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Weight training in combination with protein supplementation in older overweight people

Submission date
26/01/2023

Recruitment status
No longer recruiting

Registration date
26/01/2023

Overall study status
Ongoing

Last Edited
04/12/2025

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
Nowadays people tend to live longer and longer which is a positive development. However, in the last couple of years of their prolonged live people tend to be confronted with age-related diseases (such as type 2 diabetes mellitus) and a poorer quality of life. Vital systems such as the cardiovascular and the muscular system degrade with age. This degrading of the cardiovascular and muscular systems with age often results in the loss of independence. In other words, muscles get smaller and weaker, and general fitness goes down. If this decrease in muscle and fitness is left untreated it can lead to the development of mobility limitations, increased risk of falls and, ultimately, frailty. Therefore, interventions targeting the loss of muscle with advancing age to promote mobility improvements should be a key focus.
Lifestyle-based interventions are among the most effective strategies in treating and managing type 2 diabetes mellitus. We also know that exercise is critical for enhancing mobility in older adults with chronic disease and should, therefore, form the cornerstones of therapy. While aerobic exercise (for example cycling) was thought to be the preferable approach in the treatment of type 2 diabetes mellitus, regular performance of lifting weights improves muscle mass, strength, and function and can have direct effects on the prevention of several chronic diseases. Arguably, lifting weights can lead to similar health benefits when compared with aerobic-based exercise training (cycling or running). In most cases, heavier weights (>70% 1 repetition maximum) are recommended. However, more and more evidence shows that with lighter weights (~30-50% 1 repetition maximum) people are still able to gain muscle. In older adults lifting heavy lighter weights is preferred to reduce the risk of injuries and to keep the exercise more enjoyable.
Dietary interventions are crucial in the treatment and management of type 2 diabetes mellitus. In order to grow muscle a certain amount of protein intake is required. The protein provides “building blocks” for the muscle which can eventually be built into new muscle. With sufficient protein intake and exercise the build-up of muscle can be elevated. However, not every protein sources have the same effect. Dairy protein sources (whey, which is derived from milk) indicates to be a good source of protein to stimulate the build-up of muscle. In contrast, collagen protein is seen as a lower-quality protein and is potentially not as good at stimulating the build-up of muscle as dairy protein. However, the effect of collagen is yet to be determined. We think that collagen is suboptimal for skeletal muscle adaptation. This study will investigate the effect of a 12-week, lower-load (lighter weight) training protocol in combination with protein

supplementation (whey or collagen) on muscular strength/mobility, the blood sugar response to an oral glucose tolerance test (OGTT), muscle protein synthesis rates (rate of the build-up of muscle), and whole body muscle mass in overweight/obese elderly men and women (i.e. 60-80 years, inclusive).

Who can participate?
Overweight/obese elderly men and women (i.e. aged 60-85 years, inclusive)

What does the study involve?
Participants will participate in a 12-week training protocol (three training sessions per week) in which they train the lower and upper body. In addition, participants are randomly divided into two groups. One group will ingest a collagen protein supplement twice daily, two times 25 g. The other group will ingest a whey protein supplement twice daily, two times 25 g.

What are the possible benefits and risks of participating?
The benefits are a potential increase in the general health of the participants and the prevention /delay of the development of sarcopenia and/or diabetes. In this specific case, health is stated as the amount of muscle mass, fat mass, the functionality of the muscle, blood sugar response, and cardiovascular fitness.
The risks involved in participating in this study are very limited. This study involves taking blood, which comes with the risk of damaging blood vessels and some infection risks. During the study, physical exercise will be performed which comes with a very small risk of injuries. The riskiest procedure would be the muscle biopsy. The biopsy technique is routinely used in research, and complications are rare if proper precautions are taken. The muscle biopsy procedure will only be carried out by trained and experienced personnel delegated to conduct the procedure. There is a risk of internal bleeding at the site of the biopsy, which can result in bruising and temporary skin discoloration. There is also a risk that participants will be lightheaded or faint as the procedure occurs. In healthy young subjects, 1 in 2,200 have experienced a local skin infection; 1 in 500 have experienced a small lump at the site of the biopsy (in all cases, this disappeared within ~2-3 weeks by rubbing the area); 1 in 1,500 have experienced a temporary loss of sensation in the skin at the site of incision (an area of numbness about the size of a quarter which lasted up to 3-4 months), and 1 in 30 have experienced bruising around the site of incision which lasted for ~4-5 days. To our knowledge, older subjects who have undergone the muscle biopsy procedure have reported no adverse reactions.

Where is the study run from?
McMaster University (Canada)

When is the study starting and how long is it expected to run for?
February 2022 to February 2026

Who is funding the study?
Friesland-Campina (Netherlands)

Who is the main contact?
1. Tom Janssen, jansst1@mcmaster.ca
2. Dr Stuart Phillips, phillis@mcmaster.ca

Contact information

Type(s)

Principal investigator

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Prof Stuart Phillips

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Type(s)
Scientific

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Mr Tom Janssen

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
15350

Study information

Scientific Title

Practical strength training combined with high-quality dairy protein consumption to promote metabolic health and physical function in older overweight/obese men and women: a randomized controlled trial

Study objectives
12 weeks of lower-load resistance exercise training (RET) combined with whey protein supplement consumption will lead to greater improvement in strength and physical function, glycemic control, muscle mass, and muscle protein synthesis (MPS) rate, versus the changes seen in those consuming lower-quality collagen protein.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 19/12/2022, Hamilton Integrated research ethics board (HiREB, 293 Wellington St. N., Suite 120 Hamilton, ON L8L 8E7, Canada; +1 (0)905 521 2100, Ext. 42013; eREBHelpdesk@HHSC.CA), ref: 15350

Study design
Double-blinded randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Sarcopenia

Interventions
Participants will participate in a 12-week training protocol (three training sessions per week) in which they train the lower and upper body. In addition, participants are randomly divided into two groups using a blocked randomisation list from Sealed Envelope Ltd. 2022 (https://www.sealedenvelope.com/simple-randomiser/v1/lists).

One group will ingest a collagen protein supplement twice daily, two times 25 g. The other group will ingest a whey protein supplement twice daily, two times 25 g.

Intervention Type
Supplement

Primary outcome(s)
Lean body mass measured using dual-energy X-ray absorptiometry (DEXA) at week 0 and week 12, pre- and post-training protocol

Key secondary outcome(s))
Current secondary outcome measures as of 04/04/2024:
1. Muscular isometric strength measured using biodex at week 0 and week 12, pre- and post-training protocol

2. Physical function measured using several physical function tests such as the chair-stand test at week 0 and week 12, pre- and post-training protocol
3. Glycemic control measured using an oral glucose tolerance test at week 0 and week 12, pre- and post-training protocol
4. Muscle protein synthesis rate measured using deuterated water at week 0 and week 12, pre- and post-training protocol

Previous secondary outcome measures:
1. Muscular isometric strength measured using biodex at week 0 and week 12, pre- and post-training protocol
2. Physical function measured using several physical function tests such as the chair-stand test at week 0 and week 12, pre- and post-training protocol
3. Aerobic capacity measured using VO_2peak test at week 0 and week 12, pre- and post-training protocol
4. Glycemic control measured using oral glucose tolerance test at week 0 and week 12, pre- and post-training protocol
5. Muscle protein synthesis rate measured using deuterated water at week 0 and week 12, pre- and post-training protocol

Completion date
28/02/2026

Eligibility

Key inclusion criteria
Current participant inclusion criteria as of 04/04/2024:
1. Male or female, between the ages of 60-85 years, inclusive
2. Willing and able to provide informed consent
3. Be in general good health meaning that the participant doesn't have any conditions that could pose a risk when performing the measurements (determined by a medical questionnaire and according to the results of several physical performance tests)
4. Non-smoking
5. Have a body mass index (BMI) between 25-40 kg/m² (inclusive)
6. Be able to carry out normal daily living activities and not engage in an exercise training program or diet
7. Not currently taking any protein or weight loss supplements or medications known to affect protein metabolism (i.e., glucocorticoids)

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Participant type(s)
Other

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
60 years

Upper age limit
85 years

Sex
All

Total final enrolment
0

Key exclusion criteria
Current participant exclusion criteria:
1. Use of tobacco or related products
2. Vegan or vegetarian diet
3. Any concurrent medical, orthopedic, or psychiatric condition that, in the opinion of the Investigator, would compromise his/her ability to comply with the study requirements
4. Use assistive walking devices (e.g., cane or walker)
5. History of cancer within the last 5 years, except basal cell carcinoma, non-squamous skin carcinoma, prostate cancer or carcinoma in situ, with no significant progression over the past 2 years
6. Significant orthopedic, cardiovascular, pulmonary, renal, liver, infectious disease, immune disorder, metabolic/endocrine disorders, or other diseases that would preclude oral protein supplement ingestion and/or assessment of safety and study objectives (except for drug-treated stage 1 or 2 hypertension)
7. Any cachexia-related condition (e.g., relating to cancer, tuberculosis, or human immunodeficiency virus infection and acquired immune deficiency syndrome) or any genetic muscle diseases or disorders
8. Current illnesses which could interfere with the study (e.g. prolonged severe diarrhea, regurgitation, difficulty swallowing)
9. Hypersensitivity or known allergy to any of the components in the test formulations
10. Excessive alcohol consumption (>21 units/week for men and >14 units/week for women)
11. History of bleeding diathesis, platelet or coagulation disorders, or antiplatelet /anticoagulation therapy (up to 81mg of baby aspirin per day taken as a prophylactic is permitted)
12. Personal or family history of a clotting disorder or deep vein thrombosis
13. Routine/daily usage of non-steroidal anti-inflammatory drugs (NSAIDs, prescription use or daily use of over-the-counter medication), use of corticosteroids, testosterone replacement therapy (ingestion, injection, or transdermal), any anabolic steroid, creatine, whey protein supplements, casein or branched-chain amino acids (BCAAs) within 45 days prior to screening
14. Type 2 diabetics

Previous participant exclusion criteria:
1. Use of tobacco or related products
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4. Use assistive walking devices (e.g., cane or walker)
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Date of first enrolment
10/02/2023

Date of final enrolment
01/12/2025

Locations

Countries of recruitment
Canada

Study participating centre
McMaster University
1280 Main Street West
Ivor Wynne Centre
hamilton
Canada
L8S4K1

Sponsor information

Organisation
McMaster University

ROR
https://ror.org/02fa3aq29

Funder(s)

Funder type
Industry

Funder Name
FrieslandCampina

Alternative Name(s)
FrieslandCampina Nederland, FrieslandCampina N.V.

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
Netherlands

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analyzed during the current study are/will be available upon request from Stuart Phillips, phillis@mcmaster.ca. Data will be shared with researchers who have relevant questions or researchers that want to perform a systematic review or meta-analysis (up to Dr. Phillips' discretion). All data provided will be blinded and without any identifiers like name or contact details, as is stated in the signed consent form.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Statistical Analysis Plan			04/12/2025	No	No