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Impact of personalised nutrition advice on diet quality

Submission date
08/06/2020

Recruitment status
No longer recruiting

Registration date
10/06/2020

Overall study status
Completed

Last Edited
05/12/2023

Condition category
Nutritional, Metabolic, Endocrine

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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, metabotypes have been suggested as a potential tool. Metabotypes are groups of individuals defined based on their similarities in the metabolic profile. Metabotypes 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 metabotypes. They compared the advice delivered by the metabotype 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
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Contact information

Type(s)
Public

Contact name
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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
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

Study design
Single-blind randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Home

Study type(s)
Treatment

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

Secondary outcome measures
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.

Overall study start date
20/11/2019

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
98

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

Sponsor details
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Sponsor type
University/education

Website
http://www.ucd.ie/

ROR
https://ror.org/05m7pjf47

Funder(s)

Funder type
Other

Funder Name

Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
01/10/2023

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