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Effect of a diet of healthy food or a Mediterranean diet on change in the composition and function of faecal microbiota

Submission date
28/03/2017

Recruitment status
No longer recruiting

Registration date
07/04/2017

Overall study status
Completed

Last Edited
07/06/2023

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Current plain English summary as of 20/04/2021:
Background and study aims
Metabolic syndrome is a term used to describe a combination of factors which increase a person' s risk of heart disease and other health problems, such as diabetes and stroke. Many of these factors are linked with obesity, such as high blood pressure, cholesterol and body fat. Recent research has shown that there may be a link between the composition of different bacteria that live in the gut (gut microbiota) and the biological processes of disease. In a previous study, it was found that a Mediterranean diet, supplemented with nuts, led to a major reduction in disease risk factors. The aim of this study is to look at two different diets to find out what effect they have on the composition of bacteria in the gut and metabolic risk factors.

Who can participate?
Overweight obese men and women aged 30-65 ,with Metabolic Syndrome.

What does the study involve?
Participants are randomly allocated to two different interventions in a random order. Each of the intervention periods will last for eight weeks, and there is a four week period of consuming thier habitual diet in between them, to ensure the results of the different interventions do not influence each other. The first intervention involves eating 50g of nuts every day in addition to the regular non-Mediterranean diet. The second intervention involves eating a Mediterranean diet, with high consumption of vegetables and olive oil and moderate consumption of protein. Before and after each dietary period, participants provide stool and blood samples which are then examined to assess the composition of bacteria living in the gut and to see if there has been any change to metabolic syndrome risk factors.

What are the possible benefits and risks of participating?
Participants may benefit from following a healthier dietary patterns with demonstrated benefits on cardiometabolic health. There is a small risk of pain or bruising when blood samples are collected.

Where is the study run from?
1. Rovira i Virgili University (Spain)
2. Hospital Universitari Sant Joan (Spain)
3. Primary Care Centers from the Catalan Institute of Health

When is the study starting and how long is it expected to run for?
January 2017 to December 2019

Who is funding the study?
Instituto de Salud Carlos III (Spain)

Who is the main contact?
Dr Mònica Bulló Bonet
monica.bullo@urv.cat

Previous plain English summary:
Background and study aims
Metabolic syndrome is a term used to describe a combination of factors which increase a person' s risk of heart disease and other health problems, such as diabetes and stroke. Many of these factors are linked with obesity, such as high blood pressure, cholesterol and body fat. Recent research has shown that there may be a link between the composition of different bacteria that live in the gut (gut microbiota) and the biological processes of disease. In a previous study, it was found that a Mediterranean diet, supplemented with nuts, led to a major reduction in disease risk factors. The aim of this study is to look at two different diets to find out what effect they have on the composition of bacteria in the gut and on metabolic risk factors.

Who can participate?
Men and women aged 30-65 who have three or more signs of metabolic syndrome

What does the study involve?
Participants are randomly allocated to consume two diets in a random order. Each of the diets lasts for eight weeks, and there is a four week period of consuming a normal diet in between them, to ensure the results of the different diets don't influence each other. The first diet involves eating 50g of nuts every day in addition to regular diet. The second diet involves eating a Mediterranean diet, which involves high consumption of vegetables and olive oil and moderate consumption of protein. Before and after each dietary period, participants provide stool and blood samples which are then examined to assess the composition of bacteria living in the gut and to see if there has been any change to metabolic syndrome risk factors.

What are the possible benefits and risks of participating?
Participants may benefit from taking part due to the well founded benefits of consuming nuts and following a Mediterranean diet. There is a small risk of pain or bruising when blood samples are collected.

Where is the study run from?
1. Rovira i Virgili University (Spain)
2. Hospital Universitari Sant Joan (Spain)

When is the study starting and how long is it expected to run for?
January 2017 to December 2019

Who is funding the study?
Instituto de Salud Carlos III (Spain)

Who is the main contact?
Dr Mònica Bulló Bonet
monica.bullo@urv.cat

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
PI/00516

Study information

Scientific Title
Effect of a diet on healthy food or a Mediterranean diet on change in the composition and function of faecal microbiota and its relationship with the metabolic improvement

Acronym
METADIET

Study objectives

Current study hypothesis as of 20/04/2021:
The consumption of certain foods typical of the Mediterranean diet in the context of a non-Mediterranean diet will modify the composition and functionality of the intestinal microbiota towards a healthier profile and this will be associated with a metabolic improvement.

Previous study hypothesis:
The consumption of certain foods typical of the Mediterranean diet in the context of a non-Mediterranean diet will modify the composition and functionality of the intestinal microbiota towards a healthier profile.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee (Hospital Universitari Sant Joan; Reus), 26/01/2017, Ref. CEIm: 04/2017

Study design
Randomised cross over trial

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Obesity and metabolic syndrome

Interventions
Participants are randomised to consume two dietary interventions in a random order. Each intervention period lasts for a total of eight weeks, with a four week wash out period between them.

Diet one: Participants consume their regular diet (RD) with the addition of 50g of nuts/day.
Diet two: Participants consume the Mediterranean diet. This consists of high consumption of vegetables and olive oil and moderate consumption of protein.

Participants will be followed up before and after each intervention period. Classic metabolic risk markers will be analyzed (glucose, lipid profile) as well as inflammation, oxidation and endothelial function markers by routine methods. The taxonomic composition in faeces will be determined as well as a quantitative metagenomic analysis in one sub-group. For the

metabolomic analysis in plasma and faeces samples it will be use different analytic platforms according to the sample.

Intervention Type
Behavioural

Primary outcome measure
Current primary outcome measure as of 09/12/2020:
Faecal microbiota is assessed through measuring the taxonomic composition in faeces (16S RNA) and quantitative metagenomic analysis at baseline and 8 weeks in each intervention period.

Previous primary outcome measure:
Metabolic risk markers are assessed by measuring glucose and lipid profile, inflammation, oxidation, and endothelial function markers by routine methods, ELISA and Luminex platform at baseline and 8 weeks in each intervention period.

Secondary outcome measures
Current secondary outcome measures as of 09/12/2020:
Metabolic risk markers are assessed by measuring glucose and lipid profile, inflammation, oxidation, and endothelial function markers by routine methods, ELISA and Luminex platform at baseline and 8 weeks in each intervention period.

Previous secondary outcome measures:
Faecal microbiota is assessed through measuring the taxonomic composition in faeces (16S RNA) and quantitative metagenomic analysis at baseline and 8 weeks in each intervention period.

Overall study start date
01/01/2017

Completion date
31/12/2019

Eligibility

Key inclusion criteria
Current inclusion criteria as of 20/04/2021:
1. Men and women
2. 30-60 years old - updated 17/10/2018: 30-65 years old
3. BMI≥25 and <35 kg/m2
4. ≥3 Metabolic Syndrome criteria according to the ATP III harmonised criteria (doi: 10.1016/j.amjcard.2006.08.045)
4.1. Hypertension or hypertension treatment
4.2. Altered glycemia (≥100mg/dl) or treatment
4.3. HDL cholesterol (men<40mg/dl or women <50mg/dl) or treatment
4.4. Altered triglycerides (≥150mg/dl) or treatment
4.5. Abnormal waist circumference (men ≥ 102cm or women ≥ 88)
5. Following a non-Mediterranean Diet (scoring ≤9 in the 17-items MedDiet score used in the PREDIMED-Plus intervention trial) (questionnaire available at doi: 10.1093/ije/dyy225)

Previous inclusion criteria:
1. Men and women

2. 30-60 years old - updated 17/10/2018: 30-65 years old
3. BMI≥25 and <35
4. ≥3 Metabolic Syndrome criteria:
4.1. Hypertension or hypertension treatment
4.2. Altered glycemia (≥100mg/dl)
4.3. HDL cholesterol (men<40mg/dl or women <50mg/dl)
4.4. Altered triglycerides (≥150mg/dl)
4.5. Abnormal waist circumference (men ≥ 102cm or women ≥ 88)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
50 individuals

Total final enrolment
44

Key exclusion criteria
Current inclusion criteria as of 20/04/2021:
1. BMI<25kg/m2 or BMI≥35
2. Type 2 diabetes
3. Secondary obesity or related pathologies
4. Non-controlled hypertension (Systolic arterial pressure (SAP)>159mmHg; Diastolic arterial pressure (DAP)>99mmHg)
5. LDL cholesterol >160mg/dl
6. Tryglicerides >400mg/dl
7. Mediterranean adscription punctuation >9 (17-items MedDiet PREDIMED Plus questionnaire)
8. Frequent nuts consumption (≥90g/week)
9. Different chronic diseases (inflammatory, infectious, chronic obstructive pulmonary, neoplasias, endocrine, or hematological diseases)
10. Leucocytosis (leucocytes >11x10E9)
11.Pharmacological treatment (anti-inflammatory, corticoids, hormones or antibiotics)
12. Changes of hypertension of lipidic profile medication (last 3 months).
13. Body weight loss (>5kg in the last 3 months).
14. Lost weight medication changes (last 3 months).
15. Breeding or pregnancy.
16. Diseases history (hepatic cirrhosis, intestinal inflammatory, intestinal resection).
17. Nuts allergy.
18. Probiotics, prebiotics or laxatives consumption

Previous exclusion criteria:
1. BMI<25kg/m2 or BMI≥35
2. Type 2 diabetes
3. Secondary obesity or related pahologies
4. Non-controlled hypertension (Systolic arterial pressure (SAP)>159mmHg; Diastolic arterial pressure (DAP)>99mmHg)
5. LDL cholesterol >160mg/dl
6. Tryglicerides >400mg/dl
7. Mediterranean adscription punctuation ≥7 (PREDIMED trial)
8. Frequent nuts consumption (≥90g/week)
9. Frequent legumes consumption (≥120g/week)
10. Different chronic diseases (inflammatory, infectious, chronic obstructive pulmonary, neoplasias, endocrine, or hematological diseases)
11. Leucocytosis (leucocytes >11x10E9)
12.Pharmacological treatment (anti-inflammatory, corticoids, hormones or antibiotics)
13. Changes of diabetes, hypertension of lipidic profile medication (last 3 months).
14. Body weight loss (>5kg in the last 3 months).
15. Lost weight medication changes (last 3 months).
16. Breeding or pregnancy.
17. Diseases history (hepatic cirrhosis, intestinal inflammatory, intestinal resection).
18. Nuts or legumes allergy.
19. Probiotics, prebiotics or laxatives consumption

Date of first enrolment
16/02/2017

Date of final enrolment
09/07/2018

Locations

Countries of recruitment
Spain

Study participating centre
Rovira i Virgili University (URV) / Institute of Health Pere Virgili (IISPV)
Nutrition and Metabolic Disorders Research Group
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43201

Study participating centre
Hospital Universitari Sant Joan (HUSJ)
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Study participating centre
Primary Care Centers-Catalan Institute of Health (ICS)
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Sponsor information

Organisation
Instituto de Salud Carlos III

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Sponsor type
Government

Website
http://www.isciii.es/ISCIII/es/general/index.shtml

ROR
https://ror.org/00ca2c886

Funder(s)

Funder type
Government

Funder Name
Instituto de Salud Carlos III

Alternative Name(s)

SaludISCIII, InstitutodeSaludCarlosIII, Instituto de Salud Carlos III | Madrid, Spain, Carlos III Institute of Health, Institute of Health Carlos III, Carlos III Health Institute, ISCIII

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Spain

Results and Publications

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

Intention to publish date
31/12/2019

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Mònica Bulló Bonet (monica.bullo@urv.cat)

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/06/2021	17/06/2021	Yes	No
Other publications		29/11/2021	07/06/2023	Yes	No