

The effect of dairy fat on metabolic health

Submission date 05/08/2015	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 22/09/2015	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 16/02/2023	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

Recent studies suggest that dairy may affect the body in different ways depending on the form in which it is eaten. This study will examine the effect of dairy fat, in three different forms (presented in three different food types) on how much lipid (fat) is present in the blood, and other aspects of metabolic health (for example, the amount of energy used by the body, or how substances are broken down/made in the body). This study aims to improve understanding about how fats are processed in the body.

Who can participate?

Healthy adults, between the ages of 50-70, with a BMI of over 25kg/m², and not on a prescribed diet.

What does the study involve?

At the start of the study, all participants attend the UCD volunteer suites for an assessment. This includes them having a fasting blood sample and body measurements taken. They also have their diet assessed by a trained nutritionist, involving the completion of a questionnaire on that they eat and when and what they have eaten the day the day before. The participants are then randomly allocated into one of four groups and are given their test foods, on portioned packs with instructions on how to eat them, for the next 6 weeks. Those in group one are given dairy fat in the form of regular fat cheese. Those in group two are given dairy fat in the form of reduced fat cheese plus butter. Those in group three are given dairy fat in the form of butter alone. Those in group four are controls and are asked to limit dairy intake to very small amounts, but to otherwise maintain their normal diet. During the 6 weeks of the study, all participants are asked to complete more dietary assessments over the phone with a nutritionist and also to record whether they have stuck to the diet or not. At the end of the 6 weeks, the participants return to the volunteer suites, and complete the same tests as they did at the beginning of the study. A random selection of people are then asked to do a 'metabolic challenge' test. They are given a high fat food to eat. Blood samples are then taken over the next 5 hours to monitor how quickly their body responds to the challenge. A small cannula, like a small tap, is inserted into the vein to avoid multiple pricks for blood tests. The participants are given more food to eat after the test.

What are the possible benefits and risks of participating?

There are no known benefits of taking part. However, those who take part will be contributing

to research. There may be some slight discomfort upon the blood samples but it will be conducted by trained experienced professionals and will only consist of a small amount of blood taken (less than a blood donation). There are no other known risks associated with taking part in this study.

Where is the study run from?

UCD Institute of Food and Health (Ireland)

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

September 2015 to December 2016

Who is funding the study?

Food for Health Ireland (Ireland)

Who is the main contact?

Dr Emma Feeney

Contact information

Type(s)

Scientific

Contact name

Dr Emma Feeney

ORCID ID

<http://orcid.org/0000-0003-3234-6340>

Contact details

UCD School of Agriculture & Food Science

Institute of Food and Health

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Belfield

Dublin

Ireland

D04 N2E5

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

TC-2013-001

Study information

Scientific Title

The effect of dairy fat on metabolic health - understanding the 'matrix' effect of cheese

Study objectives

To establish whether the form (matrix) in which dairy fat is consumed has an effect on parameters of metabolic health

Ethics approval required

Old ethics approval format

Ethics approval(s)

University College Dublin Human Research Ethics Committee, 31/07/15, ref: LS-15-44-Feeney-Gibney

Study design

Single-centre intervention study

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Other

Participant information sheet**Health condition(s) or problem(s) studied**

Obesity

Interventions

Participants will be randomised into one of four groups, each receiving dairy fat in different forms:

Group 1: To receive dairy fat in the form of regular fat cheese

Group 2: To receive dairy fat in the form of reduced fat cheese plus butter

Group 3: To receive dairy fat in the form of butter alone

Group 4: A control group asked to limit dairy intake to very small amounts, to consume no cheese /cheese products during the wash out period and to maintain habitual diet throughout the 6 week intervention period

A subset of subjects from each group will then undergo a metabolic challenge in which high fat food is consumed, blood lipid profiles are measured over a course of four hours.

Intervention Type

Other

Primary outcome measure

Fasting blood markers of metabolic health following 6 weeks daily consumption of dairy fat, in 3 different matrices.
A subset of subjects (n=24) will give multiple blood samples (8 in total) over 5 hours. Analysis will be performed at all time points.

Secondary outcome measures

Postprandial blood-lipid and glucose following an oral lipid challenge in a subset of subjects.

Overall study start date

01/09/2015

Completion date

31/12/2016

Eligibility

Key inclusion criteria

1. Healthy, on no medication
2. Not following a prescribed diet for any reason (weight loss, cholesterol etc)
3. Male or female, aged between 50-70
4. BMI >25 kg/m²

Participant type(s)

Healthy volunteer

Age group

Other

Sex

Both

Target number of participants

N=240

Key exclusion criteria

1. Outside the specified age
2. BMI <25 kg/m²
3. Anyone who is currently taking prescribed medication for cholesterol-reduction purposes
4. Anyone following any specific diet to control or modify their cholesterol or weight

Date of first enrolment

01/09/2015

Date of final enrolment

01/10/2016

Locations

Countries of recruitment

Ireland

Study participating centre

University College Dublin Institute of Food and Health

University College Dublin School of Agriculture & Food Science

Science Centre - South

University College Dublin

Belfield

Dublin

Ireland

D04 N2E5

Sponsor information

Organisation

Food for Health Ireland

Sponsor details

UCD Institute of Food and Health

Level 2

Science Centre South

University College Dublin

Belfield

Dublin

Ireland

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Sponsor type

University/education

ROR

<https://ror.org/01nvbq395>

Funder(s)

Funder type

Research organisation

Funder Name

Food for Health Ireland

Results and Publications

Publication and dissemination plan

Publications planned to include (but not limited to):

1. Changes in anthropometry (if any) following 6 weeks of different diets
2. Changes in blood lipid markers
3. Changes in fasting glucose/insulin levels

A further publication will examine postprandial responses to a lipid tolerance test , before and after 6 weeks consumption of the different diets.

Publications are planned for submission to high impact clinical nutrition journals.

Intention to publish date

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are not expected to be made available

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	results	01/10/2018		Yes	No
Results article		15/12/2022	16/02/2023	Yes	No