at least one event during the intervention and follow-up [45].

Study timeline

Table 4 shows the schedule of enrolment, intervention and assessments. Baseline assessment will be completed within the two weeks preceding allocation. Each assessment session will last 60–75 min and will be carried out under standardised conditions (no vigorous activity in the previous 24–48 h; fasting and controlled hydration for impedance analysis).

Table 4
Study time schedule (SPIRIT 2025 participant timeline)

Eligibility screening (GPAQ, health); informed consent	**Screening (− 4 to − 2 wk)**	**T0 (− 2 to 0 wk)**	**Allocation (0)**	**Intervention (wk 1–16)**	**T1 (wk 8)**	**T2 (wk 16)**	**T3 (+ 3 mo)**
	X						
Allocation by minimisation			X				
Intervention: exercise sessions and workshops (IG)				X			
Usual lifestyle (CG)				X			X
Sociodemographic and clinical questionnaire		X					
Handgrip strength and SPPB (primary outcomes)		X			X	X	X
Body composition		X			X	X	X
MEDAS		X			X	X	X
3-day dietary record		X				X	
ESAGE-Sp-19, CAF-MAY, SEE, ASES		X			X	X	X
Attendance and fidelity logs (IG)				X			
Self-reported attendance and out-of-session activity					X	X	X
Adverse events (both arms)				X	X	X	X
Acceptability questionnaire						X	
Focus groups (IG subsample)						X	X

CG control group, IG intervention group, mo months, wk weeks; other abbreviations as in Table 3

Sample size calculation

The sample size was calculated for the first primary outcome, i.e. a greater increase in handgrip strength in the IG than in the CG from T0 to T2; no separate calculation was made for the SPPB, which is tested second in the hierarchy described below. The target standardised difference was set at d = 0.43, the pooled effect of resistance training on handgrip strength in older women with sarcopenia reported in a recent meta-analysis (SMD 0.43, 95% CI 0.11–0.74) [46], which is the closest published estimate for this outcome. With a two-sided α of 0.05 and a power of 0.80, the number of participants per group needed to detect a difference in change scores is $n = 2(z_{1-\alpha/2} + z_{1-\beta})^2 \times 2(1 - \rho)/d^2$, where ρ is the assumed correlation between baseline and week-16 handgrip strength. Under the planning assumption ρ = 0.5 this expression reduces to the two-sample formula $n = 2[(1.96 + 0.84)/0.43]^2 = 85$ per group (170 in total); the calculation was done analytically. The assumed baseline–follow-up correlation is distinct from short-term test–retest reliability, and the achieved power will also depend on clustering, retention and the observed variability of the outcome. Allowing for 20% attrition over the intervention and follow-up as a planning assumption, the target enrolment is 107 per group (214 in total). No sample size calculation was made for feasibility or secondary outcomes. Three limitations are acknowledged: the effect size comes from women with sarcopenia and may overestimate the effect in a sample with better baseline function; no design effect for clustering by training group or venue was included, which will be addressed in the analysis; and, given the sampling method, inference refers to the volunteers reached rather than to the regional population.

Data collection and management

Outcome assessors will be trained with a written procedures manual, and inter-assessor reliability for handgrip strength and SPPB will be checked before data collection. Questionnaires will be completed on tablets or paper with assistance available; MEDAS will be administered by interview. Reasons for non-adherence and withdrawal will be recorded, and participants who stop the intervention will be invited to complete the remaining assessments. Data will be pseudonymised with a participant code, entered twice with range checks, and stored in an access-controlled database of the University of Oviedo (data controller) in accordance with Regulation (EU) 2016/679 and Spanish Organic Law 3/2018. The key linking codes to identities will be kept separately by the principal investigator. Data will be retained while the research purpose persists and then anonymised or destroyed, as stated in the approved participant information sheet.

Statistical analysis

The analysis will follow a pre-specified statistical analysis plan. Baseline characteristics will be described by arm with means and standard deviations, medians and interquartile ranges, or frequencies and percentages, and balance on the minimisation variables will be examined; no baseline hypothesis tests will be performed. Feasibility indicators will be reported as proportions with 95% confidence intervals and compared with the progression criteria.

The primary analysis will use linear mixed-effects models for the post-baseline measurements (T1, T2, T3) of each outcome, with the baseline value (T0) as a covariate and fixed effects for time, group and the

group × time interaction, adjusted for age, menopausal status, baseline physical activity, socioeconomic status, urban/rural residence and use of hormone therapy, corticosteroids or supplements. Given the non-random allocation, the adjusted analysis will be the main analysis. Random intercepts will be specified for participants and for training group/venue, to account for the clustering produced by group-based delivery and venue-constrained allocation. The two primary outcomes will be tested in a fixed hierarchical sequence to control the family-wise error rate at $\alpha = 0.05$: first the between-group difference in change in handgrip strength from T0 to T2, and, only if this is statistically significant, the between-group difference in change in SPPB total score over the same interval; each will be reported as an adjusted mean difference with 95% CI and two-sided p value. Separate models will be fitted for each secondary outcome; within each outcome domain the Holm–Bonferroni procedure will be applied, and results will be interpreted mainly through standardised effect sizes (Hedges' g with 95% CI) and percentage change from baseline, with a view to the design of a definitive trial. All participants will be analysed in the group to which they were allocated. Missing outcome data will be handled by restricted maximum likelihood estimation under the assumption that data are missing at random, an assumption that cannot be verified from the observed data and will be examined through sensitivity analyses [47]: multiple imputation (20 datasets) with delta-adjusted imputations, a per-protocol analysis restricted to participants with at least 80% attendance at exercise sessions and complete assessments, and models with the SDS-13 score as covariate for self-reported outcomes. Model assumptions will be checked graphically; rank-based longitudinal models will be used if they are clearly violated. Exploratory subgroup analyses by menopausal status and urban/rural residence will use interaction terms. Analyses will be performed in R (version to be reported).

Qualitative analysis and integration

Four to six focus groups of 6–8 IG participants, selected purposively by age, socioeconomic status and residence, will be held at T2 and T3. A psychologist with experience in qualitative methods will facilitate them with a semi-structured guide covering gender stereotypes, body perception, emotional safety in exercise settings, empowerment, and barriers and facilitators of adherence. Sessions will be audio-recorded and transcribed verbatim and analysed with reflexive thematic analysis [48], coded inductively by two researchers who will keep a reflexivity journal; qualitative analysis software will be used. Quantitative and qualitative results will be merged at the interpretation stage through a joint display comparing effect estimates with themes for each outcome domain [20].

Monitoring

Because the intervention is of low risk, no independent data monitoring committee will be set up, and no interim analysis or stopping rule is planned. The principal investigators will review recruitment, fidelity and adverse-event logs monthly and will make periodic visits to the venues. The trial management group consists of the four authors; no steering or endpoint adjudication committee is planned.

Ethical considerations and dissemination

The study will follow the Declaration of Helsinki. Substantial protocol changes will be submitted to CEImPA, updated in ClinicalTrials.gov and reported in publications. Written informed consent will be obtained by trained members of the research team after an information session, using the information sheet and consent form approved by CEImPA (version 15 June 2026); men attending the co-educational session will give separate written consent. No proxy consent is foreseen. No biological samples will be collected and no ancillary studies are planned. Participants may withdraw at any time without consequences. No financial compensation is planned; extraordinary expenses such as meals and transport will be reimbursed. Results will be disseminated through open-access publications, conferences, the trial registry, lay summaries for participants and partner organisations, and briefings to regional health and sports authorities; authorship will follow ICMJE criteria.

Discussion

This protocol describes a programme that combines progressive resistance training, nutrition-focused behavioural education and psychoeducation on gender stereotypes, personal agency and body perception, for women aged 55–75 years who are insufficiently active. Two hundred and fourteen women will be enrolled at community venues in Asturias and allocated by minimisation to the programme or to usual lifestyle. The study has not started and no results are available; what follows concerns what the study is designed to show and how its findings should be read.

The main contribution expected from the study is practical: whether women of this age can be recruited through community channels, whether they attend and complete a 16-week programme with two exercise sessions a week and a fortnightly workshop, whether the programme can be delivered as written at several venues by different professionals, and how acceptable its components, including the session open to men, are to participants. The second contribution is a set of effect estimates. Resistance training improves strength in healthy postmenopausal women [8] and handgrip strength in older women with sarcopenia [46], and exercise interventions have been reviewed in older adults with and without sarcopenia [49]; these findings do not establish the effects of the complete programme, whose dietary and psychosocial outcomes will be described with estimates and confidence intervals.

The study has limitations. Allocation is not random; minimisation with a random element, central concealment and covariate adjustment reduce but do not remove the risk of selection bias, and causal interpretation will be correspondingly cautious. Volunteers reached through community channels are likely to be more motivated than the general population of the same age; the comparison of the enrolled sample with regional data will help to describe this. The workshops may increase socially desirable responding and attention effects in self-reported outcomes; an attention-matched control was not feasible, and the social desirability score will be used in sensitivity analyses. The age range covers different menopausal stages; this is handled by balancing and adjustment, but residual heterogeneity cannot be excluded. The eligibility criteria may produce a sample with relatively good baseline function, with possible ceiling effects on the SPPB, which is why its continuous components will also be analysed, and an effect size assumption that may prove optimistic for handgrip strength. The ASES will be used

after cross-cultural adaptation but without prior validation in Spanish older women. The cardiorespiratory component is deliberately short, and the 3-month follow-up only informs about short-term maintenance.

In conclusion, this protocol sets out a replicable, gender-sensitive multicomponent intervention for older women and the procedures for assessing its feasibility and preliminary effects under community conditions. Its results, whatever their direction, are intended to guide the design of a subsequent trial and of community active-ageing programmes for women.

Statements and Declarations

Author contributions

Conceptualisation: N.B.-P., I.B.-A. Methodology: N.B.-P., I.B.-A., Á.B.-S. and G.P.G.-O. (exercise prescription and training load). Writing – original draft: N.B.-P., Á.B.-S., I.B.-A. Writing – review and editing: all authors. Supervision and project administration: N.B.-P. All authors read and approved the final manuscript.

Funding

No funding was received for conducting this study.

Data availability

No datasets were generated or analysed for this protocol. Individual participant data will not be shared; aggregate results will be disseminated through publications and the trial registry. The intervention manual is available from the corresponding author.

Conflict of interest The authors declare that they have no conflict of interest.

Ethics approval The protocol was approved by the Research Ethics Committee of the Principality of Asturias (Comité de Ética de la Investigación con medicamentos del Principado de Asturias, CEImPA; reference no. 2026.307; 7 July 2026).

Research involving human participants The study will be performed in accordance with the ethical standards laid down in the 1964 Declaration of Helsinki and its later amendments. This article does not contain any studies with animals performed by any of the authors.

Informed consent Written informed consent will be obtained from all participants before enrolment, and from men attending the co-educational session.

Clinical trial registration ClinicalTrials.gov NCT07860424 (protocol record WIA-2026-01), first posted on 6 October 2026, prior to enrolment of the first participant.

Sponsor The University of Oviedo is the sponsor of this investigator-initiated study (responsible party: Noelia Belando-Pedreño, belandonoelia@uniovi.es). The sponsor provides no funding and has no role in

the design, conduct, analysis or reporting of the study beyond that of the investigators.

Dissemination policy Results will be published in open-access journals and presented at conferences in aggregate and anonymised form, reported in the trial registry, and communicated to participants and partner organisations through lay summaries.

References

1. World Health Organization (2020) WHO guidelines on physical activity and sedentary behaviour. World Health Organization, Geneva
2. Moreno-Llamas A, García-Mayor J, De la Cruz-Sánchez E (2022) Gender inequality is associated with gender differences and women participation in physical activity. J Public Health (Oxf) 44:e519–e526. https://doi.org/10.1093/pubmed/fdab354
3. Meredith SJ, Cox NJ, Ibrahim K et al (2023) Factors that influence older adults' participation in physical activity: a systematic review of qualitative studies. Age Ageing 52:afad145. https://doi.org/10.1093/ageing/afad145
4. Rúa-Alonso M, Bovolini A, Costa-Brito AR et al (2023) Exploring perceived barriers to physical activity among older adults living in low-population density regions: gender differences and associations with activity dimensions. Healthcare (Basel) 11:2948. https://doi.org/10.3390/healthcare11222948
5. Deshayes M, Palermo A, Korchi K, Philippe AG (2022) Influence of negative stereotype on physical activity level among older adults during a training session. Front Sports Act Living 4:998724. https://doi.org/10.3389/fspor.2022.998724
6. Cruz-Jentoft AJ, Bahat G, Bauer J et al (2019) Sarcopenia: revised European consensus on definition and diagnosis. Age Ageing 48:16–31. https://doi.org/10.1093/ageing/afy169
7. Fragala MS, Cadore EL, Dorgo S et al (2019) Resistance training for older adults: position statement from the National Strength and Conditioning Association. J Strength Cond Res 33:2019–2052. https://doi.org/10.1519/JSC.0000000000003230
8. González-Gálvez N, Moreno-Torres JM, Vaquero-Cristóbal R (2024) Resistance training effects on healthy postmenopausal women: a systematic review with meta-analysis. Climacteric 27:296–304. https://doi.org/10.1080/13697137.2024.2310521
9. Knowlton M, Newland BL (2024) Beyond the barbell: women in strength-based sports and the reshaping of gender norms. Sex Roles 90:1567–1584. https://doi.org/10.1007/s11199-024-01521-x
10. Vasudevan A, Ford E (2022) Motivational factors and barriers towards initiating and maintaining strength training in women: a systematic review and meta-synthesis. Prev Sci 23:674–695. https://doi.org/10.1007/s11121-021-01328-2
11. Sotos-Prieto M, Ortolá R, López-García E, Rodríguez-Artalejo F, García-Esquinas E (2021) Adherence to the Mediterranean diet and physical resilience in older adults: the Seniors-ENRICA cohort. J Gerontol A Biol Sci Med Sci 76:505–512. https://doi.org/10.1093/gerona/glaa277

12. Eglseer D, Traxler M, Schoufour JD et al (2023) Nutritional and exercise interventions in individuals with sarcopenic obesity around retirement age: a systematic review and meta-analysis. Nutr Rev 81:1077–1090. https://doi.org/10.1093/nutrit/nuad007
13. Palombi T, Chirico A, Cazzolli B et al (2025) Motivation, psychological needs and physical activity in older adults: a qualitative review. Age Ageing 54:afaf180. https://doi.org/10.1093/ageing/afaf180
14. Mosanya M, Kassie S (2024) Psychological empowerment and exercising: the relationships between exercising, self-stereotyping, agency, autonomy and physical self-efficacy in non-Western women. J Community Appl Soc Psychol 34:e2791. https://doi.org/10.1002/casp.2791
15. Seguin RA, Eldridge G, Lynch W, Paul LC (2013) Strength training improves body image and physical activity behaviors among midlife and older rural women. J Ext 51:4FEA2. https://doi.org/10.34068/joe.51.04.18
16. Streetman AE, Walden RL, Orr CJ, Heerman WJ (2026) Exercise empowerment: a scoping review of randomized controlled trials and quasi-experimental physical activity interventions. Int J Behav Nutr Phys Act 23:5. https://doi.org/10.1186/s12966-025-01859-9
17. Casas-Herrero Á, Sáez de Asteasu ML, Antón-Rodrigo I et al (2022) Effects of Vivifrail multicomponent intervention on functional capacity: a multicentre, randomized controlled trial. J Cachexia Sarcopenia Muscle 13:884–893. https://doi.org/10.1002/jcsm.12925
18. Valenzuela PL, Saco-Ledo G, Morales JS et al (2023) Effects of physical exercise on physical function in older adults in residential care: a systematic review and network meta-analysis of randomised controlled trials. Lancet Healthy Longev 4:e247–e256. https://doi.org/10.1016/S2666-7568(23)00057-0
19. Saldanha IJ, Skelly AC, Ley KV et al (2022) Inclusion of nonrandomized studies of interventions in systematic reviews of intervention effectiveness: an update. Methods Guide for Comparative Effectiveness Reviews. Agency for Healthcare Research and Quality, Rockville (MD). https://doi.org/10.23970/AHRQEPCMETHODSGUIDENRSI
20. Fetters MD, Curry LA, Creswell JW (2013) Achieving integration in mixed methods designs—principles and practices. Health Serv Res 48:2134–2156. https://doi.org/10.1111/1475-6773.12117
21. Eldridge SM, Chan CL, Campbell MJ et al (2016) CONSORT 2010 statement: extension to randomised pilot and feasibility trials. BMJ 355:i5239. https://doi.org/10.1136/bmj.i5239
22. Chan A-W, Boutron I, Hopewell S et al (2025) SPIRIT 2025 statement: updated guideline for protocols of randomised trials. BMJ 389:e081477. https://doi.org/10.1136/bmj-2024-081477
23. Des Jarlais DC, Lyles C, Crepaz N, TREND Group (2004) Improving the reporting quality of nonrandomized evaluations of behavioral and public health interventions: the TREND statement. Am J Public Health 94:361–366. https://doi.org/10.2105/AJPH.94.3.361
24. Hoffmann TC, Glasziou PP, Boutron I et al (2014) Better reporting of interventions: template for intervention description and replication (TIDieR) checklist and guide. BMJ 348:g1687. https://doi.org/10.1136/bmj.g1687

25. Bull FC, Maslin TS, Armstrong T (2009) Global Physical Activity Questionnaire (GPAQ): nine country reliability and validity study. J Phys Act Health 6:790–804. https://doi.org/10.1123/jpah.6.6.790
26. Harlow SD, Gass M, Hall JE et al (2012) Executive summary of the Stages of Reproductive Aging Workshop + 10: addressing the unfinished agenda of staging reproductive aging. Menopause 19:387–395. https://doi.org/10.1097/gme.0b013e31824d8f40
27. Pocock SJ, Simon R (1975) Sequential treatment assignment with balancing for prognostic factors in the controlled clinical trial. Biometrics 31:103–115. https://doi.org/10.2307/2529712
28. American College of Sports Medicine (2025) ACSM's guidelines for exercise testing and prescription, 12th edn. Wolters Kluwer, Philadelphia
29. Currier BS, D'Souza AC, Fiatarone Singh MA et al (2026) American College of Sports Medicine position stand. Resistance training prescription for muscle function, hypertrophy, and physical performance in healthy adults: an overview of reviews. Med Sci Sports Exerc 58:851–872. https://doi.org/10.1249/MSS.0000000000003897
30. Pareja-Blanco F, Loturco I (2026) Level of effort: a practical approach for resistance training monitoring and prescription. J Hum Kinet 102:259–266. https://doi.org/10.5114/jhk/221229
31. Sánchez-Medina L, González-Badillo JJ (2011) Velocity loss as an indicator of neuromuscular fatigue during resistance training. Med Sci Sports Exerc 43:1725–1734. https://doi.org/10.1249/MSS.0b013e318213f880
32. Marques DL, Neiva HP, Marinho DA, Marques MC (2022) Velocity-monitored resistance training in older adults: the effects of low-velocity loss threshold on strength and functional capacity. J Strength Cond Res 36:3200–3208. https://doi.org/10.1519/JSC.0000000000004036
33. Robertson RJ, Goss FL, Rutkowski J et al (2003) Concurrent validation of the OMNI perceived exertion scale for resistance exercise. Med Sci Sports Exerc 35:333–341. https://doi.org/10.1249/01.MSS.0000048831.15016.2A
34. Hwang CL, Yoo JK, Kim HK et al (2016) Novel all-extremity high-intensity interval training improves aerobic fitness, cardiac function and insulin resistance in healthy older adults. Exp Gerontol 82:112–119. https://doi.org/10.1016/j.exger.2016.06.009
35. Lesinski M, Hortobágyi T, Muehlbauer T, Gollhofer A, Granacher U (2015) Effects of balance training on balance performance in healthy older adults: a systematic review and meta-analysis. Sports Med 45:1721–1738. https://doi.org/10.1007/s40279-015-0375-y
36. Sherrington C, Fairhall NJ, Wallbank GK et al (2019) Exercise for preventing falls in older people living in the community. Cochrane Database Syst Rev 1:CD012424. https://doi.org/10.1002/14651858.CD012424.pub2
37. Guralnik JM, Ferrucci L, Pieper CF et al (2000) Lower extremity function and subsequent disability: consistency across studies, predictive models, and value of gait speed alone compared with the short physical performance battery. J Gerontol A Biol Sci Med Sci 55:M221–M231. https://doi.org/10.1093/gerona/55.4.M221

38. Schröder H, Fitó M, Estruch R et al (2011) A short screener is valid for assessing Mediterranean diet adherence among older Spanish men and women. J Nutr 141:1140–1145. https://doi.org/10.3945/jn.110.135566
39. Rodríguez Pellejero JM, Núñez Alonso JL, Martel Á et al (2023) Validación española de la Escala de Agencia Personal y Empoderamiento (ESAGE-Sp-19). Rev Evaluar 23:61–76. https://doi.org/10.35670/1667-4545.v23.n3.43900
40. Moreno Delgado A (2016) Estructura interna y medida del autoconcepto físico de personas mayores. Contextos 35:49–67
41. Resnick B, Jenkins LS (2000) Testing the reliability and validity of the Self-Efficacy for Exercise scale. Nurs Res 49:154–159. https://doi.org/10.1097/00006199-200005000-00007
42. Chalabaev A, Emile M, Corrion K et al (2013) Development and validation of the Aging Stereotypes and Exercise Scale. J Aging Phys Act 21:319–334. https://doi.org/10.1123/japa.21.3.319
43. Beaton DE, Bombardier C, Guillemin F, Ferraz MB (2000) Guidelines for the process of cross-cultural adaptation of self-report measures. Spine 25:3186–3191. https://doi.org/10.1097/00007632-200012150-00014
44. Reynolds WM (1982) Development of reliable and valid short forms of the Marlowe-Crowne Social Desirability Scale. J Clin Psychol 38:119–125. https://doi.org/10.1002/1097-4679(198201)38:1<119::AID-JCLP2270380118>3.0.CO;2-I
45. Ioannidis JPA, Evans SJW, Gøtzsche PC et al (2004) Better reporting of harms in randomized trials: an extension of the CONSORT statement. Ann Intern Med 141:781–788. https://doi.org/10.7326/0003-4819-141-10-200411160-00009
46. Zhou Y, Wen K, Zhang X, Sun Y (2026) Effects of resistance training on muscle mass, strength, and physical function in older women with sarcopenia: a systematic review and meta-analysis. Front Public Health 13:1735899. https://doi.org/10.3389/fpubh.2025.1735899
47. Heymans MW, Twisk JWR (2022) Handling missing data in clinical research. J Clin Epidemiol 151:185–188. https://doi.org/10.1016/j.jclinepi.2022.08.016
48. Braun V, Clarke V (2006) Using thematic analysis in psychology. Qual Res Psychol 3:77–101. https://doi.org/10.1191/1478088706qp063oa
49. Cabrolier-Molina J, Martín-Rodríguez A, Clemente-Suárez VJ (2025) The effects of exercise intervention in older adults with and without sarcopenia: a systematic review. Sports (Basel) 13:152. https://doi.org/10.3390/sports13050152

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