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Impact of dietary shifts on nutrition and health

Submission date 05/05/2023	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 05/05/2023	**Overall study status** Ongoing	
Last Edited 09/11/2026	**Condition category** Nutritional, Metabolic, Endocrine	

Plain English summary of protocol

Background and study aims
There are calls to reduce intake of animal proteins and increase consumption of plant proteins. Dietary choices are key determinants of environmental sustainability and human health. This study will group participants into dietary patterns based on their current dietary intake. Based on this, personalised nutrition advice will be given to achieve protein diversification. Assessment of diet and biomarkers (a unique signature that we can get from blood and urine samples) will help to determine if protein diversification was achieved. This study will try to identify a method to introduce different types of protein into the diets of the Irish population that will be achievable for them, while ensuring that people still meet their nutritional needs and maintain a balanced diet.

Who can participate?
Adults aged 18 – 65 years old, in good health, who have a BMI ≥18 and ≤35 kg/m², do not have a diagnosed medical condition (e.g. cancer or diabetes) and who do not follow a medically prescribed or energy-restricted diet

What does the study involve?
Participants are randomly allocated to the intervention group or the control group. The intervention group will be guided to diversify their protein intake using their current protein dietary pattern as a starting point. Reports with dietary goals and detailed advice on the incorporation of the goals into the participants' daily lives will be provided. The control group will receive general healthy eating advice based on national healthy eating guidelines.

The intervention and control group will differ in terms of the type of dietary advice provided to them during the study duration, where the intervention group will receive personalised dietary advice aiming to expand or diversify their current protein intake, and the control group will receive dietary advice based on national guidelines for healthy eating.
Blood and urine samples will be collected before and after the intervention.

What are the possible benefits and risks of participating?
By taking part in this research study, participants will have the opportunity to positively change their dietary habits.

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

When is the study starting and how long is it expected to run for?
June 2023 to May 2028

Who is funding the study?
The Department of Agriculture, Food and the Marine (Ireland)

Who is the main contact?
1. Aoife Courtney, metabomarkers@ucd.ie
2. Prof. Lorraine Brennan, lorraine.brennan@ucd.ie

Contact information

Type(s)
Principal investigator

Contact name
Prof Lorraine Brennan

ORCID ID
https://orcid.org/0000-0002-7711-7499

Contact details
Conway Institute
School of Agriculture and Food Science
University College Dublin
Belfield
Dublin
Ireland
-
+333 (0)1 716 6815
lorraine.brennan@ucd.ie

Type(s)
Scientific

Contact name
Ms Aoife Courtney

Contact details
Conway Institute
School of Agriculture and Food Science
University College Dublin
Dublin
Ireland
-
+353 (0)1 716 6806
aoife.courtney.1@ucdconnect.ie

Type(s)
Public

Contact name
Ms Aoife Courtney

Contact details
Conway Institute
School of Agriculture and Food Science
University College Dublin
Dublin
Ireland
-
+353 (0)1 716 6806
aoife.courtney.1@ucdconnect.ie

Additional identifiers

Study information

Scientific Title
Protein-i: the impact of diversification of protein intake on biomarkers of nutrition status and health in an adult population - a randomized controlled trial

Acronym
Protein-i

Study objectives
This study aims to diversity protein intake in the diet whilst ensuring nutritional adequacy. The primary outcome is dietary quality measured by the Healthy Eating Index (HEI). The hypothesis is that through diversifying protein intake in the intervention group, the HEI score will increase. Secondary outcomes include biomarkers of nutrient status, intake and health.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 06/03/2023, University College Dublin Human Subject (Sciences) Ethical Review, Office of Research Ethics (ORE) (Roebuck Castle, University College Dublin, Belfield, Dublin 4, Ireland; +353 (01) 716 8762; hrec@ucd.ie), ref: LS-23-14-Courtney-Br

Primary study design
Interventional

Study design
Single-centre 16-week interventional single-blinded randomized controlled trial

Study type(s)
Other

Health condition(s) or problem(s) studied
Dietary protein intake

Interventions
The research design is a 16-week, single-centre, single-blinded randomised controlled trial, where participants will be guided to diversify their protein intake using their current protein dietary pattern as a starting point. Participants (n = 220 in total) will be men and women aged 18 - 65 years old and recruited from the general public using established recruitment mechanisms. Participants will be randomised using block randomisation. Personalised dietary advice will be provided to the intervention group, with the aim of diversifying protein intake. Reports with dietary goals and detailed advice on the incorporation of the goals into the participants' daily lives will be provided. The control group will receive general healthy eating advice based on national healthy eating guidelines.

The intervention and control group will differ in terms of the type of dietary advice provided to them during the study duration, where the intervention group will receive personalised dietary advice aiming to expand or diversify their current protein intake, and the control group will receive dietary advice based on national guidelines for healthy eating.

Intervention Type
Behavioural

Primary outcome(s)
Dietary quality is measured using the Healthy Eating Index, which will be calculated from dietary intake data collected from the participants via two 24-hour dietary recalls completed at the study baseline (Week 0) and study completion (Week 16)

Key secondary outcome(s)
1. Biomarkers of dietary intake measured via blood and urine samples at study baseline (Week 0) and study completion (Week 16)
2. Biomarkers of health measured via blood and urine samples, anthropometric and strength measurements at study baseline (Week 0) and study completion (Week 16)
3. Biomarkers of nutrient adequacy measured via blood and urine samples at study baseline (Week 0) and study completion (Week 16)
4. Barriers to and facilitators of diversifying protein intake examined using an optional focus group/interview with participants in the intervention group after study completion (after week 16)

Completion date
01/05/2028

Eligibility

Key inclusion criteria
1. Men and women aged 18–65 years old
2. In good health
3. Body mass index (BMI) 18–35 kg/m²

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
65 Years

Sex
All

Total final enrolment
220

Key exclusion criteria
1. A diagnosed medical condition (such as cancer or diabetes)
2. An energy-restricted diet or a medically prescribed diet

Date of first enrolment
25/06/2023

Date of final enrolment
06/11/2024

Locations

Countries of recruitment
Ireland

Study participating centre
University College Dublin
Conway Institute
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
Department of Agriculture, Food and the Marine, Ireland

Alternative Name(s)
An Roinn Talmhaíochta, Bia agus Mara, An Roinn Talmhaiochta Bia agus Mara, Department of Agriculture, Food and the Marine, agriculture_ie, Department of Agriculture, Food and the Marine (Ireland), DAFM

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Ireland

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. Lorraine Brennan (lorraine.brennan@ucd.ie)

IPD sharing plan summary
Available on request