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Does a 12-hour fast influence weight loss and cardiovascular risk in people with obesity?

Submission date
09/12/2020

Recruitment status
No longer recruiting

Registration date
15/12/2020

Overall study status
Completed

Last Edited
15/12/2020

Condition category
Nutritional, Metabolic, Endocrine

[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
Currently, one of the most commonly employed strategies for reducing body weight in overweight or obese individuals is to reduce the number of calories in the diet and to increase physical activity. However, the desired success is not always achieved or secondary effects arise in the state of health. Another of the strategies put forward for achieving weight loss without focusing on reducing the calories in a diet is to act on the meal times. According to this strtategy, having earlier lunches or dinners is associated with greater weight loss and an reduced risk of suffering heart disease. These results have given rise to a boom in 'chrononutritional' research (looking at meal times). The main aim of this study is to get to know the effect that fasting for 12 hours has on weight loss, body composition, and heart disease risk in overweight or obese elderly population in comparison with a control group without any intervention.

Who can participate?
Healthy men and women from the general population (aged 18-65 years)

What does the study involve?
We will carry out a randomised parallel trial in healthy volunteers.
The intervention will consist of implementing, over six months, a 12-hour fasting period between the last evening-night food intake and the next intake during the morning of the following day. The intervention group will be able to choose the time they eat and without restriction, depending on each participant’s preference. This will be backed up by dietary and chronobiological advice in individual sessions, where recommendations on how to undertake and to maintain that fasting period over time will be provided. The control group will not undertake any fasting period and will continue to follow their normal dietary pattern. The participants in the intervention group will also maintain their customary diet so that both groups have a diet without any set calorie restrictions. The participants of both groups will be asked to continue with their habitual physical activity.

What are the possible benefits and risks of participating?
Participants will be informed that there are not 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 2020 to December 2022

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

Who is the main contact?
Prof. José V. Sorlí, sorli@uv.es

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
PCT1E-20

Study information

Scientific Title
Chronobiological influence of fasting time on weight loss and cardiovascular risk profile in an overweight or obese adult population: A randomized controlled trial

Acronym

FASTING-12

Study objectives
A 12-hour per day fasting period over 6 months compared to a restriction-free diet can modify weight loss and cardiovascular risk profile, as well as have an influence on the metabolome.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 04/12/2020, Institutional review board of Valencia University (Avda. Blasco Ibanez 13. Valencia, 46010, Spain; +34 963864109; vicerec.investigacio@uv.es), ref: UV-INV_ETICA-1501553

Study design
Interventional randomized parallel trial

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Obesity

Interventions
The intervention will consist of implementing, over six months, a 12-hour fasting period between the last evening-night food intake and the next intake during the morning of the following day.

Participants will be randomly assigned 1:1 to the order of the intervention by simple random assignment through a computer program.

The intervention group will be able to choose the time they eat and without restriction, depending on each participant's preference. This will be backed up by dietary and chronobiological advice in individual sessions, where recommendations on how to undertake and to maintain that fasting period over time will be provided.

The control group will not undertake any fasting period and will continue to follow their normal dietary pattern.

The participants in the intervention group will also maintain their customary diet so that both groups have an "at libitum" diet without any a priori calorie restrictions. The participants of both groups will be asked to continue with their habitual physical activity.

Intervention Type
Behavioural

Primary outcome(s)
Measured at baseline and during intervention (the first month, the third month and the sixth month):

1. Weight (kg)
2. Height (cm)
3. Waist circumference (cm)
4. Body composition measured by bioimpedance
5. Blood pressure and heart rate will be measured in triplicate using a validated semiautomatic oscillometer (Omron HEM-705CP, Netherlands) with 5 minutes of rest in-between measurements

Key secondary outcome(s))
At baseline and after the intervention:
1. Biochemistry (serum lipid concentrations, fasting glucose, glycated hemoglobin and uric acid) measured by blood and urine samples
2. Food intake and adherence to the Mediterranean diet will be measured using the 14-item Mediterranean diet adherence PREDIMED scale
3. The compliance with food and nutrient targets and dietary patterns will be evaluated using a validated 143-item food frequency questionnaire (FFQ)
4. Preference for different tastes will be measured using a Likert scale which has differents levels such as: 0-totally disagree to 3: totally agree
5. Physical activity will be measured using the short form of the Minnesota physical activity questionnaire
6. Sleep characteristics will be measured using the Pittsburgh Sleep Quality Index questionnaire
7. Chronotype will be measured using the Horne and Östberg questionnaire
8. Cognitive function will be measured using some tests (TMT-A, TMT-B, COWAT, Wechsler Adult Intelligence Scale-III)

Completion date
16/12/2022

Eligibility

Key inclusion criteria
1. Volunteers recruited from the general population
2. Between 18 and 65 years old
3. BMI between 25 and 40 kg/m²

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria

1. Individuals who have previously undergone diets that include fasting for a period of greater than 12 hours over the last year or who have undertaken a restricted calorie intervention over the last six months, and those who have skipped normal meal times as a dietary practice.
2. Pregnant or breast-feeding women
3. Individuals with infectious diseases.
4. Liver cirrhosis or chronic renal failure
5. Serious psychiatric disorders: schizophrenia, bipolar disease, eating disorders, depression, etc
6. Cancer
7. Alcohol abuse or addition
8. Current treatment with systemic corticosteroids
9. Current use of weight loss medication
10. Any other condition that may interfere with the completion of the study protocol

Date of first enrolment
17/12/2020

Date of final enrolment
01/04/2022

Locations

Countries of recruitment
Spain

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

Study participating centre
CIBER Fisiopatología de la Obesidad y Nutrición
Instituto de Salud Carlos III
Calle Sinesio Delgado 10
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

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 (Dr JV Sorlí) 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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes