

Impact of dietary shifts on nutrition and health

Submission date 05/05/2023	Recruitment status Recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 05/05/2023	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 05/05/2023	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

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?

January 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

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Principal investigator

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Additional identifiers**Clinical Trials Information System (CTIS)**

Nil known

Protocol serial number

Nil known

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 diversify 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

Study design

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

Primary study design

Interventional

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

Adult

Lower age limit

18 years

Upper age limit

65 years

Sex

All

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

17/05/2023

Date of final enrolment

01/12/2027

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 Talmhaíochta 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