

Resistance and aerobic exercise with protein in older adults with obesity during energy restriction

Submission date 14/08/2025	Recruitment status Recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 15/08/2025	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 15/08/2025	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Individual participant data
		<input checked="" type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Without appropriate intervention, older adults with obesity pursuing weight loss are likely to display reductions in muscle mass, accelerating the decline in muscle function and physical performance, and increasing the risk of illness. The current study aims to determine the effect of a higher protein intake on lean mass and myofibrillar protein synthesis during a 4-week period of energy restriction and combined resistance and aerobic exercise training in older adults with obesity. The inclusion of a follow-up visit will also provide more comprehensive data on the lasting effects of the exercise and protein interventions for muscle health.

Who can participate?

Males and females with a BMI of 28 kg/m² or over or waist circumference above specified thresholds and with a stable weight in the 6 months before enrolment

What does the study involve?

Participants will attend six testing visits and 12 supervised exercise sessions at the University of Birmingham campus over a 35-day period. The study includes a 7-day baseline phase followed by a 28-day intervention, during which participants will complete a combined resistance and aerobic exercise training programme alongside specific dietary interventions. Throughout the study, participants will undergo measures of body composition, muscle strength, physical function, and metabolic health, with assessments repeated at multiple time points. Participants will also be invited to a follow-up visit approximately three months after completing the exercise and diet intervention.

What are the possible benefits and risks of participating?

Possible benefits include an individualised, supervised exercise programme and a tailored dietary plan designed to support weight loss and/or improve health. The study will provide food for 21 days of the intervention, with recipes and food lists provided for the remaining days. Participants will also receive detailed feedback on their health, including body composition, metabolic health markers, and muscle strength. Possible risks include low-dose radiation exposure during DXA scans, minor discomfort during and/or rare complications from muscle

biopsies, and rare side effects such as dizziness or nausea from consuming deuterium oxide. Blood sampling may cause brief discomfort, and exercise testing or training may feel strenuous, particularly for those unaccustomed to such activity. All procedures will be carried out by trained staff using safe practices to minimise risks.

Where is the study run from?

The study will be run from the School of Sport, Exercise and Rehabilitation Sciences and the Centre for Movement and Wellbeing at the University of Birmingham (UK)

When is the study starting and how long is it expecting to run for?

December 2023 to September 2026

Who is funding the study?

This study is funded by the Biotechnology and Biological Sciences Research Council (BBSRC) and the University of Birmingham funded Midlands Integrative Biosciences Training Partnership (MIBTP) BB/T00746X/1. The follow-up component of the study is funded by the British Society for Research on Ageing (BSRA).

Who is the main contact?

Prof. Leigh Breen, l.breen@leicester.ac.uk

Study website

https://bit.ly/UoB_REPOWER

Contact information

Type(s)

Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

338877

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

RG_23-168, BB/T00746X/1

Study information

Scientific Title

The effect of dietary protein intake on body composition and muscle protein turnover during a 4-week period of energy restriction and exercise in older adults with obesity

Acronym

REPOWER

Study objectives

The main questions this study aims to address are:

1. Does a higher dietary protein intake (1.6 g protein/kg body mass/day) improve lean mass retention compared to a normal protein intake (0.8 g protein/kg body mass/day) when consumed in combination with exercise and energy restriction?
2. How do these dietary protein levels affect myofibrillar protein synthesis in older adults with obesity?

Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 05/06/2024, Solihull Research Ethics Committee (2 Redman Place, Stratford, E20 1JQ, United Kingdom; +44 (0)2071048124; solihull.rec@hra.nhs.uk), ref: 24/WM/0095

Study design

Single-centre interventional single-blinded randomized controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

University/medical school/dental school

Study type(s)

Treatment

Participant information sheet

See study outputs table

Health condition(s) or problem(s) studied

Overweight or obesity

Interventions

Participants will be block randomised to one of three groups, stratified by sex. Randomisation will be performed using <https://www.randomizer.org> by an independent researcher not involved in recruitment, data collection or data analysis. Group allocation will be concealed from the research team until the start of the 28-day intervention.

Participants will be randomised into one of three groups:

1. A control group consuming 0.8 g protein/kg body mass/day under energy balance conditions
2. An intervention group consuming 0.8 g protein/kg/day under energy-restricted conditions
3. An intervention group consuming 1.6 g protein/kg/day under energy-restricted conditions

The 35-day intervention includes a 7-day energy balance lead-in phase and a 28-day intervention phase. The intervention is followed by a 3-month follow-up component. During the intervention, all participants will undertake supervised exercise (resistance exercise and high-intensity interval training) three times per week. The diet component will involve periods of food provision and food prescription to participants. Participants will be blinded to their protein intake through twice-daily consumption of a supplemental study drink, used to achieve the intended level of protein intake. Biological samples (saliva, blood, urine and muscle) will be collected for analysis, and deuterium oxide will be administered for muscle protein synthesis measurement. Assessments at baseline, post-intervention, and 3-month follow-up will include body composition (dual energy X-ray absorptiometry [DXA], bioelectrical impedance analysis [BIA]), muscle strength and functional performance tests, resting metabolic rate, plasma biomarkers, intervention adherence parameters, anthropometrics, and physical activity monitoring.

Intervention Type

Other

Primary outcome measure

Total and regional lean mass measured using DXA at PRE (Day 0), POST (Day 28) and 3-month follow-up (Day 112)

Secondary outcome measures

1. Total and regional fat mass measured using DXA at PRE (Day 0), POST (Day 28) and 3-month follow-up (Day 112)
2. Body mass and height measured at PRE (Day 0), POST (Day 28) and 3-month follow-up (Day 112)
3. Integrated myofibrillar protein synthesis measured using IRMS at PRE (Day 0) and POST (Day 28)
4. Intramuscular protein and gene expression, and lipid content at PRE (Day 0) and POST (Day 28)
5. Biomarkers of metabolic health measured using an automated biochemistry analyser and ELISA at Baseline (Day -7), PRE (Day 0), POST (Day 28) and 3-month follow-up (Day 112)
6. Nitrogen balance measured at Baseline (Day -7), PRE (Day 0), POST (Day 28) and 3-month follow-up (Day 112)
7. Resting energy expenditure measured using indirect calorimetry at PRE (Day 0) and POST (Day 28)
8. Muscle strength measured using resistance exercise machines at PRE (Day 0) and POST (Day 28)
9. Handgrip strength and physical performance measured using handheld dynamometer and SPPB equipment at PRE (Day 0), POST (Day 28) and 3-month follow-up (Day 112)
10. Physical activity monitoring measured using accelerometry at Baseline (Day -7), PRE (Day 0), POST (Day 28) and 3-month follow-up (Day 112)

Overall study start date

15/12/2023

Completion date

27/09/2026

Eligibility

Key inclusion criteria

1. Males and females between the ages of 65 and 80 years
2. BMI ≥ 28 kg/m², or waist circumference ≥ 102 cm for males, and ≥ 88 cm for females
3. Generally healthy, assessed via a General Health Questionnaire (GHQ)
4. Weight stable (body mass loss or gain < 2 kg in the 6-month period before the study)
5. Able and willing to attend six testing visits and 12 training visits to the University of Birmingham campus

Participant type(s)

Patient

Age group

Senior

Lower age limit

65 Years

Upper age limit

80 Years

Sex

Both

Target number of participants

60

Key exclusion criteria

1. Habitual smoker or vaper
2. Participated in a body mass loss and/or resistance exercise training programme in the 5 years before being enrolled in the study
3. Currently performing regular, structured exercise on >2 days per week
4. Uncontrolled hypertension
5. Cardiovascular or neuromuscular disease
6. Considered unwilling or unable to comply with the study protocol requirements by the research team
7. Regular use of non-steroidal anti-inflammatory drugs (including aspirin) or use of anticoagulants (e.g., warfarin, rivaroxaban) precludes muscle biopsy sampling

Date of first enrolment

16/09/2024

Date of final enrolment

14/06/2026

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

University of Birmingham

School of Sport, Exercise and Rehabilitation Sciences

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Sponsor information

Organisation

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Sponsor type

University/education

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ROR

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Funder(s)

Funder type

Government

Funder Name

Biotechnology and Biological Sciences Research Council

Alternative Name(s)

UKRI - Biotechnology And Biological Sciences Research Council, BBSRC UK, BBSRC

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Funder Name

British Society for Research on Ageing

Alternative Name(s)

BSRA

Funding Body Type

Government organisation

Funding Body Subtype

Associations and societies (private and public)

Location

United Kingdom

Funder Name

University of Birmingham

Results and Publications

Publication and dissemination plan

Planned publication in a peer-reviewed journal.

Intention to publish date

27/09/2027

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be available upon request from Prof. Leigh Breen (l.breen@leicester.ac.uk)

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 3.0	19/02/2025	15/08/2025	No	Yes