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

Submission date
14/08/2025

Recruitment status
Recruiting

Registration date
15/08/2025

Overall study status
Ongoing

Last Edited
15/08/2025

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] 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

Contact information

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Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
338877

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
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

Study type(s)
Treatment

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

Key secondary outcome(s))
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 accelerometery at Baseline (Day -7), PRE (Day 0), POST (Day 28) and 3-month follow-up (Day 112)

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

Healthy volunteers allowed
No

Age group
Senior

Lower age limit
65 years

Upper age limit
80 years

Sex
All

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
United Kingdom

England

Study participating centre
University of Birmingham
School of Sport, Exercise and Rehabilitation Sciences
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Sponsor information

Organisation
University of Birmingham

ROR
https://ror.org/03angcq70

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, Biotechnology and Biological Sciences Research Council (BBSRC), 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)
Club for Research on Ageing, 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

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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes

Study website	Study website	11/11/2025	11/11/2025	No	Yes