

# Relationship between a low fructose consumption and insulin resistance

<b>Submission date</b> 04/11/2016	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 15/11/2016	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 06/05/2020	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Insulin resistance (IR) is a condition in which the cells of the body do not respond normally to the hormone insulin, leading to high blood sugar levels. IR is a strong predictor for the development of type 2 diabetes mellitus and cardiovascular disease (heart and blood vessel disease). Fructose (a natural sugar found in plants) has become a widely-used additive in many food industry products such as soft drinks and nonalcoholic beverages, generally in the form of fructose-enriched corn syrup. The aim of this study is to determine whether a low fructose diet supervised by a physician or nurse decreases IR compared to a standard diet.

### Who can participate?

Overweight and obese adults aged between 29 and 66.

### What does the study involve?

Health care zones are randomly allocated to one of two groups. Those in the first group are asked to follow a low fructose diet. Those in the second group are advised to eat a standard diet. The calories in diets in both groups contain around 30-40% less than each individual's calorie requirements to help them to lose weight. Participants in both groups provide blood samples at the start of the study and then again after 24 and 48 weeks to assess insulin resistance. In addition, the cholesterol and fat levels in the blood and their BMI are measured at the same timepoints.

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

There are no direct benefits involved with participating. There is a small risk of pain, bruising or bleeding when blood samples are taken.

### Where is the study run from?

Primary care centers in the island of Tenerife (Canary Islands, Spain)

### When is the study starting and how long is it expected to run for?

May 2012 to December 2017

Who is funding the study?

1. Instituto de Salud Carlos III (Spain)
2. Fundacion Caja Canarias (Spain)

Who is the main contact?

Dr Santiago Domínguez-Coello

sdomcoe@gobiernodecanarias.org

## Contact information

### Type(s)

Scientific

### Contact name

Dr Santiago Dominguez Coello

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## Additional identifiers

EudraCT/CTIS number

IRAS number

**ClinicalTrials.gov number**

**Secondary identifying numbers**

ISCT 012/00231 and OBE04/2013

## Study information

**Scientific Title**

Effect of a diet low in fructose and sucrose on insulin resistance: clinical trial in primary care

**Acronym**

DISFRUTE

**Study objectives**

A low fructose/sucrose diet reduces insulin resistance more than a standard diet.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

CEIC Hospital Universitario Nuestra Señora de Candelaria-Tenerife-Canary Islands Spain, 23/05/2012, ref: 160

**Study design**

Single-blind multi-centre randomised controlled trial

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

GP practice

**Study type(s)**

Prevention

**Participant information sheet**

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

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

Insulin resistance

**Interventions**

Participants are randomized by health care zone to one of two groups.

Low-fructose diet intervention (LFDI) group: Participants are assigned to health centers in the western zone of Tenerife island. They are advised to eat a low-fructose diet (1000, 1250, 1500,

1750, 2000, 2250, 2500 or 2750 kcal/day). Low-fructose diets are designed by calculating free and total (free + fructose associated with sucrose) fructose contents in standard diets. Foods with a fructose content in the highest quartile for the amounts corresponding to the standard diet are removed from the standard diet.

**Standard diet control (SDC) group:** Participants are assigned to health centers in the eastern zone of the island. They are advised to eat a standard diet (recommended by the Canary Health Service).

The kcal/day in the prescribed diets are calculated as 30% or 40% less than the kcal/day in the participant's energy requirements for his or her ideal weight according to age, sex and physical activity.

Follow up for all participants takes place at 4, 8, 12, 20, 24 and 48 weeks, and involves nutrition counseling and reinforcement, as well as the measure of weight, waist circumference and blood pressure.

### **Intervention Type**

Other

### **Primary outcome measure**

Insulin resistance is estimated from fasting serum glucose (measured with enzymatic methods) and insulin concentrations (measured with a chemiluminescence immunoassay method) with a computer-based Homeostasis Model Assessment system (HOMA2-IR) at baseline, 24 and 48 weeks.

### **Secondary outcome measures**

1. Body mass index is determined using weight and height measurements at baseline, 4, 8, 12, 20, 24 and 48 weeks
2. Waist circumference is determined using a nonstretchable measuring tape at baseline, 4, 8, 12, 20, 24 and 48 weeks
3. Total Cholesterol, HDL cholesterol and triglycerides are measured using enzymatic methods at baseline, 24 and 48 weeks. LDL cholesterol is calculated using the Friedewald formula

### **Overall study start date**

31/05/2012

### **Completion date**

01/04/2018

## **Eligibility**

### **Key inclusion criteria**

1. Age between 29-66 years
2. BMI between 29 and 40.99 kg/m<sup>2</sup>

### **Participant type(s)**

Patient

### **Age group**

Adult

**Sex**

Both

**Target number of participants**

245 in each group

**Total final enrolment**

438

**Key exclusion criteria**

1. Pregnancy (female participants only)
2. Behavioral eating disorders
3. Relevant gastrointestinal disease (ulcerating colitis, Crohn's disease, celiac disease, digestive tract cancer)
4. Excessive alcohol consumption (>28 U or 280 g/week in men, > 17 U or 168 g/week in women)
5. Severe cardiovascular disease
6. Diabetes,
7. Polycystic ovary disease
8. Treatment with any medication that could alter insulin sensitivity or body weight (corticosteroids, antipsychotics, antidepressants)
9. Pharmacological treatment for clinical or subclinical hypothyroidism
10. Hyperthyroidism
11. Depression
12. Psychosis
13. Microalbumin/creatinine ratio >100 mg/g or stage IIIB or higher chronic kidney disease (glomerular filtration rate < 45 mL/min)
14. Use of medication requiring frequent dose adjustments
15. Low intellectual or mental functioning that could interfere with the participant's compliance with the recommendations
16. If the result of the glucose overload test is blood glucose  $\geq 200$  mg/dL the participant is excluded if the physician opts to add medication or insulin to the dietary and physical exercise regime.

**Date of first enrolment**

01/05/2014

**Date of final enrolment**

30/06/2017

**Locations****Countries of recruitment**

Spain

**Study participating centre**

**Centro de Salud (CS) de La Victoria de Acentejo**

C/Domingo Salazar 21

La Victoria de Acentejo

Spain  
38380

**Study participating centre**  
**CS La Matanza de Acentejo**  
Carretera General del Norte  
Ermita  
La Matanza de Acentejo  
Spain  
38370

**Study participating centre**  
**CS Santa Úrsula**  
C/Calvo Sotelo s/n  
Santa Ursula  
Spain  
38390

**Study participating centre**  
**Consultorio La Perdoma**  
C/ Manuel Vega Santos, nº 7  
La Orotava  
Spain  
38315

**Study participating centre**  
**CS Los Realejos**  
C/San Isidro nº 10  
Los Realejos  
Spain  
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**Study participating centre**  
**CS Casco Botánico**  
Carretera Las Dehesas nº 8  
Puerto de La Cruz  
Spain  
38400

**Study participating centre**

**CS Tacoronte**

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**Study participating centre**

**Consultorio La Esperanza**

Carretera Sardinera s/n  
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**Study participating centre**

**Consultorio Valle Guerra**

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La Laguna  
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**Study participating centre**

**CS Taco**

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Santa Cruz de Tenerife  
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**Study participating centre**

**CS Guimar**

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**Study participating centre**

**CS Barranco Grande**

Calle Ruiseñor, s/n  
Santa Cruz de Tenerife  
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**Study participating centre****CS Ofra Delicias**

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**Study participating centre****CS Toscal-Centro**

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**Study participating centre****CS Finca España**

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**Study participating centre****Consultorio Igueste de Candelaria**

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## **Sponsor information**

**Organisation**

Fundación Canaria de Investigación Sanitaria

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**Sponsor type**

Research organisation

**Website**

www.funcanis.org

**ROR**

<https://ror.org/03vhx9d88>

## Funder(s)

**Funder type**

Government

**Funder Name**

Instituto de Salud Carlos III

**Alternative Name(s)**

SaludISCI, InstitutodeSaludCarlosIII, Instituto de Salud Carlos III | Madrid, Spain, Carlos III Institute of Health, Institute of Health Carlos III, Carlos III Health Institute, ISCI

**Funding Body Type**

Government organisation

**Funding Body Subtype**

National government

**Location**

Spain

**Funder Name**

Fundacion Caja Canarias

**Funder Name**

Fundación DISA: premios de investigación médica 2018

## Results and Publications

## Publication and dissemination plan

Planned publication of the study protocol immediately once the trial is registered. This protocol details how all foods and nutrient contents were obtained. Planned submission of the results for publication during the first months of 2019.

## Intention to publish date

01/04/2019

## Individual participant data (IPD) sharing plan

The datasets generated and analysed during the current study will be available upon request from Santiago Domínguez-Coello (sdomcoe@gobiernodecanarias.org; sdominguezc@telefonica.net) once this study has been published. These datasets will be available at any time and will be anonymous. All the requirements will have to be motivated on specific scientific reasons which must be detailed.

## IPD sharing plan summary

Available on request

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol article</a>	protocol	07/08/2017		Yes	No
<a href="#">Basic results</a>		14/01/2018	14/01/2019	No	No
<a href="#">Basic results</a>		03/12/2019	03/12/2019	No	No
<a href="#">Results article</a>	results	19/04/2020	06/05/2020	Yes	No