

# Psycho-nutritional intervention to reduce weight and improve body image and self-esteem in people who are overweight or obese

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		<input type="checkbox"/> Protocol
<b>Registration date</b> 10/11/2023	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 10/11/2023	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

The current growing levels of prosperity have led to habits such as inactivity and high-calorie diets, which can result in overweight and obesity. These diseases are associated with decreases in self-esteem and deterioration of body image, ultimately leading to psychological disorders such as depression and anxiety. The aim of this study is to assess the suitability of a psycho-nutritional model to improve the perception of body image and increase the self-esteem of individuals who are overweight or obese.

### Who can participate?

Overweight and obese individuals who are aged between 25 and 70 years old

### What does the study involve?

The study involves a cognitive-behavioral and nutritional intervention and there will be measurements of weight, self-esteem, and perception of body image obtained at specific time points throughout the study.

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

The possible benefits include weight loss and improvements in self-esteem and body image. There are no expected risks.

### Where is the study run from?

San Antonio Catholic University of Murcia (Universidad Católica San Antonio de Murcia) (Spain)

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

March 2015 to March 2018

### Who is funding the study?

Investigator initiated and funded

Who is the main contact?

Elvira González Fernández, [egonzalez495@alu.ucam.edu](mailto:egonzalez495@alu.ucam.edu)

## Contact information

### Type(s)

Public, Scientific, Principal Investigator

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Principal Investigator

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## Additional identifiers

### EudraCT/CTIS number

Nil known

### IRAS number

### ClinicalTrials.gov number

Nil known

## **Secondary identifying numbers**

CPMS55773

# **Study information**

## **Scientific Title**

Psycho-nutritional intervention to improve the self-concept of body image and increase self-esteem of overweight and obese individuals

## **Study objectives**

The aim of the present study was to assess the suitability of a psycho-nutritional model to improve the perception of body image and increase the self-esteem of individuals who are overweight or obese

## **Ethics approval required**

Ethics approval required

## **Ethics approval(s)**

Approved 22/07/2022, Catholic University of Murcia (UCAM) (Campus de los Jerónimos s/n. 30107 Guadalupe, Murcia., 30107, Spain; +34968278800; info@ucam.edu), ref: CE072205

## **Study design**

Quasi-experimental study with repeated pretest-posttest measurements

## **Primary study design**

Interventional

## **Secondary study design**

Randomised controlled trial

## **Study setting(s)**

Other therapist office

## **Study type(s)**

Treatment

## **Participant information sheet**

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

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

Overweight and obese individuals

## **Interventions**

This is a quasi-experimental study with repeated pretest-posttest measurements of a single group, without a group control, with three differentiated moments in time (pretest, posttest, and follow-up a year after the end of the therapeutic process).

The procedure will be implemented in such a way that initial significant achievements in overweight and obesity are obtained through a psycho-nutritional program. This intervention will begin in 2015 with data collected until 2018, by asking for the voluntary, anonymous, and confidential participation of users who visited a private clinical nutrition center in Galicia (Spain) to ask for services to treat overweight and obesity. A cognitive-behavioral and nutritional intervention is applied. The intervention will be performed by a psychologist who is also a nutritionist. Thus, the users are informed that they will be assigned a numerical tag to associate their data, which are collected at three separate points in time (before the intervention [pretest], at the end of the intervention [post-test], and a year after discharge [follow-up]). Before collecting information, the participants were informed in detail about the objectives and the content of the study, after which they signed the informed consent form. At all times, they have ensured the confidentiality of the information collected, according to the ethical guidelines of the Declaration of Helsinki, aside from the approval from the Ethics Committee from the Catholic University of Murcia, Spain.

The number of kilos lost in each case will be agreed upon with the users, who are also informed that the intervention will last between 15 to 20 weekly therapeutic sessions through which reductions in weight between 1 and 5 kg can be obtained.

### **Intervention Type**

Behavioural

### **Primary outcome measure**

1. Weight measured using a digital floor scale at the end of the intervention and at follow-up (a year after the end of the intervention)

### **Secondary outcome measures**

The following secondary outcome measures were assessed before the intervention (at the pretest), at the end of the intervention (posttest) and a year after discharge (follow-up):

1. Self-esteem measured using the Rosenberg Self-Esteem Scale (RSES)
2. Self-evaluation of body image using the Body-Esteem Scale (BES)

### **Overall study start date**

19/03/2015

### **Completion date**

25/07/2023

## **Eligibility**

### **Key inclusion criteria**

1. Men and women
2. Between 25 and 70 years old
3. Overweight and obese individuals

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

Patient

### **Age group**

Mixed

**Lower age limit**

25 Years

**Upper age limit**

70 Years

**Sex**

Both

**Target number of participants**

55

**Total final enrolment**

55

**Key exclusion criteria**

1. Normal weight
2. Over 70 years old
3. Under 25 years of age

**Date of first enrolment**

20/03/2018

**Date of final enrolment**

07/03/2020

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

Spain

**Study participating centre****Euromedical**

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Pontevedra

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**Sponsor information****Organisation**

Universidad Católica San Antonio de Murcia

**Sponsor details**

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**Sponsor type**

University/education

**Website**

<http://international.ucam.edu/>

**ROR**

<https://ror.org/05b1rsv17>

## **Funder(s)**

**Funder type**

Other

**Funder Name**

Investigator initiated and funded

## **Results and Publications**

**Publication and dissemination plan**

Planned publication in a high-impact peer-reviewed journal

**Intention to publish date**

01/12/2023

**Individual participant data (IPD) sharing plan**

The datasets generated during and/or analysed during the current study will be available upon request from Elvira González Fernández (evirgalicia@gmail.com). The data that will be provided will be the results obtained in the different measurement instruments used, always from the confidentiality and anonymity of the participants who gave their consent.

**IPD sharing plan summary**

Available on request