

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

Submission date 27/05/2020	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 28/05/2020	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 02/06/2023	Condition category Other	<input type="checkbox"/> 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

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

No participant information sheet available

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 measure

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

Secondary outcome measures

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

Overall study start date

01/08/2020

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

Age group

Adult

Lower age limit

20 Years

Upper age limit

75 Years

Sex

Both

Target number of participants

120

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

31/07/2022

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

Sponsor details

Department of Endocrinology and Metabolism

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Sponsor type

Hospital/treatment centre

Website

<https://www.cgh.org.tw/>

ROR

<https://ror.org/03c8c9n80>

Funder(s)

Funder type

Other

Funder Name

Investigator initiated and funded

Results and Publications

Publication and dissemination plan

The researchers will try to publish if the intervention has a significant result.

Intention to publish date

01/12/2022

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