Statistical Analysis Plan

Study	Effects of precision nutrition combined with structured resistance training on muscle mass and function in older adults at risk of sarcopenia: a randomized controlled trial
SAP version/date	Version 1.0 - 31 January 2026
Analysis software	R (R Foundation for Statistical Computing)
Randomized sample	147 participants; 74 PRIME and 73 control
Primary population	Intention-to-treat
Primary comparison	PRIME nutrition plus structured resistance training versus structured resistance training plus standard nutrition guidance
Follow-up	Baseline to week 12

1. Purpose and general principles

This Statistical Analysis Plan specifies analysis of the completed two-arm randomized trial. All effect estimates will be accompanied by 95% confidence intervals where appropriate. Primary hypothesis testing is two-sided. The intention-to-treat population includes all randomized participants according to assigned group.

2. Analysis populations

1. Intention-to-treat (ITT): all randomized participants, analyzed according to randomized assignment.
2. Per-protocol sensitivity population: participants who completed the intervention without a major protocol deviation and had the outcome information required for the relevant sensitivity model.
3. Safety population: all randomized participants who commenced at least one intervention session or nutrition contact.

3. Baseline description

Baseline variables include age, sex, body mass index, protein intake, physical activity (IPAQ-SF), skeletal muscle mass index, handgrip strength, gait speed, five-times sit-to-stand, Timed Up-and-Go and SPPB. Continuous variables are summarized as mean and standard deviation or median and interquartile range as appropriate; categorical variables are summarized as frequency and percentage. Baseline significance testing is descriptive and is not used to determine covariate inclusion.

4. Co-primary outcomes

Outcome name	Metric or method of measurement	Timepoint(s)
Skeletal muscle mass index (SMMI)	Skeletal muscle mass (kg) estimated from multi-frequency bioelectrical impedance analysis (InBody 770) and indexed to height squared (kg/m²). Two consecutive fasting morning scans are averaged; skeletal muscle mass is derived using the prespecified Janssen equation.	Baseline (week 0) and post-intervention (week 12).

Outcome name	Metric or method of measurement	Timepoint(s)
Handgrip strength	Maximum handgrip strength (kg) measured using a calibrated Jamar Smart Digital Hand Dynamometer. Three trials are performed per hand with 60-second rest intervals; the maximum recorded value is used.	Baseline (week 0) and post-intervention (week 12).

Each co-primary outcome is modeled using a linear mixed-effects model containing fixed effects for group, time and group-by-time, a participant-level random intercept, and adjustment for age, sex and baseline protein intake. The group-by-time interaction is the primary treatment-effect parameter. The primary hypothesis is considered supported only when both co-primary outcomes show a statistically significant group-by-time effect favoring PRIME at two-sided alpha=0.05. Because success requires both co-primary tests to be positive, no additional alpha splitting is applied to the co-primary pair.

5. Secondary outcomes

Outcome name	Metric or method of measurement	Timepoint(s)
Gait speed	Usual-pace 4-m gait speed (m/s), measured on a marked walkway; two trials are performed and the faster trial is used.	Baseline (week 0) and week 12.
Five-times sit-to-stand performance	Time (seconds) to complete five chair rises from a standardized 43-cm chair with arms crossed, after one familiarization trial.	Baseline (week 0) and week 12.
Timed Up-and-Go performance	Time (seconds) to stand from a chair, walk 3 m, turn, return and sit; two trials are performed and the faster trial is used.	Baseline (week 0) and week 12.
Short Physical Performance Battery (SPPB)	Total SPPB score (0-12 points) calculated from balance, gait-speed and chair-stand components using the standard scoring rubric.	Baseline (week 0) and week 12.
Protein intake	Mean daily protein intake (g/kg/day) calculated from 3-day food records (two weekdays and one weekend day) using nutrient-composition data.	Baseline and every 2 weeks during the 12-week intervention (weeks 2, 4, 6, 8, 10 and 12).
Protein target attainment	Ratio of achieved protein intake to the prespecified protein benchmark/prescription; values are derived from the 3-day food records.	Baseline and every 2 weeks during the intervention, with the principal post-intervention comparison at week 12.
Meal protein distribution	Proportion of main meals meeting the prespecified per-meal protein threshold (meal distribution score, 0-1).	Baseline and every 2 weeks during the intervention, with the principal post-intervention comparison at week 12.
Training session completion	Proportion of scheduled resistance-training sessions attended, calculated from supervised session logs.	Recorded at every session across 36 planned sessions over 12 weeks and summarized at week 12.
Training progression fidelity	Achieved weekly resistance-training volume load divided by prescribed weekly volume load, calculated from	Calculated weekly throughout the 12-week intervention and summarized at week 12.

Outcome name	Metric or method of measurement	Timepoint(s)
	training logs.	
Intervention-related adverse events	Musculoskeletal symptoms, dizziness, falls, exercise-related symptoms, gastrointestinal intolerance and other adverse events recorded by exercise professionals, dietitians and study staff, including action taken and relationship to the intervention.	Monitored continuously from randomization to completion of the 12-week intervention.

Gait speed, five-times sit-to-stand, Timed Up-and-Go and SPPB are analyzed using linear mixed-effects models corresponding to the co-primary models. Protein intake, target attainment and meal-distribution score are summarized by group and time and may be modeled using repeated-measures mixed models. Session completion and progression fidelity are summarized by group across the 12-week period. Adverse events are summarized by group using counts, proportions and event descriptions. Secondary analyses are supportive; nominal two-sided p values and 95% confidence intervals are reported without a formal family-wise multiplicity adjustment.

6. Moderator and adherence analyses

Prespecified moderator analyses add group-by-time-by-moderator interaction terms for sex and baseline protein-intake category (<1.0 versus >=1.0 g/kg/day). Associations between achieved protein intake, protein target attainment, meal-distribution score, session completion, progression fidelity and change in the primary outcomes are assessed in adjusted exploratory models. These analyses are interpreted as explanatory rather than confirmatory.

7. Missing data

Mixed-effects models use all available repeated outcome observations under the missing-at-random assumption. The amount and pattern of missing outcome data are summarized by group. The ITT analysis is primary. Per-protocol sensitivity analyses assess robustness among participants without major protocol deviations. No single imputation of primary outcomes is planned.

8. Model diagnostics

Residual distributions, homoscedasticity, influential observations and model convergence are evaluated before inference. If marked deviations are identified, appropriate transformations or robust/sensitivity analyses may be used and will be reported transparently. For interaction models, estimates and confidence intervals are reported rather than relying only on p values.

9. Reporting

Participant flow, baseline characteristics, intervention exposure, co-primary outcomes, secondary outcomes, adverse events, moderator analyses and sensitivity analyses are reported consistently with the randomized parallel design and CONSORT principles. Continuous outcomes are reported in their original clinical units with adjusted group-by-time estimates, 95% confidence intervals and two-sided p values.