

Impact of personalised nutrition advice on diet quality

Submission date 08/06/2020	Recruitment status No longer recruiting	☒ Prospectively registered ☐ Protocol
Registration date 10/06/2020	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 05/12/2023	Condition category Nutritional, Metabolic, Endocrine	☐ Individual participant data

Plain English summary of protocol

Background and study aims:

Personalised nutrition is commonly described as dietary advice tailored to an individual. Recent studies successfully demonstrated that personalised dietary advice is more effective in producing appropriate changes in dietary intake and health outcomes compared to general population level advice. However, the focus on individuals is still not easily achievable in a public health perspective and may have limited impact on populations.

To take into account the individual biological characteristics in personalised healthcare, metatypes have been suggested as a potential tool. Metatypes are groups of individuals defined based on their similarities in the metabolic profile. Metatypes have been successfully associated with diet-related diseases and differential responses to interventions, which support their use as a means to deliver personalised dietary advice at a group level.

The investigators previous work developed a framework to deliver personalised nutrition advice based on metatypes. They compared the advice delivered by the metatype approach to the advice delivered by a dietician and demonstrated that there was a good agreement. This study aims to examine the effectiveness of such an approach to induce behaviour changes and in this instance changes in dietary quality.

Who can participate?

Healthy adults aged between 18 and 65 years old.

What does the study involve?

Participants will be randomly allocated to receive either dietary advice or personalised dietary advice. Measurements include the following: weight, height, waist circumference, hip circumference, blood pressure, blood sample levels of fats and sugars, urine sample, and a 4-day food diary. Participants will follow this dietary guidance for 12 weeks and then measurements will be repeated to see if there have been any improvements.

What are the possible benefits and risks of participating?

Risk: A small percentage of individuals feel faint or faint after giving blood. We will ask all participants to rest for a few minutes following the blood collection. Trained phlebotomists or

health care individuals will take blood samples.

Benefits: There will be no direct benefit to the participants from taking part in the study. However, all participants will get to learn about their dietary intake.

Where is the study run from?

University College Dublin (Ireland)

When is the study starting?

From June 2020 to June 2021

Who is funding the study?

University College Dublin (Ireland)

Who is the main contact?

Professor Lorraine Brennan

lorraine.brennan@ucd.ie

Contact information

Type(s)

Public

Contact name

Prof Lorraine Brennan

ORCID ID

<https://orcid.org/0000-0002-7711-7499>

Contact details

University College Dublin

Belfield

Dublin

Ireland

Dublin 4

+35317166815

lorraine.brennan@ucd.ie

Additional identifiers

Study information

Scientific Title

Impact of personalised nutrition advice on diet quality compared to general population advice in healthy volunteers: a randomised controlled trial

Study objectives

Personalised dietary advice delivered using a biomarker-driven approach is more effective in changing diet quality than general dietary advice delivered at a population level.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 20/12/2019, UCD Human Research Ethics Committee (Roebuck Castle, University College Dublin, Belfield, Dublin 4, Ireland; +353 1 716 8767; hrec@ucd.ie), ref: LS-19-98-Brennan

Primary study design

Interventional

Study design

Single-blind randomised controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Improving quality of dietary intake

Interventions

Participants will be randomised (please give ratio of randomisation and method use to randomise) to one of two groups:

1. Intervention group receiving personalised dietary advice using a biomarker-driven approach
2. Control group receiving general dietary advice based on the Healthy Ireland food pyramid

Participants will be followed over a period of 12 weeks. Following a baseline assessment (anthropometry, blood pressure, blood and urine samples, diet intake), participants will receive a report indicating key foods and guidance to follow to improve dietary quality. This will be delivered via email. Measurements will be repeated following 12 weeks and change in diet quality assessed.

Intervention Type

Behavioural

Primary outcome(s)

Diet quality assessed by the Alternate Mediterranean Diet Score at baseline and 12 weeks

Key secondary outcome(s)

1. Change in blood biochemistry assessed from lipid parameters and glycaemic parameters (For ex: glucose, Cholesterol, HDL, Triacylglycerol) of blood samples taken at baseline and 12 weeks.
2. Change in metabolite levels assessed from blood and urine samples taken at baseline and 12 weeks using untargeted metabolomic analysis.

Completion date

28/06/2021

Eligibility

Key inclusion criteria

1. Aged between 18 and 65 years
2. BMI ≥ 18.5 Kg/m²

Participant type(s)

Healthy volunteer

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Total final enrolment

107

Key exclusion criteria

1. Pregnant or lactating
2. Diagnosed with metabolic disease which interferes with nutritional requirements

Date of first enrolment

15/06/2020

Date of final enrolment

01/08/2020

Locations**Countries of recruitment**

Ireland

Study participating centre

University College Dublin

Belfield

Dublin

Ireland

D4

Sponsor information**Organisation**

University College Dublin

ROR

<https://ror.org/05m7pjf47>

Funder(s)

Funder type

Other

Funder Name

Investigator initiated and funded

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 as consent from participants does not include this.

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	secondary analysis	15/11/2023	05/12/2023	Yes	No