

# Impact of dietary shifts on nutrition and health

<b>Submission date</b> 05/05/2023	<b>Recruitment status</b> Recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 05/05/2023	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 05/05/2023	<b>Condition category</b> 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  $\geq 18$  and  $\leq 35$  kg/m<sup>2</sup>, 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](mailto:metabomarkers@ucd.ie)

2. Prof. Lorraine Brennan, [lorraine.brennan@ucd.ie](mailto:lorraine.brennan@ucd.ie)

## Contact information

### Type(s)

Principal Investigator

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## **Additional identifiers**

**EudraCT/CTIS number**

Nil known

**IRAS number****ClinicalTrials.gov number**

Nil known

**Secondary identifying numbers**

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

## **Secondary study design**

Randomised controlled trial

## **Study setting(s)**

Community

## **Study type(s)**

Other

## **Participant information sheet**

Not available in web format, please use contact details to request a participant information sheet

## **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 measure**

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)

## **Secondary outcome measures**

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)

## **Overall study start date**

01/01/2023

## **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/m<sup>2</sup>

## **Participant type(s)**

Healthy volunteer

## **Age group**

Adult

## **Lower age limit**

18 Years

## **Upper age limit**

65 Years

## **Sex**

Both

## **Target number of participants**

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**

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

### Sponsor details

Belfield

Dublin 4

Ireland

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+ 353 (0)1 716 7777

communications@ucd.ie

### Sponsor type

University/education

### Website

<https://www.ucd.ie/>

### 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

**Publication and dissemination plan**

Planned publication in a peer-reviewed journal

**Intention to publish date**

01/05/2029

**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](mailto:lorraine.brennan@ucd.ie))

**IPD sharing plan summary**

Available on request