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The effect of lay health advisor approach of periodontal care intervention for type II diabetes patients

Submission date
16/10/2015

Recruitment status
No longer recruiting

Registration date
18/11/2015

Overall study status
Completed

Last Edited
12/08/2022

Condition category
Oral Health

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

Plain English summary of protocol

Background and study aims
Type 2 diabetes mellitus (T2DM) is a growing problem worldwide. People with T2DM have difficulty controlling their blood sugar (glucose) as they do not produce enough insulin to function properly (insulin deficiency), or that the body's cells don't react to insulin as they should do (insulin resistance). When a person is suffering from diabetes, it is common to develop complications, which affect other parts of the body. Gum disease (periodontitis) is where the gums become swollen (inflamed), sore or infected because of a build-up of bacteria in the mouth. People suffering from T2DM have a higher chance of developing periodontitis because high blood sugar causes the levels of sugar in the saliva to increase. This sugary saliva creates a breeding ground for bacteria, which in turn leads to gum disease and tooth decay. Taking care of the mouth (oral healthcare) is very important for preventing the build-up of bacteria. By educating diabetics about the importance of good oral hygiene, it may be possible to protect them against oral complications such as periodontitis. The aim of this study is to find out whether providing oral health education by a lay heath advisor (members of the public who are trained to educate people about healthcare) to diabetics can improve their oral healthcare habits, protecting against periodontitis.

Who can participate?
Adults with T2DM, who have at least 16 functional teeth and bleeding gums.

What does the study involve?
Participants are randomly allocated to one of two groups. Participants in both groups receive the standard non-surgical periodontal treatment, including scaling (scraping plaque from the gum line) and root planing (where rough spots on the tooth roots are made smooth). For those in group one, as well as the treatment, participants receive 30 minutes of oral health education from a trained lay health advisor (LHA). They also are given additional education sessions once a week for 4-5 weeks. For those in the second group, as well as the treatment, participants are given a brochure to read which includes general information about oral health. Participants in both groups complete a number of questionnaires at the start of the study, and again after 1, 3 and 6 months in order to find out if there has been any change to their oral healthcare habits.

What are the possible benefits and risks of participating?
Participants may benefit from an improvement to their oral health. Risks of participating in the study are low, although participants may feel uncomfortable during the periodontal treatment.

Where is the study run from?
Three hospitals in Kaohsiung (Taiwan)

When is the study starting and how long is it expected to run for?
November 2014 to December 2018

Who is funding the study?
Ministry of Science and Technology, R.O.C. (Taiwan)

Who is the main contact?
Professor Hsiao-Ling Huang

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Follow-up evaluation study by the lay health advisor (LHA) approach of periodontal care intervention for type ii diabetes patients: assessment, LHA training, and effects

Study objectives
The Lay Health Advisor (LHA) approach of periodontal care intervention is an effective intervention method for type II diabetes patient.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Institutional review board of Kaohsiung Medical University Chung-Ho Memorial Hospital, 16/10 /2015, ref: KMUH-IRB-20140291

Study design
Randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Not Specified

Participant information sheet

Health condition(s) or problem(s) studied
Periodontal disease in type II diabetic patients

Interventions
Participants will be randomly assigned by their sequence of date they signed inform consent form to the LHA intervention group or to a brochure-only control group. Both the intervention and control groups will receive non-surgical periodontal treatment (NSPT) including scaling, root planning and oral hygiene instruction.

LHV intervention group: In addition to the conventional periodontal therapy (subgingival scaling and root planning), participants will receive additional professional oral health education by a well-trained lay health advisor (LHA) during NSPT period, lasting for 30 minutes, as well as instruction once a week for 4-5 weeks.

Brochure-only control group: In addition to the conventional periodontal therapy, participants receive a brochure providing information about oral health.

The follow-up surveys will conduct at 1, 3 and 6 months after they finished treatment.

Intervention Type

Mixed

Primary outcome measure
1. Level of change on oral health-related quality of life is measured using Taiwanese version of the oral health impact profile-14 (OHIP-14T) at baseline, 1, 3 and 6 months
2. Level of change on food intake is measured using food intake questionnaire at baseline, 1, 3 and 6 months
3. Periodontal status (i.e. probing pocket depth, plaque index, gingival index, and clinical attachment loss) is measured using periodontal examination record at baseline, 1, 3 and 6 months
4. The level of change on blood value (i.e. AC Sugar, T-CHO, HDL, LDL, TG, HbA1c, BUN, Creatinine, CRP, Hb(Hct), RBC and MCV) is collected using electronic medical record at baseline, 1, 3 and 6 months

Secondary outcome measures
1. Oral health awareness is measured using awareness scale at baseline, 1, 3 and 6 months
2. Attitude towards oral health is measured using attitude toward oral health scale at baseline, 1, 3 and 6 months
3. Self-efficacy is measured using self-efficacy toward oral health scale at baseline, 1, 3 and 6 months
4. Oral health behavior is measured using oral health behaviors questionnaire at baseline, 1, 3 and 6 months

Overall study start date
30/11/2014

Completion date
01/02/2019

Eligibility

Key inclusion criteria
1. Aged between 36 and 65 years
2. Diagnosis of type II diabetes
3. Patients who have at least 16 functional teeth, with 4 or more than 4 supporting zones (minimum of one in the premolar and molar region on each side)-Eichner index: class A
4. Patients who have gingival bleeding
5. Periodontal pockets with a depth of at least 5mm

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
200

Total final enrolment
76

Key exclusion criteria
1. Periodontitis patients who have undergone periodontal treatment within the last 6 months
2. Regular use of antibiotics and bisphosphonates, or other similar medication
3. Smokers or betel quid chewers, or both users who have quit less than 6 months
4. Systematic diseases (such as cancer, kidney or liver failure, heart disease)

Date of first enrolment
20/11/2015

Date of final enrolment
15/06/2018

Locations

Countries of recruitment
Afghanistan

Taiwan

Tokelau

Tunisia

Turkmenistan

Turks and Caicos Islands

Tuvalu

Türkiye

Uganda

Ukraine

United Arab Emirates

United Kingdom

United States Minor Outlying Islands

United States of America

Uruguay

Uzbekistan

Vanuatu

Venezuela

Viet Nam

Virgin Islands, British

Virgin Islands, U.S.

Wallis and Futuna

Western Sahara

Study participating centre
Kaohsiung Medical University Hospital
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Study participating centre
Kaohsiung Municipal Ta-Tung Hospital
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Sponsor information

Organisation
Ministry of Science and Technology, R.O.C.

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Sponsor type
Government

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Funder(s)

Funder type
Government

Funder Name
Ministry of Science and Technology, R.O.C.

Results and Publications

Publication and dissemination plan
Three-four papers disseminating the study results will be submitted for publication in peer reviewed journals.

Intention to publish date
30/06/2020

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	19/10/2019	07/04/2020	Yes	No
Basic results		28/04/2020	28/04/2020	No	No
Results article		07/08/2021	12/08/2022	Yes	No