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The effects of consuming melted cheese and grass-fed cheese on markers of metabolic health

Submission date
19/02/2021

Recruitment status
No longer recruiting

Registration date
16/03/2021

Overall study status
Completed

Last Edited
18/05/2022

Condition category
Nutritional, Metabolic, Endocrine

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Research suggests that foods with the same nutrient composition but eaten in different forms may have different effects on digestion and absorption. This concept, known as the food matrix, suggests that the predicted health effects of single nutrients may be different to the actual health effects when consumed as a whole food. Dairy foods are of particular interest. Recent studies have demonstrated a beneficial effect of dairy fat when eaten in the form of solid cheddar cheese on markers of metabolic health and cardiovascular disease risk. However, there is a need to examine whether melting cheese can affect these health benefits. In addition, evidence shows that cows fed primarily on pasture (grass) produce milk with higher nutrient concentrations compared to milk produced from grain-fed cows, namely CLA and n-3 fatty acids. Therefore, the aim of this study is to firstly, examine the effect of cheese form (solid or melted) on blood lipid profiles and other aspects of metabolic health, and secondly, to examine the effects of grass-fed vs grain-fed cheese on the same, as well as circulating levels of vitamins /fatty acids in a population of people aged 50-69. This type of research will help us understand more about how dairy fats are processed in the body and may help to inform food intake guidelines in the future.

Who can participate?
Healthy volunteers aged 50 and over with a BMI over 25 kg/m²

What does the study involve?
Participants will be randomly allocated to eat one of four test foods daily for a period of 6 weeks. Test food 1 is 120 g of solid, full fat, grass-fed cheddar cheese. Test food 2 is 120 g of melted, full fat, grass-fed cheddar cheese. Test food 3 consists of 49 g of butter, 30 g of calcium caseinate powder (protein powder) and a calcium supplement (control). Test food 4 is 120 g of solid, full fat, grain-fed cheddar cheese. Blood lipids, glucose and inflammatory markers will be measured from fasted blood samples collected at the start of the study and after the 6-week intervention period. Optional faecal samples will also be taken at the start and the end of the study to look at the differences in faecal composition and the microbiome.

What are the possible benefits and risks of participating?
There are no known benefits to participating. Potential risks are discomfort or bruising from the blood sampling, and the risk of finding the study food unpleasant.

Where is the study run from?
University College Dublin (Ireland)

When is the study starting and how long is it expected to run for?
July 2019 to September 2023

Who is funding the study?
Enterprise Ireland (Ireland)

Who is the main contact?
Prof Eileen Gibney
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Study website
https://www.ucd.ie/foodandhealth/cheesestudy/

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
LS-19-78-Gibney

Study information

Scientific Title
A randomized control trial to investigate the impact of long-term consumption of melted cheddar, and to examine the effect of grass-fed vs total mixed ration (TMR) cheddar, on markers of metabolic health

Study objectives
1. The form of the cheese matrix (solid or melted) has no impact on markers of metabolic health and there will be no difference in LDL-cholesterol or other markers of heart health between solid and melted cheese.
2. Dairy fat, eaten in the form of melted cheese, will have a different effect on blood lipids compared with the same constituents eaten in a different matrix (control).
3. Consumption of grass-fed cheese will have different outcomes on blood lipids and other markers of health compared to TMR-fed cheese consumption.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 12/11/2019, Human Research Ethics Committee (UCD Office of Research Ethics, Roebuck Castle, University College Dublin, Belfield, Dublin 4; + 353 (0)1 716 8767; research.ethics@ucd.ie), ref: LS-19-78-Gibney

Study design
Single-centre randomized parallel intervention trial

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Other

Study type(s)
Other

Participant information sheet
https://www.ucd.ie/foodandhealth/t4media/DAIRY%20FOODS%20STUDY%20PARTICIPANT%20INFORMATION%20SHEET%20%C3%A2%C2%80%C2%93%20cheese_grass_printable.pdf

Health condition(s) or problem(s) studied

Blood lipids

Interventions
In this parallel, multi-arm study examining the effect of the intervention over 6 weeks, participants will consume one of the following diet treatments per day;
1. 120 g solid cheddar (non-melted), 100% pasture-fed cheddar
2. 120 g melted, 100% pasture-fed cheddar (test)
3. 'Deconstructed cheese' (49 g butter, 30 g calcium caseinate powder and a calcium supplement) (control)
4. 120 g solid 100% TMR cheddar (non-melted)
For each block, n=80 participants will be recruited and randomly assigned to the study arm. However, the inclusion of interim analysis will test the effect of each treatment group compared to the control throughout the study period. This will be conducted after every 80 participants complete the intervention. If the interim analysis demonstrates sufficient statistical power at any stage, the total sample size may not be required. Due to the nature of the meals, the arms cannot be masked.

Intervention Type
Behavioural

Primary outcome measure
Blood lipids measured with the HORIBA Pentra C400 from fasted blood samples collected at baseline and after the 6-week intervention period

Secondary outcome measures
Blood glucose and inflammatory markers measured with the HORIBA Pentra C400 from fasted blood samples collected at baseline and after the 6-week intervention period

Overall study start date
01/07/2019

Completion date
01/09/2023

Eligibility

Key inclusion criteria
Current participant inclusion criteria as of 18/05/2022:
1. Healthy, not taking medication for cholesterol, blood pressure or digestion
2. Not following a prescribed diet for any reason (weight loss, cholesterol etc)
3. Free from dairy intolerance/allergy and consume an omnivorous diet
4. Male or female, aged ≥50 years
5. BMI >25 kg/m²

Previous participant inclusion criteria:
1. Healthy, not taking medication for cholesterol, blood pressure or digestion
2. Not following a prescribed diet for any reason (weight loss, cholesterol etc)
3. Free from dairy intolerance/allergy and consume an omnivorous diet
4. Male or female, aged between 50– 69 years
5. BMI >25 kg/m²

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
320 (this is dependent on interim analysis previously described)

Key exclusion criteria
Current participant exclusion criteria as of 18/05/2022:
1. Taking medication for cholesterol, blood pressure, or digestion
2. Following a prescribed diet for any reason (weight loss, cholesterol, etc)
3. Dairy intolerance/allergy and consuming an omnivorous diet
4. Male or female, aged <50 years
5. BMI <25 kg/m²

Previous participant exclusion criteria:
Immunocompromised and aged >70 years to be excluded as a COVID-19 precaution

Date of first enrolment
16/01/2020

Date of final enrolment
31/08/2022

Locations

Countries of recruitment
Ireland

Study participating centre
University College Dublin
Institute of Food & Health
Science Centre South
Belfield
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Study participating centre

Food for Health Ireland
UCD Centre for Molecular Innovation and Drug Discovery
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Sponsor information

Organisation
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Sponsor type
Research organisation

Website
https://www.fhi.ie/

Funder(s)

Funder type
Government

Funder Name
Enterprise Ireland

Alternative Name(s)

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Ireland

Results and Publications

Publication and dissemination plan
The results will be prepared for publication and submitted to high-impact peer reviewed journals such as the American Journal of Clinical Nutrition, British Journal of Nutrition, European Journal of Clinical Nutrition, Nutrients, Journal of Lipid Nutrition. At the moment, the study protocols and statistical analysis plan will not be made available.

Intention to publish date
31/12/2023

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available. The data will be stored on a password-protected computer (encrypted) as per UCD data protection recommendations.

IPD sharing plan summary
Not expected to be made available