

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

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<b>Registration date</b> 17/08/2015	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 17/08/2015	<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

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**  
<https://orcid.org/0000-0002-7207-7088>

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

## Additional identifiers

**Protocol serial number**  
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

**Study type(s)**

Prevention

### **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(s)**

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

### **Key secondary outcome(s)**

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.

### **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

### **Healthy volunteers allowed**

No

### **Age group**

Adult

**Sex**

All

**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

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

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

Keelung City

Taiwan

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**Sponsor information****Organisation**

Health Promotion Administration, Ministry of Health and Welfare

**ROR**

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

**Funder(s)**

**Funder type**  
Government

**Funder Name**  
Health Promotion Administration, Ministry of Health and Welfare (Taiwan)

## **Results and Publications**

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

**IPD sharing plan summary**  
Available on request