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Protein intake and health outcomes

Submission date 22/09/2021	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 01/10/2021	**Overall study status** Completed	
Last Edited 18/11/2024	**Condition category** Other	

Plain English summary of protocol

Background and study aims
Emerging evidence suggests that increased protein intake is associated with several health outcomes. Higher total protein intake is proposed to help preserve lean body mass and improve body composition during weight loss in adults. Other literature suggests high protein diets may help improving blood lipids, markers of glycaemic control, and blood pressure. Further, some studies observed a better sleep quality among persons with high compared to low protein intake. However, thus far evidence is either limited to a few studies examining this research question or inconclusive about the role of the type and timing of protein intake.
The aim of the project is to investigate the ability of increased protein intake to alter health outcomes including muscle function, sleep quality, metabolic health, and quality of life.

Who can participate?
Male and female healthy adults aged 50 years or older.

What does the study involve?
Participants will be randomly allocated to one of the following:
1) an intervention group receiving a high protein ready-to-mix drink (~20g of milk protein isolate),
2) an intervention group receiving a high protein ready-to-mix drink (~20g of plant protein mix),
3) a control group receiving a ready-to-mix drink based on carbohydrates (maltodextrin).
Samples and measurements will be taken before the intervention and at 12 weeks.

What are the possible benefits and risks of participating?
Higher total protein intake is proposed to help preserve lean body mass and improve body composition in older adults. Other literature suggests high protein diets may help improve blood lipids, markers of glycaemic control, blood pressure, as well as sleep quality. In older adults, general health, including the mentioned markers, is more and more limited. Protein intake is often insufficient. The high-protein drink will offer an easy way to increase the amount of protein in this age group.

Where is the study run from?
University College Dublin, Conway Institute (Ireland)

When is the study starting and how long is it expected to run for?
September 2021 to January 2023

Who is funding the study?
We received funding from multiple sources including the H2020 European Research Council and the Marie Skłodowska-Curie Career Development Fellowship in the National Technology Centre Programme funded through a co-fund with the European Union's Horizon 2020 and Enterprise Ireland. All test products were provided by Kerry Group, Ireland.

Who is the main contact?
Dr. Janine Wirth, janine.wirth@ucd.ie

Contact information

Type(s)
Scientific

Contact name
Dr Janine Wirth

ORCID ID
https://orcid.org/0000-0001-7075-9686

Contact details
UCD Institute of Food and Health
Belfield
Dublin
Ireland
4
+353 (0)1 716 6811
janine.wirth@ucd.ie

Additional identifiers

Study information

Scientific Title
Impact of protein intake on health outcomes

Study objectives
The aim of the project is to investigate the ability of increased protein intake to alter health outcomes including muscle function, metabolic health, sleep quality, and quality of life (QoL). We hypothesise a positive effect of increased protein intake on these health outcome that might depend on the type of protein consumed.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Approved 23/09/2021, UCD Human Research Ethics Committee (Roebuck Castle, University College Dublin
Belfield, Dublin 4, Ireland; +353 1 716 8767; hrec@ucd.ie), ref: LS-21-67-Wirth-Brennan

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Study type(s)
Other

Health condition(s) or problem(s) studied
Improve muscle function (and body composition, metabolic health, sleep quality, and overall quality of life) in older adults

Interventions
This is a double-blinded randomised controlled intervention study with older adults designed to measure the impact of increased protein intake and markers of general health, including muscle function, metabolic health, sleep quality, and QoL.

Participants will be randomly allocated (using an online tool) to one of the following:
1) an intervention group receiving a high dairy-based protein ready-to-mix (RTM) drink (~20g of milk protein isolate),
2) an intervention group receiving a high plant-based protein RTM drink (~20g of pea/rice protein mix),
3) a control group receiving a RTM drink based on carbohydrates (maltodextrin).

Prior to the intervention, the participants will have the following measured: dietary intake, sleep quality (Pittsburgh sleep quality index = PSQI), and quality of life (SF-36 questionnaire). All will be posted or emailed and filled out by participants.
In addition, blood pressure will be measured, a blood sample will be taken, handgrip and leg press strength tests will be performed, as well as a timed up and go test. Furthermore, anthropometry (weight, height, waist circumference, hip circumference, and body composition using BODPOD) will be measured.

At week 12, participants will return for the final visit when all the measurements will be repeated in the same way as before.

Intervention Type
Supplement

Primary outcome(s)
Muscle strength (hand grip, leg press) at baseline and 12 weeks

Key secondary outcome(s))
Measured at baseline and 12 weeks:
1. Functional mobility (timed up and go test)
2. Body composition (fat mass, fat-free mass) measured using BodPod.

3. Biomarkers: cholesterol, glucose, triglycerides
4. Sleep quality (Pittsburgh Sleep Quality Index)
5. Quality of life (SF-36 questionnaire)

Completion date
27/01/2023

Eligibility

Key inclusion criteria
Healthy male and female adults aged 50 years and older

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. A diagnosed chronic/metabolic disease which alters nutritional needs (e.g. thyroid disorders, diabetes, inflammatory bowel diseases).
2. Food allergy/intolerance against peas, milk products
3. Athletes/bodybuilders meeting all the following:
4. Training in sports to improve his/her performance
5. actively competing in sports competitions
6. formally registered in a local/national/regional sport
7. To have sport training or competition as his/her major activity or focus of personal interest; devoting several hours in all or most of the days for these activities, exceeding the time allocated to other types of professional or leisure activities.
8. Pregnant, lactating
9. Anyone unable to give consent or converse fluently in English

Date of first enrolment
01/10/2021

Date of final enrolment
31/10/2022

Locations

Countries of recruitment
Ireland

Study participating centre
University College Dublin
UCD Institute of Food and Health
Belfield
Dublin
Ireland
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Sponsor information

Organisation
University College Dublin

ROR
https://ror.org/05m7pjf47

Funder(s)

Funder type
Government

Funder Name
Horizon 2020

Alternative Name(s)
EU Framework Programme for Research and Innovation, Horizon 2020 - Research and Innovation Framework Programme, European Union Framework Programme for Research and Innovation

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to ethical restrictions.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/05/2024	18/11/2024	Yes	No