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# Effect of nut consumption on semen quality and functionality in healthy males

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|---|---|---|
| **Submission date**<br>20/05/2016 | **Recruitment status**<br>No longer recruiting | [_] Prospectively registered<br>[_] Protocol<br>[_] Statistical analysis plan<br>[X] Results<br>[_] Individual participant data |
| **Registration date**<br>25/05/2016 | **Overall study status**<br>Completed | |
| **Last Edited**<br>09/06/2025 | **Condition category**<br>Other | |

## Plain English summary of protocol

Background and study aims
Human semen quality has declined in industrialized nations, with pollution, smoking, and trends toward a Western-style diet as possible causes. Although the importance of diet to human reproductive success is clear, existing dietary recommendations primarily focus on women's reproductive health with less attention given to men. Because nuts have a considerable amount of several nutrients that are involved in male fertility, we believe that tree nut consumption added to a Western-style diet would improve semen quality and functionality. The aim of this study is to evaluate the effect of eating tree nuts on semen quality.

Who can participate?
Healthy men aged between 18 and 35

What does the study involve?
Participants are randomly allocated to one of two groups. One group continues to consume their usual diet supplemented with 60 g per day of a mixture of raw nuts. The other group continues to consume their usual diet, avoiding consumption of nuts. Blood and sperm samples are collected at the start of the study and after 14 weeks to assess sperm quality.

What are the possible benefits and risks of participating?
Participation in the study may help the participants to better understand their health. The information obtained may benefit other patients in the future and contribute to a better understanding of the effect of nut consumption on male fertility. There are no health risks involved in this study. The extraction of the blood sample can cause a burning sensation at the point where the needle is inserted and can cause a small bruise which disappears in a few days. More rarely it can cause transient dizziness.

Where is the study run from?
1. Universitat Autònoma de Barcelona (Spain)
2. Universitat Rovira i Virgili (Spain)

When is the study starting and how long is it expected to run for?
September 2015 to August 2017

Who is funding the study?
INC International Nut and Dried Fruit Council Foundation (Spain)

Who is the main contact?
Dr Mònica Bulló Bonet
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# Contact information

### Type(s)
Scientific

### Contact name
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# Additional identifiers

# Study information

### Scientific Title
Effect of nut consumption on semen quality and functionality in a cohort of healthy males

### Acronym
FERTINUTS

### Study objectives
Because nuts have a considerable amount of several nutrients that have been implicated in the modulation of several mechanism implicated in male fertility, we hypothesize that tree nut consumption added to a Western-style diet would beneficially affect semen quality and functionality.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Comitè d'Ètica d'Investigació Clínica (Hospital Universitari Sant Joan de Reus), 29/10/2015, Ref. CEIC: 15-10-29/10aclaassN1

### Primary study design
Interventional

### Study design
Randomized 14-week parallel two-group dietary intervention trial with single-blind masking of outcome assessors

### Study type(s)
Treatment

### Health condition(s) or problem(s) studied
Semen quality and functionality

### Interventions
Participants will be randomly assigned to one of two intervention groups for 14 weeks:
1. Continue to consume their usual diet supplemented with 60 g/day of a mixture of raw nuts.
2. Continue to consume their usual diet, avoiding consumption of nuts.

### Intervention Type
Supplement

### Primary outcome(s)
Improvement of sperm vitality and motility. Semen samples will be collected at baseline and the end of the intervention period. All men will be instructed to abstain for 3 days prior to providing the study specimen, with abstinence period verified by self-report on day of sample collection. Semen samples will be collected allowing analysis within 60 min of sample production. A single researcher, who was blinded as to intervention versus control group status, will perform the conventional semen analyses. For the rest of analysis aliquots of semen will be frozen at -196°C until analysis.

### Key secondary outcome(s)
Semen samples will be collected at baseline and the end of the intervention period:
1. Other conventional semen parameters
2. Plasma lipid profile, glucose and insulin concentrations
3. Serum folic acid and alpha-linolenic concentrations
4. Sperm DNA fragmentation
5. Sperm ROS evaluation
6. Sperm miRNA expression profiles
7. Sperm DNA methylation
8. Sperm chromosome stability

### Completion date
31/08/2017

## Eligibility

### Key inclusion criteria
1. Healthy males
2. 18-35 years old
3. Reported a western-style diet

**Participant type(s)**
Healthy volunteer

**Healthy volunteers allowed**
No

**Age group**
Adult

**Lower age limit**
18 Years

**Upper age limit**
35 Years

**Sex**
Male

**Total final enrolment**
119

**Key exclusion criteria**
1. Frequent consumption of nuts or a known history of allergy
2. Use of plant sterol or fish oil supplements and multivitamins, vitamin E or other antioxidant supplements
3. History of reproductive disorders or vasectomy
4. Current smokers
5. Taking antioxidant supplements or medications for chronic illness
6. Use of illegal drugs

**Date of first enrolment**
02/12/2015

**Date of final enrolment**
30/09/2016

# Locations

**Countries of recruitment**
Spain

**Study participating centre**
**Universitat Autònoma de Barcelona**
Facultat Biociències, Edifici C, despatx C2/-120
Bellaterra (Cerdanyola del Vallès)
Spain
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**Study participating centre**
**Universitat Rovira i Virgili**
C/Sant Llorenç, 21
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# Sponsor information

**Organisation**
INC International Nut and Dried Fruit Council Foundation (Spain)

**ROR**
https://ror.org/030wfqt16

# Funder(s)

**Funder type**
Other

**Funder Name**
INC International Nut and Dried Fruit Council Foundation (Spain)

# Results and Publications

## Individual participant data (IPD) sharing plan

**IPD sharing plan summary**
Available on request

**Study outputs**

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | | 01/11/2018 | | Yes | No |
| Results article | | 04/03/2019 | | Yes | No |
| Results article | | 19/06/2019 | 20/06/2019 | Yes | No |
| Basic results | | 29/11/2018 | 29/11/2018 | No | No |
| Other publications | Cross-sectional and prospective analysis | 29/04/2024 | 09/06/2025 | Yes | No |