

# Self-perceived impacts on daily living after periodontal treatment in a Brazilian elderly population.

<b>Submission date</b> 24/07/2015	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 21/08/2015	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 11/08/2015	<b>Condition category</b> Oral Health	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Periodontitis (PD) is a very common chronic gum infection that damages the soft tissue and destroys the bone supporting the teeth. It can lead to tooth loss, difficulties chewing, poor appearance of teeth and gums and it can even increase the risk of a heart attack or stroke. It is caused by the build-up of bacteria in the mouth which, over time, combines with saliva and small food particles to form a sticky film over the teeth, called plaque. The bacteria in the plaque can result in gum disease, leading to swollen, painful gums. If not treated, this gum disease will get worse and will develop into periodontitis. This study investigates how elderly people think their quality of life has been affected by having treatment for their periodontitis, taking into account physical, psychological, social and environmental aspects as well as individual belief (OMS). The patients with chronic periodontal disease may experience emotional changes that can affect their daily life. The aim of this study was to compare these effects on daily living in an elderly Brazilian population after they have had periodontal treatment.

### Who can participate?

Adults older than 60 with periodontal disease.

### What does the study involve?

All participants have an initial periodontal clinical examination and have their quality of life (as affected by their oral health) assessed by them answering a set of questions and completing a questionnaire. They are then randomly allocated into one of two groups. Those in group 1 (test group) are given conventional non-surgical periodontal treatment that includes scaling and root planing along with oral hygiene instructions. Those in group 2 (control group) are not given the treatment at this time. Both groups of participants are then invited back for a second clinical examination and quality of life assessment 30 days after the start of the study and after the test group participants have had their treatment. Finally, the participants in the control group are offered the same non-surgical periodontal treatment once the study is complete.

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

There is no immediate direct benefit to those taking part. However, there should be benefits to

research related to periodontal health and quality of life in an elderly population. There are no risks to participating because patients are treated with conventional non-surgical periodontal treatment.

Where is the study run from?

Department of Dental Clinics, Division of Graduate Periodontics, Federal University of Rio de Janeiro (Brazil)

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

July 2004 to March 2005

Who is funding the study?

Federal University of Rio de Janeiro (Brazil)

Who is the main contact?

1. Mrs Flávia Santos

2. Mrs Anna Leão

## Contact information

### Type(s)

Scientific

### Contact name

Mrs Flávia Santos

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## Additional identifiers

**Protocol serial number**

N/A

## **Study information**

### **Scientific Title**

Self-perceived impacts on daily living in an elderly population regarding periodontal treatment.

### **Study objectives**

The periodontal treatment does not cause impacts on the daily living of an elderly Brazilian population.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Clementino Fraga Filho University Hospital Human Research Committee, Federal University of Rio de Janeiro (UFRJ) - RJ, Brazil, 01/07/2004, ref: 089/04

### **Study design**

Interventional single-centre study.

### **Primary study design**

Interventional

### **Study type(s)**

Quality of life

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

Periodontal disease

### **Interventions**

A sample of 53 patients aged over 60 were randomly allocated into one of 2 groups: control or test.

Participants in both groups had a periodontal clinical examination and had their oral health impact on their quality of life assessed by a set of 22 questions (PHQ-QoL) and through completing a questionnaire (OHIP-14) at baseline and then after the test group have had the therapy described below. Participants in the control group received the same therapy after the study was complete.

Therapy: full-mouth scaling and root planing.

### **Intervention Type**

Other

### **Primary outcome(s)**

1. PHQ-QoL - a set of 22 questions related to gingival bleeding, halitosis, sensitivity, aesthetics dissatisfaction, eating and social restriction
2. OHIP-14 questionnaire, assessing quality of life.

Measurements were taken at baseline and after the periodontal treatment period

**Key secondary outcome(s))**

1. Probing pocket depth
2. Clinical attachment level
3. Visible plaque
4. Bleeding on probing
5. Tooth mobility
6. Number of Teeth

Measured at baseline and after the periodontal treatment period

**Completion date**

30/03/2005

**Eligibility**

**Key inclusion criteria**

1. Patients older than 60
2. Males or females
3. At the minimum of 15 teeth
4. At least 1 site with pocket depth >5 mm
5. Two teeth with clinical attachment level > 6 mm at baseline

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Senior

**Sex**

All

**Key exclusion criteria**

1. Total edentulism
2. Presence of acute periodontal diseases
3. Neurologic and auditive problems

**Date of first enrolment**

22/07/2004

**Date of final enrolment**

30/01/2005

**Locations**

## Countries of recruitment

Brazil

## Study participating centre

Department of Dental Clinics

Division of Graduate Periodontics

Federal University of Rio de Janeiro

Rio de Janeiro

Brazil

21.941-902

## Sponsor information

### Organisation

Federal University of Rio de Janeiro

### ROR

<https://ror.org/03490as77>

## Funder(s)

### Funder type

Not defined

### Funder Name

Investigator initiated and funded (Brazil)

## Results and Publications

### Individual participant data (IPD) sharing plan

### IPD sharing plan summary

Other

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes