

# Neurocognition and emotional regulation in extreme weight conditions: study of brain activity and cognitive changes associated with an intervention based on a therapeutic videogame

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<b>Last Edited</b> 17/08/2018	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

Background and study aims:

Extreme weight conditions can be resistant to treatment in some cases, especially when linked to eating disorders. The first aim of this study is to assess the brain activity, impulsivity and emotional stimuli response of patients with abnormal eating and situations of altered weight (i. e.: underweight with anorexia (AN) or overweight/obesity with bulimia nervosa (BN) or binge eating disorder (BED)) compared to healthy women. The second aim is to evaluate the short-term effectiveness of Playmancer, a therapeutic videogame designed to improve emotion regulation and impulsivity control.

Who can participate?

Women aged 18-60 referred to the Eating Disorder Unit of the Bellvitge University Hospital (AN-underweight or BN/BED-overweight), and women of the same age range with no mental health conditions

What does the study involve?

All participants are assessed at the start of the study with a psychological and neuropsychological tests and an electroencephalogram (EEG) (a recording of brain activity). After the assessment patients are randomly allocated to either treatment as usual (Cognitive Behavioral Therapy [CBT]) or treatment as usual and Playmancer. Patients with AN receive 12 weeks of CBT treatment while in day care; patients with BN/BED and obesity or overweight receive 16 weekly session of CBT treatment in outpatient premises. The Playmancer intervention consists of nine 20-minute sessions over 3 weeks (3 sessions per week). Changes in neuronal activity and functioning are evaluated at 4 weeks and at the end of treatment.

What are the possible benefits and risks of participating?

Although the neural changes associated with Playmancer treatment have not yet been studied,

the effectiveness of Playmancer has been proved in different populations and it is associated with improved emotion regulation and decreased impulsivity. Patients may benefit from receiving Playmancer treatment and if they do not receive Playmancer they still receive treatment as usual. There are no risks associated with the study.

Where is the study run from?

1. Bellvitge University Hospital (Spain)
2. University of Granada: Centro de Investigación Mente, Cerebro y Comportamiento (CIMCYC) (Spain)

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

January 2016 to August 2019

Who is funding the study?

1. Instituto de Salud Carlos III
2. European Regional Development Fund
3. Ministerio de Educación, Cultura y Deporte

Who is the main contact?

1. Dr Fernando Fernández-Aranda
2. Dr Núria Mallorquí-Bagué

## Contact information

### Type(s)

Scientific

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## Additional identifiers

**Protocol serial number**  
PR146/14

## Study information

### Scientific Title

Neurocognition and emotional regulation in extreme weight conditions: study of brain activity and cognitive changes associated with an intervention based on a therapeutic videogame

### Study objectives

This study aims to test if two extreme weight conditions groups (i.e.: Anorexia Nervosa-underweight and Bulimia Nervosa/Binge Eating Disorder-overweight/obesity) present some shared processes of brain activity and neuropsychological-clinical functioning underlying impulsivity and emotion regulation which differ from the ones observed in healthy controls. It also aims to assess if the two clinical groups are differentiated by specific patterns underlying impulsivity and emotion regulation. Finally, it tests if the therapeutic videogame (Playmancer) efficiently enhance emotion regulation and impulsivity control when measured through neurophysiological (EEG) and cognitive functioning techniques.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

University Bellvitge Hospital Research Ethics Committee, 21/01/2016, ref: PR146/14

### Primary study design

Interventional

### Study design

Interventional randomised controlled trial

### Study type(s)

Treatment

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

Eating disorders and extreme weight conditions (i.e.: underweight- Anorexia (AN), overweight /obesity-Bulimia Nervosa (BN)/Binge Eating Disorder (BED)

### Interventions

Participants are randomly allocated to two different interventions:

1. Treatment as usual (TAU, which is Cognitive Behavioral Therapy [CBT])
2. TAU + Playmancer (a therapeutic videogame to improve emotional regulation through biofeedback techniques)

The TAU is part of daily clinical practice and is a protocolized CBT intervention which has been proven to be effective for eating disorders. Patients with Anorexia Nervosa receive 12 weeks of CBT treatment while in day care; patients with Bulimia Nervosa (BN)/Binge Eating Disorder (BED) and obesity or overweight receive 16 weekly sessions of CBT treatment in outpatient premises. The Playmancer intervention consists of nine 20-minute sessions which are implemented during 3 weeks (3 sessions per week).

At a baseline level, a healthy control group (HC) is recruited which is matched in age and education level with the participants of the intervention groups.

## **Intervention Type**

Behavioural

## **Primary outcome(s)**

Primary outcome measures at baseline (cross-sectional study): differences between the three groups: AN-underweight, BN/BED-overweight/obesity, healthy controls (HC)

Primary outcome measures for the intervention (randomized clinical trial): differences in changes between the two intervention groups in two different extreme weight conditions.

The two clinical groups are assessed at three different timepoints: 1) baseline before starting treatment (pre), 2) after 4 weeks of treatment coinciding with the end of the Playmancer intervention (Post 1) and 3) at the end of treatment (Post 2). The HC is only part of the baseline assessment.

Assessment battery:

1. Emotion regulation and impulsivity measures (Pre-Post 1- Post 2): UPPS -P Conducta Impulsiva Scale (Whiteside y Lynam , 2001), Escala de dificultades en la Regulación Emocional Escala (Ders; Gratz y Roemer , 2004), Cuestionario de Regulación Emocional (ERQ; Gross & John, 2003), Yale Food Addiction Scale (YFAS; Gearhardt et al., 2009)
2. Neuropsychological measures. Pre-Post 1-Post 2: Stroop Colours and Words Test (SCWT; Stroop, 1935; Golden, 1978), Iowa Gambling Task (IGT): (IGT; Bechara et al., 1994), Continuous Performance Test-II (CPT-II; Conners & Staff, 2000). Pre: Subtest de Vocabulario de la Wechsler Adult Intelligence Scale-III (WAIS-III)
3. Neurophysiological measures (EEG) (Pre-Post 1-Post 2). Three paradigms: emotion regulation task, craving regulation task, emotion go no go task. Event-related potentials will be analyzed for the different paradigms

## **Key secondary outcome(s)**

1. Clinical measures (Pre, Post 1, Post 2): Symptom CheckList-90 items-Revised (SCL-90-R; Derogatis et al., 1977), Eating Disorders Inventory- 2 (EDI-2; Garner, 1991), Screening diagnóstico SCID-I para trastornos mentales del Eje I (First, 1996)
2. Personality scale (Pre): Temperament and Character Inventory-Revised (TCI-R; Cloninger, 1999)
3. Weight, height and Body Mass Index (Pre, Post 1, Post 2): TANITA MC-180 Multifrecuencia. (TANITA 8, Bioimpedancia)

## **Completion date**

01/08/2019

## **Eligibility**

### **Key inclusion criteria**

1. Female gender
2. Age 18-60
3. Eating disorder patients must be diagnosed following DSM-5 criteria
4. Eating disorder patients must present a BMI (Body mass index)  $\leq 18.5$  or BMI  $\geq 25$
5. Healthy control individuals must be normoweight and present no psychiatric/neurological condition

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Lower age limit**

18 Years

### **Upper age limit**

60 Years

### **Sex**

Female

### **Key exclusion criteria**

1. History of medical chronic disease, neurological condition, learning disorder or intellectual disabilities that could be affecting cognitive functioning
2. Use of psychostimulant or any unprescribed drug during the last 6 months. Changes in medication regime, such as type of drug and dose
3. Male gender
4. For patients with obesity/overweight, to have previously suffered from Anorexia Nervosa
5. For patients with Anorexia Nervosa, to have previously suffered from Bulimia Nervosa or Binge Eating Disorder or presented overweight/obesity
6. In patients with obesity, to suffer from endocrine obesity (excepting hypothyroidism under treatment) and to not present and eating disorder

### **Date of first enrolment**

01/06/2016

### **Date of final enrolment**

01/09/2018

## **Locations**

### **Countries of recruitment**

Spain

### **Study participating centre**

Bellvitge University Hospital-IDIBELL

Spain

08907

**Study participating centre**

University of Granada: Centro de Investigación Mente, Cerebro y Comportamiento (CIMCYC)

Spain

18071

## Sponsor information

**Organisation**

Hospitalet de Llobregat

**ROR**

<https://ror.org/01nv2xf68>

## Funder(s)

**Funder type**

Research organisation

**Funder Name**

Instituto de Salud Carlos III (FISPI14/00290)

**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, La misión del Instituto de Salud Carlos III (ISCI), ISCI

**Funding Body Type**

Government organisation

**Funding Body Subtype**

National government

**Location**

Spain

**Funder Name**

European Regional Development Fund

**Alternative Name(s)**

Fondo Europeo de Desarrollo Regional, Europäischer Fonds für regionale Entwicklung, Европейски фонд за регионално развитие, Evropský fond pro regionální rozvoj, Fundo Europeu de Desenvolvimento Regional, ERDF, FEDER, EFRE, EФPP, EFRR

**Funding Body Type**

Government organisation

**Funding Body Subtype**

National government

**Location**

**Funder Name**

Ministerio de Educación, Cultura y Deporte (FPU15/02911)

**Alternative Name(s)**

Ministry of Education, Culture and Sports, MECD

**Funding Body Type**

Government organisation

**Funding Body Subtype**

National government

**Location**

Spain

## Results and Publications

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

There are restrictions on the availability of data for the study due to the signed consent agreements around data sharing, which only allow access to external researchers for research following the project purposes. Requestors wishing to access the data used in this study can send a request to Fernando Fernández-Aranda. The request will then be passed for deliberation.

**IPD sharing plan summary**

Available on request