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Does eating mandarin oranges impact cardiometabolic risk factors and omics biomarkers in a general population intervention trial?

Submission date
24/09/2024

Recruitment status
No longer recruiting

Registration date
25/09/2024

Overall study status
Completed

Last Edited
25/09/2024

Condition category
Other

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

Plain English summary of protocol

Background and study aims
This study focuses on precision nutrition, which aims to tailor dietary recommendations based on new biological markers. The goal is to understand how eating mandarins affects various health markers and gene expressions. Mandarins are rich in vitamin C, fiber, and antioxidants, which may have multiple health benefits.

Who can participate?
-Volunteers from the general population
-Aged 18 to 55 years old
-Body mass index (BMI) between 23 and 32 kg/m²

What does the study involve?
Participants will be randomly assigned to one of two groups:
Intervention group: Receive 1 kg of mandarins per day for 15 days along with their usual diet.
Control group: Continue their usual diet with recommendations for low mandarin consumption.

What are the possible benefits and risks of participating?
Participants will be informed that there are no benefits and risks expected.

Where is the study run from?
The study is conducted by the University of Valencia and the Centro de Investigación Biomédica en Red.

When is the study starting and how long is it expected to run for?
October 2023 to l December 2025.

Who is funding the study?
University of Valencia (Spain)
Conselleria de Cultura, Educació, Universitats i Ocupació, Generalitat Valenciana (Spain)

Who is the main contact?
Dr Eva Asensio Márquez, eva.m.asensio@uv.es

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
PM_2405

Study information

Scientific Title
Effect of mandarin orange consumption on omics biomarkers and cardiometabolic phenotypes: A Randomized clinical trial in the general population (MANSomics)

Acronym
MANSomics

Study objectives

The intervention with the daily consumption of a high amount of mandarins in the diet compared to the control group will result in several changes in omic biomarkers. Among them, we will detect metabolic changes in "intake" metabolites in plasma/urine, including the increase of known biomarkers of orange consumption (proline-betaine, among others), as well as other "effect" metabolites. Likewise, the consumption of mandarins will have a positive impact on new transcriptomic biomarkers due to the differential expression of genes that we will be able to identify, such as changes in DNA methylation leading to differential CpG profiles compared to the control group. In turn, these effects can be modulated by genomic markers, by sex, and other characteristics of the individual. Furthermore, we will be able to observe an association with the reduction of oxidative stress, an increase in vitamin C, improvements in blood pressure, blood glucose levels, plasma lipid concentrations, and other classic biochemical and metabolomic markers, as well as in anthropometric parameters (body-weight and body fat distribution).

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 18/12/2023, Institutional review board of Valencia University (human subjects) (Avda. Blasco Ibanez 13, Valencia, 46010, Spain; +34 (0)963864109; vicerec.investigacio@uv.es), ref: UV-INV_ETICA-3132572

Study design
Interventional randomized parallel trial

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Prevention of cardiovascular and metabolic diseases in subjects from the general population

Interventions
Randomized controlled clinical trial with two parallel groups including 70 participants in total. Participants will be randomly assigned 1:1 into two groups using a software program.
1. Intervention group receiving 1 kg (with skin) of mandarins per day for 15 days along with their usual diet.
2. Control group with no provision of mandarins, usual diet with the recommendations for low consumption of mandarins.

Intervention Type
Behavioural

Primary outcome(s)
Changes in multi-omics biomarkers (gene-expression, DNA-methylation, and plasma metabolites) from baseline to 15 days following a daily intervention with 1 kg of mandarin oranges in comparison with the control group. Gene-expression will be measured with a whole transcriptomics human array at baseline and after 15 days. DNA-methyation will be measured by

a genome-wide methylation human array at baseline and after 15 days. Metabolomics will be measured in plasma by Nuclear Magnetic Resonance at baseline and after 15 days.

Key secondary outcome(s))
1. Biochemical analysis with hematocrit, lipid profile, blood glucose, renal and hepatic function at baseline and after 15 days.
2. Analysis of parameters related to oxidative stress at baseline and after 15 days.
3. Measurement of blood pressure at the baseline visit and after the intervention at baseline and after 15 days.
4. Weight, height, waist circumference, and body composition through baseline bioimpedance at baseline and after 15 days.
5. Food intake and adherence to the Mediterranean Diet using the food consumption frequency questionnaire and the 14-point adherence questionnaire at baseline and after 15 days.
6. Physical activity measured through the use of accelerometers at baseline and after 15 days.
7. Characteristics of sleep measured using the Epworth Sleepiness Scale and chronotype assessed with the Morningness-Eveningness Questionnaire by Horne and Östberg at baseline and after 15 days.

Completion date
19/12/2025

Eligibility

Key inclusion criteria
1. Volunteers recruited from the general population
2. Aged 18 to 55 years old
2. Body mass index (BMI) between 23 and 32 kg/m²

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
55 years

Sex
All

Key exclusion criteria
1. Do not meet the inclusion criteria.
2. People allergic or intolerant to the consumption of oranges.
3. Pregnant women or breastfeeding period

4. Alcoholism or drug addiction
5. Individuals presenting the following current situations: infectious diseases, renal diseases, liver diseases, cancer, obesity, type 2 diabetes, or other pathologies that may bias the study.

Date of first enrolment
15/11/2024

Date of final enrolment
30/04/2025

Locations

Countries of recruitment
Spain

Study participating centre
University of Valencia. School of Medicine
Avda. Blasco Ibanez 15
Valencia
Spain
46010

Study participating centre
Centro de Investigación Biomédica en Red, Instituto de Salud Carlos III
C/ Monforte de Lemos 3-5.
Pabellón 11. Planta 0
Madrid
Spain
28029

Sponsor information

Organisation
University of Valencia

ROR
https://ror.org/043nxc105

Organisation
Centro de Investigación Biomédica en Red

ROR
https://ror.org/02g87qh62

Funder(s)

Funder type
University/education

Funder Name
Universitat de València

Alternative Name(s)
University of Valencia, UV

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
Spain

Funder Name
Conselleria de Cultura, Educació, Universitats i Ocupació, Generalitat Valenciana / Department of Culture, Education, Universities, and Employment General, Generalitat Valenciana

Results and Publications

Individual participant data (IPD) sharing plan
Data will not be available outside the core research group as the informed consent form signed by participants stated that individual-level data will not be publicly available. Researchers who are interested in this study can contact the main investigator (Dra. Eva Asensio Márquez) if they have any questions regarding the data or are interested in further collaborations. The participants will receive written information about what the study involves and sign a consent form before entering the study.

IPD sharing plan summary
Not expected to be made available