

# The health implications of consuming processed meat deep-fried in extra virgin olive oil, with and without vegetables, within a cohort of cohabiting women

<b>Submission date</b> 09/08/2023	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 11/08/2023	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 01/09/2025	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Dietary habits have been one of the most stable factors in all of human sociocultural heritage. Currently, we are witnessing a revolution because these habits are undergoing significant changes, resulting in a major impact on nutritional status. The trend of studying the influence of different foods on each other to achieve a diet rich in various nutrients while maintaining dietary culture in the field of health is important, especially for our elders. Few studies demonstrate that the proper consumption of meat with a balanced percentage of fat and lean, combined with vegetables, can result in greater fat removal through the food bolus. Fats consumed without accompanying high fibre content may have a higher absorption in the stomach. Therefore, using a processed and modified animal product with 50% lean and 50% fat can provide adequate nutrition without increasing absorption when taken with vegetables.

The overall aim of this study is to evaluate the health effects of the intake of processed meat deep fried in extra virgin olive oil combined with vegetables versus the same intake without vegetables.

### Who can participate?

A community of cohabiting women with similar lifestyle habits in the city of Soria, Spain

### What does the study involve?

Participants will be randomly assigned to the control and experimental groups. Both groups will consume 150 g of pork crackling deep-fried in EVOO twice a week; the experimental group will combine the intake with 200 g of vegetables while the control group will not. For all the participants, the rest of their regular diet will remain unchanged. Participants' measurements will be collected at baseline, before starting the dietary intervention, at 55 and 98 days into the intervention, and 34 days after the intervention ends.

### What are the possible benefits and risks of participating?

The potential anticipated advantages include an improved lipid profile resulting from the

increased intake of EVOO in the control group, and both EVOO and fibre in the experimental group. There are no risks associated with participation in the study.

Where is the study run from?  
University of Valladolid (Spain)

When is the study starting and how long is it expected to run for?  
May 2021 to December 2021

Who is funding the study?  
Scientific Foundation of Caja Rural de Soria (Spain)

Who is the main contact?  
Patricia Romero-Marco, patricia.romero@uva.es

## Contact information

**Type(s)**  
Scientific

**Contact name**  
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## Additional identifiers

**Protocol serial number**  
CASVE-NM-21-525

## Study information

**Scientific Title**  
Effect of the consumption of processed meat and dietary fiber among older women

**Acronym**  
PROMEDIF

**Study objectives**  
This study hypothesizes that the combined intake of processed meat and dietary fiber, as opposed to the sole consumption of processed meat, could influence fat absorption and,

consequently, the lipid profile of the participants. This could lead to a reduction in total cholesterol levels in the combined consumption group compared to the sole processed meat consumption group.

### **Ethics approval required**

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### **Ethics approval(s)**

approved 01/07/2021, Ethics Committee for Research with Medications (c/ Ramón y Cajal, 7, Valladolid, 47005, Spain; +34 (0)983 423077; jalvarezgo@saludcastillayleon.es), ref: CASVE-NM-21-525

### **Study design**

Single-center randomized controlled clinical trial

### **Primary study design**

Interventional

### **Study type(s)**

Other, Prevention, Quality of life, Efficacy

### **Health condition(s) or problem(s) studied**

Consumption of processed meat and dietary fiber

### **Interventions**

Randomized controlled clinical trial conducted within a community of women with similar lifestyle habits, where twice a week for a period of 98 days, one group (experimental) consumes 150 g of pork crackling along with 200 g of vegetables, and another group (control) consumes 150 g of pork crackling. Participants will be assigned a unique study identification number that will be randomly allocated (50% of participants in each group), without knowledge of the investigators collecting the samples or those analyzing them.

### **Intervention Type**

Behavioural

### **Primary outcome(s)**

Measured fasting at baseline, 55, 98 and 132 days:

1. BMI measured using a bioimpedance analyzer and a talmeter. Waist circumference is measured using a non-stretch tape measure halfway between the last rib and the iliac crest to the nearest millimeter by a trained nutritionist.
2. Systolic and diastolic blood pressure collected with an OMRON BP7200 upper arm blood pressure monitor
3. Blood lipids measured are taken in fasting status from arterial blood by trained nurses

### **Key secondary outcome(s)**

Measured fasting at baseline, 55, 98 and 132 days:

1. Fat mass and fat-free mass measured using a bioimpedance analyzer
2. Heart rate measured with an OMRON BP7200 upper arm blood pressure monitor

### **Completion date**

31/12/2021

# Eligibility

## Key inclusion criteria

1. Female gender
2. Homogeneous dietary habits
3. Very similar lifestyle habits
4. Signing the informed consent

## Participant type(s)

Healthy volunteer

## Healthy volunteers allowed

No

## Age group

Adult

## Sex

Female

## Total final enrolment

41

## Key exclusion criteria

1. Diagnosed with dementia
2. Swallowing difficulty
3. Diagnosed with hypercholesterolemia

## Date of first enrolment

02/07/2021

## Date of final enrolment

15/11/2021

# Locations

## Countries of recruitment

Spain

## Study participating centre

Religious institution of the Clares in Soria

Spain

42002

# Sponsor information

## Organisation

University of Valladolid

## ROR

<https://ror.org/01fvbaw18>

## Funder(s)

### Funder type

Research organisation

### Funder Name

Scientific Foundation of Caja Rural de Soria

## Results and Publications

### Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be available upon request from Patricia Romero Marco ([patricia.romero@uva.es](mailto:patricia.romero@uva.es)). Informed consent was obtained from each and every participant, outlining the study's objectives, and procedures, as well as data anonymization and ethical and/or legal constraints. The data will be accessible from July 2022 to December 2025 upon request via email. Aggregate data pertaining to body composition, lipid profile, and biomarkers from any of the evaluation time points will be shared. Individual data will not be disclosed in any case.

### IPD sharing plan summary

Available on request

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>		16/05/2025	01/09/2025	Yes	No