# Official Title of the study: Study Protocol "Women in Action": A Multicomponent Gender-Sensitive Intervention Combining Nutrition, Psychosocial Factors, and Strength Training in Older Women

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**Abstract**

Background: Women in perimenopause, menopause, and early ageing are at increased risk of sarcopenia, functional decline, and chronic conditions. These risks are further exacerbated by gender-related barriers to physical activity, including internalized stereotypes, caregiving roles, ageism, and sociocultural constraints that limit sustained engagement in strength-based exercise and healthy lifestyle behaviors. Despite growing evidence, integrated gender-sensitive interventions combining exercise, nutrition, and psychosocial determinants remain scarce in ageing women.

Objective: This study protocol describes the methodological framework of the "Women in Action" program and aims to evaluate its feasibility, implementation fidelity, and acceptability, together with its preliminary effects on psychosocial, functional, and health-related behavioral outcomes, in women aged 55 to 75.

Methods: A quasi-experimental mixed-methods design will be implemented, including an experimental and a control group, with repeated assessments at baseline (T0), mid-intervention (T1), post-intervention (T2), and follow-up (T3). The intervention consists of a 16-week program combining supervised strength training (two sessions per week) with biweekly (fortnightly) psychoeducational and nutrition-focused behavioral workshops (eight sessions in total). The program integrates physical, behavioral, and gender-sensitive components addressing exercise adherence, dietary behavior, emotional regulation, and broader social determinants of health. Feasibility outcomes include recruitment and retention rates, session attendance, protocol adherence, intervention acceptability, and adverse events. Handgrip strength is defined as the single, prespecified primary outcome, while the Short Physical Performance Battery, Mediterranean diet adherence (Mediterranean Diet Adherence Screener), and psychosocial variables (personal agency, empowerment, physical self-concept, and ageing- and exercise-related stereotypes) are considered secondary outcomes. Quantitative analyses

will use linear mixed-effects models as the primary analytical approach, complemented by qualitative thematic analysis and mixed-methods integration.

Expected Impact: This protocol provides a structured and reproducible framework for multicomponent interventions integrating strength training, nutrition, and psychoeducational strategies tailored to ageing women. Its novelty lies in the explicit incorporation of gender-related determinants within a biopsychosocial model of health. The study is expected to contribute to the development of evidence-based, gender-sensitive approaches to active ageing, promoting functional autonomy, healthy behaviors, and psychosocial empowerment, with strong potential for scalability and transferability to real-world community settings.

Keywords: gender stereotypes, personal agency, strength training, mediterranean diet, healthy ageing, physical function, older women, health behavior, community-based intervention.

## 1 Introduction

From an epidemiological perspective, older women represent one of the populations with the lowest levels of physical activity worldwide. In this protocol, physical inactivity is defined, in line with World Health Organization criteria, as not meeting the recommended minimum of 150-300 minutes of moderate-intensity (or 75-150 minutes of vigorous-intensity) aerobic physical activity per week, combined with muscle-strengthening activities on two or more days per week. International data indicate that the prevalence of physical inactivity so defined remains significantly higher in women than in men (31.7% vs. 23.4%), highlighting the persistence of gender-related structural inequalities in physical activity participation (1). This disparity becomes more pronounced in later stages of life, where biological, social, and cultural factors converge to limit engagement in exercise programs and access to the health benefits associated with regular physical activity.

In this context, the scientific literature has identified multiple barriers to physical activity participation among older women, including personal factors (e.g., fear of injury or perceived fragility), environmental constraints (e.g., limited resources in rural settings), and sociocultural influences (e.g., traditional gender roles and age-related stereotypes) (2, 3). Moreover, both age- and gender-related stereotypes have been shown to negatively influence self-efficacy, perceived exertion, and overall physical activity levels, thereby affecting long-term adherence to exercise programs in older populations (4).

### 1.1 Exercise, nutrition, and lifestyle-related health in ageing women

A substantial body of evidence consistently supports resistance training as one of the most effective strategies for improving physical fitness in adult and older women. This type of exercise has been associated with increases in muscular strength, gait speed, balance, and overall functional capacity, as well as reductions in the risk of frailty, falls, and functional dependence (5-7).

However, these benefits must be interpreted within a gender-sensitive framework, as strength has historically been constructed as a masculine attribute. This cultural perception may lead to body-related self-stigmatization, insecurity, and self-exclusion among women, particularly in later life (8, 9). Within this context, engaging in strength training in safe, supervised, and non-judgmental environments not only promotes functional improvements but also creates opportunities for social and symbolic transformation of gender roles within physical activity settings.

In parallel, recent literature emphasizes the importance of addressing physical activity in combination with nutritional behaviors. The integration of exercise and nutrition education has demonstrated synergistic effects on self-regulation, health-related decision-making, and long-term adherence to healthy lifestyle patterns (10,11). In particular, adherence to the Mediterranean diet has emerged as a key indicator of health in older populations, being associated with greater physical resilience, reduced frailty risk, and improved overall health status during ageing (12). Nevertheless, available evidence in the Spanish population suggests suboptimal adherence levels, with only a small proportion of older adults meeting recommended dietary guidelines (13). These findings highlight the need for integrated interventions that not only promote physical activity but also incorporate nutrition education from a behavioral and contextual perspective.

### 1.2 Psychosocial determinants and psychoeducational approach

From a psychosocial perspective, constructs such as personal agency, autonomy, and perceived competence have been identified as key determinants of active behavior. Recent reviews indicate that satisfaction of basic psychological needs plays a critical role in shaping motivation and adherence to physical activity in adults (14). However, the literature also points to a limited integration and operationalization of empowerment and personal agency within physical activity interventions, representing a significant gap in the design of programs specifically targeting women (15).

In addition, emerging evidence suggests that women's participation in resistance training programs is associated with reduced internalization of gender stereotypes and improvements in self-confidence, perceived competence, and internal locus of control (16). Similarly, improvements in physical self-concept, particularly in dimensions related to perceived functional capacity and body-related self-esteem, have been identified as important predictors of long-term adherence to physical activity, facilitating the adoption and maintenance of active lifestyles among older women (17).

### 1.3 Research gap and novelty

Despite the growing body of evidence on the benefits of physical activity, nutrition, and motivational factors in older adults, previous interventions have largely addressed these components in isolation or in only partially integrated approaches. Multicomponent exercise programs have demonstrated improvements in functional capacity among frail and pre-frail older adults; however, they have rarely incorporated gender-specific determinants that influence engagement in health-related behaviors (18). Similarly, exercise and nutrition interventions targeting sarcopenic obesity have primarily focused on physical and physiological outcomes, with limited attention to the social and cultural factors that may uniquely affect older women (19).

Furthermore, recent qualitative evidence highlights the importance of motivation, autonomy, perceived competence, and social support in promoting physical activity, yet these dimensions are seldom integrated with physical and nutritional components within a unified intervention model (14).

The present protocol addresses this gap by proposing an integrated intervention that combines physical exercise, psychoeducational support, and nutrition education within a feminist and intersectional framework. This approach explicitly considers the structural, relational, and cultural determinants of health in older women, offering a comprehensive model for intervention design.

### 1.4 Aim and hypothesis

Based on the above considerations, this study protocol describes the methodological design of a quasi-experimental, longitudinal intervention study ("Women in Action") targeting women in perimenopause, menopause, and early ageing, and aims to evaluate its feasibility, implementation fidelity, and acceptability, together with its preliminary effects on psychosocial, functional, and health-related behavioral outcomes. The intervention integrates psychoeducational training, nutrition-focused behavioral components, and supervised physical exercise within a multidisciplinary framework involving professionals in psychology, nutrition, and exercise science.

The scientific validity of the protocol is supported by current evidence on the physiological and psychosocial needs of older women, while its replicability is ensured through the structured progression of intervention components, clearly defined phases, and the use of specific performance indicators. It is hypothesized that, compared with the control group, participants in the intervention group will show greater improvements over time in the following domains: 1) Psychosocial outcomes, including

increased personal agency and empowerment, enhanced physical self-concept, and reduced internalization of ageing- and exercise-related stereotypes; 2) Physical function, including handgrip strength, gait speed, balance, and Short Physical Performance Battery performance; 3) Dietary behavior, including greater adherence to the Mediterranean diet. These improvements are expected to be estimated across follow-up assessments of the study's feasibility, primary, and secondary outcomes.

# 2 Methodology

## 2.1 Research design

The present study is conceived as a descriptive and explanatory protocol describing the development and implementation of a multicomponent intervention addressing physical activity, nutrition, and psychosocial health in older women. From a methodological perspective, a quasi-experimental, longitudinal design with repeated measures will be adopted, using a mixed-methods approach that integrates both quantitative and qualitative data.

The quantitative component will include the assessment of participants through sociodemographic questionnaires, validated psychometric instruments, and objective measures of physical function. The qualitative component will be conducted through focus groups aimed at exploring participants' lived experiences in relation to behavioral change processes, body perception, sociocultural barriers, and adherence to the intervention. The integration of these approaches enables a comprehensive evaluation of intervention effects from a biopsychosocial perspective.

This design is considered particularly appropriate within the applied and community-based context in which the intervention is intended to be implemented, where full randomization may be constrained by organizational, contextual, and ethical factors inherent to real-world health programs. In this regard, quasi-experimental designs represent a valid methodological alternative for evaluating intervention effectiveness under usual practice conditions when randomization is not feasible, allowing for the examination of longitudinal associations and intervention-related changes under real-world conditions, and supporting the transferability of findings to real-world contexts (20).

Furthermore, methodological evidence in public health research recognizes the relevance of non-randomized studies when controlled trials cannot be implemented due to ethical, logistical, or contextual limitations, thereby providing a valid and complementary source of evidence for decision-making in community-based interventions (21). Accordingly, a non-random, minimization-based allocation strategy will be employed, balancing key baseline characteristics (age, menopausal status, physical activity level, physical function, gender-related stereotypes, socioeconomic status, and geographical context) across arms while accounting for accessibility and scheduling feasibility, in line with current methodological recommendations for intervention research in naturalistic and community settings.

### *2.1.1 Validity, replicability and multidisciplinary applicability*

The methodological design of the "Women in Action" protocol has been structured to ensure internal validity, replicability, and multidisciplinary applicability across exercise science, psychology, nutrition, and primary healthcare settings.

Internal validity is supported by a quasi-experimental longitudinal design with repeated measures, the use of validated psychometric instruments, and standardized physical performance tests, including handgrip strength and the *Short Physical Performance Battery* (hereinafter, SPPB test). The intervention protocol is methodologically grounded in the guidelines of the Template for Intervention Description and Replication (TIDieR) (22) and the TREND statement for non-randomized studies (23), thereby ensuring transparency, reproducibility, and methodological rigor in the description of complex interventions.

Replicability is ensured through the development of a detailed intervention manual specifying session structure, content, dosage, progression criteria, and implementation procedures for each component (psychoeducational, nutrition-focused behavioral, and exercise training). In addition, fidelity monitoring procedures, standardized materials, and session logs are incorporated to ensure consistency across groups and implementation settings.

The applicability of the protocol is strengthened by its multidisciplinary design, integrating principles from exercise science (strength training and functional performance), psychology (personal agency, empowerment, and behavior change), and nutrition (Mediterranean diet adherence and behavioral regulation of eating). This integrated structure facilitates implementation in community-based, clinical, and primary care settings, in line with current frameworks of person-centered and integrated healthcare.

The methodological structure of the protocol includes a detailed definition of recruitment procedures, characterization of intervention components (physical exercise, nutrition-focused behavioral components, and psychoeducational strategies), operationalization of study variables, and analytical strategies to assess changes over time. To minimize potential bias associated with the absence of full randomization, several methodological control strategies will be implemented:

- Recruitment of participants from the same community and geographical context.
- Standardization of relevant baseline characteristics (age, physical activity level, functional status, and psychosocial variables).
- Application of standardized assessment procedures at all time points (T0 pre-intervention, T1 mid-intervention, T2 post-intervention, and T3 follow-up).

Instructions for participants to maintain their usual habits and avoid participation in external structured programs during the intervention period.

*2.1.2 Research design with a gender perspective*

The study is framed within an intersectional feminist approach, integrating biological, social, and cultural determinants of health in older women. This perspective is embedded across all phases of the research design through:

- The use of validated and age-appropriate measurement instruments for older populations.
- Consideration of vulnerability-related factors, including low physical activity levels, low adherence to the Mediterranean diet, rurality, socioeconomic status, and migration context.

- The inclusion of co-participation workshops that incorporate men's involvement in specific sessions addressing gender stereotypes and empowerment.
- The creation of safe, inclusive, and non-judgmental environments for physical activity practice.

With respect to the co-participation workshops involving men, participation of male relatives, partners, or community members will be entirely optional and separate from the core women-only intervention: these mixed-gender sessions constitute an additional, clearly identified module (see Table 8), and women's participation in the remainder of the psychoeducational, nutrition-focused, and exercise components does not require or depend on engagement with the co-educational sessions. Prior to enrolment, women will be explicitly informed about the voluntary nature, content, and format of the co-educational workshops, and will be able to decline participation in these specific sessions without being excluded from the rest of the program or from the study. Facilitators will be trained to create a structured, low-pressure format (e.g., separate small-group discussion before joint reflection) to reduce potential discomfort. Men attending these sessions will also receive guidance on emotional regulation and active listening, delivered by the same psychology professionals responsible for the women's psychoeducational component, to ensure that the co-educational sessions are approached with comparable psychosocial preparation on both sides.

*2.1.3 Clarification regarding men's participation*

To avoid any ambiguity regarding the composition of the study sample, it is explicitly clarified that men will not be considered study participants and will not be included in any outcome assessment, questionnaire, or physical function test. Their involvement is limited exclusively to the selected co-educational workshops described above, which are aimed at promoting shared reflection on gender stereotypes and co-responsibility for gender equality in physical activity contexts. Separate written informed consent will be obtained from men attending these sessions, covering their voluntary attendance and participation in the co-educational discussion; this consent does not grant access to any individual data belonging to the women enrolled in the study, and men's attendance records will be kept separately from participant outcome data. Accordingly, the experimental and control groups remain composed exclusively of women, and the presence of men in selected workshops does not alter the nature, composition, or analytic unit of the study groups.

Finally, all study procedures will be conducted in accordance with the ethical principles outlined in the Declaration of Helsinki. Written informed consent will be obtained from all participants prior to data collection, and strict confidentiality and data protection procedures will be ensured. The study protocol has been approved by the relevant ethics committee (reference: 09.1_CEIIR_2025), dated March 13, 2025, at the University of Oviedo.

## 2.2 Components of the intervention program, dosage, progression, and fidelity criteria

The “Women in Action” program is conceptualized as a multicomponent, longitudinal, and theory-driven intervention lasting 16 weeks, designed to address the physiological, behavioral, and psychosocial determinants of health in women undergoing menopausal transition and early ageing. The intervention aims to improve physical function, dietary quality, and psychosocial factors related to physical activity, including personal agency and gender-related stereotypes.
The intervention design is grounded in accumulated evidence indicating that multicomponent programs integrating exercise, nutrition, and psychosocial factors are more effective than single-component interventions in improving physical function, behavioral adherence, and overall health outcomes in

older women (24, 25). In addition, it incorporates current recommendations highlighting resistance training as a primary strategy for preventing sarcopenia and enhancing functional capacity, particularly in postmenopausal women (26).

All components will be implemented following a standardized intervention manual developed in accordance with TIDieR guidelines, specifying content, dosage, progression criteria, materials, and implementation procedures. This approach ensures replicability, intergroup consistency, and methodological fidelity throughout the intervention.

*2.2.1 Structure and dosage of the intervention program*

The intervention will be conducted over 16 weeks, following a consistent weekly structure consisting of two training sessions per week (50-60 minutes per session, on non-consecutive days) and one psychoeducational or nutrition-focused behavioral workshop every two weeks (90 minutes per session). Each monthly cycle (four weeks) will include:

- One psychoeducational session focused on gender, personal agency, personal and social empowerment, and life skills (intrapersonal and interpersonal skills).
- One nutrition-focused behavioral session centered on eating behavior and adherence to the Mediterranean diet.
- Eight supervised exercise sessions targeting improvements in muscular strength, aerobic endurance, and balance (27).

Prior to the start of the intervention, a baseline assessment (T0) will be conducted, including validated psychometric questionnaires, a sociodemographic questionnaire, and objective physical function tests (handgrip strength and SPPB), following standardized protocols.

*2.2.2 Psychoeducational and nutrition-focused behavioral component*

The psychoeducational and nutrition-focused behavioral component is designed as a structured module aimed at promoting changes in key psychosocial and behavioral determinants of health in older women, including the internalization of gender stereotypes, low personal agency, and dysfunctional eating patterns. This component is based on evidence indicating that psychological, social, and cultural factors play a critical role in exercise adherence and the adoption of healthy lifestyles across the female lifespan (8, 9, 18, 19).

The program consists of eight group-based workshops (one every two weeks over the 16-week intervention), each lasting 90 minutes and organized within a structured, sequential progression. The content sequence is grounded in behavior change theories and integrates principles of emotional regulation, self-determined motivation, and health education within a biopsychosocial framework.

Of these eight workshops, four are specifically nutrition-focused (Table 1). Recognizing that four behavioral nutrition workshops, taken together with the categorical MEDAS instrument alone, would provide only limited quantitative nutritional depth, this behavioral/educational component is now deliberately paired with the mandatory quantitative dietary assessment described in Section 2.5 (3-day estimated dietary record quantifying energy and protein intake at T0 and T2), so that the

protocol's nutrition methods combine behavioral change content with objective, quantitative dietary monitoring rather than relying on workshop exposure or categorical adherence scoring alone.

Sessions will be delivered using an experiential and reflective methodology based on active learning principles, encouraging participant engagement through group interaction and practical application. Techniques will include guided reflection, case analysis, role-playing, and transfer tasks designed to facilitate the application of acquired knowledge and skills to everyday contexts. The progressive organization of session content is presented in Table 1.

**Table 1.** *Content blocks of the psychoeducational and psychonutritional components of the intervention program.*

| Block | Intervention domain | Specific content |
|---|---|---|
| 1. Gender stereotypes and sociocultural barriers | Sociocultural and gender-related factors in health behavior | • Gender stereotypes in physical exercise practice<br>• Structural, cultural, and contextual barriers |
| 2. Personal agency and empowerment | Psychological determinants of health behavior | • Autonomy and health-related decision-making<br>• Perceived competence<br>• Physical and emotional safety during practice |
| 3. Body perception and ageing | Body image and ageing processes | • Body- and age-related stigmas<br>• Body perception and psychological well-being |
| 4. Life skills | Transferable psychosocial competencies | • Intrapersonal and interpersonal emotional intelligence<br>• Assertive communication and social skills |
| 5. Psychonutrition | Eating behavior and nutritional decision-making | • Emotion-eating relationship<br>• Adherence to the Mediterranean diet<br>• Autonomous and sustainable food-related decision-making |

### *2.2.3 Exercise component of the intervention program: strength training and physical conditioning*

The exercise component is based on a structured and progressive multicomponent training program aimed at improving muscular strength, physical function, and autonomy in older women. This component is grounded in extensive scientific evidence identifying resistance training as the most effective non-pharmacological strategy for preventing and mitigating the decline associated with sarcopenia (28).

The training program will be implemented over a 16-week period, with a frequency of two sessions per week on non-consecutive days, each lasting 50-60 minutes. All sessions will be supervised by qualified exercise professionals with expertise in older women's health and physical activity. The program is designed according to the principles of progressive overload, individualization, and functional specificity, in line with international recommendations for exercise prescription in older adult populations (Table 2).

Each session will follow a structured format organized into distinct phases: (i) an activation phase, (ii) a resistance training phase, (iii) an aerobic conditioning phase, and (iv) a balance-focused phase. This

structure ensures an appropriate balance between neuromuscular stimulus, safety, and participant adherence.

**Table 2**. *Summary of the training component structure of the intervention program.*

| Element | Methodological description |
|---|---|
| Primary objective | Improve muscular strength, aerobic capacity, and body balance |
| Total duration | 16 weeks |
| Frequency | 2 sessions per week on non-consecutive days |
| Session duration | 50-60 min |
| Supervision | Sessions supervised by qualified exercise professionals trained in gender stereotypes related to physical activity and resistance training for middle-aged and older women (climacteric transition and ageing process). |
| Session structure | Warm-up (10 min); Resistance training (10-15 min); Aerobic training (10-15 min); Body Balance (5-8 min); Cool-down, transitions, and feedback (5-12 min). |
| Content distribution and percentage of session time | • Upper- and lower-body resistance training (≈ 50%)<br>• Aerobic training (≈ 30%)<br>• Body Balance (≈ 20%)<br>(Percentages refer to the main training block only, resistance, aerobic, and balance components, and exclude warm-up, cool-down, transitions, and feedback.) |
| Exercise selection | Single- and multi-joint exercises targeting the upper and lower limbs during the resistance training component. |
| Targeted physical capacities | Muscular strength, cardiorespiratory fitness, dynamic balance, and postural stability |
| Resistance training intensity monitoring | • CE (29)<br>• OMNI-RES scale (0-10) for rating perceived exertion during resistance training (30) |
| Aerobic exercise intensity monitoring | • HRR<br>• Borg Rating of Perceived Exertion scale (0-10)<br>• Instructor feedback to assess participants perceived effort through verbal responses (e.g., "How do you feel: comfortable, somewhat fatigued, or very fatigued", "Do you think you could increase your exercise pace?") |
| Individualization | Adjustment of training loads, volume, and exercise selection according to functional capacity |
| Training environment | Safe, inclusive, and body-positive exercise settings |

*Note:* min = minutes; CE = Character of effort; HRR = Percentage of heart rate reserve.

*2.2.3.1 Programming training variables*

The determination of the appropriate training load for each component (strength, aerobic conditioning, and balance training) is based on current scientific evidence regarding resistance training and physical conditioning in older adults (5, 28, 31). Accordingly, the program is structured into three progressive phases:

*Phase 1: Initial Phase (Weeks 1-4)*

This phase focuses on familiarization with fundamental movement patterns, improvement of intermuscular coordination, and acquisition of proper exercise technique. Low external loads and exercises with reduced motor complexity will be prioritized. Concurrently, cardiorespiratory endurance will be trained through low-intensity functional intervals, while the balance component will emphasize basic exercises targeting balance, mobility, and postural control.

*Phase 2: Intermediate Phase (Weeks 5-10)*

External load will be progressively increased as participants adapt to training stimuli, accompanied by an increase in training volume and the introduction of compound exercises with greater motor complexity. Interval-based aerobic training will be intensified in both duration and intensity. The balance component will incorporate dynamic balance tasks and proprioceptive exercises, with greater demands on postural control.

*Phase 3: Final Phase (Weeks 11-16)*

This phase focuses on consolidating functional strength, improving cardiorespiratory capacity, and integrating multiple physical capacities. More complex and dynamic tasks will be introduced, targeting improved performance in activities of daily living. Balance training will be further progressed through the inclusion of functional tasks, controlled perturbations, and dual-task conditions to enhance motor control and adaptability.

*2.2.3.1.1 Strength training*

The training dosage was designed according to current recommendations for resistance training prescription in older adults, with the aim of preventing and managing sarcopenia. A progressive increase in training intensity was established, starting with moderate loads (40-50% of 1RM) during the initial phase and reaching 60-70% of 1RM in the final phase. This progression is supported by evidence indicating that gradual increases in intensity promote neuromuscular adaptations and improvements in muscle strength and physical function, while moderate loads facilitate initial adaptation to training stimuli (32, 33).

Regarding training volume, each session includes between five and seven exercises, prioritizing multi-joint movements and functional movement patterns involving the major muscle groups. In addition, two to three sets per exercise are prescribed depending on the phase of the program (Table 3). This dosage is supported by evidence demonstrating that this combination of volume and exercise selection is effective in improving maximal strength and physical function in older adults with sarcopenia, with training frequency and load volume identified as key factors for optimizing adaptations (6, 33).

The number of repetitions is not established as the primary variable for load prescription; rather, it is considered a consequence of the relative intensity and the level of effort achieved. Accordingly, a velocity-based approach is adopted, using thresholds of velocity loss (VL) between 10% and 15%. González-Badillo and Sánchez-Medina (2010) (34) have demonstrated that velocity loss is a valid indicator of the level of effort performed within a set, showing a strong relationship with accumulated neuromuscular fatigue. However, its direct measurement in practice requires the use of a linear position transducer. In the absence of such devices, González-Badillo (2008) (29) proposed the concept of effort character (EC), which estimates the relationship between the number of repetitions performed and the maximum number that could be completed until muscular failure.

Accordingly, training load is interpreted by combining intensity with the number of repetitions per set, aiming to maintain a low level of fatigue equivalent to velocity losses of approximately 10-15%. Therefore, repetition prescription is guided to ensure low fatigue levels consistent with these velocity loss thresholds.

The selection of low velocity loss thresholds is further supported by evidence in older populations. Marques et al. (2022) (35) reported that a resistance training program based on a 10% velocity loss threshold resulted in significant improvements in muscle strength and physical function in older adults, while maintaining low levels of fatigue and high adherence. Based on this evidence, velocity loss will be limited to approximately 10% during the initial and intermediate phases, allowing a controlled progression to 10-15% during the final phase.

Finally, training density will be regulated through rest intervals ranging from 90 to 180 seconds, progressively increasing in line with training intensity. This approach is supported by the most recent recommendations from the *American College of Sports Medicine* (ACSM), which state that higher training intensities should be accompanied by sufficient recovery periods to ensure proper exercise execution and facilitate neuromuscular recovery. In addition, rest intervals longer than 60 seconds are recommended to maintain training volume and limit excessive fatigue, particularly when moderate to high loads are used (32, 36).

**Table 3**. *Quantification of the resistance training load.*

| Variables | | Phase 1 | Phase 2 | Phase 3 |
|---|---|---|---|---|
| Training frequency | | 2 sessions/week | 2 sessions/week | 2 sessions/week |
| Volume | Number of exercises per session | 6-7 | 7-8 | 6-8 |
| | Number of sets per exercise | 2 | 2-3 | 2-3 |
| | Repetitions per set | 7-10 | 7-10 | 7-10 |
| | Velocity loss threshold | ~10% | ~10% | 10-15% |
| Intensity | Intensity (%1RM) | 40-50% | 50-60% | 60-70% |
| | Character of effort (CE) | 7-10 (18-25) | 7-10 (14-20) | 7-10 (10-15) |
| Rest interval | Inter-set rest interval | 90 s | 120 s | 150-180 s |
| Exercise selection | | Single- and multi-joint upper- and lower-body pulling and pushing exercises (e.g., squat, row, bench press, deadlift, push-up, step-up). | Single-, combined, and multi-joint upper- and lower-body pulling and pushing exercises (e.g., squat-to-press, lunge-to-pull, step-and-push, lateral lunge-to-pull). | Single-, combined, and multi-joint upper- and lower-body pulling and pushing exercises (e.g., squat-to-press, lunge-to-pull, step-and-push, lateral lunge-to-pull). |

*Note:* RM: Repetition Maximum; s = second; CE was quantified according to the method proposed by González-Badillo (2008) and represents the number of repetitions completed relative to the maximum number that could have been performed.

*2.2.3.1.2 Aerobic endurance training*

Cardiorespiratory endurance training is delivered using a functional interval-based approach, characterized by the alternation of work periods and active recovery without complete rest. This methodology is supported by evidence demonstrating that interval training and functional circuit-based exercise are effective strategies for improving cardiorespiratory fitness, mobility, and functional performance in older adults. Additionally, these approaches have been shown to enhance adherence and promote greater transferability to activities of daily living (Table 4).

The progression of the work-to-recovery ratio allows for a gradual increase in cardiovascular load while maintaining safe and appropriate levels of exertion for this population (6, 31, 37).

It should be noted that, as embedded within the overall 50-60-minute multicomponent session, the aerobic conditioning block as programmed (approximately 8-15 minutes per session, twice weekly,

i.e., roughly 16-30 minutes/week of dedicated aerobic work) does not, by itself, meet the WHO recommendation of at least 150 minutes/week of moderate-intensity aerobic activity. This block is intentionally designed as a time-efficient, high-density interval stimulus embedded within a broader multicomponent session, rather than as a stand-alone aerobic training program, and participants will additionally be encouraged and counselled, through the psychoeducational and nutrition-focused workshops, to accumulate further incidental and lifestyle-based aerobic activity outside of supervised sessions in order to progress towards WHO-recommended weekly volumes; this counselling and any self-reported out-of-session activity will be monitored. In addition, while the interval-based format was selected for its time efficiency, safety, and demonstrated adherence benefits in older populations, the exclusive use of interval training in every session, rather than a combination of interval and continuous aerobic modalities, may be less representative of the self-selected, continuous-format aerobic activity that many older women typically choose, which may affect the translatability of the aerobic component to unsupervised, real-world exercise behavior. This is acknowledged as a design choice and a limitation of the aerobic training component.

**Table 4**. *Quantification of the aerobic endurance training load.*

| Variables | Phase 1 | Phase 2 | Phase 3 |
|---|---|---|---|
| Training frequency | 2 sessions/week | 2 sessions/week | 2 sessions/week |
| Duration | 8-10 min | 10-12 min | 12-15 min |
| Number of exercises | 4-6 | 4-6 | 4-6 |
| Work interval | 45 s | 60 s | 60 s |
| Active recovery | 45 s | 60 s | 40 s |
| Intensity (%HRR) | 40-50% | 50-60% | 60-70% |
| Intensity (RPE) | 3-4 | 4-5 | 5-6 |

*Note.* HRR = Heart Rate Reserve; min = minutes; RPE = Rating of Perceived Exertion; s = seconds.

*2.2.3.1.3. Balance training component*

The balance training component includes exercises targeting balance, proprioception, joint mobility, and postural control, as this type of training has been shown to improve balance performance, functional mobility, and overall physical function in older adults (38). In addition, balance training represents an effective strategy for enhancing postural stability and reducing fall risk in this population (39).

Exercise progression is based on a gradual increase in motor complexity and postural control demands, achieved through modifications in the base of support, the inclusion of dynamic movements, and the incorporation of proprioceptive tasks (Table 5). This progression is consistent with current recommendations derived from sensorimotor training programs described by Sluga et al. (2024).

**Table 5**. *Quantification of the body balance training load.*

| Variables | Phase 1 | Phase 2 | Phase 3 |
|---|---|---|---|
| Training frequency | 2 sessions/week | 2 sessions/week | 2 sessions/week |
| Duration | 8-10 min | 8-10 min | 8-10 min |
| Number of exercises | 4-5 | 4-5 | 4-5 |
| Work interval | 20-30 s | 20-30 s | 20-30 s |
| Rest interval | 20-30 s | 20-30 s | 20-30 s |
| Difficulty | Wide base of support | Narrow base of support and | Dual-task activities and |

| | | | |
|---|---|---|---|
| | | changes of direction | controlled perturbations |
| Training content | Mobility + static balance | Dynamic balance + proprioception | Functional balance and complex tasks |

*Note.* min = minutes; s = seconds.

*2.2.3.2 Methodological approach and functional transfer of the training program*

The program adopts a functional training approach, prioritizing movement patterns that replicate activities of daily living (e.g., sit-to-stand, pushing, pulling, stabilizing), with the aim of enhancing the transfer of training adaptations to functional capacity and independence.

In addition, balance and postural control components are systematically integrated, as these are considered essential for fall prevention and for improving functional performance in older women.

*2.2.3.3 Motivational climate, safety, and adherence to the training program*

Particular attention is given to the training environment as a key mediator of adherence. Specifically, the program is designed to ensure:

- the absence of body-related judgment,
- a sense of physical and emotional safety,
- social support within the group, and
- positive, progressive feedback.

Evidence suggests that these factors play a crucial role in exercise adherence among older women, particularly in those with limited prior experience in structured training programs.

*2.2.4 Fidelity Monitoring*

Intervention fidelity will be ensured through a structured monitoring and control system designed to guarantee methodological consistency, replicability, and the accurate implementation of all components of the "Women in Action" program. In line with current recommendations for complex health interventions, this system will be based on the following elements:

- A standardized intervention manual specifying the content, objectives, sequencing, and methodology of each session.
- A fixed session schedule predefined for the full 16-week intervention period.
- Standardized educational materials and resources applied consistently across all groups.
- Systematic fidelity logs completed by the responsible professionals after each session.

Each fidelity log will include detailed information on: (i) the content delivered, (ii) any deviations from the protocol, (iii) participant engagement and attendance, and (iv) contextual factors that may have influenced implementation (e.g., logistical barriers, group dynamics, or environmental conditions).

Fidelity reports will be periodically reviewed by the principal research team to ensure adherence to the study design, identify potential methodological deviations, and document any adjustments made during

implementation. This procedure enables full protocol traceability and strengthens the internal validity of the study.

The overall structure of the intervention, content progression, and the weekly distribution of components (physical exercise, psychoeducational sessions, and nutrition-focused behavioral workshops) are summarized in Table 6.

**Table 6.** *Timeline and content for the implementation of the "Women in Action" intervention (16 weeks).*

| Week | Activity type | Objectives of workshops and training sessions | Session content | Duration | Responsible staff |
|---|---|---|---|---|---|
| | | | Month 1 | | |
| W1-W2 | Psychoeducational workshops and training sessions | Introduction to the program objectives and initial awareness of beliefs regarding exercise and nutrition. | Gender stereotypes.<br><br>Training: Familiarisation with fundamental movement patterns; resistance training using single-joint exercises, low-intensity interval training, and basic balance, mobility, and postural control exercises. | WS = 90 min (morning workshop)<br>TS = 50 min (afternoon training session) | *Psychologist and educational psychologist; exercise professional |
| W3-W4 | Psychoeducational workshops and training sessions | Identification of sociocultural barriers and body self-perception (body image and physical fitness). | Guided reflection, body image, and physical and functional self-perception.<br><br>Training: Technical consolidation; progression of basic strength, increased interval work duration, and static balance with postural control. | | Psychologist and educational psychologist; exercise professional |
| | | | Month 2 | | |
| W5-W6 | Psychonutrition workshops and training sessions | Emotional regulation and eating behaviour during the climacteric. | Emotional eating workshop.<br><br>Training: Progressive increases in training load; introduction of multi-joint exercises, higher cardiorespiratory training intensity, and proprioceptive and dynamic balance training. | WS = 90 min (morning workshop)<br>TS = 50 min (afternoon training session) | *Nutritionist; exercise professional |

| | | | | | |
|---|---|---|---|---|---|
| W7-W8 | Psychoeducational workshops and training sessions | Development of personal agency for self-care through exercise and strategies to address body-related stigma. | Decision-making.<br><br>Training:<br>Progression to multi-joint and functional exercises; increased interval-training demands and dynamic postural control. | | Psychologist and educational psychologist; exercise professional |
| | | | Month 3 | | |
| W9-W10 | Psychonutrition workshops and training sessions | Improvement of dietary habits. | Mediterranean diet.<br><br>Training: Consolidation of functional strength; progressive increases in cardiorespiratory training intensity and integration of stability, proprioceptive, and dynamic balance exercises. | WS = 90 min (morning workshop)<br>TS = 50 min (afternoon training session) | Nutritionist; exercise professional |
| W11-W12 | Psychoeducational workshops and training sessions | LS.<br>Personal autonomy in exercise. | LS: Intrapersonal (self-control, personal autonomy, ...); interpersonal (social skills, assertive communication, setting personal boundaries, ...).<br><br>Training: Integration of functional movement patterns; maintenance of interval training and progression to more complex functional balance exercises. | | Psychologist and educational psychologist; exercise professional |
| | | | Month 4 | | |
| W13-W14 | Psychonutrition workshops and training sessions | Autonomous dietary decision-making.<br>Combined strength and coordination training. | Meal planning.<br><br>Training:<br>Integrated training focused on functional strength, cardiorespiratory endurance, trunk stability, coordination, and dynamic balance. | WS = 90 min (morning workshop)<br>TS = 50 min (afternoon training session) | Nutritionist; exercise professional |
| W15-W16 | Psychoeducational workshops and training sessions | Consolidation and transfer of the knowledge and skills acquired during the workshops and training sessions. | Summary of key learning outcomes; autonomous functional training.<br><br>Training:<br>Functional integration and transfer through combined strength, cardiorespiratory endurance, and Body Balance exercises designed to support activities of daily living. | | Psychologist and educational psychologist; exercise professional |

*Note.* LL = lower limbs; LS = Life skills; UL = upper limbs; TS = training sessions; W = week; WS = workshop. *Workshops are delivered by a psychologist and educational psychologist specialised in women's health. Training sessions are supervised and delivered by a qualified exercise professional trained to implement the Women in Action resistance-training program.

## 2.3 Target population and sample

The target population will consist of adult women aged between 55 and 75 years residing in the Principality of Asturias. This age range is justified from a physiological, functional, and psychosocial perspective, as it corresponds to the stages of perimenopause, menopause, and early ageing, periods characterized by increased vulnerability across key health and behavioral outcomes.

For clarity, the term 'early ageing' is used throughout this protocol to denote the initial stage of the normative ageing process (i.e., the years immediately following the menopausal transition, broadly corresponding to the early older-adult/young-old stage), and not to premature or accelerated ageing syndromes. This terminology follows its established use in the exercise-science and gerontology literature to describe the period in which early, often subclinical, declines in muscle mass, strength, and functional capacity begin to emerge and can be most effectively targeted through preventive intervention.

From a physiological perspective, the menopausal transition is associated with a progressive decline in estrogen levels, which contributes to an accelerated deterioration of muscle mass and function, commonly referred to as sarcopenia. This condition results in reduced muscle strength, typically assessed through handgrip strength, and decreased overall physical performance, often evaluated using functional tests such as the SPPB test. Both measures have been identified as robust predictors of frailty, disability, and mortality in older populations (26, 40).

### *2.3.1 Sample size calculation*

Sample size estimation was conducted a priori, tied directly to the study's single primary outcome (handgrip strength) and its primary group × time contrast (Intervention vs. Control, baseline [T0] to post-intervention [T2]). The expected effect size was set at d = 0.43, corresponding to the pooled standardized mean difference for handgrip strength following resistance training in older women with sarcopenia reported in a recent systematic review and meta-analysis (SMD = 0.43, 95% CI: 0.11-0.74) (27), which we consider the most directly applicable published effect estimate for this specific outcome and population.

Using the standard formula for an independent-samples comparison of the primary outcome at the primary post-intervention time point ($n = 2 \times [(z\alpha/2 + z\beta)/d]^2$), with $\alpha = 0.05$ (two-tailed; $z\alpha/2 = 1.96$), power ($1-\beta$) = 0.80 ($z\beta = 0.84$), and d = 0.43, the required sample size is 85 participants per group (170 total) before attrition. This calculation deliberately uses the simpler, fully transparent two-sample formula rather than G*Power's repeated-measures interaction routine, because the former is independently reproducible by the editorial team and reviewers using only a calculator or standard statistical software; the planned primary analysis (linear mixed-effects models exploiting the correlation between repeated assessments; Section 2.7.1) is expected to yield equal or greater power than this conservative estimate, so the reported sample size represents an upper-bound, conservative target.

Accounting for an anticipated attrition rate of 20% over the 16-week intervention and 3-month follow-up, consistent with dropout rates reported in comparable long-term, multicomponent exercise interventions in older women (24, 25), the target enrollment is 107 participants per group (85 / 0.80, rounded up), i.e., 214 participants in total. No separate power calculations were performed for

550 feasibility or secondary outcomes; consistent with the single-primary-outcome design of this protocol,
551 sample size is driven exclusively by the primary outcome, and feasibility and secondary outcomes will
552 be estimated, with appropriate descriptive precision, within this same sample.

553 **2.4 Eligibility criteria, recruitment, and group allocation**

554 *2.4.1 Eligibility criteria*

555 Participants will be selected based on predefined criteria aimed at ensuring alignment with the target
556 population and strengthening the internal validity of the study.

557 Women will be considered eligible if they meet the following inclusion criteria: aged between 55 and
558 75 years, residing in the Principality of Asturias, providing written informed consent, and presenting
559 medical clearance for participation in supervised moderate-to-vigorous physical activity. In addition,
560 participants must exhibit suboptimal levels of physical activity, operationally defined as not meeting
561 WHO physical activity recommendations (i.e., less than 150 minutes/week of moderate-intensity, or
562 less than 75 minutes/week of vigorous-intensity, aerobic activity, and/or fewer than two muscle-
563 strengthening sessions per week) and/or reporting low adherence to previously prescribed or self-
564 initiated exercise routines, as identified through an initial screening process using the Global Physical
565 Activity Questionnaire (GPAQ) or an equivalent standardized instrument, administered in a digital
566 format. Furthermore, eligibility will require a relevant degree of exposure to gender-related stereotypes
567 associated with physical activity. Participants must also be willing to complete all assessment phases
568 of the study (T0, T1, T2, and T3 follow-up).

569 Exclusion criteria will include the presence of medical conditions contraindicating supervised exercise,
570 severe cognitive impairment limiting program participation, concurrent involvement in structured
571 resistance training interventions, and any physical or functional condition that would prevent the safe
572 execution of physical performance assessments, including handgrip strength and the SPPB test. All
573 eligibility criteria will be verified prior to group allocation.

574 In view of the marked hormonal, functional, and clinical heterogeneity that can exist between early
575 perimenopausal and late postmenopausal women within this age range, menopausal status (peri-, early
576 post-, or late post-menopausal, based on self-reported time since final menstrual period, following
577 STRAW+10 criteria) will be collected at baseline and used, together with chronological age, as a
578 stratification/covariate variable in the statistical models described in Section 2.7.2. In addition, given
579 their potential influence on muscle mass, strength, and functional outcomes, the baseline
580 sociodemographic and clinical questionnaire will systematically record the use of menopausal hormone
581 therapy (MHT), corticosteroids, and calcium/vitamin D or other relevant supplementation, as well as
582 other medications with known effects on body composition or physical function. These variables will
583 be treated as covariates in the analytical models (Section 2.7.2) and will be reported descriptively by
584 study arm to evaluate baseline comparability.

585 *2.4.2 Participant recruitment*

586 Recruitment will be conducted using a multichannel, community-based strategy to ensure
587 representativeness of the target population and to minimize selection bias. Participants will be recruited
588 through sports and healthcare centers, women's associations, third-sector organizations, and public
589 administrations involved in active ageing programs.

The recruitment process will be carried out simultaneously for both study groups (intervention and control), ensuring consistency in participant selection and minimizing potential bias associated with differential recruitment procedures. All participants will receive detailed information about the study objectives and procedures, ensuring adherence to ethical principles of transparency and informed consent.

*2.4.3 Group allocation and assignment*

Following verification of eligibility criteria, participants will be assigned to study groups (intervention vs. control) using a non-random, minimization-based allocation procedure designed to balance key baseline characteristics between arms (rather than random or alternation-based assignment). Specifically, participants recruited from each community or organizational site (e.g., sports centre, women's association) will first be characterized on a set of key baseline variables -- chronological age, menopausal status, physical activity level (GPAQ), physical function (SPPB score), level of gender-related stereotype internalization (ASES), socioeconomic status, and geographical context (urban/rural) -- and will then be allocated using Pocock and Simon's minimization algorithm, implemented as follows in strict order: (1) a researcher independent of recruitment and assessment (the trial statistician) will first determine, for each new participant, which of the two group-scheduling/venue configurations logistically available to her (based solely on travel distance and session-timetable availability, without reference to her baseline characteristics) are feasible; (2) among only the logistically feasible option(s) identified in step 1, the minimization algorithm will compute, for each candidate group assignment, the resulting between-group imbalance across the weighted balancing variables (age, menopausal status, physical activity level, physical function, gender-related stereotype internalization, socioeconomic status, and geographical context; equal weighting) using the sum of variances method; (3) the participant will be allocated to the candidate group that minimizes total imbalance with probability 0.8, and to the alternative feasible group with probability 0.2 (biased-coin element), to preserve unpredictability of allocation; where only one logistically feasible option exists, the participant will be allocated to that option deterministically and this instance will be recorded and reported as a logistically constrained allocation. All allocations will be generated centrally by the trial statistician using a pre-specified computer algorithm, concealed from the personnel enrolling participants until immediately after each participant's baseline assessment is complete. Group-level baseline comparability on all balancing variables will be verified statistically (independent-samples t-tests or chi-square tests, as appropriate) before the start of the intervention, and any residual imbalance will be addressed through covariate adjustment in the analytical models described in Section 2.7.2. This approach is intended to ensure comparability between groups in the absence of full randomization, thereby minimizing selection bias and strengthening the internal validity of the study design.

The study will include two groups: an intervention group (IG), which will participate in the multicomponent program, and a control group (CG), which will maintain their usual lifestyle habits without exposure to the intervention during the study period.

Data collection will be conducted at four time points: baseline (T0), mid-intervention (T1), post-intervention (T2), and follow-up (T3). This longitudinal design will allow for the evaluation of initial responses to the program, post-intervention effects, and the maintenance of changes over time.

Efforts will be made to ensure group comparability with respect to key baseline variables, including age, physical activity level, physical function (assessed via handgrip strength and SPPB), levels of gender-related stereotypes, socioeconomic status, and geographical context.

The overall group structure and the assessment timeline are summarized in Table 7.

**Table 7**. *Study group structure and assessment procedures*.

| Element | Intervention Group | Control group |
|---|---|---|
| Experimental condition | Participation in the multicomponent intervention | Passive control |
| Duration | 16 weeks | 4 months |
| Intervention components | Strength (resistance) training; aerobic endurance training; balance training;<br>psychoeducational workshops (gender stereotypes, empowerment, personal agency);<br>nutrition-focused (psychonutrition) intervention | No intervention |
| Mixed participation in the psychoeducational component | Participation in dedicated psychoeducational workshops (gender stereotypes and exercise) promoting shared responsibility for gender equality | Not applicable |
| Assessments | T0 (baseline), T1 (mid-intervention), T2 (post-intervention), T3 (follow-up) | Same assessment time points |
| Group allocation | Non-random, minimization-based allocation balancing baseline characteristics | |
| Balancing variables | Age; physical activity level; physical function; gender stereotypes; socioeconomic status; geographical area | |
| Ethical compensation | The control group will receive basic information after completion of the study | |

*Note*. T0, T1, T2, T3 = data collection periods.

The combination of a structured selection process, a homogeneous recruitment strategy, and a group allocation procedure based on baseline balance criteria ensures initial group comparability, representativeness of the target population, and the overall methodological robustness of the study design. Furthermore, the standardization of assessment procedures across all time points strengthens both the internal validity and the reliability of the expected outcomes.

## 2.5 Variables and instruments

In accordance with the conceptual framework underpinning this protocol, the "Women in Action" intervention is designed to target key psychosocial, behavioral, and functional determinants that influence overall health in older women. Consistent with the feasibility-oriented aim of this protocol (Section 1.4), study outcomes are organized into three tiers: (i) feasibility outcomes, addressing the feasibility, implementation fidelity, and acceptability of the intervention; (ii) a single, prespecified primary outcome (handgrip strength), selected as the main functional marker to limit multiplicity and preserve interpretability; and (iii) secondary outcomes, operationalized as a set of psychological, social, and behavioral competencies alongside complementary objective indicators of physical function and dietary behavior, all of which are directly associated with the adoption and maintenance of active and healthy lifestyles.

### *2.5.1 Feasibility outcomes*

Given that feasibility constitutes the primary aim of this protocol (Section 1.4), the following feasibility indicators will be systematically recorded and reported, in line with recommended frameworks for feasibility and pilot studies: recruitment rate (proportion of approached women who enrol); retention rate (proportion of enrolled participants completing the study through T3); session attendance (proportion of strength-training and workshop sessions attended per participant); protocol adherence (proportion of participants meeting the ≥80% attendance criterion); intervention acceptability (assessed

through a brief satisfaction questionnaire and qualitative feedback at T2); adverse events (recorded as described in Section 2.6.5); implementation fidelity (assessed via the fidelity checklist described in Section 2.6.4); logistical feasibility (indicators of scheduling, venue, and staffing feasibility recorded by the research team); and assessment completion rate (proportion of scheduled assessments completed at each time point). These indicators will be reported descriptively (frequencies, percentages, and 95% confidence intervals where appropriate) and will inform judgements about the readiness of the "Women in Action" program for a subsequent, adequately powered effectiveness trial.

Accordingly, study variables are organized into three main domains: (i) psychosocial determinants related to gender and personal agency, (ii) psychological variables associated with physical self-concept, and (iii) indicators of physical function and dietary behavior.

This multidimensional framework allows for a comprehensive assessment of intervention effects, integrating behavioral, psychosocial, and functional dimensions of health within a unified analytical model.

The alignment between independent variables, dependent variables, and control variables is presented in Table 8.

**Table 8**. *Variables under study*.

| Variable type | Variable(s) | Instrument / Data source |
|---|---|---|
| **Independent variable** | Study group (Intervention vs. Control) | Group allocation record (Section 2.4.3) |
| **Feasibility outcomes** | Recruitment rate; retention rate; session attendance; protocol adherence; intervention acceptability; adverse events; implementation fidelity; logistical feasibility; assessment completion rate | Study records, attendance logs, fidelity checklist, adverse-event log, satisfaction questionnaire (Section 2.5.1) |
| **Primary outcome** | Handgrip strength | Manual dynamometer |
| **Secondary outcomes – physical function** | SPPB (balance, gait speed, chair-stand); body composition (fat mass, fat-free mass, skeletal muscle mass) | SPPB test; bioelectrical impedance analysis (BIA) |
| **Secondary outcomes – psychosocial** | Personal agency; empowerment; physical self-concept; ageing- and exercise-related stereotypes; exercise self-efficacy | ESAGE-Sp-19; CAF-MAY; ASES; SEE |
| **Secondary outcomes – dietary behavior** | Mediterranean diet adherence | MEDAS |
| **Secondary outcomes – qualitative** | Participants' lived experience of gender stereotypes, body perception, and empowerment processes | Focus groups (Section 2.6.4) |
| **Control variables / covariates** | Age; menopausal status; baseline physical activity level; socioeconomic status; geographical context; use of menopausal hormone therapy, corticosteroids, or calcium/vitamin D supplementation | Sociodemographic and clinical questionnaire (Section 2.4.1) |

*Note*: IG (Intervention group); T = Time 0, 1, 2, 3 (data collection periods); SPPB = *Short Physical Performance Battery*.

Within the domain of sociocultural determinants, gender-related stereotypes associated with physical activity and exercise will be assessed using the *Ageing Stereotypes and Exercise Scale* (ASES) developed by (41). This instrument was specifically designed to measure stereotype-related beliefs in the context of physical activity among older adults, including perceptions about functional decline, perceived physical limitations, and motivational barriers to exercise. Unlike more general gender stereotype scales, the ASES focuses directly on beliefs linked to exercise behavior in ageing

682 populations, making it particularly suitable for capturing the sociocultural factors that influence
683 engagement in physical activity in later life. The selection of this instrument is based on its conceptual
684 specificity and ecological validity within the exercise domain, as it allows for the assessment of
685 internalized beliefs that directly impact behavioral regulation, perceived competence, and adherence
686 to physical activity in older populations. The ASES is therefore treated in this protocol as a secondary
687 outcome measuring ageing- and exercise-related stereotypes, rather than as a direct measure of gender
688 stereotypes. While stereotypes related to ageing and physical capacity are plausibly intertwined with
689 gender norms in women, particularly during menopausal and post-menopausal stages, this potential
690 gendered dimension is considered indirect and is not assumed a priori; it will instead be explored
691 through the qualitative focus-group component (Section 2.6.4), which is specifically designed to
692 capture participants' own accounts of gender-related stereotypes and sociocultural barriers (Table 9).

693 However, as no validated Spanish version of the ASES has been identified in the literature, a cross-
694 cultural adaptation process will be conducted prior to its application. This process will include
695 translation and back-translation procedures, as well as a content validity assessment through expert
696 consensus involving specialists in exercise science, psychology, and gender studies. Following this
697 phase, psychometric analyses will be carried out within the study sample to evaluate internal
698 consistency and explore the structural validity of the scale in this specific population. This approach
699 ensures both methodological rigor and contextual appropriateness, while contributing to the
700 advancement of measurement tools for the assessment of gendered stereotypes in physical activity
701 among older women.

702 With respect to psychological variables, personal agency and empowerment will be assessed using the
703 *Personal Agency and Empowerment Scale* (ESAGE-Sp-19) (42), a validated instrument that enables
704 the evaluation of key dimensions such as action capacity, self-confidence, internal locus of control,
705 and both personal and social empowerment. This construct is central to the present study, as existing
706 evidence indicates that perceived control and autonomy directly influence physical activity adherence
707 and the adoption of health-related behaviors in older adults (14, 15). Responses are collected using a
708 Likert-type scale, allowing for the longitudinal assessment of changes in perceived agency as a result
709 of the intervention.

710 In addition, exercise self-efficacy will be incorporated as a complementary psychosocial outcome,
711 given its well-established role as a proximal determinant of exercise initiation and adherence. Exercise
712 self-efficacy will be assessed using a validated Spanish-language adaptation of the Self-Efficacy for
713 Exercise Scale (SEE), which evaluates participants' confidence in their capacity to maintain exercise
714 behavior under common barrier conditions (e.g., fatigue, low mood, lack of time, or bad weather). This
715 measure will be collected at T0, T1, T2, and T3, alongside the other psychosocial instruments described
716 in this section.
717 To account for the possibility of socially desirable responding, the 13-item short form of the
718 Marlowe-Crowne Social Desirability Scale (SDS-13; Reynolds, 1982) will be administered at T0 and
719 T2. This dichotomous (true/false) self-report scale yields a total score reflecting the tendency to
720 respond in a socially desirable manner, and will be entered as a covariate in sensitivity analyses of
721 self-reported psychosocial and dietary outcomes.

722 In addition, physical self-concept will be evaluated using the *Physical Self-Concept Questionnaire for*
723 *Older Adults* (CAF-MAY), adapted by Moreno-Delgado et al. (2016) (43) from the original *Physical*
724 *Self-Perception Profile for Adults* (PSPP-A) developed by Chase (1991) (44). This instrument assesses
725 multiple dimensions of physical self-concept, including perceived physical competence, health status,
726 physical appearance, functional capacity, and overall physical self-perception. These dimensions are

727 particularly relevant in older women, as body perception has been identified as a key determinant of
728 physical activity behavior and psychological well-being in this population (16, 17).

729 Regarding physical fitness indicators, muscle strength will be assessed through handgrip strength using
730 a manual dynamometer. This measure represents a valid, reliable, and widely recognized marker of
731 overall strength and functional status in older adults, and it has demonstrated high sensitivity to change
732 following resistance training interventions. Handgrip strength has also been identified as a robust
733 predictor of functional autonomy, frailty, and disability risk (26, 40).

734 Global physical function will be evaluated using the SPPB test, which integrates tests of balance, gait
735 speed, and lower limb strength (assessed through the chair stand test). This composite measure provides
736 an overall indicator of physical function and is widely used to identify frailty levels and predict the risk
737 of functional disability in older adults (26, 40).

738 In addition, body composition will be assessed through bioelectrical impedance analysis (BIA), using
739 a validated, standardized, portable BIA device suitable for field-based research applications (e.g., a
740 validated multi- or single-frequency segmental BIA analyzer such as Tanita-type devices). This method
741 provides estimates of fat mass, fat-free mass, and skeletal muscle mass, and will allow the study team
742 to determine whether observed improvements in strength and physical function are accompanied by
743 favourable changes in body composition. Assessments will be conducted under standardized
744 conditions (e.g., fasting state, controlled hydration status, and avoidance of vigorous physical activity
745 in the hours preceding measurement) at all four assessment points (T0, T1, T2, T3), following the
746 manufacturer's calibration and measurement protocol.

747 In terms of nutritional behavior, adherence to the Mediterranean dietary pattern will be assessed using
748 the *Mediterranean Diet Adherence Screener* (MEDAS), developed by Schröder et al. (2011) (10). This
749 14-item dichotomous questionnaire evaluates the frequency and quality of consumption of key
750 components of the Mediterranean diet and constitutes a validated indicator of healthy eating behavior
751 in adult populations.

752 In terms of administration procedures, the MEDAS questionnaire will be administered by trained study
753 personnel through a structured interview format at each assessment point (T0, T1, T2, T3), taking
754 approximately 5-10 minutes to complete, with clarifying prompts provided as needed to standardize
755 interpretation of portion sizes and frequency categories across participants. Because the MEDAS
756 provides a categorical adherence score rather than quantitative nutrient intake, a 3-day estimated
757 dietary record (two weekdays and one weekend day) will be additionally administered at T0 and T2 to
758 quantify total energy intake (kcal/day) and protein intake (g/day and g/kg body weight/day). Dietary
759 records will be analyzed using a validated food-composition database/software (e.g., the Spanish
760 BEDCA database or equivalent validated nutrient-analysis software), applied consistently across all
761 participants and time points, to contextualize changes in strength outcomes relative to dietary protein
762 adequacy.

763 Complementing the quantitative analyses, a qualitative approach will be implemented through focus
764 groups aimed at exploring participants' subjective experiences related to gender stereotypes, body-
765 related stigma, emotional safety within the physical activity context, and processes of personal and
766 social empowerment throughout the intervention. This approach allows for an in-depth understanding
767 of underlying mechanisms of change and supports the contextual interpretation of findings, in line with
768 the study's intersectional feminist framework.

**Table 9**. *Relationship between the specific objectives, outcome variables, measurement instruments, and protocol outcome indicators.*

| Specific objective | Outcome variable | Measurement instrument | Outcome indicator |
|---|---|---|---|
| Assess the effects on gender stereotypes | Gender stereotypes related to exercise | Ageing Stereotypes and Exercise Scale | Significant reduction in the experimental group compared with the control group (T0-T1) |
| Assess personal agency | Personal agency | ESAGE-Sp-19 | Significant increase in the experimental group |
| Assess self-confidence | Self-confidence | ESAGE-Sp-19 | Significant improvement in the experimental group |
| Assess internal locus of control | Internal locus of control | ESAGE-Sp-19 | Increase in the experimental group |
| Assess empowerment | Social empowerment | ESAGE-Sp-19 | Significant increase in the experimental group |
| Assess physical self-concept | Physical self-concept | CAF-MAY | Improvement in physical self-concept dimensions and self-esteem |
| Assess physical function and nutritional status | Handgrip, SPPB test, MEDAS | Handgrip dynamometer, SPPB, MEDAS | Improvement in muscle strength, physical function, and an increase of ≥2 points on the MEDAS |
| Assess body composition | Fat mass, fat-free mass, skeletal muscle mass | Bioelectrical impedance analysis (BIA) | Favourable change in body composition indicators (e.g., increase in skeletal muscle mass and/or decrease in fat mass) in the experimental group |

*Note*: ESAGE-Sp-19 = *Personal Agency and Empowerment Scale;* CAF-MAY = *Physical Self-Concept Questionnaire for Older Adults; MEDAS = Mediterranean Diet Adherence Screener; SPPB* = Short Physical Performance Battery.

The use of validated psychometric instruments alongside objective measures of physical function enables an integrated analysis of the intervention's effects across physical, psychological, and social dimensions of health.

This methodological approach enhances the internal validity of the study, facilitates the interpretation of findings, and contributes to the generation of meaningful evidence in the fields of physical exercise, nutrition, and women's empowerment.

## 2.6 Procedure

El The study procedure will follow a structured sequence consisting of four main phases: (1) study preparation and design; (2) baseline assessment (T0); (3) implementation of the 16-week multicomponent intervention, including an intermediate assessment (T1); and (4) post-intervention assessment (T2), follow-up evaluation (T3), data analysis, and knowledge translation. All procedures will be standardized to ensure replicability, methodological consistency, and data quality.

### *2.6.1 Phase 1: Preparation, training, and recruitment*

During the preparatory phase (approximately one month), methodological and organizational aspects of the protocol will be finalized. This phase will include:

- Obtaining approval from the relevant research ethics committee.
- Finalizing the intervention protocol, including content, scheduling, and sequencing.
- Recruiting participants in accordance with predefined eligibility criteria.

- Assigning participants to study groups (Intervention Group and Control Group) using a non-random, minimization-based procedure that balances key baseline characteristics between arms.

In addition, specific training will be delivered to the technical staff (n ≈ 10 exercise professionals) responsible for implementing the training program. Eligible exercise professionals will be required to hold a university degree in Sport and Exercise Science (or equivalent, e.g., Physiotherapy with an exercise-prescription specialization), together with accredited specific training and/or documented practical experience in resistance-training prescription for older or clinical populations. This training will ensure:

- Technical competence in resistance training for women aged 55-75 years.
- Application of principles of progression and exercise safety.
- Integration of a co-educational, body-positive approach.
- Appropriate monitoring of training load variables (e.g., perceived exertion) and identification of potential risks.
- Understanding of physiological (menopausal transition) and psychosocial factors influencing exercise participation in women.

Parallel coordination meetings will be held with the multidisciplinary team (psychology, nutrition, mind-body specialists, and experts in emotional safety) to structure the content and methodological approach of the psychoeducational and nutrition-focused behavioral workshops.

*2.6.2 Phase 2: Baseline assessment (T0)*

Prior to the start of the intervention, a baseline assessment (T0) will be conducted. During this phase, participants from both groups will complete:

- An ad hoc sociodemographic questionnaire (age, marital status, family context, place of residence, health status, etc.).
- A questionnaire battery integrating the psychometric scales corresponding to the primary and secondary outcomes described in the Variables and Instruments section.
- A set of standardized physical tests, including handgrip strength and the SPPB test.

All assessments will be conducted under standardized conditions, using identical instruments, protocols, and environmental conditions for all participants. Participants will be instructed to avoid vigorous physical activity for 24-48 hours prior to assessment and to maintain their usual sleep and dietary habits.

Given the nature of the intervention, participants and the professionals delivering the psychoeducational, nutrition-focused, and exercise-training sessions cannot be blinded to group allocation. However, outcome assessors administering the physical performance tests (handgrip strength and SPPB) and collecting psychometric questionnaire data at T0-T3 will be different individuals from those delivering the intervention and will remain blinded to group assignment whenever logistically feasible; participants will be reminded not to disclose their group allocation during assessment sessions. Where blinding of outcome assessment cannot be fully guaranteed (e.g., in smaller recruitment sites with limited staff), this will be documented and reported transparently as a

potential source of detection bias, in line with TREND statement recommendations for non-randomized studies.

*2.6.3 Phase 3: Intervention delivery (16-Week program) and Intermediate assessment (T1)*

Participants allocated to the intervention group will take part in the 16-week multicomponent program described in Section 2.2.

All sessions will be implemented following a standardized intervention manual specifying content, methodological sequencing, materials, and professional roles. The exercise component will be supervised by trained exercise professionals, while workshops will be delivered by professionals in psychology, nutrition, and related disciplines.

During the intervention, a fidelity monitoring system will be implemented through weekly records documenting adherence to the protocol, participant engagement, and any methodological deviations. To minimize confounding factors, participants will be instructed not to engage in other structured exercise, nutritional, or psychological programs during the study period.

*2.6.3.1 Intermediate assessment (T1)*

At the midpoint of the intervention (week 8), an intermediate assessment (T1) will be conducted to evaluate:

- Changes in gender-related stereotypes.
- Improvements in personal agency and empowerment.
- Modifications in physical self-concept.
- Progress in physical fitness and dietary behaviors (Mediterranean diet adherence).

This assessment will allow for the evaluation of intermediate outcomes and, if necessary, the adjustment of implementation procedures.

*2.6.4 Phase 4: Post-intervention (T2), follow-Up (T3), and aata analysis*

*2.6.4.1 Post-intervention assessment (T2)*

Upon completion of the intervention (week 16), a post-intervention assessment (T2) will be conducted, replicating the measurement protocol used at baseline. This will allow for the analysis of pre-post changes in the study outcomes.

*2.6.4.2 Follow-up assessment (T3)*

Three months after the end of the intervention, a follow-up assessment (T3) will be conducted to evaluate the sustainability of changes in physical function, nutritional behavior, and psychosocial variables.

This longitudinal design enables the assessment of both the effectiveness of the intervention and the maintenance of its effects over time.

*2.6.4.3 Data management and Analysis*

- Data management procedures will include:
- Anonymous coding of participants.
- Storage in structured databases.
- Double data entry for quality control.

Quantitative analyses will be conducted using *R* (version 4.5.2; *R Foundation for Statistical Computing*, Vienna, Austria), including descriptive analyses and the linear mixed-effects models described in Section 2.7.1. The exact software version used will be reported in the final study report once analyses have been performed.

Qualitative data from focus groups will be analyzed through transcription, thematic coding, and a phenomenological approach. Quantitative and qualitative findings will be integrated using triangulation strategies to provide a comprehensive interpretation of the results.

*2.6.5 Safety monitoring and ethical considerations*

Throughout all phases of the study, any incidents, adverse events, or conditions that may compromise participant safety will be systematically recorded. Specific protocols will be implemented to ensure appropriate referral procedures in cases of physical risk or significant psychosocial distress.

A specific adverse event (AE) monitoring plan will be implemented for the exercise and physical assessment components. Exercise professionals will record, at every training session, any musculoskeletal complaint, fall, near-fall, cardiovascular symptom (e.g., chest pain, dizziness, excessive dyspnoea), or other adverse event using a standardized incident-report form, classifying events as mild, moderate, or severe and as related, possibly related, or unrelated to the intervention. Moderate and severe AEs will be reported to the principal investigators within 24 hours and will be reviewed at monthly intervals by the multidisciplinary research team; serious adverse events (e.g., fracture, hospitalization) will trigger an immediate review of the participant's continued involvement and, if necessary, temporary or permanent modification of the exercise prescription. Participants will be instructed to inform the exercise professional immediately of any pain, discomfort, or symptoms during or after sessions, and a physician with expertise in exercise medicine will be available for consultation and referral when required. Cumulative AE rates will be reported by study arm in accordance with CONSORT harms-reporting recommendations.

All study procedures will be conducted in accordance with the ethical principles outlined in the *Declaration of Helsinki*, ensuring informed consent, data confidentiality, and the protection of participant rights. In addition, the study incorporates a gender-sensitive and community care-oriented approach, aligned with current frameworks in women’s health research.

## 2.7 Statistical analysis

All statistical analyses will be conducted in accordance with APA 7th edition reporting standards, ensuring transparency and methodological rigor throughout all analytical stages. Descriptive statistics will be calculated for all variables at each assessment point (T0, T1, T2, T3), including means and standard deviations for continuous variables, medians where distributions are non-normal, and frequencies and percentages for categorical variables. Baseline equivalence between groups will be

examined using independent-samples t tests or $\chi^2$ tests, as appropriate, to assess initial comparability and identify potential pre-existing differences.

*2.7.1 Primary analytical model*

Linear mixed-effects models will be used as the primary analytical approach, because they can accommodate repeated observations, unequal spacing between assessment points, and missing data under appropriate assumptions, without requiring complete-case data. Time (T0, T1, T2, T3), group (Experimental vs. Control), and the group × time interaction will be included as fixed effects, with participant-level random intercepts specified to account for within-subject correlation. The group × time interaction constitutes the primary effect of interest in the present quasi-experimental longitudinal design. Traditional repeated-measures ANOVA will be retained as a complementary analysis when the data are complete, to facilitate comparison with the broader effectiveness literature.

Separate mixed-effects models will be estimated for the primary effectiveness outcome (handgrip strength) and for each secondary outcome domain, namely, ageing- and exercise-related stereotypes, personal agency and empowerment, physical self-concept, SPPB performance, and Mediterranean diet adherence, in order to preserve interpretability and avoid unnecessary model complexity. This approach is consistent with the conceptual structure of the intervention and reduces the risk of inflated Type I error associated with indiscriminate multivariate aggregation.

*2.7.2 Covariates and control variables*

When appropriate, baseline values of the dependent variables, along with theoretically relevant covariates such as chronological age, menopausal status, baseline physical activity level, initial functional status, socioeconomic context, baseline levels of gender stereotype internalization, and use of menopausal hormone therapy, corticosteroids, or calcium/vitamin D supplementation, will be included in the analytical models. The selection of covariates will be theoretically justified and limited to those variables plausibly associated with the outcomes, following methodological recommendations for non-randomized intervention designs.

*2.7.3 Assumptions and robust alternatives*

Model assumptions, including normality of residuals, homogeneity of variance, and sphericity, will be evaluated using both graphical inspection and formal statistical tests (*Shapiro-Wilk, Kolmogorov-Smirnov, Levene,* and *Mauchly tests*). When sphericity assumptions are violated, Greenhouse-Geisser corrections will be applied.

In cases of moderate deviations from normality, analyses will rely on the robustness of repeated-measures general linear models, particularly given the expected sample size and group balance. However, if substantial violations are detected that cannot be addressed through data transformation, equivalent longitudinal models based on rank-based or mixed-model approaches will be employed to preserve the within-subject dependency structure, avoiding the use of isolated non-parametric tests that may compromise the interpretation of longitudinal effects.

*2.7.4 Missing data and attrition*

Following recommendations for the analysis of quasi-experimental and randomized intervention designs, the primary analysis will be conducted under an intention-to-treat (ITT) framework, including

all participants as allocated regardless of the level of adherence achieved. Missing data arising from dropout or missed assessment points will be handled through the restricted maximum likelihood (REML) estimation inherent to the linear mixed-effects models specified as the primary analytical approach (Section 2.7.1), which use all available data from each participant without requiring case deletion or imputation, under a missing-at-random (MAR) assumption. Multiple imputation will not be used as an alternative primary method; it will be applied only as a pre-specified sensitivity analysis (generating 20 imputed datasets) to evaluate the robustness of the primary results to departures from the MAR assumption. A complementary per-protocol analysis, restricted to participants meeting a predefined adherence criterion (≥ 80% session attendance) and completing all required assessment points, will be conducted as a secondary/sensitivity analysis to explore the efficacy of the intervention under conditions of high fidelity. Attrition rates, reasons for dropout, and the pattern of missingness (missing completely at random, at random, or not at random) will be examined and reported in accordance with CONSORT-extension recommendations for non-randomized designs, and will be compared descriptively between study arms to evaluate the plausibility of the missing-at-random assumption.

Attrition rates and reasons for participant dropout will be systematically recorded and reported to enhance transparency and reproducibility.

*2.7.5 Multiple comparisons and effect size reporting*

Given the multidimensional nature of the outcomes, statistical inference will prioritize consistency and pattern of effects across domains rather than reliance on isolated *p*-values. When multiple comparisons are conducted, appropriate corrections (e.g., Holm-Bonferroni or Bonferroni adjustments) will be applied within each outcome domain to control the family-wise error rate.

Effect sizes will be systematically reported alongside significance values to facilitate interpretation of practical relevance. Partial eta squared ($\eta^2p$) will be reported for repeated-measures ANOVA models, and standardized mean differences (Cohen's *d* or Hedges'*g*) will be calculated for pairwise comparisons. Additionally, relative percentage change from baseline (T0-T1; T0-T2; T0-T3) will be computed to support applied interpretation of intervention effects.

*2.7.6 Qualitative analysis and mixed-methods integration*

Qualitative data obtained through focus groups will be analyzed using thematic coding within a phenomenological framework, with particular attention to gender experiences, emotional safety, body perception, and empowerment processes. Transcripts will be systematically coded and categorized, following an inductive approach.

To fully operationalize this component: focus groups will be conducted at two time points, post-intervention (T2) and follow-up (T3), to capture both immediate and sustained participant experiences. Approximately 4-6 focus groups (2-3 per time point) will be conducted, each comprising 6-8 participants recruited from the intervention group using purposive sampling to ensure diversity in age, socioeconomic status, and geographical context. Sessions will be facilitated by a trained psychologist experienced in qualitative methods, following a semi-structured discussion guide, and will last approximately 60-90 minutes. All sessions will be audio-recorded with participants' consent and transcribed verbatim by trained research staff. Two independent coders will code the transcripts; disagreements in coding will be resolved through discussion and, where necessary, consultation with a third member of the research team, in order to reach consensus. Reflexivity will be addressed through

a reflexive journal maintained by the research team throughout data collection and analysis, documenting positionality and potential sources of bias. Coding and thematic analysis will be supported by qualitative data analysis software (e.g., ATLAS.ti or NVivo).

Subsequently, a mixed-methods integration strategy will be implemented through triangulation, enabling the convergence and complementarity of quantitative and qualitative findings. This approach will provide a more comprehensive understanding of the effects and mechanisms of the intervention within a feminist and biopsychosocial framework.

Specifically, integration will follow a convergent parallel design, in which quantitative and qualitative data are collected concurrently but analyzed separately, and subsequently merged at the interpretation stage using a joint display comparing quantitative effect estimates with qualitative themes for each outcome domain. This will allow the identification of convergence, complementarity, or divergence between data sources, thereby strengthening the interpretive validity of the study's feasibility and preliminary effectiveness findings.

*2.7.7 Statistical software and significance level*

Quantitative analyses will be conducted using R statistical software (*R Foundation for Statistical Computing*, Vienna, Austria). Statistical significance will be established at $p < .05$, with $p < .001$ considered indicative of high statistical significance.

## 3 Desired outcomes and discussion

This section summarizes the anticipated contribution of the “Women in Action” protocol, situates its expected outcomes within the existing evidence base, and outlines the study’s methodological strengths and limitations. As a feasibility-oriented, methodological protocol, this section does not report definitive outcomes; rather, it articulates the effects the intervention is designed to produce, organized around functional, psychosocial, nutritional, and community-level relevance (Sections 3.1-3.5), followed by a discussion of the protocol’s strengths (Section 3.6) and limitations (Section 3.7).

As a methodological protocol, the present study does not aim to report definitive outcomes but rather to define expected effects as indicators of successful implementation of the “Women in Action” intervention. Favorable changes are anticipated across psychosocial, behavioral, and physical domains, reflecting the program’s multidimensional and transdisciplinary design. Specifically, expected outcomes include a reduction in the internalization of ageing- and exercise-related stereotypes, alongside improvements in personal and social empowerment, physical self-concept, and personal agency.

Concurrently, improvements are expected in physical function parameters, including handgrip strength and performance in the SPPB test, as well as in dietary behaviors, particularly adherence to the Mediterranean diet as assessed by the MEDAS questionnaire. As a feasibility-oriented protocol, this study is not powered to establish definitive statistical significance for its secondary outcomes; rather, it will estimate the magnitude and direction of preliminary effects, reported as standardized effect sizes (e.g., Cohen’s d or Hedges’ g) with 95% confidence intervals, to inform the design and sample size calculation of a subsequent, adequately powered effectiveness trial. Overall, these expected outcomes are consistent with the program’s biopsychosocial framework, which integrates physical activity, psychosocial determinants, and nutrition to promote health and wellbeing in middle-aged and older women.

### 3.1 Expected outcomes regarding exercise in older women

The "Women in Action" protocol proposes an integrative design that combines resistance training, nutrition-focused behavioral education, and gender-sensitive psychoeducational strategies, addressing a relatively underexplored intersection between exercise science, gender studies, and health promotion in older women.

The expected outcomes are grounded in prior evidence on exercise interventions, multicomponent training, and combined exercise–nutrition strategies in older populations. Multicomponent programs such as Vivifrail have demonstrated positive effects on functional capacity, muscle strength, mobility, and autonomy in frail and pre-frail older adults (18, 45). Similarly, exercise interventions adapted to residential and community contexts have been associated with improvements in functional capacity and the prevention of weakness and falls, reinforcing the importance of structured, progressive, and individualized training programs for older populations (46).

Specifically, in older women, recent evidence suggests that resistance training contributes to improvements in body composition, muscle strength, and physical function, particularly in the context of sarcopenia and sarcopenic obesity (47, 48). These findings support the inclusion of a strength training component in the "Women in Action" program, aimed at improving handgrip strength, functional performance assessed through the SPPB, and overall physical autonomy in women undergoing menopausal transition and early ageing.

From a nutritional perspective, current evidence also supports the integration of exercise and dietary interventions, particularly when aiming to improve functional health, body composition, and to prevent age-related physical decline (19, 49).

Taken together, this body of evidence supports the development of a multicomponent intervention integrating physical exercise, nutrition-focused behavioral strategies, and psychoeducational components within a gender-sensitive framework. Unlike traditional approaches focused solely on physiological or nutritional outcomes, "Women in Action" adopts a biopsychosocial model aimed at improving functional capacity, promoting healthy behaviors, and addressing the psychosocial and sociocultural determinants influencing physical activity participation in older women.

### 3.2 Expected psychoeducational outcomes

The protocol addresses key determinants of active behavior that have been insufficiently considered in interventions targeting older women. Scientific evidence indicates that internalized gender stereotypes, low perceived competence, and age-related biases constitute significant barriers to physical activity engagement across the lifespan (1-2,4).

Accordingly, the intervention is expected to reduce the internalization of gender stereotypes while promoting improvements in personal agency, self-confidence, and internal locus of control. These factors have been consistently associated with adherence to healthy behaviors and sustained engagement in physical activity (14, 15).

In addition, improvements are anticipated in physical self-concept, particularly in dimensions related to perceived functional capacity, body acceptance, and health-related self-esteem. These outcomes are especially relevant during menopausal transition and early ageing, periods characterized by physical, emotional, and identity-related changes that may affect exercise participation and continuity.

### 3.3 Expected outcomes in the field of psychonutrition

In relation to dietary behavior, the nutrition-focused component is expected to promote increased adherence to the Mediterranean diet, a dietary pattern consistently associated with improved health outcomes, greater physical resilience, and reduced risk of frailty in older adults (12,13).

The integration of content addressing the emotion–eating relationship and autonomous decision-making in nutrition responds to the need for a comprehensive approach to dietary behavior. This perspective considers not only the physiological changes associated with ageing but also the emotional, social, and contextual factors that influence food choices.

From an innovation perspective, "Women in Action" explicitly integrates physiological, behavioral, and sociocultural components within a single intervention model. In contrast to traditional approaches focused on isolated domains, this protocol adopts a feminist and biopsychosocial framework, recognizing that health behaviors in women are deeply shaped by structural, relational, and cultural determinants.

### 3.4 Limitations

Despite its methodological strengths, there are some limitations that should be taken into account when applying the methodology described in this protocol. First, the quasi-experimental design, although appropriate for real-world and community-based settings, may limit causal inference compared to fully randomized controlled trials. Second, as a protocol study, the findings are prospective and based on expected outcomes rather than observed results. In addition, although validated psychometric instruments are employed, some measures may require further validation in older women populations; specifically, confirmatory factor analyses would be necessary to fully establish their structural validity and measurement invariance within this target group. Finally, contextual and implementation-related factors inherent to applied interventions (e.g., adherence variability, environmental influences) may affect the generalizability of the findings.

Several additional sources of bias inherent to the recruitment and design of this quasi-experimental protocol should also be acknowledged. Recruitment will rely on voluntary enrolment through community, sports, and healthcare centres; this strategy is likely to attract women who are already relatively motivated, health-conscious, and proactive with respect to lifestyle change (self-selection or 'healthy volunteer' bias), which may limit the external validity and generalizability of the findings to less engaged or more vulnerable segments of the target population. This limitation will be addressed descriptively by comparing the sociodemographic and health profile of enrolled participants with available population-level data for women of the same age range in the Principality of Asturias.
Given the educational and empowerment-oriented nature of the psychoeducational and nutrition-focused workshops, participants in the intervention group may become aware of socially desirable responses regarding diet and psychosocial constructs over the course of the program, which could artificially inflate post-intervention scores on self-reported questionnaires (social desirability bias) or reflect a Hawthorne-type effect associated with increased attention and social contact rather than the specific intervention content. To address this limitation, the 13-item short form of the *Marlowe-Crowne Social Desirability Scale* (Reynolds, 1982) will be administered at T0 and T2 alongside the psychosocial questionnaires, and will be used as a covariate in sensitivity analyses of self-reported outcomes.

The relatively wide eligibility age range (55-75 years) encompasses women in substantially different stages of the menopausal transition, from early perimenopause to late post-menopause, which are associated with markedly different hormonal profiles and rates of muscle loss. Although this heterogeneity will be addressed statistically through stratification and covariate adjustment by menopausal status and age (see Sections 2.4.1 and 2.7.2), residual heterogeneity within groups cannot be fully excluded and should be considered when interpreting pooled effect estimates.

The application of strict eligibility criteria, including the exclusion of women with significant physical limitations, is expected to produce a relatively high-functioning baseline sample. It is therefore possible that a subset of participants will score at or near the ceiling of the SPPB (12/12 points) at baseline, which would limit the sensitivity of this instrument to detect further functional improvement in those individuals. This potential ceiling effect will be evaluated descriptively by examining the baseline distribution of SPPB scores; if a substantial proportion of participants score at the maximum, complementary continuous or more sensitive measures (e.g., gait speed alone, five-times sit-to-stand time, or extended SPPB protocols) will be analyzed alongside the composite SPPB score to better capture change at the upper end of the functional spectrum.

With respect to dietary assessment, the MEDAS questionnaire provides a validated measure of adherence to the overall Mediterranean dietary pattern but does not, on its own, quantify absolute macronutrient intake. To address this directly, a 3-day estimated dietary record has been incorporated as a mandatory secondary outcome measure (Section 2.5), quantifying total energy and protein intake at T0 and T2, which will allow the study team to contextualize any observed changes in strength outcomes relative to dietary protein adequacy.

To address the initial absence of a body composition measure, the protocol now incorporates bioelectrical impedance analysis (BIA) as a standard anthropometric assessment at all evaluation time points (T0-T3), using a validated, standardized, and field-applicable BIA device (see Section 2.5). This measure will allow the study team to determine whether observed strength gains are accompanied by favourable changes in body composition (e.g., increases in skeletal muscle mass or reductions in fat mass) or reflect neural and functional adaptations occurring independently of changes in muscle mass. Finally, the post-intervention follow-up period (T3, three months after completion of the 16-week program) is relatively short and only allows for the evaluation of short-term maintenance of behavioral and functional changes. Extending the follow-up period to 6-12 months would provide more robust evidence regarding the sustainability of intervention effects and will be considered for future iterations of this protocol, resources permitting.

### 3.5 Expected outcomes at the community level

At the community and societal level, the application of the methodological framework described in this protocol may contribute to the creation of inclusive, safe, and non-discriminatory physical activity environments, fostering active participation of women in settings that have traditionally been male-dominated. The protocol thus provides an applied model for the implementation of the scientific method in community contexts, with the potential to generate meaningful impact not only at the level of the target population but also across the broader older adult community.

Furthermore, the inclusion of men in selected psychoeducational workshops introduces a relational and systemic dimension, enabling the examination and potential transformation of gender norms within a shared social context. This approach may promote co-responsibility and support processes of social

change, reinforcing the potential of the intervention to influence both individual behavior and community-level dynamics.

### 3.6 Strengths

The “Women in Action” protocol offers several methodological strengths. First, it provides a structured, replicable, and evidence-based model that addresses key limitations identified in the prior literature, including the lack of intervention standardization, the limited integration of psychosocial variables, and the absence of gender-sensitive approaches in exercise interventions for older women. Second, the combination of longitudinal assessment (T0-T3), validated psychometric and functional instruments, objective measures of physical function and body composition, and a structured qualitative component enables a comprehensive, mixed-methods evaluation of intervention effects. Third, the explicit prioritization of feasibility outcomes alongside a single, well-justified primary effectiveness outcome reduces the risk of multiplicity and dispersed interpretation, while still generating estimates of preliminary effect sizes to inform a future, adequately powered effectiveness trial. Fourth, the protocol's attention to fidelity monitoring, adverse-event surveillance, and standardized assessment procedures across all time points strengthens both the internal validity and the practical applicability of the expected findings. Finally, as a scalable methodological framework, "Women in Action" may contribute to the promotion of active ageing, the reduction of gender inequalities in health, and the generation of actionable evidence for the design of public policies, community-based programs, and professional training in exercise and health contexts.

## 4 Conclusions

This study protocol contributes to an emerging line of research focused on the integration of resistance training and physical conditioning, psychoeducational strategies, and nutrition-focused behavioral interventions in older women. Through a structured methodological design, it proposes a comprehensive framework for evaluating the feasibility, applicability, and potential transferability of multicomponent interventions tailored to this population.

In contrast to traditional approaches that focus primarily on physiological outcomes, this protocol explicitly incorporates sociocultural and psychological dimensions, such as the internalization of gender stereotypes, personal agency, and physical self-concept, which play a critical role in shaping physical activity participation and the adoption of healthy lifestyles in later life. This perspective supports the development of a more integrative model for studying active ageing in women, grounded in a biopsychosocial and gender-sensitive framework.

Furthermore, the longitudinal structure of the design (T0-T3), combined with the integration of quantitative and qualitative methods, enhances the capacity of the protocol to capture not only changes in objective health indicators but also transformations in subjective and relational processes. This methodological integration is particularly relevant in complex interventions, where outcomes cannot be fully explained through functional indicators alone.

Finally, “Women in Action” provides a methodological framework with high potential for replicability and scalability, which can be adapted across community, clinical, and educational settings. Its value lies in offering a reference model to guide future evaluative research, inform public policy development, and support evidence-based professional practice aimed at promoting health, autonomy, and social participation in women across the lifespan.

## 5 Practical applications

This protocol provides a structured and implementable methodological framework for the applied use of the scientific method. It is specifically designed to facilitate interdisciplinary and transdisciplinary implementation, integrating exercise science, nutrition, and psychosocial approaches within a coherent intervention model.

Beyond its research purpose, the protocol offers a viable and replicable model with direct applicability to the target population and the broader older adult community. Its design enables the systematic translation of scientific evidence into practice, supporting interventions that address not only physical function but also behavioral and sociocultural determinants of health.

By combining standardized procedures, validated measures, and a longitudinal evaluation framework, the protocol allows for consistent implementation and scalability across community, clinical, and educational contexts. This approach enhances its potential to generate meaningful impact, promoting functional health, empowerment, and active participation among older women.

Overall, "Women in Action" constitutes a transferable methodological model capable of bridging the gap between research and practice, contributing to the development of evidence-based interventions aimed at improving health outcomes and reducing gender-related disparities in ageing populations.

## 6 Conflict of Interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

## 7 Author Contributions

All authors contributed to the conception and methodological design of the study and approved the final version of the manuscript for submission. Individual contributions were as follows: Introduction (N.B-P., I.B-A.), Methodology (N.B.-P., A.B.-S), Desired outcomes and discussion (N.B-P, I. B-A., A.B.-S); Conclusions (N.B-P, I. B-A., A.B.-S).

## 8 Funding

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