

Identification of metabolomic biomarkers to assess dietary exposure in free-living adults

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Registration date 03/04/2014	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 18/11/2021	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

The aim of this study is to find a new way of measuring what people eat and drink on a regular basis. What people eat and drink and how it is prepared can affect our weight and our chances of developing certain diseases, such as heart disease, diabetes and many cancers. The aim is to understand what substances end up in the urine and blood after eating different foods and drinks, and whether these chemicals can be used to identify what someone has been eating, how much, how long ago, how it was cooked and the quality. The study's findings should enable better monitoring of the nation's diet and whether people are following healthy eating guidelines.

Who can participate?

Healthy people between the ages of 18-80 who are normal weight or overweight and live in the North East of England

What does the study involve?

Over a two or three week period, participants follow set meal plans and collect urine samples at regular times. The meal plans are made up of regular food and organised into a normal meal pattern. Participants visit the research facility at the beginning of each week to collect their food and drink. They make a second visit to the research facility at the end of each week to give a blood sample, return the urine samples they collected, and discuss how the study went for them.

What are the possible benefits and risks of participating?

There are no direct benefits to those taking part, but participating may help the researchers to develop a more accurate way of measuring what food and drink people consume on a regular basis and how healthy the British diet is. Participants may experience minor discomfort when giving blood and mild bleeding or bruising afterwards. If a participant has never eaten some of the test foods, there is a very small chance of an allergic reaction. However, all the foods are commonly eaten by most people and participants are asked to declare any known food allergy before joining the study.

Where is the study run from?

The study is a collaboration between Newcastle University, Aberystwyth University and Imperial

College London, but all participants come to the Newcastle University research facilities to take part.

When is the study starting and how long is it expected to run for?
March 2014 to December 2014

Who is funding the study?
Medical Research Council (UK)

Who is the main contact?
1. Dr Naomi Willis (naomi.willis@ncl.ac.uk)
2. Prof. John Mathers (john.mathers@ncl.ac.uk)

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
16037

Study information

Scientific Title
Identification of metabolomic biomarkers to assess dietary exposure in free-living adults

Acronym
MAIN

Study objectives
Current strategies for reducing chronic disease burden in the UK emphasize the importance of changing dietary habits. Determining the effectiveness of healthy eating initiatives requires

robust tools to assess dietary intake at the population level. The aim of this study is to identify novel chemicals (biomarkers) in blood and urine which are associated with healthy and unhealthy diets.

Ethics approval required

Old ethics approval format

Ethics approval(s)

First MREC approval date 14/01/2014, ref: 14/EM/0040

Study design

Randomised; Interventional; Design type: Not specified

Primary study design

Interventional

Study type(s)

Diagnostic

Health condition(s) or problem(s) studied

Topic: Metabolic and endocrine disorders; Subtopic: Metabolic and Endocrine (all Subtopics);
Disease: Metabolic & Endocrine (not diabetes)

Interventions

Participants will be given short-term diets lasting three days and will take part for a maximum of three consecutive weeks. These diets will contain specific test foods deemed to have high public health importance (oily fish, wholegrain foods, fruits and vegetables), as well as high fat and sugary foods which are associated with obesity. Participants will follow the diets in different orders and the order they follow will be decided by a random number generator (random.org). Whilst provided with these diets, urine and blood samples will be collected to identify new biomarkers for these different foods/food groups and to establish the optimum urine sampling procedure which has minimal intrusion on normal daily life but is suitable for assessment of dietary exposure in large scale epidemiological studies. No follow-up will take place after the study has been completed.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Clearly distinguishable metabolomic profiles for chosen foods/food groups, measured using mass spectrometry from samples collected on Days 1 - 5 of each study week

Key secondary outcome(s)

1. Distinguishable metabolomic profiles for chosen foods when using minimally invasive urine sampling
 2. Distinguishable metabolomic profiles for different food formulations
- Both measured using mass spectrometry from samples collected on Days 1 - 5 of each study week

Completion date

19/12/2014

Eligibility

Key inclusion criteria

1. Age 18-80
2. Male or female
3. Normal weight or overweight (body mass index 18.5-29.9 kg/m²)

Participant type(s)

Healthy volunteer

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

80 years

Sex

All

Total final enrolment

51

Key exclusion criteria

1. Weight change of more than 3kg in the preceding 2 months
2. Current smokers
3. Substance abuse
4. Excess alcohol intake
5. Pregnancy
6. Diabetes (Type 1 and Type 2)
7. Cardiovascular disease
8. Cancer
9. Gastrointestinal disease e.g. inflammatory bowel disease or irritable bowel syndrome
10. Kidney disease
11. Liver disease
12. Pancreatitis
13. Food allergy
14. Use of medications likely to interfere with energy metabolism, appetite regulation and hormonal imbalance, including but not exclusive to: antiinflammatory drugs (NSAIDs), steroids or other immunosuppressive medication, androgens, phenytoin, erythromycin or thyroid hormones

Subjects with the above conditions/taking the above medications would have an altered pattern of hormones and inflammatory molecules because of their disease process which may lead to misleading results.

Date of first enrolment

31/03/2014

Date of final enrolment

19/12/2014

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Human Nutrition Research Centre

Institute of Cellular Medicine

Newcastle University

Campus for Ageing and Vitality

Newcastle Upon Tyne

United Kingdom

NE4 5PL

Sponsor information

Organisation

Newcastle upon Tyne Hospitals NHS Foundation Trust (UK)

ROR

<https://ror.org/05p40t847>

Funder(s)

Funder type

Research council

Funder Name

Medical Research Council (MRC) (UK); Grant Codes: MR/J010308/1

Alternative Name(s)

Medical Research Council (United Kingdom), UK Medical Research Council, Medical Research Committee and Advisory Council, MRC

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

The current data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		21/10/2020	18/11/2021	Yes	No
HRA research summary			28/06/2023	No	No