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Effect of health coaching on the willingness and success rate of quitting smoking in diabetics

Submission date
27/05/2020

Registration date
28/05/2020

Last Edited
02/06/2023

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Other

[X] Prospectively registered

[_] Protocol

[_] Statistical analysis plan

[X] Results

[_] Individual participant data

Plain English summary of protocol

Background and study aims
Smoking has a considerable negative impact on the control and treatment of diabetes. However, there is currently a lack of relevant studies in Taiwan on the referral rate of smoking cessation, especially for people with diabetes. Since 2012, the second-generation smoke cessation project has been implemented. All departments in the hospital can refer patients to smoking cessation clinics to quit smoking. However, so far, the referral rate and the 6-month success rate are lower than 30%. This study will be implemented in the Cathay General Hospital, and the major aims are to evaluate the impact of a new approach/intervention to improve smoke cessation referral rate and smoking cessation rate by using health coaching.

Who can participate?
Diabetic patients aged 20-75 who smoke

What does the study involve?
Participants are randomly allocated to the intervention group or the control group. Participants in the intervention group receive a health coaching intervention provided by a single qualified coach. They have an initial face-to-face session and are offered 10- to 20-minute telephone coaching sessions biweekly for six sessions within the first 3 months and three sessions within the last 3 months. Participants in the control group only receive a face-to-face coaching session and measurement at the start of the study and do not have any coaching calls. Smoking cessation rate is measured at the start of the study and at 3-month and 6-month follow-up.

What are the possible benefits and risks of participating?
The possible benefits are successful smoking cessation and improved blood glucose control. There are no risks of participating since this is a behavior coaching study without any invasive intervention, and everyone is free to decide whether to withdraw from the study.

Where is the study run from?
Cathay General Hospital (Taiwan)

When is the study starting and how long is it expected to run for?
August 2020 to July 2022

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Yao-Tsung Chang
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CGH-OP106001

Study information

Scientific Title
Effect of health coaching on the willingness and success rate of quitting smoking in diabetics: a randomized controlled trial

Study objectives
Health coaching can help diabetic patients to quit smoking and reduce smoking more effectively than traditional health education.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Approved 29/04/2020, Institutional Review Board (IRB) of Cathay General Hospital (Cathay General Hospital, No. 280, Sec. 4, Ren'ai Rd, Da'an Dist, Taipei City 106, Taipei, 10630, Taiwan; +886 (0)2-27082121; irb@cgh.org.tw), ref: CGH-OP109002

Study design

Two-year randomized control intervention design study

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Diabetics who smoke

Interventions

Participants are recruited from Cathay General Hospital in Taipei, Taiwan. Two physicians who specialize in endocrine and metabolic disorders screen potential patients with type 2 diabetes mellitus who smoke and recruit them when they return to the hospital. Before recruiting, the doctor will first randomly assign the patient to the intervention group or the control group, and then recruit them to avoid the Hawthorne effect.

The coaching is provided by a single coach who had over 120 hours of certified coach training, received the International Coach Federation's (ICF) Associated Certified Coach (ACC) credential and master's level degrees in public health. Patients in the intervention group have an initial face-to-face session, together with baseline measurement, then are offered telephone coaching sessions monthly for 6 months. In the first session, the coach asks each participant to set his or her 6-month HbA1c goal and first behavior change goal. The behavior goal must be one of behaviors related to diabetes self-management, including physical activity, healthy diet, medical adherence, and/or regular self-blood glucose monitoring (SMBG). If a patient has more than one behavior change goal, the coach asks him or her to prioritize the goals. The goal must design followed the "SMART" rule (i.e., specific, measurable, attainable, realistic, and timely). The coach records the goals setting by the patient and the content of the coaching for follow-up and analysis. The only difference from the previous study is that the coaching frequency of this study is changed to once per month.

Each patient in the control group only receives a face-to-face coaching session and baseline measurement at baseline, and they do not have any coaching calls at all.

Intervention Type

Behavioural

Primary outcome(s)

Measured at baseline, 3-month and 6-month follow-up:
1. Smoking cessation rate measured with general definition of smoking cessation formula, including nicotine dependence scale, daily smoking count and CO test, at 6 months
2. Number of cigarettes per day measured by one self-rating question

Key secondary outcome(s))

Measured at baseline, 3-month and 6-month follow-up:
1. HbA1c collected from patients medical records
2. BMI collected from patients medical records
3. Diabetes management self-efficacy measured by a single question
4. Smoking cessation self-efficacy measured by a single question
5. Physical activity behavior measured with Godin leisure time physical activity scale
6. Diet measured by Food Frequency Questionnaire

Completion date
31/07/2022

Eligibility

Key inclusion criteria
1. 20 to 75 years old
2. Diagnosed with type 2 diabetes for at least 1 year
3. Having smoke habit in the past 6 months
4. Not taking other smoking cessation courses at the same time

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
20 years

Upper age limit
75 years

Sex
All

Total final enrolment
68

Key exclusion criteria
1. Any clinically significant depression or cognitive dysfunction
2. Serious hearing impairment
3. Cannot speak Chinese
4. Does not have phone at home

Date of first enrolment
01/08/2020

Date of final enrolment

Locations

Countries of recruitment
Taiwan

Study participating centre
Cathay General Hospital
No. 280, Sec. 4, Ren'ai Rd., Da'an Dist., Taipei City 106
Taipei
Taiwan
10630

Sponsor information

Organisation
Cathay General Hospital

ROR
https://ror.org/03c8c9n80

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Yao-Tsung Chang (promiselove02@gmail.com). The format of the data will be Excel or .sav (SPSS or SAS), and it will be available for at least 3 years under the IRB's approval.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
[Results article](#)		12/03/2023	02/06/2023	Yes	No