ISRCTN37127474 https://doi.org/10.1186/ISRCTN37127474

Precision nutrition and resistance training in sarcopenia

Submission date
28/09/2026

Recruitment status
No longer recruiting

Registration date
28/09/2026

Overall study status
Completed

Last Edited
28/09/2026

Condition category
Musculoskeletal Diseases

[_] Prospectively registered
[X] Protocol
[X] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
As people age, they can lose muscle strength and muscle mass. When these changes become substantial, they can contribute to sarcopenia, which may make everyday activities harder and increase the risk of falls and disability. Resistance exercise is one of the main ways to maintain or improve muscle function. Protein intake is also important because older muscles may respond less strongly to ordinary amounts of dietary protein.
This study examined whether a personalized nutrition programme called Protein and Resistance Integrated for Muscle Enhancement (PRIME), when added to a structured resistance-training programme, improves muscle mass and strength more than the same resistance-training programme combined with standard, non-personalized nutrition guidance. The main outcomes were skeletal muscle mass index and handgrip strength after 12 weeks. The study also examined walking speed, chair-rise performance, mobility, overall physical performance, protein intake and adherence to the training programme.

Who can participate?
Community-dwelling adults aged 65 years or older could participate if they were at risk of or had probable sarcopenia based on low muscle strength, were able to walk independently with or without their usual aid, and were willing to complete dietary records and supervised resistance training. People with unstable conditions that made resistance exercise unsafe, severe cognitive impairment, significant kidney impairment, or recent regular resistance-training participation were excluded.

What does the study involve?
After screening and written informed consent, 147 participants were assigned by chance to one of two groups. Both groups completed the same supervised resistance-training programme for 12 weeks, with three sessions each week. Sessions lasted about 60 minutes and included progressive exercises for the major muscle groups. The exercise programme became gradually more challenging as participants improved.
The PRIME group also received individualized protein targets based on body mass, advice on spreading protein across meals and on eating protein after training, and regular dietitian reviews. The dietitian used three-day food records to check progress and increased support when targets were not being met. The control group received the same exercise programme and

the same schedule of nutrition contacts, but nutrition advice was general rather than individually prescribed.
Muscle mass and handgrip strength were measured before the programme and after 12 weeks. Walking speed, chair-rise performance, Timed Up-and-Go and the Short Physical Performance Battery were also measured. Participants completed food records every 2 weeks, and attendance and training progression were recorded at each exercise session.

What are the possible benefits and risks of participating?
Participants may improve muscle strength, muscle mass, mobility, confidence with resistance exercise or dietary habits, but individual benefit cannot be guaranteed. The study may also help improve future programmes for older adults at risk of sarcopenia.
Resistance exercise can cause temporary muscle soreness, fatigue or joint discomfort and carries a small risk of strains, falls, dizziness or other exercise-related symptoms. Higher protein intake may cause gastrointestinal discomfort in some people. Kidney function was screened before enrolment, and participants with significant renal impairment were excluded. Exercise sessions were supervised, loads were progressed gradually, and symptoms or adverse events were recorded and managed according to study safety procedures.

Where is the study run from?
School of Physical Education, University of Sanya, No. 191 Xueyuan Road, Jiyang District, Sanya, Hainan 572022, China. Institutional telephone: +86 898 88386000. School email: tiyu@sanyau.edu.cn.

When did the study run?
Participant enrolment began on 1 February 2026 and final enrolment occurred on 31 May 2026. Each participant completed a 12-week intervention, and the study was completed on 31 August 2026.

Who is funding the study?
Funding: None.

Who is the main contact?
Yan Shi, Associate Professor, School of Physical Education, University of Sanya, No. 191 Xueyuan Road, Jiyang District, Sanya, Hainan 572022, China. Email: stellas007@126.com. Telephone: +86 898 88386000.

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Prof Yan Shi

Contact details
School of Physical Education, University of Sanya, No. 191 Xueyuan Road, Jiyang District
Sanya
China
572022
+86 (0)898 88386000
stellas007@126.com

Additional identifiers

Study information

Scientific Title
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

Acronym
PRIME

Study objectives
To determine whether adding rule-based precision nutrition (PRIME) to an identical structured resistance-training programme produces greater 12-week improvements in skeletal muscle mass index and handgrip strength than structured resistance training with standard non-personalized nutrition guidance in community-dwelling adults aged 65 years or older at risk of or with probable sarcopenia.

Secondary objectives are to compare physical performance outcomes and to assess nutrition and training adherence metrics and prespecified response moderators.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 15/01/2026, Ethics Committee of University of Sanya (University Research Office, University of Sanya, No. 191 Xueyuan Road, Jiyang District, Sanya, 572022, China; +86 (0)898 88386011; research@sanyau.edu.cn), ref: IRB-2026-001

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Active

Assignment
Parallel

Purpose
Prevention

Study type(s)

Health condition(s) or problem(s) studied
Risk of/probable sarcopenia in community-dwelling older adults

Interventions
Participants were randomized in a 1:1 ratio using stratified block randomisation. Stratification was based on:
1. Sex
2. Baseline protein intake category: <1.0 g/kg/day versus ≥1.0 g/kg/day

Within each stratum, participants were allocated to either structured resistance training plus PRIME precision nutrition or structured resistance training plus standard non-personalized nutrition guidance using fixed block sizes. Allocation was concealed until group assignment. Outcome assessors remained blinded to treatment allocation.

Intervention arm: PRIME nutrition plus structured resistance training
Participants complete supervised resistance training for 12 weeks, three sessions per week, approximately 60 minutes per session. Training is identical in both groups and progresses from approximately 50%-60% of estimated one-repetition maximum in weeks 1-2 to 60%-70% in weeks 3-8 and 70%-80% in weeks 9-12, using major upper- and lower-body exercises. In the PRIME arm, a dietitian prescribes individualized protein intake, generally targeting 1.2 g/kg/day with escalation up to 1.5 g/kg/day when appropriate, a per-meal target of at least 0.4 g/kg across three main meals, and approximately 0.3 g/kg within 2 hours after training. Three-day food records are reviewed every 2 weeks. If target attainment remains below 90% for two consecutive review windows, counselling is intensified; persistent under-attainment triggers a standardized food-first protein top-up equivalent to approximately 20 g/day.

Control arm: structured resistance training plus standard nutrition guidance
Participants complete the identical supervised resistance-training programme and receive nutrition contacts on the same schedule, but guidance is standardized and non-personalized. It covers healthy eating, hydration and general protein education without individualized g/kg/day targets, meal-distribution scoring or escalation rules. Three-day food records are collected on the same schedule for measurement only.

Intervention Type
Behavioural

Primary outcome(s)
1. Skeletal muscle mass index (SMMI) measured using 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; measured at baseline (week 0) and post-intervention (week 12)

2. 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; measured at baseline (week 0) and post-intervention (week 12)

Key secondary outcome(s)
1. Gait speed measured using usual-pace 4-m gait speed (m/s), measured on a marked walkway; two trials are performed and the faster trial is used; measured at baseline (week 0) and week 12

2. Five-times sit-to-stand performance measured using the time (seconds) to complete five chair rises from a standardized 43-cm chair with arms crossed after one familiarization trial, at baseline (week 0) and week 12

3. Timed Up-and-Go performance measured using the time (seconds) to stand from a chair, walk 3 m, turn, return and sit; two trials are performed and the faster trial is used; measured at baseline (week 0) and week 12

4. Total Short Physical Performance Battery (SPPB) score (0-12 points) measured using the balance, gait-speed and chair-stand components using the standard scoring rubric at baseline (week 0) and week 12

5. Protein intake measured using the mean daily protein intake (g/kg/day) calculated from 3-day food records (two weekdays and one weekend day) using nutrient-composition data at baseline and every 2 weeks during the 12-week intervention (weeks 2, 4, 6, 8, 10 and 12)

6. Protein target attainment measured using the ratio of achieved protein intake to the prespecified protein benchmark/prescription; values are derived from the 3-day food records at baseline and every 2 weeks during the intervention, with the principal post-intervention comparison at week 12

7. Meal protein distribution measured using the proportion of main meals meeting the prespecified per-meal protein threshold (meal distribution score, 0-1) at baseline and every 2 weeks during the intervention, with the principal post-intervention comparison at week 12

8. Training session completion measured using the 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

9. Training progression fidelity measured using achieved weekly resistance-training volume load divided by prescribed weekly volume load, calculated from training logs weekly throughout the 12-week intervention and summarized at week 12

10. Intervention-related adverse events measured using 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, at monitored continuously from randomization to completion of the 12-week intervention

Completion date
31/08/2026

Eligibility

Key inclusion criteria
1. Aged 65 years or older
2. Community dwelling and able to ambulate independently with or without a usual walking aid
3. At risk of or with probable sarcopenia, defined by low muscle strength: handgrip strength below 27 kg in men or below 16 kg in women and/or five-times sit-to-stand time greater than 15 seconds
4. Willing and able to complete dietary records and attend supervised resistance-training

sessions
5. Risk enrichment by low habitual physical activity (<150 min/week of moderate-to-vigorous activity) and/or habitual protein intake <1.0 g/kg/day

Healthy volunteers allowed
No

Age group
Senior

Lower age limit
65 Years

Upper age limit
100 Years

Sex
All

Total final enrolment
147

Key exclusion criteria
1. Structured resistance training more than once weekly during the previous 12 weeks
2. Unstable cardiometabolic or musculoskeletal condition that contraindicates resistance exercise
3. Severe cognitive impairment that precludes protocol adherence (Mini-Cog score <3)
4. Moderate-to-severe renal impairment (eGFR <45 ml/min/1.73 m²)

Date of first enrolment
01/02/2026

Date of final enrolment
31/05/2026

Locations

Countries of recruitment
China

Study participating centre
School of Physical Education, University of Sanya
No. 191 Xueyuan Road, Jiyang District, Sanya
Hainan
China
572022

Sponsor information

Organisation
Sanya University

ROR
https://ror.org/04fa2qd52

Funder(s)

Funder type

Funder Name
University of Sanya

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other files			28/09/2026	No	No
Participant information sheet			28/09/2026	No	Yes
Protocol file			28/09/2026	No	No
Statistical Analysis Plan			28/09/2026	No	No