

Change of periodontal inflammatory indicators through a 4-week weight control intervention including caloric restriction and exercise training in young Koreans

Submission date 27/07/2015	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 14/08/2015	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 17/12/2020	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

The aim of this study was to examine the effects of a 4-week weight control program on periodontal (gum) health.

Who can participate?

Obese individuals in their twenties.

What does the study involve?

Participants stayed in the camp under surveillance for two hours of aerobic exercise, three hours of weight training, and a low salt, low fat diet. They were not allowed to have any private foods or drinks except water. We examined their dental plaque at the start and end of the study. We made no attempt to change the participants' toothbrushing method or frequency so as not to affect gum inflammation during the study.

What are the possible benefits and risks of participating?

Not provided at time of registration.

Where is the study run from?

Konyang University (South Korea).

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

September 2009 to June 2012.

Who is funding the study?

National Research Foundation of Korea (South Korea).

Who is the main contact?

Dr Soo-Jeong Hwang

Contact information

Type(s)

Scientific

Contact name

Dr Soo-Jeong Hwang

Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

Change of MMP-8, MMP-9, and IL-1beta in gingival crevicular fluid through a 4-week weight control intervention including caloric restriction and exercise training in young Koreans

Study objectives

Obesity control can influence periodontal inflammation through systemic and local change.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethical Committee of Konyang University Hospital, KYUH 13-89, KYUH 9-25

Study design

Pre-post study

Primary study design

Interventional

Secondary study design

Non randomised study

Study setting(s)

Other

Study type(s)

Prevention

Participant information sheet

Health condition(s) or problem(s) studied

Body mass index of >25

Interventions

The subjects stayed in the camp under surveillance for two hours of aerobic exercise, three hours of weight training, and a low salt-low fat diet ($\leq 1,300$ kcal/day). They were not allowed to have any private foods or drinks except water. We examined the dental plaque index at the baseline and final state to serve as a proxy for the maintenance of the subjects' habitual oral health behavior. We made no attempt to change the subjects' toothbrushing method or frequency so as not to affect gingival inflammation during the program. Smoking was not prohibited to maintain the other conditions as confounding factors except weight control.

Intervention Type

Behavioural

Primary outcome measure

MMP-8, MMP-9, and IL-1beta in gingival crevicular fluid

Secondary outcome measures

Gingival index

Overall study start date

01/09/2009

Completion date

01/06/2012

Eligibility

Key inclusion criteria

Obese individuals (body mass index of >25) aged 20 to 29 and 13 camp trainers of the same age

Participant type(s)

Healthy volunteer

Age group

Adult

Sex

Both

Target number of participants

62

Total final enrolment

41

Key exclusion criteria

1. Systemic disease exclusive of obesity
2. Use of steroidal or non-steroidal anti-inflammatory drugs or antibiotics in the last three months or during the program
3. Use of mouthwash in the last three months or during the program
4. Need of dental or medical treatment during the program
5. Fewer than 24 teeth
6. Sites with probing periodontal pocket depth (PD) > 3.5 mm
7. Self-directed dropout during the course of the weight-control program

Date of first enrolment

01/06/2011

Date of final enrolment

28/06/2011

Locations**Countries of recruitment**

Korea, South

Study participating centre

Konyang University

Nonsan

Korea, South

320-711

Sponsor information**Organisation**

National Research Foundation of Korea

Sponsor details

201 Gajeong-Ro

Yuseong-Gu

Daejeon

Korea, South

305-754

Sponsor type

Government

ROR

<https://ror.org/013aysd81>

Funder(s)

Funder type

Government

Funder Name

National Research Foundation of Korea

Alternative Name(s)

, National Research Foundation (South Korea), NRF

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

Korea, South

Results and Publications

Publication and dissemination plan**Intention to publish date**

30/09/2015

Individual participant data (IPD) sharing plan**IPD sharing plan summary**

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	18/09/2015	17/12/2020	Yes	No