ISRCTN15421598 https://doi.org/10.1186/ISRCTN15421598

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

Submission date
09/08/2023

Recruitment status
No longer recruiting

Registration date
11/08/2023

Overall study status
Completed

Last Edited
11/08/2023

Condition category
Nutritional, Metabolic, Endocrine

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

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
Dr Patricia Romero-Marco

ORCID ID
http://orcid.org/0000-0002-7020-7109

Contact details
C/ Universidad s/n
Soria
Spain
42005
+34 (0)637289401
patricia.romero@uva.es

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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
Ethics approval required

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

Secondary study design
Randomised controlled trial

Study setting(s)
Laboratory, Medical and other records, Other

Study type(s)
Other, Prevention, Quality of life, Efficacy

Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet

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 measure
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

Secondary outcome measures
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

Overall study start date
02/05/2021

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

Age group
Adult

Sex
Female

Target number of participants
42

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

Sponsor details
University Campus Duques de Soria
C/ Universidad, s/n
Valladolid
Spain
42004
+34 (0)975 12 91 00
unidad.administrativa.soria@uva.es

Sponsor type
University/education

Website
http://www.uva.es/export/sites/uva/

ROR
https://ror.org/01fvbaw18

Funder(s)

Funder type
Research organisation

Funder Name
Scientific Foundation of Caja Rural de Soria

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
30/09/2023

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). 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