

Periodontal impact of anorexia nervosa and bulimia nervosa

Submission date 06/11/2016	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 16/11/2016	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 07/10/2022	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims:

Eating disorders are serious mental health conditions where the sufferer has an unhealthy relationship with food. The most common forms of eating disorders are anorexia nervosa, where the sufferer tries to keep their body weight as low as possible usually by severely restricts the amount they eat and exercising excessively, and bulimia nervosa, where the sufferer tries to control their weight by severely restricting the amount of food they eat, then binge eating and purging the food from their body by making themselves vomit or using laxatives. Nowadays, unknowns exist regarding the role of malnutrition (lack of proper nutrition) in the causes and management of periodontitis (gum disease). Therefore, there is an urgent need of studies exploring the relationship between eating disorders and periodontal conditions. The aim of this study is to determine the link between gum disease and eating disorders.

Who can participate?

Adult women with anorexia nervosa or bulimia nervosa and healthy women of the same age.

What does the study involve?

Participants in all groups attend a single study visit. At the visit, participants are interviewed about their oral hygiene behaviours, whether they smoke and how long they have had an eating disorder for (if from the anorexic or bulimic group). They then receive a full mouth examination to check for missing teeth and to assess gum health. At the end of the study, the results from the three patient groups are compared.

What are the possible benefits and risks of participating?

Participants benefit from receiving a specialized full-mouth examination, a gum disease assessment and dental advice. There are no notable risks involved with participating in this study.

Where is the study run from?

1. Paul Brousse Hospital (France)
2. Rothschild Hospital (France)

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

January 2014 to January 2018

Who is funding the study?
Assistance Publique Hôpitaux de Paris (France)

Who is the main contact?
1. Dr Hélène Rangé (public)
helene.range@aphp.fr
2. Professor Philippe Bouchard (scientific)
philippe.bouchard@aphp.fr

Contact information

Type(s)

Public

Contact name

Dr Hélène Rangé

Contact details

Department of Periodontology
Service of Odontology, Rothschild Hospital, AP-HP
5 rue Santerre
Paris
France
75012
+33 6 1465 6947
helene.range@aphp.fr

Type(s)

Scientific

Contact name

Prof Philippe Bouchard

Contact details

Department of Periodontology
Service of Odontology, Rothschild Hospital, AP-HP
5 rue Santerre
Paris
France
75012
+33 6 1465 6947
philippe.bouchard@aphp.fr

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

CPP n°13588

Study information

Scientific Title

Periodontal Impact of Eating Disorders: the PERIOED case-control study

Acronym

PERIOED

Study objectives

Eating disorder patients have a higher risk for periodontal inflammation than non-eating disorder subjects.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethical Research Committee CPP Ile de France I, 08/09/2014, ref: IRB 00008522

Study design

Observational cross-sectional case-control single-centre study

Primary study design

Observational

Secondary study design

Case-control study

Study setting(s)

Hospital

Study type(s)

Diagnostic

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

1. Anorexia nervosa
2. Bulimia nervosa

Interventions

All participants attend one single visit at baseline.

Firstly, this visit involves a patient interview in order to record the oral hygiene behaviors (dental visits frequency and toothbrushing habits), addictions (tobacco smoking status) and characteristics associated with eating disorders (duration in months, restricted eating profile

and self-induced vomiting profile). Secondly, participants receive a full-mouth periodontal examination, at 6 sites per tooth (except third molars), using a manual periodontal probe (HuFriedy PCP UNC 15 probe, Chicago, IL, USA). The number of missing teeth is reported. Dental plaque index and bleeding on probing score are recorded using a dichotomic approach. Periodontal probing depths and gingival recession are measured in millimeters using the periodontal probe.

Intervention Type

Other

Primary outcome measure

Clinical Attachment Level (CAL) is calculated as follows: periodontal probing depth (in mm) added to gingival recession height (in mm), which are measured with a manual periodontal probe (6 sites per tooth) at the day of the oral examination.

Secondary outcome measures

Gingival inflammation is measured using the bleeding on probing score (% of sites) at the day of the oral examination.

Overall study start date

01/01/2014

Completion date

01/01/2018

Eligibility

Key inclusion criteria

Anorexia nervosa participants:

1. Age 18 to 65 years old
2. Female
3. A proper diagnosis of anorexia nervosa for at least 5 years
4. Affiliated to the French social insurance

Bulimia nervosa participants:

1. Age 18 to 65 years old
2. Female
3. A proper diagnosis of bulimia nervosa for at least 5 years
4. Affiliated to the French social insurance

Non-eating disorder participants:

1. Age 18 to 65 years old
2. Female
3. Non-eating disorder volunteer
4. Affiliated to the French social insurance

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Female

Target number of participants

The target number of participants was 90, with 30 anorexia nervosa inpatients, 30 bulimia nervosa inpatients and 30 controls.

Total final enrolment

140

Key exclusion criteria

1. Unable to speak French
2. Unable to read and/or understand the information form
3. Taking anti-inflammatory medications or antibiotics at dental examination
4. Previously received any dental treatment that could interfere with the periodontal status 3 months before the clinical examination (scaling and root planning, orthodontic treatment ongoing)
5. Having less than 10 teeth

Date of first enrolment

07/10/2014

Date of final enrolment

07/11/2016

Locations

Countries of recruitment

France

Study participating centre

Psychiatric and Addiction Department, Paul Brousse Hospital, AP-HP

12 avenue Paul Vaillant Couturier

Villejuif

France

94800

Study participating centre

Department of Periodontology, Service of Odontology, Rothschild Hospital, AP-HP

5 rue Santerre

Paris
France
75012

Sponsor information

Organisation

Assistance Publique Hôpitaux de Paris (APHP)

Sponsor details

3 Avenue Victoria
Paris
France
75004

Sponsor type

Hospital/treatment centre

Website

<http://www.aphp.fr>

ROR

<https://ror.org/00pg5jh14>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Assistance Publique - Hôpitaux de Paris

Alternative Name(s)

Assistance Publique Hôpitaux de Paris, Assistance Publique–Hôpitaux de Paris, AP-HP

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

France

Results and Publications

Publication and dissemination plan

Publish in an international journal on nutrition in 2017 (first semester)

Intention to publish date

01/01/2017

Individual participant data (IPD) sharing plan

Requests for data should be sent to the corresponding authors Hélène Rangé (helene.jan@aphp.fr) or Philippe Bouchard (philippe.bouchard@aphp.fr)

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		16/12/2019	06/10/2022	Yes	No
Results article		12/03/2019	06/10/2022	Yes	No