ISRCTN30788922 https://doi.org/10.1186/ISRCTN30788922

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

Submission date
20/06/2018

Recruitment status
No longer recruiting

Registration date
17/08/2018

Overall study status
Completed

Last Edited
17/08/2018

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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

Contact name
Dr Fernando Fernández-Aranda

Contact details
Department of Psychiatry
University Hospital of Bellvitge-IDIBELL
Feixa Llarga s/n
Hospitalet de Llobregat
Barcelona
Spain
08907

Type(s)
Scientific

Contact name
Dr Núria Mallorquí-Bagué

Contact details
Department of Psychiatry
University Hospital of Bellvitge-IDIBELL
Feixa Llarga s/n
Hospitalet de Llobregat
Barcelona

Spain
08907

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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 neurophysisiological (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

Study design
Interventional randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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
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 session 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 measure
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

Secondary outcome measures
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)

Overall study start date
01/01/2016

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) ≤ 18.5 or BMI ≥ 25
5. Healthy control individuals must be normoweight and present no psychiatric/neurological condition

Participant type(s)
Mixed

Age group
Adult

Lower age limit
18 Years

Upper age limit
60 Years

Sex
Female

Target number of participants
60 (20 anorexia-underweight, 20 BN/BED-overweight/obesity, 20 healthy controls)

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

Sponsor details
c/o Fernando Fernandez Aranda
Feixa Llarga s/n
Barcelona
Spain
08907

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/01nv2xf68

Funder(s)

Funder type
Research organisation

Funder Name
Instituto de Salud Carlos III (FISPI14/00290)

Alternative Name(s)
SaludISCIII, InstitutodeSaludCarlosIII, Instituto de Salud Carlos III | Madrid, Spain, Carlos III Institute of Health, Institute of Health Carlos III, Carlos III Health Institute, ISCIII

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Spain

Funder Name
European Regional Development Fund

Alternative Name(s)
Europski Fond za Regionalni Razvoj, Den Europæiske Fond for Regionaludvikling, Europees Fonds voor Regionale Ontwikkeling, Euroopa Regionaalarengu Fond, Fonds Européen de Développement Régional, Europäischer Fonds für regionale Entwicklung, Európai Regionális Fejlesztési Alap, Fondo Europeo di Sviluppo Regionale, Eiropas Reģionālās attīstības fonds, Europos Regionines Pletros Fondas, Europejski Fundusz Rozwoju Regionalnego, Fundo Europeu de Desenvolvimento Regional, Fondul European de Dezvoltare Regională, Európsky Fond Regionálneho Rozvoja, Fondo Europeo de Desarrollo Regional, Европейски фонд за регионално развитие, Evropský fond pro regionální rozvoj, Ευρωπαϊκό Ταμείο Περιφερειακής Ανάπτυξης, Il-Fond Ewropew għall-Iżvilupp Reġjonali, Evropski sklad za regionalni razvoj, Euroopan aluekehitysrahasto, Europeiska regionala utvecklingsfonden, ERDF, FEDER, EFRE, ΕΦΡΡ, EFRR, EFRU, ERFi, ΕΤΠΑ, FEDER, FESR, ERAF, ERPF, ERFA, L-FEŻR, EFRO, EFRR, FEDR, ESRR, EAKR, Eruf

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

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal.

Intention to publish date
01/08/2020

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