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Markers of excess weight, weight loss and weight regain in candidates for surgical treatment of obesity

Submission date
29/06/2020

Recruitment status
No longer recruiting

Registration date
06/07/2020

Overall study status
Completed

Last Edited
13/08/2021

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
The prevalence of overweight and obesity in Portugal has increased during the last decade, following the trend that is seen globally. Bariatric surgery is an operation that helps people lose weight by making changes to their digestive system. Some recent studies have found that, following bariatric surgery, people with obesity have shown changes in food preferences. In general, these changes may suggest that there is a change in the mechanisms of food reward in the brain. However, no study to date has compared the different methods of weight loss or evaluated the changes associated with each of them. This study aims to find out whether bariatric-induced weight loss is mediated, at least in part, by modulating the effects of food reward, and whether measures of food reward are predictive of weight loss after bariatric surgery.

Who can participate?
Patients aged between 18 and 65 with obesity who are being followed in an obesity management center in which surgical alternatives are offered for the treatment of obesity. Participants may also be chosen, despite not being overweight and/or being included in any weight loss consultation, to obtain data from healthy volunteers.

What does the study involve?
This study involves completing a questionnaire assessing demographic characteristics, health information and habits. If no factors are found in this questionnaire that prevent the individual from participating in the study, volunteers will be asked to collaborate on a test session to assess taste function. An electrogustometric procedure will be carried out to measure individual taste detection threshold, as well as another test in which participants will be asked to taste several substances absorbed in filter papers. Then, participants will be asked to answer some questions about the sensations caused by each of these substances. Once these taste assessment procedures are finished, the researchers will carry out a psychometric assessment using self-report reward-related measures and questionnaires about mood, feeding behavior traits and food acceptance.

What are the possible benefits and risks of participating?
This study does not involve receiving a particular medication or treatment for a disease. The general inconveniences related to the participation result from traveling to the place where the test sessions take place and the time spent in those sessions. There are no immediate benefits from participating in this study. However, participants will be contributing to the development of scientific knowledge in this area. It is also possible that, in the longer term, the results of this study contribute to an improvement in the care provided to patients with obesity or eating disorders.

Where is the study run from?
Champalimaud Research and Clinical Centre (Portugal)

When is the study starting and how long is it expected to run for?
January 2012 to June 2017

Who is funding the study?
1. BIAL Foundation (Portugal)
2. Fundação para a Ciência e Tecnologia (Portugal)

Who is the main contact?
Prof. Albino J. Oliveira-Maia
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Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
8353/2011

Study information

Scientific Title
Reward-related gustatory and psychometric markers of excess weight, weight loss and weight regain in candidates for surgical treatment of obesity

Study objectives
It is hypothesized that measures of food-reward sensitivity, namely sweet taste perception and self-assessed reward-related feeding behaviors, predict weight loss after bariatric surgery. Additionally the study had the following exploratory aims:
1. To test postoperative changes in these measures of food-reward sensitivity in comparison with a control group (patients on the surgery waiting list, receiving conservative treatment for obesity, including medical, nutritional and psychological support)
2. To test associations of weight loss with postoperative changes in measures of food-reward sensitivity
3. To assess differences according to surgery type in weight-loss prediction by measures of food-reward sensitivity, as well in associations between weight-loss and postoperative changes in these variables

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 24/09/2012, Comissão de Ética - Área da Saúde Humana e Bem-Estar (Universidade de Évora. Largo dos Colegiais 2, 7000-645 Évora, Portugal; +351 (0)266 740 800; comissao.

etica@uevora.pt), ref: 12031
2. Approved 22/07/2013, Comissão de Ética da Fundação Champalimaud (Fundação Champalimaud. Avenida Brasília 1400-038 Lisboa, Portugal; +351 (0)210 480 200; info@fundacaochampalimaud.pt), ref: N/A
3. Approved 05/12/2013, Comissão de Ética para a Saúde do Centro Hospitalar de São João E.P.E. (Alameda Professor Hernâni Monteiro 4200-319 Porto, Portugal; +351 (0)225 512 100; geral@hsjao.min-saude.pt), ref: CES254-13
4. Approved 06/08/2014, Conselho de Administração do Centro Hospitalar de Setúbal E.P.E. (Rua camilo castelo Branco 2910-446, Setúbal, Portugal; +351 (0)265 549 000; geral@chs.min-saude.pt), ref: 280/C.A

Study design
Multicenter prospective cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Other

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
Obesity (Class II to III)

Interventions
This cohort will include consecutive patients with obesity at three Portuguese tertiary care outpatient centers specialized in surgical treatment of obesity. Patients will be selected according to approval for bariatric surgery, following the criteria defined in the Portuguese National Health Service. A group of patients scheduled for surgery (surgical group) will be assessed at baseline when surgery was scheduled and twice after surgery in early (up to 8 months post-surgery) and late (up to 18 months post-surgery) follow-up. A control group of patients will be recruited at admission to the bariatric surgery waiting list for baseline assessment, and re-assessed at a single follow-up, occurring within the periods defined for the surgical group, and necessarily prior to surgery, i.e., patients in the control group will not transition to the surgical group within the study.

Intervention Type
Procedure/Surgery

Primary outcome measure

Primary response (dependent) variable:
Weight change from baseline [%WL = (weight lost/baseline weight)*100] assessed up to 18 months after surgery

Main explanatory (independent) variables:
1. Mean intensity and pleasantness ratings given to four concentrations of sucrose (sweet) as assessed with general labeled magnitude scales (gLMS) at baseline up to 18 months after surgery
2. Hedonic hunger assessed with the Power of Food Scale assessed at baseline and up to 18 months after surgery
3. Addiction-like feeding behavior assessed with the Yale Food Addiction Scale assessed up to 18 months after surgery

Secondary outcome measures
Secondary explanatory (independent) variables:
1. Intensity and pleasantness ratings given to four concentrations of citric acid (sour) as assessed with a gLMS at baseline up to 18 months after surgery
2. Intensity and pleasantness ratings given to four concentrations of sodium chloride (salty) as assessed with a gLMS at baseline up to 18 months after surgery
3. Intensity and pleasantness ratings given to four concentrations of quinine hydrochloride (bitter) as assessed with a gLMS at baseline up to 18 months after surgery
4. Acuity in tastant identification (sour, salt, sweet and bitter) assessed in a multiple forced choice test, at baseline and up to 18 months after surgery
5. Taste thresholds assessed with electrogustometry at baseline and up to 18 months after surgery
6. Feeding behavior traits assessed by the Dutch Eating Behavior Questionnaire (DEBQ) assessed at baseline and up to 18 months after surgery
7. Food acceptance assessed by the Food Action Rating Scale (FARS) assessed at baseline and up to 18 months after surgery
8. Depressive symptom severity assessed with the Beck Depression Inventory II (BDI-II) assessed up to 18 months after surgery

Overall study start date
08/01/2012

Completion date
07/06/2017

Eligibility

Key inclusion criteria
Consecutive adult patients with obesity at three Portuguese tertiary care outpatient centers specialized in the surgical treatment of obesity, namely Hospital do Espírito Santo de Évora, Hospital de São Bernardo de Setúbal, and Centro Hospitalar Universitário de São João for bariatric surgery, following the criteria defined in the Portuguese National Health Service:
1. Body mass index (BMI) greater than 40 kg/m2 with or without associated comorbidities or greater than 35 Kg/m2 in the presence of at least 1 comorbidity (type 2 diabetes mellitus, dyslipidemia, obstructive sleep apnea syndrome, obese hypoventilation syndrome, arterial hypertension or osteoarticular degenerative pathology, with marked functional limitation).
2. Age between 18 and 65 years
3. Failure of non-surgical interventions for weight reduction, for at least one year, obesity that is not secondary to an identified endocrine disease

4. Ability to understand the surgical procedure and to adhere to a long-term follow-up program
5. Absence of psychiatric disorders, absence of alcohol or drug dependence
6. Balanced relationship between operative risk and clinical risk

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
300

Total final enrolment
212

Key exclusion criteria
1. Active acute respiratory infection
2. Active neurological or psychiatric disease
3. Active gastrointestinal, hepatic or pancreatic disease
4. Illicit substance use or alcohol abuse
5. Illiteracy or otherwise not understanding instructions for the study
6. Prior major gastrointestinal surgery
7. Intra-gastric balloon
8. History of food allergies
9. Pregnancy or breastfeeding

Date of first enrolment
05/11/2012

Date of final enrolment
07/06/2017

Locations

Countries of recruitment
Portugal

Study participating centre
Hospital do Espírito Santo de Évora, EPE
Largo do Sr. da Pobreza, 7000-811 Évora

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Study participating centre
Hospital de São Bernardo
R. Camilo Castelo Branco 175
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Study participating centre
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Sponsor information

Organisation
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Sponsor type
Research organisation

Website
https://www.fchampalimaud.org/

ROR
https://ror.org/05b75nt23

Funder(s)

Funder type
Government

Funder Name
Fundação Bial

Alternative Name(s)
Bial Foundation

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Portugal

Funder Name
Fundação para a Ciência e a Tecnologia

Alternative Name(s)
Foundation for Science and Technology, Portuguese Science and Technology Foundation, Fundacao para a Ciencia e a Tecnologia, FCT

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Portugal

Results and Publications

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

Intention to publish date
05/10/2020

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Albino J. Oliveira-Maia (albino.maia@neuro.fchampalimaud.org).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file			07/08/2020	No	No
Results article		11/03/2021	13/08/2021	Yes	No