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A study analyzing if a healthy diet improves the taste preference profile and flavor perception

Submission date 10/12/2021	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 13/12/2021	**Overall study status** Completed	
Last Edited 10/07/2024	**Condition category** Other	

Plain English summary of protocol

Background and study aims

Taste and smell alterations represent an increasingly important problem in nutrition, and in public health. Currently, it is of enormous interest, not only to know the relationship between perception and preferences taste, smells and eating patterns and cardiometabolic and cognitive variables at a specific moment, but also to know their dynamic evolution, and what is more important, to know the factors that can improve taste and smell perception and preference patterns. Following the COVID-19 epidemic, some pharmacological interventions have been proposed to regain taste and olfactory ability in people who had lost it. However, our aim is to study if an intervention with a healthy diet can improve the perception of flavors (taste and smell), as well as change the preference for certain flavors (tastes and smell) in a general Mediterranean population after 6 months of intervention, compared to a control group.

Who can participate?

Men and women from the general population (aged 25-75 years)

What does the study involve?

Participants will be randomly allocated 1:1 to two groups (intervention and control group) using a computer algorithm: The intervention group consisting of 100 individuals will receive nutritional advice to follow a healthy diet (Mediterranean-based diet low in ultra-processed foods) for 6 months (with an individual session every month). No intervention will be carried out in the control group. The primary outcomes will be changes in flavor (taste and smell) preferences, taste perception, and odor perception from baseline to 6 months using standard tests. In addition, anthropometric, blood pressure, food intake, physical activity, sleep, chronotype, and some cognitive variables will be measured.

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?

University of Valencia (Spain)

When is the study starting and how long is it expected to run for?
October 2021 to January 2025

Who is funding the study?
University of Valencia (Spain)

Who is the main contact?
Carolina Ortega-Azorín
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
PTN_1896892

Study information

Scientific Title
Effect of the intervention with a healthy diet on the flavor preference profile and improvement of taste and odor perception in a Mediterranean population: A randomized and controlled clinical trial

Acronym
TASTOR

Study objectives

The intervention with a healthy diet can improve the perception of flavors (taste and smell), as well as change the preference for certain flavors (tastes and smell) in a general Mediterranean population after 6 months of intervention, compared to a control group.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 09/11/2021, Institutional review board of Valencia University (human subjects) (Avda. Blasco Ibanez 13, Valencia, ZIP 46010, Spain; +34 963864109; vicerec.investigacio@uv.es), ref: PTN_1896892

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Improving flavor perception and preferences in the general population

Interventions
Participants (n=200) will be randomized 1:1 to 2 arms (intervention and control groups) using an online tool (compute program). One study arm (n=100 participants) will receive the intervention consisting of a healthy diet for 6 months. The other study arm, the control group (n=100 participants) will receive no intervention for 6 months, only the baseline visit and the final visit after 6 months. The intervention group will receive nutritional advice to follow a healthy diet (consisting of a Mediterranean-based dietary pattern low in ultra-processed foods) for 6 months by a registered dietitian. In addition, every months a face-to-face individual session for reinforcing the nutritional advice and increasing compliance with the healthy diet will be carried out

Intervention Type
Behavioural

Primary outcome(s)
Measured at baseline and 6 months:
1. Flavor preferences (all the tastes and selected odors will be measured using the 9-item hedonic scales)
2. Taste perception: intensity rating test with prototypic tastants for (bitter, sweet, sour, umami, and salty) at different concentrations will be carried out in the laboratory
3. Odor perception tests using the "NHANES Odor Test" (US National Health and Nutrition Examination Survey) protocol

Key secondary outcome(s))
1. Anthropometric measures (by bioimpedance) at baseline and 6 months in both groups.
2. Blood pressure and heart rate parameters, at baseline and after 6 months in both groups by standard procedures

3. The level of adherence to the Mediterranean Diet through the 17-ite questionnaire at baseline and at 6 months.
4. Food intake (by a FFC) at baseline and 6 months.
5. Physical activity measured using the short form of the Minnesota physical activity questionnaire at baseline.
6. Sleep characteristics measured using the Pittsburgh Sleep Quality Index questionnaire at baseline and at 6 months.
7. Chronotype at baseline, measured using the Horne and Östberg questionnaire.
8. Cognitive tests, measuring semantic and phonemic verbal capacity and average executive control, the Controlled Oral Word Association Test (COWAT), and the memory alteration test (T @ M) at baseline and after 6 months.
9. Quality of life (SF-36 or SF-12) at baseline and after 6 months.

Completion date
01/01/2025

Eligibility

Key inclusion criteria
1. Adults from the general population (50% women)
2. Age range of 25 to 75 years
3. Body mass index (BMI) of 25 to 35 kg/m²

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
25 years

Upper age limit
75 years

Sex
All

Key exclusion criteria
Those individuals who do not meet the inclusion criteria or who present the following conditions:
1. Allergy to the tastants or to any food recommended in the healthy dietary pattern
2. Pregnant or lactating women
3. Infectious diseases
4. Kidney or liver diseases
5. Cancer
6. Other relevant pathologies that could bias the study

Date of first enrolment
21/12/2021

Date of final enrolment
31/03/2024

Locations

Countries of recruitment
Spain

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

Study participating centre
CIBER
C/Melchor Fernandez de Almagro
Pabellon 11
Madrid
Spain
28029

Sponsor information

Organisation
University of Valencia

ROR
https://ror.org/043nxc105

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
Dotacion PremiRJI_DC

Results and Publications

Individual participant data (IPD) sharing plan
Data will not be available outside the core research group. Researchers who are interested in this study can contact the main investigator (Carolina.ortega@uv.es) 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. In the informed consent form, the participant is informed that the individual-level data will not be publicly available.

IPD sharing plan summary
Not expected to be made available