

Effect of periodontal non-surgical treatment for pre-diabetes/type 2 diabetes patients

Submission date 13/07/2015	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 17/08/2015	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 17/08/2015	Condition category 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

People with diabetes are at greater risk for periodontal (gum) disease than the general population. While dental scaling and root planning works well for treating early periodontal disease (PD), little is known about how well preventive non-surgical treatment for periodontal disease works among pre-diabetes/diabetes patients, especially for middle aged people 35-54. The aim of this study is to evaluate the effectiveness of periodontal non-surgical treatment on pre-diabetes/diabetes patients.

Who can participate?

Adults aged 35-54 with pre-diabetes/diabetes.

What does the study involve?

Participants are randomly allocated into one of two groups. Those in group 1 (intervention) are given the preventive non-surgical PD treatment (intervention). This includes checking with each participant how much they already know and an assessment on how bad their PD is. They are then given instructions on how best to use the tooth brush and dental floss, information on the causes and signs of PD, link between hyperglycemia (high blood sugar) and PD and general oral practice. Those in group 2 (control) are not given the intervention. All participants PD is assessed 2 months later, along with their knowledge of oral hygiene and PD.

What are the possible benefits and risks of participating?

Participants in the intervention group may get some positive benefit from the non-surgical PD treatment. There are no risks.

Where is the study run from?

Health Bureau of Keelung City and the Dr. Lo Dental Clinic (Taiwan)

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

August 2006 to March 2008

Who is funding the study?

Health Promotion Administration, Ministry of Health and Welfare (Taiwan)

Who is the main contact?
Dr Sherry Yueh-Hsia Chiu

Contact information

Type(s)
Public

Contact name
Dr Sherry Yueh-Hsia Chiu

ORCID ID
<http://orcid.org/0000-0002-7207-7088>

Contact details
No. 259, Wen-Hwa 1st Road, 333 Kwei-Shan
Taoyuan
Taiwan
333

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
DOH 95-HP-1307

Study information

Scientific Title
Effect of periodontal non-surgical treatment for pre-diabetes/type 2 diabetes patients: a randomized controlled trial among adults aged 35-54 years

Study objectives
The effectiveness of periodontal non-surgical treatment for pre-diabetes/diabetes patients could improve the status of periodontal status

Ethics approval required
Old ethics approval format

Ethics approval(s)
Institutional Review Board, Ethics Committee of Chang Gung Memorial Hospital, 05/09/2014, ref: 103-3920B

Study design

Randomized controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Community

Study type(s)

Prevention

Participant information sheet

Not available

Health condition(s) or problem(s) studied

Periodontal disease in pre-diabetes/diabetes for adults aged 35-54 years

Interventions

Participants were randomly allocated into either the intervention or the control group. The intervention included oral hygiene instruction and periodontal disease (PD) care and periodontal non-surgical treatment. The oral hygiene instruction was carried out by senior professional dental nurses individually. The contents included tooth brush, dental floss use, the causes and signs of PD, association between hyperglycemia and PD, and general oral hygiene practice. Periodontal non-surgical intervention was implemented by three dentists with profession in PD treatment with more than 10-year expertise, which were calibrated CPI examination and standardized procedure of non-surgical periodontal treatment were performed before study implementation. baseline of PD status were examined for six sextants and recorded by CPI (Community Periodontal Index), that included 0 for healthy periodontium, 1 for gingival bleeding, 2 for calculus, 3 for a 4-5mm periodontal pocket, and 4 for a >6mm periodontal pocket. Considering the feasibility and manpower, the severest quarter was taken as treatment site for intervention group compared with no treatment on control. After the follow-up measure, the non-surgical periodontal treatment was compensated for subjects in control group.

Intervention Type

Mixed

Primary outcome measure

Periodontal community periodontal index (CPI), measured by periodontal CPI examination and fasting blood chemical biomarker- HbA1C, measured 2 months after the intervention.

Secondary outcome measures

Knowledge of oral hygiene and periodontal disease, assessed using a questionnaire of knowledge and attitude for periodontal health and oral hygiene. This was collected after 2 months after the intervention.

Overall study start date

01/08/2006

Completion date

30/03/2008

Eligibility

Key inclusion criteria

Those aged 35-54 with pre-diabetes/diabetes and without severe diseases (cancer /hospitalization)

Participant type(s)

Healthy volunteer

Age group

Adult

Sex

Both

Target number of participants

1399

Key exclusion criteria

84

Date of first enrolment

08/01/2007

Date of final enrolment

30/01/2008

Locations

Countries of recruitment

Taiwan

Study participating centre**Health Bureau of Keelung City**

No.266, Sin 2nd Rd., Sinyi District

Keelung City

Taiwan

201

Study participating centre**Dr. Lo Dental Clinic**

2F, No. 7, Jen-Ai district, 3rd Jen Rd.

Keelung City

Taiwan
208

Sponsor information

Organisation

Health Promotion Administration, Ministry of Health and Welfare

Sponsor details

6F., No.95, Mincyuan Rd., West District
Taichung
Taiwan
40341

Sponsor type

Government

ROR

<https://ror.org/024w0ge69>

Funder(s)

Funder type

Government

Funder Name

Health Promotion Administration, Ministry of Health and Welfare (Taiwan)

Results and Publications

Publication and dissemination plan

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Available on request