

# Lifestyle programme in obese children with non-alcoholic fatty liver disease

|                                        |                                                                |                                                      |
|----------------------------------------|----------------------------------------------------------------|------------------------------------------------------|
| <b>Submission date</b><br>05/02/2015   | <b>Recruitment status</b><br>No longer recruiting              | <input type="checkbox"/> Prospectively registered    |
|                                        |                                                                | <input type="checkbox"/> Protocol                    |
| <b>Registration date</b><br>12/02/2015 | <b>Overall study status</b><br>Completed                       | <input type="checkbox"/> Statistical analysis plan   |
|                                        |                                                                | <input checked="" type="checkbox"/> Results          |
| <b>Last Edited</b><br>09/08/2018       | <b>Condition category</b><br>Nutritional, Metabolic, Endocrine | <input type="checkbox"/> Individual participant data |

## Plain English summary of protocol

### Background and study aims

There is evidence that family dietary education programmes are effective in children with obesity, but there is little evidence of this in children with non-alcoholic fatty liver disease (a build-up of fat in the liver cells). The aim in this study is to assess the effect of a nutritional counselling programme on hepatic abnormalities associated with non-alcoholic fatty liver disease in obese children.

### Who can participate?

Children who are obese and have non-alcoholic fatty liver disease

### What does the study involve?

Patients will have a clinical assessment and liver function tests at baseline and after 4 months of intervention. They will attend nutrition counselling sessions with their parents or guardians every 15 days.

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

The possible benefits are body-mass index reduction and improvement in the primary alterations in liver function associated with non-alcoholic fatty liver disease in obesity. Risks not provided at time of registration.

### Where is the study run from?

Pediatric Hospital of the National Medical Center XXI Century (Mexico)

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

From October 2008 to December 2012

### Who is funding the study?

National Council of Science and Technology (Mexico)

### Who is the main contact?

Dr Segundo Moran

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# Contact information

## Type(s)

Scientific

## Contact name

Dr Segundo Moran

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## Contact details

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# Additional identifiers

## Protocol serial number

2006/3603/022

# Study information

## Scientific Title

Effect of lifestyle intervention in children with obesity and non-alcoholic fatty liver disease

## Study objectives

The lifestyle of children with obesity and non-alcoholic fatty liver disease can improve with a lifestyle intervention programme

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Ethics board of the Pediatric Hospital at the National Medical Center Century XXI of the Mexican Institute of Social Security (Mexico), 02/05/2006, 37B5032500/232/06

## Primary study design

Interventional

## Study design

Interventional single-centre study

## Study type(s)

Treatment

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

Non-alcoholic liver disease

**Interventions**

From the start of the study and every 15 days thereafter during 4 months, both children and their parents in small groups had one-hour sessions conducted by a dietitian and a medical doctor. These sessions provided educational material about the importance of adequate food intake, with emphasis on lowering the amount of refined sugar and sugary sodas, reducing the amount of carbohydrates and fat consumed every day, and increasing the amount of fibre.

**Intervention Type**

Behavioural

**Primary outcome(s)**

At baseline and after 4 months of intervention:

1. Clinical evaluation
2. Liver function tests

**Key secondary outcome(s)**

Lipid profile at baseline and after 4 months of intervention

**Completion date**

14/12/2012

## **Eligibility**

**Key inclusion criteria**

1. Age 6–16 years old
2. Obesity
3. Non-alcoholic fatty liver disease (ultrasound findings of steatosis, alanine aminotransferase > 40 U/L and alanine aminotransferase to aspartate aminotransferase ratio > 1)
4. No other cause of liver disease

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Child

**Lower age limit**

6 Years

**Upper age limit**

16 Years

**Sex**

All

**Key exclusion criteria**

1. History of medication misuse
2. Alcohol misuse
3. Hepatitis C
4. Hepatitis B
5. Wilson's disease

**Date of first enrolment**

01/10/2008

**Date of final enrolment**

17/12/2010

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

Mexico

**Study participating centre**

**Pediatric Hospital of the National Medical Center XXI Century**

Avenida Cuauhtémoc 330

Colonia Doctores

Mexico

Mexico

06725

**Sponsor information****Organisation**

Fondo para el Fomento de la Investigación en Salud

**Funder(s)****Funder type**

Government

**Funder Name**

Consejo Nacional de Ciencia y Tecnología (Mexico)

# 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? |
|---------------------------------|---------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a> | results | 01/01/2017   |            | Yes            | No              |