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

Submission date
24/07/2015

Recruitment status
No longer recruiting

Registration date
21/08/2015

Overall study status
Completed

Last Edited
11/08/2015

Condition category
Oral Health

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

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Additional identifiers

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 Commitee, Federal University of Rio de Janeiro (UFRJ) - RJ, Brazil, 01/07/2004, ref: 089/04

Primary study design
Interventional

Study design
Interventional single-centre study.

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 questionnnaire (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
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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