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Does an intervention with a healthy lifestyle change taste perception and smell detection?

Submission date
11/12/2019

Recruitment status
No longer recruiting

Registration date
13/12/2019

Overall study status
Completed

Last Edited
14/07/2022

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
Taste and smell perception decreases with age and both are characteristic of ageing. An impaired olfactory capacity has been significantly associated with all-cause mortality, mainly due to neurodegenerative and cardiovascular diseases. Likewise, a decreased taste perception has been associated with greater adiposity, including weight, waist circumference and body mass index. Therefore, the aim of this study is to analyze if an intervention with a healthy lifestyle including a healthy diet, increased physical activity and a healthy sleep pattern (for 1 year) is able to improve taste and smell perception in the general population, compared to a control group.

Who can participate?
Healthy men and women from the general population (aged 30-65)

What does the study involve?
Participants are randomly allocated to two groups (intervention and control group). The intervention (healthy lifestyle) includes nutritional education to increase adherence to a healthy diet, the Mediterranean diet. The intervention also includes increasing physical activity, personalized to the characteristics of the participants. In addition, interventions promoting healthy sleep habits according to age are carried out according to the recommendations of the Spanish Sleep Society. Every three months intervention group participants are requested for individual sessions and visits to reinforce the intervention. The control group do not have any type of intervention, only first and final visits. In addition, anthropometric, blood pressure and other lifestyle variables are assessed and compared. The duration of follow-up is 1 year.

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 2019 to December 2023

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

Who is the main contact?
Prof. José V. Sorlí
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
PCT2E-19

Study information

Scientific Title
Changes in taste perception and smell detection after a healthy lifestyle intervention: a randomized and controlled clinical trial

Acronym
TASMELL

Study objectives

The hypothesis is that a healthy lifestyle intervention consisting of nutritional education for a healthy diet, increased physical activity and healthy sleep habits, improves taste and smell perception, when compared to a control group.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 05/12/2019, Institutional review board of Valencia University (human subjects) (Avda. Blasco Ibanez 13, Valencia, ZIP 46010, Spain; Tel: +34 (0)963864109; Email: vicerec.investigacio@uv.es), ref: UV-INV_ETICA-1205661

Study design
Interventional randomised controlled trial

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Taste-smell

Interventions
This is a parallel randomized controlled trial including 60 participants (30 people in the intervention group and 30 people in the control group). Participants will be randomly assigned to the control or intervention group 1:1 by simple random assignment through a computer program. The intervention (healthy lifestyle) will be carried out with nutritional education to increase adherence to a healthy diet, the Mediterranean diet. The intervention also will consist of increasing physical activity, in which physical activity will be personalized to the characteristics of the participants. In addition, the intervention promoting healthy sleep habits according to age will be carried out according to the recommendations of the Spanish Sleep Society. The intervention will be carried out for one year. Every three months intervention group participants will be requested for individual sessions and visits to reinforce the intervention. The control group will not have any type of intervention, only baseline and final visits. The duration of follow-up will be 1 year.

Intervention Type
Behavioural

Primary outcome(s)
1. Taste perception measured by a validated test (for sweet, salty, bitter, acid and umami flavors) at baseline and after intervention
2. Smell detection measured by a validated test called “Sniffin´Sticks” at baseline and after intervention

Key secondary outcome(s))
1. Blood pressure measured at baseline and after intervention
2. Weight, height, waist circumference and body composition by bioimpedance measured at

baseline and after intervention
3. Food intake and adherence to the Mediterranean diet measured using the 14-item Mediterranean diet adherence PREDIMED scale at baseline and after intervention
4. Physical activity measured using the short form of the Minnesota physical activity questionnaire at baseline and after intervention
5. Sleep characteristics measured using the Pittsburgh Sleep Quality Index questionnaire at baseline and after intervention
6. Chronotype measured using the Horne and Östberg questionnaire at baseline and after intervention
7. Cognitive function measured using some tests (TMT-A, TMT-B, COWAT, Wechsler Adult Intelligence Scale-III) at baseline and after intervention

Completion date
18/12/2023

Eligibility

Key inclusion criteria
1. Volunteers recruited from the general population
2. Between 30 and 65 years old
3. BMI between 23 and 35 kg/m2

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
30 years

Upper age limit
65 years

Sex
All

Key exclusion criteria
1. Diseased
2. Diabetics
3. Immunodeficiency or HIV-positive status
4. Liver cirrhosis or chronic renal failure
5. Serious psychiatric disorders: schizophrenia, bipolar disease, eating disorders, depression, etc
6. Any severe co-morbid condition
7. Alcohol abuse or addition
8. History of major organ transplantation
9. Concurrent therapy with immunosuppressive drugs or cytotoxic agents

10. Current treatment with systemic corticosteroids
11. Current use of weight loss medication
12. Patients with an acute infection or inflammation
13. Pregnant or breastfeeding women
14. Any other condition that may interfere with the completion of the study protocol

Date of first enrolment
20/12/2019

Date of final enrolment
01/06/2023

Locations

Countries of recruitment
Spain

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

Study participating centre
CIBER OBN
Instituto de Salud Carlos III. Calle Sinesio Delgado 10
Madrid
Spain
28029

Sponsor information

Organisation
University of Valencia

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

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 (Dr JV Sorlí, sorli@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